



ACCREDITATION REQUIREMENTS FOR ACUTE CARE HOSPITALS

2017

Healthcare Facilities Accreditation Program

The mission of the Healthcare Facilities Accreditation Program (HFAP) is to advance high quality patient care and safety through objective application of recognized standards

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Healthcare Facilities Accreditation Program (HFAP)

142 E. Ontario Street

Chicago, IL 60611

info@hfap.org

FOREWARD

The 2017 publishing of the Healthcare Facilities Accreditation Program (HFAP) accreditation requirements for acute care hospitals contains all updates to the Medicare Conditions of Participation and standards changes recommended by the Bureau of Healthcare Facilities Accreditation through December 2016. These updates reflect our continuing effort to meet the following goals:

1. Provide assurance to the general public that facilities accredited by HFAP are operating within approved standards and providing patient care satisfactory to the public interest.
2. Assure that the manual reflects the current Medicare Conditions of Participation for Hospitals as published by the Centers for Medicare and Medicaid Services (CMS).
3. Respond to comments and suggestions from our accredited facilities and surveyors on ways to improve the manual and the survey process to assure a cost-effective, user-friendly program.

The HFAP is grateful for and encourages comments by accredited health care facilities. Such feedback helps our ongoing efforts to improve our program and assist health care facilities in maintaining a high quality of patient care.

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INTRODUCTION

The Healthcare Facilities Accreditation Program (HFAP) of the American Osteopathic Association (AOA) has been providing medical facilities with an objective, standards-based review of their services since 1945. The program is recognized nationally by the federal government, state governments, insurance carriers, and managed care organizations.

Deeming Authority

In 1965 the HFAP program was granted “Deeming Authority” to conduct accreditation surveys of acute care hospitals by the Health Care Financing Administration (HCFA), now the Centers for Medicare and Medicaid Services (CMS). The HFAP was the first accreditation organization granted deeming authority or deemed status under Section 1865 of the Social Security Act and implementing regulations 42 CFR 488.5. This means that a facility accredited by the HFAP is deemed to comply with the Medicare Conditions of Participation for Hospitals as published by CMS.

The HFAP program was also granted “Deeming Authority” from HCFA, now CMS, to survey hospital laboratories under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) as published in the Federal Register, Vol. 60, No. 140, page 37657, Friday, July 21, 1995. Questions about either program should be directed to the:

Healthcare Facilities Accreditation Program (HFAP)
142 East Ontario Street
Chicago, Illinois 60611-2864
Phone: (312) 202-8258 or (800) 621-1773 ext. 8258
Fax: (312) 202-8370

Features of Interest in this Manual

The manual has been formatted into four columns to allow simultaneous viewing of several items related to each requirement.

1. Column one, STANDARD/ELEMENT, lists the requirement to be met. Where applicable, Medicare Conditions and Standards are indicated by the CfR reference number (§482.xx, §483.xx, §485.xx) immediately after the requirement. Exact wording for the Medicare Conditions and Standards are printed in italics.
2. Column two, EXPLANATION, provides further explanation for the requirement as necessary.
3. Column three, SCORING PROCEDURE, identifies what surveyors will be reviewing when surveying healthcare facilities.
4. Column four, SCORE, identifies the potential scores available and in some circumstances ‘Not Applicable’.

Using This Manual

The HFAP strongly recommends that each health care facility use this manual as a management tool and perform a self-assessment of the facility's compliance to the standards. If done periodically, a facility may be assured that it is always ready for survey and thus avoid the need for a flurry of "ramp up" activity in anticipation of a survey. More importantly, performing a periodic self-assessment of the facility's compliance to the standards will ensure the facility's ability to render care, treatment or services in a safe and effective manner. At its core, these standards represent a validated risk-reduction strategy for the organization. Continuous compliance with all the standards diminishes the likelihood of adverse events occurring. Compliance will not prevent every adverse event but compliance will substantially reduce the likelihood of these events occurring and mitigate the environments of which they spawn.

The HFAP recognizes that health care facilities may find a variety of ways in which to comply with the accreditation requirements. For example, a facility with 1,000 beds and an accompanying relatively large staff will have the ability to address issues with a variety of committees. In contrast, a facility with 50 beds and a relatively small staff may elect to address issues with a committee of the whole. Regardless of the approach taken, as long as the facility can demonstrate compliance with the requirements, they will be eligible for the HFAP accreditation.

ELIGIBILITY FOR ACCREDITATION

A hospital desiring accreditation by the Healthcare Facilities Accreditation Program (HFAP) shall comply with the following requirements before its application will be considered. The hospital shall:

1. Be located in the United States or its territories, is operated by the U.S. government or is under the charter of the U.S. Congress.
2. Meet all state and local licensing requirements.
3. Recognize and accept specialty certification through the certifying boards of the American Board of Medical Specialist (ABMS), and the American Osteopathic Association (AOA) on an equal basis.
4. Provide professional care and hospital service on a 24-hour basis.

BASIC REQUIREMENTS

In addition, the hospital shall comply with each of the following basic requirements:

1. There must be an effective governing body that is legally responsible for the conduct of the institution; or, if a hospital does not have an organized governing body, persons legally responsible for the conduct of the hospital.
2. The hospital must be licensed or approved as meeting standards for licensing by the state as required.
3. Patient safety in all areas shall comply with the applicable provisions of the 2012 edition of the NFPA 101 *Life Safety Code*® (LSC).
4. The hospital shall provide the facilities and equipment for diagnosis and treatment of patients appropriate to the needs of the community.
5. The medical records department shall be organized, appropriate to the scope and complexity of the service performed, and supervised by qualified personnel.
6. The hospital must maintain, or have available, diagnostic radiologic services and the services of a radiologist.
7. The hospital must maintain, or have available, laboratory services to meet the needs of its patients.
8. The hospital must have pharmaceutical services that meet the needs of the patients and must be directed by a registered pharmacist or have a drug storage area under competent supervision.
9. The hospital must meet the emergency needs of its patients even if it chooses not to provide emergency services in a dedicated emergency department.
10. The hospital must have organized dietary services that are directed and staff by adequate qualified personnel.
11. If the hospital furnishes anesthesia services, they must be provided in a well-organized manner under the direction of a qualified Doctor of Medicine or Doctor of Osteopathic Medicine.

12. Utilization Review policies and practices shall be in compliance with federal and state requirements for the review of services provided to Medicare and Medicaid beneficiaries.
13. If the hospital provides surgical services, the services must be well organized and provided in accordance with acceptable Standards of Practice.
14. The organized medical staff shall operate under bylaws, rules and regulations approved by the governing body and is responsible for the quality of medical care provided.
15. The nursing service shall be formally organized and include registered professional nurse supervision of patient care on all shifts.
16. All personnel are licensed or meet other standards that are required by state or local laws.
17. A physician is on duty or on call at all times.

Important Information for Acute Care Hospitals:

Any facility designated as an Acute Care Hospital by the State in which it is located shall meet all state and local licensing requirements in addition to the Medicare Conditions of Participation (CoP) for Acute Care Hospitals as found in 42 CFR Part 482, Subchapter G (see below). The HFAP standards reflecting these Medicare requirements are incorporated throughout the HFAP Accreditation Requirements for Acute Care Hospitals 2017 Manual.

Subparts A, B, and C – Conditions of Participation: Acute Care Hospitals

- §482.1 Basis and scope.
- §482.2 Provision of emergency services by nonparticipating hospitals.
- §482.11 Condition of participation: Compliance with Federal, State and local laws.
- §482.12 Condition of participation: Governing body.
- §482.13 Condition of participation: Patient's rights.
- §482.21 Condition of participation: Quality assessment and performance improvement program.
- §482.22 Condition of participation: Medical staff.
- §482.23 Condition of participation: Nursing services.
- §482.24 Condition of participation: Medical record services.
- §482.25 Condition of participation: Pharmaceutical services.
- §482.26 Condition of participation: Radiologic services.

- §482.27 Condition of participation: Laboratory services.
- §482.28 Condition of participation: Food and dietetic services.
- §482.30 Condition of participation: Utilization review.
- §482.41 Condition of participation: Physical environment.
- §482.42 Condition of participation: Infection control.
- §482.43 Condition of participation: Discharge planning.
- §482.45 Condition of participation: Organ, tissue, and eye procurement.

Subpart D – Conditions of Participation: Acute Care Hospitals (OPTIONAL Hospital Services)

- §482.51 Condition of participation: Surgical services.
- §482.52 Condition of participation: Anesthesia services.
- §482.53 Condition of participation: Nuclear medicine services.
- §482.54 Condition of participation: Outpatient services.
- §482.55 Condition of participation: Emergency services.
- §482.56 Condition of participation: Rehabilitation services.
- §482.57 Condition of participation: Respiratory care services.
- §482.58 Special requirements for hospital providers of long-term care services (“swing-beds”).

SCORING METHODOLOGY USED IN THIS MANUAL

The scoring methodology includes two levels to determine compliance with a standard, Compliant and Not-Compliant. A separate category for standards, which may be identified as ‘not applicable’ based on the care, treatment or services offered by the facility, is also identified.

1. Compliant - Indicates there is evidence of complete compliance with the requirement.
2. Not Compliant - Indicates there is less than full compliance with the requirement or no evidence of compliance with the requirement.
3. Not Applicable - Indicates that the section does not apply to the facility being surveyed.

ACCREDITATION PROCESS

I. Application Procedures

- A. All communications regarding accreditation shall be directed to the:
Healthcare Facilities Accreditation Program (HFAP)
142 East Ontario Street
Chicago, Illinois 60611
800-621-1773, x-8258 (phone)
312-202-8298 (fax)
info@hfap.org
- B. New applications
 1. Health care facilities may apply for accreditation by completing and submitting an online application.
 2. The registration fee is based on a combination of size, complexity of services and volume, among other factors, and is calculated using a triennial registration fee worksheet. Health care facilities are charged the calculated registration fee plus the cost of the on-site survey. Once the application and registration fee are submitted, the HFAP must schedule the on-site survey within six months of receiving the application and registration fee. The HFAP makes every effort to be on-site within 90 days from the date of receipt of the application and triennial registration fee. This assures that the facility's application information is current at the time of the survey.
 3. If a facility's initial survey is not conducted within six months of submitting its application, due to a facility's delay in fulfilling application requirements, the organization forfeits its application fee. The organization must then reapply and submit a new registration fee and begin the application for accreditation process anew.
- C. Renewal applications
 1. A health care facility must complete an online reapplication 9 months prior to the expiration date of their current accreditation and submit it to the HFAP. If an application is received less than 90 calendar days prior to the accreditation expiration date, the result may be a lapse in the facility's accreditation due to insufficient time to process and schedule the appropriate survey team in a manner that supports the unannounced nature of the survey. If the facility's accreditation lapses, the facility will be required to submit an application for accreditation as an initial accreditation survey.

2. Renewal applications are reviewed by the HFAP as they are received. If the triennial registration fee has not been paid, the application for renewal will not be processed. Payment in full is expected within five (5) business days following the submission of the online application.
3. Each health care facility will be scheduled for survey within 180 days prior to the expiration date of their current accreditation, assuming that all application requirements have been met.

D. Survey Procedures

1. Health care facility surveys will be unannounced and conducted on a three-year cycle. The survey team consists of a combination of the following approved surveyor categories: physician, health care facility administrator, registered nurse, and life safety. The number of surveyors, the combination of surveyors, and the survey days will vary based on the size and complexity of the health care facility. The fee for each survey will take into account the complement of the survey, i.e., the length of the survey and the number of surveyors assigned to the survey.
2. The HFAP will maintain a list of surveyors approved by the Bureau of Healthcare Facilities Accreditation (BHFA). Each survey will have a designated team captain who must be qualified by education, training and experience.
3. The total cost of the survey will be borne by the health care facility.
4. The surveyors will notify the facility by verbal report of any areas on noncompliance during the exit conference at the conclusion of the survey.
5. The HFAP reserves the right to amend survey results upon review and audit of surveyor findings, resulting in either new identification, elimination or modification of deficiencies reported at the exit conference.
6. The HFAP will notify the health care facility in writing of any areas of noncompliance within 10 business days after completion of the survey.
7. Health care facilities are required to respond formally to all areas of noncompliance with a written Plan of Correction. Failure to respond to and correct deficiencies cited may result in delay or denial of accreditation.
8. The Bureau of Healthcare Facilities Accreditation (BHFA) through its Executive Committee will render all accreditation decisions.

II. The Bureau of Healthcare Facilities Accreditation

A. Bureau Authority and Procedure - Health Care Facilities

1. The Bureau has been delegated authority by the American Osteopathic Association Board of Trustees:
 - a. To conduct accreditation surveys of health care facilities.
 - b. To evaluate the survey reports, and on the basis of the survey findings, to grant, deny, or withdraw accreditation to those health care facilities seeking accreditation.
2. Accreditation actions that may be taken for health care facilities are:
 - a. **Preliminary Accreditation** – The organization demonstrates compliance with selected standards in surveys conducted under the Early Option Survey Policy.
 - b. **Accredited** – Indicates that a health care facility meets the HFAP accreditation requirements and, based on the decision of the Executive Committee, accreditation may be granted for one, two, or three years.
 - c. **Denial of Accreditation** – Indicates that a health care facility has been denied accreditation because it does not meet HFAP requirements.
3. A random sample of five percent of accredited facilities may receive a mid-cycle review in order to demonstrate that facilities maintain their compliance with the HFAP requirements throughout the three-year accreditation period.
4. A health care facility that has been granted accreditation is provided with an HFAP Certificate of Accreditation.
5. The Bureau may alter the accreditation status of a health care facility for just cause. Just cause includes, but is not limited to, failure to maintain compliance with HFAP accreditation requirements.

B. Denial or Revocation of Accreditation

1. A denial of accreditation may be taken when during an initial survey a facility fails to demonstrate compliance with one or more CMS Conditions of Participation.
2. The Bureau may revoke accreditation from a health care facility at any time when reviewed by the Bureau and it is determined there is cause for such action. Revocation of accreditation may occur when the provider or supplier is either:
 - a) substantially noncompliant with accreditation standards and has not corrected its deficient practices within the timeframe specified by the AOA/HFAP, or
 - b) due to the provider's or supplier's nonpayment of accreditation fees.
3. The written notice of impending revocation of accreditation will be addressed to the president of the governing body, chief executive officer and the chief of staff of the health care facility.
4. Denial or revocation of accreditation becomes effective 30 days after action by the Bureau if there is no appeal by the health care facility. This enables health care facilities to maintain accreditation for 30 days while applying for state certification. However, the Bureau reserves the right to forego the 30-day period if it believes that the facility has failed to provide a safe environment for care or that the facility has failed to mitigate any situation that could pose an immediate threat to patient safety.
5. The Bureau may choose to revoke a facility's accreditation for the following reasons:
 - a. Failure to follow HFAP policy and procedure
 - b. Failure to meet accreditation requirements
 - c. Failure to meet HFAP standards
 - d. Failure to meet Medicare requirements (substantial non-compliance with CMS conditions of participation)
 - e. Non-payment of fees associated with accreditation in a timely manner
 - f. Requirements not met
 - g. Falsification of information submitted to HFAP during the application process or during survey
 - h. Failure to permit the performance of a survey
 - i. Failure to correct deficiencies related to an immediate jeopardy situation
 - j. Failure to submit a Plan of Correction for noncompliance identified during survey

- k. Inability to sustain compliance with standards after a second focused resurvey
- l. Alleged criminal activity

C. Appeal procedure

1. The health care facility may appeal the Bureau action to revoke accreditation status to the Appeal Committee of the Bureau of Healthcare Facilities Accreditation. This request must be in writing and must be filed within thirty (30) calendar days following receipt of the Bureau's decision to revoke accreditation status. The Appeal Committee is convened by teleconference within ten (10) business days of receiving notification from the facility that it wishes to appeal the decision of the Bureau. The health care facility may provide additional materials to the Appeals Committee for its consideration but may not take part in the teleconference.
2. The HFAP will notify the health care facility in writing of the action taken by the Appeal Committee within three (3) business days of the Appeal Committee hearing.
3. The health care facility may appeal denial action by the Appeal Committee to the American Osteopathic Association (AOA) Board of Trustees. Such requests must take place within seven (7) calendar days following receipt of the Appeal Committee decision. The health care facility may petition the AOA Board of Trustees Appeal Committee to appear before them and present their case.
4. The HFAP will notify the health care facility in writing of the action taken by the AOA Board of Trustees within three (3) business days of the Board hearing. The AOA Board of Trustees' action is final.

ADMINISTRATION OF THE ORGANIZATIONAL ENVIRONMENT

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
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01.00.00 Condition of Participation: Compliance with Federal, State, and Local Laws.

The hospital must ensure that all applicable Federal, State, and local law requirements are met.
§482.11

Self-explanatory.

Score this Condition based on scoring from 01.00.01 through 01.00.04

- 1 = Compliant
- 2 = Not Compliant

This standard is not met as evidenced by:

01.00.01 Governance Plan.

The administration and governance of all facility services is based upon the stated governance plan of the facility and is appropriate to the scope and complexity of the services offered.

There is a written plan for the provision of services, which supports the governance plan.

The governance plan, which may be included in the Articles of Incorporation for the facility, is the foundation for the document(s) known as the "plan for the provision of services."

Elements within the plan include identification of:

1. Governance and administration
2. Organizational relationships
3. Budget processes, including staffing
4. Scope of services provided
5. Mechanisms for planning
6. Mechanisms for assessing and improving the structure, processes and outcomes of services and care
7. Mission Statement (required)
8. Vision Statement and values (may be included)

DOCUMENT REVIEW

1. Verify that there is a published governance plan, which is central to the development of the written plan for the provision of services.
2. Verify that the plan for the provision of services effectively outlines at least the first seven of the eight major areas listed.

- 1 = Compliant
- 2 = Not Compliant

This standard is not met as evidenced by:

ADMINISTRATION OF THE ORGANIZATIONAL ENVIRONMENT

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>01.00.02 Compliance with Laws. <i>The hospital must be in compliance with applicable federal laws related to the health and safety of patients.</i></p> <p>§482.11(a)</p>	<p>Administrative policies outline the intent to conform to all applicable laws. Reports of surveys, inspections, and complaint investigations are maintained, by the hospital with copies of corrective action plans and follow-up communications to and from the appropriate agency.</p> <p>Review of findings from such reports and follow-up actions and results are acknowledged in minutes of the governing body.</p> <p>The hospital shall be in compliance with its own policies and procedures.</p>	<p><u>DOCUMENT REVIEW AND OBSERVATION</u></p> <ol style="list-style-type: none"> 1. Review all federal, state, and local surveys, inspections and investigations of the hospital that have occurred since the last accreditation survey. 2. Determine whether required corrective actions have been accomplished and monitored for compliance. 3. Determine whether the hospital is in compliance with its own policies and procedures. <p style="text-align: center;"><u>INTERVIEW</u></p> <p>Interview the CEO or appropriate individual designated by the hospital to determine compliance with federal laws related to patient health and safety (for example, ask if the hospital was cited since its last survey for any violation of section 504 of the rehabilitation act of 1973 related to denying people with Disabilities access to care. If so, verify that satisfactory corrections have been made to bring the hospital into compliance with that law). Refer or report noted noncompliance with federal laws and regulations to the appropriate agency having jurisdiction (e.g., accessibility issues, blood-borne pathogens, standard precautions, and TB control to OSHA; hazardous chemical / waste issues to EPA; etc.)</p>	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

ADMINISTRATION OF THE ORGANIZATIONAL ENVIRONMENT

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>01.00.03 Hospital Licensure. <i>The hospital must be licensed or approved as meeting standards for licensing established by the agency of the state or locality responsible for licensing hospitals.</i></p> <p>§482.11(b)(1) §482.11(b)(2)</p>	<p>In addition to any posted evidence of such licensure there is an agency letterhead communication to verify the status.</p>	<p align="center"><u>DOCUMENT REVIEW</u></p> <p>Prior to the survey, determine whether the hospital is subject to licensure requirements.</p> <ol style="list-style-type: none"> 1. Verify that the licensing agency has approved hospital as meeting the standards for licensure as set forth by the agency of the State or locality responsible for licensing hospitals. 2. Review a copy of the state license to meet the standard. Verify that all other required licenses are current (e.g., pharmacy, incinerator, CLIA, etc.). 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>
<p>01.00.04 Licensure of Personnel. <i>The hospital must assure that personnel are licensed or meet other applicable standards that are required by State or local laws.</i></p> <p>§482.11(c)</p>	<p>All staff that are required by the State to be licensed must possess a current license.</p> <p>The hospital must assure that these personnel are in compliance with the State’s licensure laws. The laws requiring licensure vary from state to state. Examples of healthcare professionals that a state may require to be licensed could include: nurses, doctor of medicine / doctor of osteopathic medicine, physician assistants, dietitians, X-ray technologists, dentists, physical therapists, occupational therapists, respiratory therapists and hospital administrators.</p> <p>All staff must meet all applicable standards required by the State or local law for hospital personnel. This would include at a minimum:</p>	<p align="center"><u>DOCUMENT REVIEW</u></p> <p>Verify for those personnel required to be licensed, certified and/or permitted by the State, that the hospital has established and follows procedures for determining that personnel are properly licensed, certified and/or permitted.</p> <p align="center"><u>FILE REVIEW</u></p> <ol style="list-style-type: none"> 1. Verify that staff and personnel are licensed, certified and/or permitted in accordance with State and local requirements including telemedicine files if applicable. 2. Verify that staff and personnel meet all standards (such as continuing education, basic qualifications, etc.) required by State 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

ADMINISTRATION OF THE ORGANIZATIONAL ENVIRONMENT

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
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- Certification Requirements;
- Minimum qualifications;
- Training education requirements; and
- Permits (such as food handlers permits.

When telemedicine is used and the practitioner and patient are located in different states, the practitioner providing the patient care service must be licensed and/or meet the other applicable standards that are required by State or local laws in both the state where the practitioner is located and the state where the patient is located.

and local laws or regulations. Verify that the hospital has a mechanism established and enforced to ensure compliance.

3. Review a sample of personnel files to verify that licensure and/or other required credentials information is up to date. Verify State licensure compliance of the direct care personnel as well as administrators and supervisory personnel.

01.00.05 Not Applicable.

01.00.06 Articles of Incorporation & Documentation of Actions.

The governing body maintains Articles of Incorporation, bylaws (or governance policies), and a record of deliberations (minutes) leading to actions in specific areas.

The required documents are preserved and safeguarded so as to provide a reasonable means of evaluating ethical and prudent business decisions impacting patient welfare and safety.

DOCUMENT REVIEW

1. Determine that Articles of Incorporation, bylaws (or governance policies) exist and are safeguarded. Copies may exist in addition to the original documents.
2. Request and review records of actions (minutes) of the governing body.

- 1 = Compliant
- 2 = Not Compliant

This standard is not met as evidenced by:

ADMINISTRATION OF THE ORGANIZATIONAL ENVIRONMENT

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>01.00.07 Governing Body Responsibilities. The governance bylaws define the responsibility for at least the following:</p> <p>A. Adoption and periodic review of governance bylaws governance policies.</p> <p>B. Approval and monitoring of budget(s).</p> <p>C. Implementation of effective fiscal accounting system(s).</p> <p>D. Provision of an organized professional medical staff structure.</p> <p>E. An ongoing hospital-wide quality assessment performance improvement (QAPI) program including a written plan of implementation. Provision of adequate resources to implement the programs of service.</p> <p>F. Provision for the adequacy of the physical plant.</p> <p>G. An annual performance evaluation by the governing body of itself.</p>	<p>Governance bylaws (or policies) effectively describe these functions. Additional components may include:</p> <ul style="list-style-type: none"> • How the governance members are selected and maintain their affiliation relationship(s) to any higher authority such as ownership (municipal, city, private, multihospital, etc.). • The process for strategic planning. <p>The Governing Body has a mechanism in place for the review of the governance bylaws no less than every three (3) years.</p>	<p style="text-align: center;"><u>DOCUMENT REVIEW</u></p> <ol style="list-style-type: none"> 1. Review the governance bylaws (policies) for acknowledgment and implementation of the listed requirements. 2. Verify the governance bylaws include a provision for periodic review. The governance bylaws have been reviewed within the past three (3) years. 3. Verify the governing body has completed a performance evaluation of itself within the past 12 months. <p>SURVEYOR: Responsibilities identified as noncompliant in the bylaws must be listed including the CFR number.</p>	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

ADMINISTRATION OF THE ORGANIZATIONAL ENVIRONMENT

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>01.01.00 Condition of Participation: Governing Body. <i>There must be an effective governing body that is legally responsible for the conduct of the hospital as an institution.</i></p> <p><i>If a hospital does not have an organized governing body, the persons legally responsible for the conduct of the hospital must carry out the functions specified in this part that pertain to the governing body.</i></p> <p>§482.12</p>	<p>The hospital must have a governing body which is effective in carrying out its responsibilities for the conduct of the hospital. In the absence of an organized governing body, there must be written documentation that identifies the individual or individuals that are legally responsible for the conduct of the hospital operations.</p> <p>If the hospital is part of a healthcare system that includes several separately certified hospitals, each with its own Medicare provider agreement and CMS Certification Number, the governing body of the healthcare system has the option to act as the governing body of each separately certified hospital, unless doing so would conflict with State law.</p> <p>A hospital system also has the option to form several governing bodies, each of which is responsible for several separately certified hospitals. For example, a health system operating hospitals in many states might choose to form regional sub-boards each responsible for the hospitals in its region, or a health system that has a mixture of types of hospitals may choose to form one sub-board responsible for its short-term acute care hospitals and another for its long term care hospitals.</p> <p>When deciding whether or not to exercise the option to have a single governing body for multiple hospitals in the system, another factor for systems to consider might be Medicare payment requirements at §§412.22(e) - (h) applicable to certain types of hospitals, i.e., non-grandfathered Hospitals-within-</p>	<p style="text-align: center;"><u>DOCUMENT REVIEW</u></p> <ol style="list-style-type: none"> 1. Verify that the hospital has an organized governing body or has written documentation that identifies the individual or individuals that are responsible for the conduct of the hospital operations. 2. If the hospital is part of a hospital system which uses one governing body for several of the hospital's separately certified within the system: <ul style="list-style-type: none"> • Review the governing body minutes to determine if it is clear which actions pertain to which hospitals. • Select for review several policy and procedure documents adopted by the system governing body to determine if it is clear that they apply to the hospital being surveyed. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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Hospitals and Hospital Satellites. In such cases where the hospital system owns both the tenant and the host hospital, using a single governing body for both hospitals would jeopardize the payment status of a hospital that is being paid by Medicare under a payment system excluded from the Hospital Inpatient Prospective Payment System (IPPS). However, surveyors do not assess compliance with or enforce the Medicare payment regulations that govern Hospitals-within-Hospitals or Hospital Satellites.

The Medicare program offers hospital facilities considerable flexibility regarding how they choose to participate. Based on the geographic and other institutional limitations set out in the “provider-based” regulation at §413.65, which addresses provider-based status for hospital facilities in multiple locations, hospital governing bodies make business decisions about how they want to participate in Medicare, and they indicate on their Medicare enrollment application the choices they have made.

It is not uncommon to find multiple hospital campuses with one owner located in the same geographic area enrolled in Medicare as one hospital.

It is also not uncommon to see a hospital system choosing to enroll its various facilities as separately certified hospitals. Various factors enter into consideration when the governing body of a system makes these decisions.

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For example, some governing bodies prefer to enroll various campuses as separate hospitals, out of a concern that problems at one hospital’s campus might jeopardize the Medicare participation of the other campuses if they were a multi-campus hospital covered under one Medicare provider agreement. In other cases a governing body may see the benefits of integrating clinical services on multiple campuses into one integrated hospital. In still other cases, the deciding factor might be the implications for Medicare reimbursement of graduate medical education, the ease of adding satellite locations, etc.

CMS defers to the governing bodies of hospitals to weigh the pertinent factors and permissible options, and to make business decisions in their best interest when applying to participate in Medicare.

CMS’s hospital certification decisions and issuance of a provider agreement and associated CCN follow from these business decisions by a hospital’s governing body. But once the “hospital,” with whatever component parts, has been certified, that hospital must independently demonstrate its compliance with the CoPs, independent of any other facility. (77 FR 29040, May 16, 2012)

If a hospital system has chosen to have a one body act as the governing body for multiple separately certified hospitals, this does not alter the fact that each hospital must independently demonstrate compliance with the CoPs.

Examples of what this means include, but are not

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limited to, the following:

- Each separately certified hospital must be separately and independently assessed for its compliance with the CoPs, through either State Survey Agency or approved Medicare hospital accreditation program surveys. There is no survey of a hospital “system,” since the Medicare provider agreement and its terms are specific to each certified hospital.

- A system governing body may wish to adopt identical policies and procedures for many aspects of a hospital’s operations across all of its hospitals within the system. It has the flexibility to do so, but the documentation of such policies and procedures must be clear that the governing body has chosen to apply them to specifically named hospitals. Also, each hospital must be able to present for inspection the system governing body policies and procedures that clearly apply to that hospital. For example:
 - A document that says “XX Healthsystem has adopted the following policy” is not acceptable. Instead, the document must be more specific, such as, “XX Healthsystem adopts the following policy and procedure for Hospital A, Hospital B, and Hospital C.” Furthermore, the names of each

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hospital (Hospitals A, B, and C in this example) must correspond to the names used for their provider agreements. For example, if Hospital C is one Medicare-certified hospital with two inpatient campuses, one called “East” and one called “West,” it is not acceptable for the policy document to state, “XX Healthsystem adopts the following policy and procedure for Hospital A, Hospital B, and Hospital East and Hospital West.” It would be acceptable to state, “XX Healthsystem adopts the following policy and procedure for Hospital A, Hospital B, and Hospital C.”

- It also is not acceptable for the policy document to state, “XX Healthsystem adopts the following policy and procedure for Hospital A, Hospital B, and Hospital East, but not Hospital West.” Since “Hospitals” East and West refer to separate campuses of Hospital C, which participates in Medicare as one multi-campus hospital, it is not appropriate to refer to these separate campuses of C as “hospitals,” since the XX Healthsystem made a business decision to enroll them as parts of one multi-campus hospital in Medicare. CMS recognizes that, depending on the particular policy topic, it may be acceptable to have policies that vary by

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type of unit/department within a hospital. The system governing body could achieve this as follows: “XX Healthsystem adopts the following policy and procedure requiring that a physician be on-site 24 hours per day, seven days per week on the inpatient campuses of Hospital A and Hospital B, but within Hospital C, only for the East inpatient campus.”

- Likewise, the minutes of the governing body must be written in such a manner so that it is clear when the governing body has taken actions that apply to a specific certified hospital.
- Departments of separately certified hospitals with one system governing body cannot be operationally integrated. For example, if a system has chosen to operate three separately certified hospitals in relatively close proximity to each other rather than to have them certified as one multi-campus hospital, then each hospital must have its own nursing service. It may not have one integrated nursing service with one Director of Nursing who manages one nursing staff for all three hospitals. The system cannot maintain one integrated schedule that assigns nursing staff among the different hospitals. The system also cannot move them back and forth between hospitals on an ad hoc, as needed basis, as if they were one hospital.

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On the other hand, the policies and procedures the governing body has adopted for the nursing service in each hospital may be identical, so long as the services operate separately. It is also permissible for the same individual to be the Director of Nursing for each hospital, provided that he or she is able to carry out all of the duties of the position in each hospital, such as managing each hospital's separate nursing staff. It is also permissible for one nurse to work at multiple hospitals within the system, in the same way that a nurse may work for multiple hospitals that do not share ownership, but the nurse must have separate work schedules for each hospital. Such schedules cannot overlap.

- Likewise, although the system may choose to operate a quality assessment/performance improvement (QAPI) program at the system level which standardizes indicators measured across system hospitals, each separately-certified hospital in the system must have a QAPI program that is specific to that hospital. This is required not only to demonstrate compliance, but also for the governing body to function effectively, since reviewing QAPI program results only at the system level would make it difficult for the governing body to identify and act upon

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problems that are localized to one hospital.

For example, the system may choose to use the same quality indicators or the same methodology to track adverse events across all system hospitals. But each certified hospital must have its own QAPI data with respect to these indicators and adverse events. If a system is tracking readmission rates across all of its hospitals, it must be able to separate out the hospital-specific results for the governing body's review and possible action.

The governing body must be functioning effectively and holds the ultimate responsibility for the hospital's compliance not only with the specific standards of the governing body CoP, but also with all of the CoPs. This is the case regardless of whether the regulatory text for a particular condition or standard within a condition specifically mentions responsibilities of the governing body.

Substantial, i.e., condition-level, non-compliance with one of the other hospital CoPs may be an indicator that the governing body is not functioning effectively. However, it is not the policy of CMS that condition-level noncompliance with any other CoP automatically results in a condition-level citation of the governing body CoP. Surveyors must consider whether the manner and degree of the other deficiencies provide sufficient evidence to conclude that the governing body is not functioning effectively.

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<p>01.01.01 Categories Eligible for Appointment. <i>The governing body must:</i></p> <ul style="list-style-type: none"> • <i>Determine, in accordance with State law, which categories of practitioners are eligible candidates for appointment to the medical staff.</i> <p>§482.12(a) §482.12(a)(1)</p>	<p>The governing body must ensure the medical staff requirements are met.</p> <p>The governing body must determine, in accordance with State law, which categories of practitioners are eligible for appointment to the medical staff.</p> <p>PHYSICIANS The medical staff must, at a minimum, be composed of physicians who are doctors of medicine or doctors of osteopathic medicine.</p> <p>In addition, the medical staff may include other types of practitioners included in the definition of a physician in Section 1861[®] of the Social Security Act:</p> <ul style="list-style-type: none"> • Doctor of dental surgery or of dental medicine; • Doctor of podiatric medicine; • Doctor of optometry; and • A Chiropractor. <p>In all cases, the practitioner included in the definition of a physician must be legally authorized to practice within the State where the hospital is located and providing services within their authorized scope of practice. In addition, in certain instances the Social Security Act and regulations attach further limitations as to the type of hospital services for which a practitioner may be considered to be a “physician.” See 42 CFR 482.12(c)(1) [see 01.01.15] for more details on these limitations.</p> <p>The governing body has the flexibility, consistent with</p>	<p style="text-align: center;">DOCUMENT REVIEW</p> <ul style="list-style-type: none"> • Review documentation and verify that the governing body has determined and stated the categories of physicians and practitioners that are eligible candidates for appointment to the medical staff or to be granted medical staff privileges. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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State law, to determine whether practitioners included in the definition of a physician other than a doctor of medicine or osteopathic medicine are eligible for appointment to the medical staff.

**For Information Only –
Not Required/ Not to be Cited**

CMS expects that all physician practitioners granted privileges are also appointed as members of the medical staff. However, if State law limits the composition of the hospital’s medical staff to certain categories of practitioners, e.g., only MDs or DOs, there is nothing in the CoPs that prohibits hospitals and their medical staffs from establishing certain practice privileges for other categories of physician practitioners excluded from medical staff membership under State law, or from granting those privileges to individual practitioners in those categories, as long as such privileges are recommended by the medical staff, approved by the governing body, and in accordance with State law. (79 FR 27114 - 27115, May 12, 2014)

For physician practitioners granted privileges only, the hospital’s governing body and its medical staff must exercise oversight, such as through credentialing and competency review, of those other physician practitioners to whom it grants privileges, just as it would for those practitioners appointed to

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its medical staff.

NON-PHYSICIAN PRACTITIONERS

Furthermore, the governing body has the authority, in accordance with State law, to grant medical staff privileges and membership to non-physician practitioners. The corresponding regulation at 42 CFR 482.22(a) allows hospitals and their medical staffs to take advantage of the expertise and skills of all types of practitioners who practice at the hospital when making decisions concerning medical staff privileges and membership. Granting medical staff privileges and membership to non-physician practitioners is an option available to the governing body; it is not a requirement.

For non-physician practitioners granted privileges only, the hospital's governing body and its medical staff must exercise oversight, such as through credentialing and competency review, of those non-physician practitioners to whom it grants privileges, just as it would for those practitioners appointed to its medical staff.

Practitioners are **described** in Section 1842(b)(18)(C) of the Act as **any of the following**:

- Physician assistant (as defined in Section 1861(aa)(5) of the Act);
- Nurse practitioner (as defined in Section 1861(aa)(5) of the Act);
- Clinical nurse specialist (as defined in Section

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1861(aa)(5) of the Act);

- Certified registered nurse anesthetist (**as defined in** Section 1861(bb)(2) of the Act);
- Certified nurse-midwife (**as defined in** Section 1861(gg)(2) of the Act);
- Clinical social worker (**as defined in** Section 1861(hh)(1) of the Act);
- Clinical psychologist (**as defined in** 42 CFR 410.71 for purposes of Section 1861(ii) of the Act);
- **Anesthesiologist’s Assistant (as defined at §410.69)** or
- Registered dietitian or nutrition professional.

Other types of licensed healthcare professionals have a more limited scope of practice and **usually are not** eligible for hospital medical staff privileges, unless their permitted scope of practice in their State makes them comparable to the above types of **non-physician** practitioners.

Some examples of types of such licensed healthcare professionals who might be eligible for medical staff privileges, depending on State law and medical staff bylaws, rules and regulations include, but are not limited to:

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- Physical Therapist (as defined at §410.60 and §484.4);
- Occupational Therapist (as defined at §410.59 and §484.4); and
- Speech Language Therapist (as defined at §410.62 and §484.4).

Furthermore, some States have established a scope of practice for certain licensed pharmacists who are permitted to provide patient care, services that make them more like the above types of non-physician practitioners, including the monitoring and assessing of patients and ordering medications and laboratory tests. In such States, a hospital may grant medical staff privileges to such pharmacists and/or appoint them as members of the medical staff. There is no standard term for such pharmacists, although they are sometimes referred to as “clinical pharmacists.”

Practitioners may be granted active, courtesy, emergency, temporary, etc. membership or privileges in accordance with state law and as specified in the medical staff bylaws, rules, and regulations.

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<p>01.01.02 Medical Staff Appointment. <i>The governing body must:</i></p> <ul style="list-style-type: none"> • <i>Appoint members of the medical staff after considering the recommendations of the existing members of the medical staff.</i> <p>§482.12(a)(2)</p>	<p>The governing body determines whether to grant, deny, continue, revise, discontinue, limit, or revoke specified privileges, including medical staff membership, for a specific practitioner after considering the recommendation of the medical staff.</p> <p>In all instances, the governing body's determination must be consistent with established hospital medical staff criteria, as well as with State and Federal law and regulations.</p> <p>Only the hospital's governing body has the authority to grant a practitioner privileges to provide care in the hospital.</p>	<p style="text-align: center;"><u>DOCUMENT REVIEW</u></p> <ol style="list-style-type: none"> 1. Confirm that there is evidence that the governing body considered recommendations of the medical staff before making medical staff appointments. 2. Review records of medical staff appointments to determine that the governing body is involved in appointments of medical staff members. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>
<p>01.01.03 Provision of Medical Staff Bylaws. <i>The governing body must:</i></p> <ul style="list-style-type: none"> • <i>Assure that the medical staff has bylaws.</i> <p>§482.12(a)(3)</p>	<p>The governing body must assure that the medical staff has bylaws and that those bylaws comply with State and Federal law and the requirements of the Medicare hospital Conditions of Participation.</p>	<p style="text-align: center;"><u>DOCUMENT REVIEW</u></p> <ul style="list-style-type: none"> • Verify that the medical staff operates under current bylaws that are in accordance with Federal and State laws and regulations. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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<p>01.01.04 <u>Approval of Medical Staff Bylaws.</u> <i>The governing body must:</i></p> <ul style="list-style-type: none"> • <i>Approve medical staff bylaws and other medical staff rules and regulations.</i> <p>§482.12(a)(4)</p>	<p>The governing body decides whether or not to approve medical staff bylaws submitted by the medical staff.</p> <p>The medical staff bylaws and any revisions must be approved by the governing body before they are considered effective.</p>	<p style="text-align: center;"><u>DOCUMENT REVIEW</u></p> <ol style="list-style-type: none"> 1. Verify that the medical staff operates under current bylaws, rules and policies that have been approved by the governing body. 2. Verify that any revisions or modifications in the medical staff bylaws, rules and policies have been approved by the medical staff and the governing body, e.g., bylaws are annotated with date of last review and initialed by person(s) responsible. 3. Verify the governing body has reviewed and approved the medical staff bylaws minimally every three (3) years. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>
<p>01.01.05 <u>Medical Staff Quality of Care.</u> <i>The governing body must:</i></p> <ul style="list-style-type: none"> • <i>Ensure that the medical staff is accountable to the governing body for the quality of care provided to patients.</i> <p>§482.12(a)(5)</p>	<p>The governing body must ensure that the medical staff as a group is accountable to the governing body for the quality of care provided to patients. The governing body is responsible for the conduct of the hospital and this conduct includes the quality of care provided to patients.</p> <p>All hospital patients must be under the care of a practitioner who meets the criteria of 42 CFR §482.12(c)(1) [01.00.18] and who has been granted medical staff privileges, or under the care of a practitioner who is directly under the supervision of a member of the medical staff.</p> <p>All patient care is provided by or in accordance with the orders of a practitioner who has been granted privileges in accordance with the criteria established</p>	<p style="text-align: center;"><u>DOCUMENT REVIEW</u></p> <ol style="list-style-type: none"> 1. Verify that the governing body is periodically apprised of the medical staff evaluation of patient care services provided hospital wide, at every patient care location of the hospital. 2. Verify that any individual providing patient care services is a member of the medical staff or is accountable to a member of the medical staff qualified to evaluate the quality of services provided, and in turn, is responsible to the governing body for the quality of services provided. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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by the governing body, and who is working within the scope of those granted privileges.

01.01.06 Selection Criteria for Appointment to the Staff.

The governing body must:

- *Ensure the criteria for selection are individual character, competence, training, experience, and judgment.*

§482.12(a)(6)

The governing body must assure that the medical staff bylaws describe the privileging process to be used by the hospital. The process articulated in the medical staff bylaws, rules, or regulations must include criteria for determining the privileges that may be granted to individual practitioners and a procedure for applying the criteria to individual practitioners that considers:

- Individual character;
- Individual competence;
- Individual training;
- Individual experience; and
- Individual judgment.

The governing body must ensure that the hospital's bylaws governing medical staff membership or the granting of privileges apply equally to all practitioners in each professional category of practitioners.

DOCUMENT REVIEW

- Verify that there are written criteria for appointments to the medical staff and granting of medical staff privileges.

FILE REVIEW

- Verify that granting of medical staff membership or privileges, both new and renewal, is based upon an individual practitioner's meeting the medical staff's membership privileging criteria.
- Verify that, at a minimum, criteria for appointment to the medical staff granting of medical staff privileges are individual character, competence, training, experience, and judgment.

- 1 = Compliant
- 2 = Not Compliant

This standard is not met as evidenced by:

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<p>01.01.07 Required Criteria for Appointment. <i>The governing body must:</i></p> <ul style="list-style-type: none"> Ensure that under no circumstances is the accordance of staff membership or professional privileges in the hospital dependent solely upon certification, fellowship or membership in a specialty body or society. <p>§482.12(a)(7)</p>	<p>In making a judgment on medical staff membership, a hospital may not rely solely on the fact that a Doctor of Medicine / Doctor of Osteopathic Medicine is, or is not, board-certified. This does not mean that a hospital is prohibited from requiring board certification when considering a Doctor of Medicine / Doctor of Osteopathic Medicine for medical staff membership, but only that such certification must not be the only factor that the hospital considers.</p> <p>In addition to matters of board certification, a hospital must also consider other criteria such as training, character, competence and judgment. After analysis of all of the criteria, if all criteria are met except for board certification, the hospital has the discretion to decide not to select that individual to the medical staff.</p>	<p style="text-align: center;"><u>FILE REVIEW</u></p> <ul style="list-style-type: none"> Verify that written criteria for appointment to the medical staff and granting of medical staff privileges are not dependent solely upon certification, fellowship, or membership in a specialty body or society. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>
<p>01.01.08 Telemedicine Agreements with Distant-Site Hospital or Distant-Site Telemedicine Entity. <i>The governing body must:</i></p> <ul style="list-style-type: none"> Ensure that, when telemedicine services are furnished to the hospital's patients through an agreement with a distant-site hospital, the agreement is written and that it specifies that it is the responsibility of the governing body of the distant-site hospital to meet the requirements in 	<p>"Telemedicine," as the term is used in this regulation, means the provision of clinical services to patients by physicians and practitioners from a distance via electronic communications. The distant-site telemedicine physician or practitioner provides clinical services to the hospital patient either simultaneously, as is often the case with teleICU services, for example, or non-simultaneously, as may be the case with many teleradiology services.</p> <p>"Simultaneously" means that the clinical services (for example, assessment of the patient with a clinical plan for treatment, including any medical orders needed) are provided to the patient in "real time" by the</p>	<p style="text-align: center;"><u>INTERVIEW</u></p> <p>Ask the hospital's leadership whether it uses telemedicine services. If yes:</p> <ol style="list-style-type: none"> Ask to see a copy of the written agreement(s) with the distant-site hospital(s) or telemedicine entity (ies). Does each agreement include the required elements concerning credentialing and privileging of the telemedicine physicians and practitioners? Does the hospital have documentation indicating that it granted privileges to each telemedicine physician and practitioner? 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant <input type="checkbox"/> NA=Not Applicable</p> <p>This standard is not met as evidenced by:</p>

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<p><i>accordance with paragraphs (a)(1) through (a)(7) of 42 CFR 482.12 with regard to the distant-site hospital's physicians and practitioners providing telemedicine services. The governing body of the hospital whose patients are receiving the telemedicine services may, in accordance with §482.22(a)(3) of 42 CFR 482.12, grant privileges based on its medical staff recommendations that rely on information provided by the distant-site hospital.</i></p> <p>§482.12(a)(8)</p> <ul style="list-style-type: none"> • <i>Ensure that, when telemedicine services are furnished to the hospital's patients through an agreement with a distant-site telemedicine entity, the written agreement specifies that the distant-site telemedicine entity is a contractor of services to the hospital and as such, in accordance with §482.12(e), furnishes the contracted services in a manner that permits the hospital to comply with all applicable conditions of participation for the contracted</i> 	<p>telemedicine physician or practitioner, similar to the actions of an on-site physician or practitioner.</p> <p>“Non-simultaneously” means that while the telemedicine physician or practitioner still provides clinical services to the patient upon a formal request from the patient’s attending physician; such services may involve after-the-fact interpretation of diagnostic tests in order to provide an assessment of the patient’s condition and do not necessarily require the telemedicine practitioner to directly assess the patient in “real time.” This would be similar to the services provided by an on-site radiologist who interprets a patient’s x-ray or CT scan and then communicates his or her assessment to the patient’s attending physician who then bases his or her diagnosis and treatment plan on these findings (see 76 FR 25551-25552, May 5, 2011).</p> <p>A hospital may make arrangements through written agreements either with a distant-site Medicare-participating hospital or a distant-site telemedicine entity for the provision of telemedicine services to the hospital’s patients by physicians or practitioners who have been granted privileges by the distant-site hospital or telemedicine entity.</p> <p>For the purposes of this rule, a distant-site telemedicine entity is defined as an entity that</p> <ul style="list-style-type: none"> (1) provides telemedicine services; (2) is not a Medicare-participating hospital; and 	<ul style="list-style-type: none"> 3. Does the documentation indicate that for each telemedicine physician and practitioner there is a medical staff recommendation, including an indication of whether the medical staff conducted its own review or relied upon the decisions of the distant-site hospital or telemedicine entity? 	

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<p><i>services, including, but not limited to, the requirements in paragraphs (a)(1) through (a)(7) of 42 CFR 482.12 with regard to the distant-site telemedicine entity's physicians and practitioners providing telemedicine services.</i></p> <p><i>The governing body of the hospital whose patients are receiving the telemedicine services may, in accordance with §482.22(a)(4) of 42 CFR 482.22, grant privileges to physicians and practitioners employed by the distant-site telemedicine entity based on such hospital's medical staff recommendations; such staff recommendations may rely on information provided by the distant-site telemedicine entity.</i></p> <p>§482.12(a)(9)</p>	<p>(3) provides contracted services in a manner that enables a hospital using its services to meet all applicable CoPs, particularly those requirements related to the credentialing and privileging of practitioners providing telemedicine services to the patients of a hospital.</p> <p>A distant-site telemedicine entity would include a distant-site hospital that does not participate in the Medicare program that is providing telemedicine services to a Medicare-participating hospital. (See 76 FR 25553, May 5, 2011).</p> <p>If a hospital enters into an agreement for telemedicine services with a distant-site hospital or telemedicine entity, the agreement must be in writing.</p> <p>Furthermore, the written agreement must specify, in the case of a:</p> <ul style="list-style-type: none"> • Distant-site hospital, that it is the responsibility of the governing body of the distant-site hospital to satisfy the requirements of §482.12(a)(1) through (a) (7) with respect to those physicians and practitioners at the distant-site hospital who furnish telemedicine services under the agreement. Since the distant-site hospital must also be a Medicare-participating hospital (see §482.22(a)(3)), it has an independent obligation to comply with these governing body requirements concerning medical staff membership and privileging. Nevertheless, the written agreement between the hospital and the distant-site hospital 		

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must explicitly include a provision addressing the distant-site hospital’s obligation to comply with these provisions.

- **Distant-site telemedicine entity**, that the written agreement specifies that the entity is a contractor providing telemedicine services to the hospital, and that, in accordance with the requirements governing services under arrangement at §482.12(e), the telemedicine entity furnishes the contracted telemedicine services in a manner that permits the hospital to comply with the Conditions of Participation, including, but not limited to, the governing body requirements of §482.12(a)(1) through (a) (7) with respect to those physicians and practitioners at the distant-site telemedicine entity who furnish telemedicine services under the agreement.

There are additional requirements for the content of the written agreement, specified at §482.22(a)(3) and §482.22(a)(4) under the medical staff Condition of Participation, which are discussed in the interpretive guidelines for those regulations.

The hospital’s governing body must grant privileges to each telemedicine physician or practitioner providing services at the hospital under an agreement with a distant-site hospital or telemedicine entity before they may provide telemedicine services. The scope of the privileges in the hospital must reflect the provision of the services via a telecommunications system. For example, a surgeon at a distant-site hospital may

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provide telemedicine consultation services at a hospital under agreement, but obviously would not be able to perform surgery by this means and must not have surgical privileges in the hospital as part of his/her telemedicine services privileges. If the surgeon also periodically performed surgery on-site at the hospital, then he or she would have to have privileges to do so, granted in the traditional manner provided for at §482.12(a)(1) through §482.12(a)(7) and §482.22(a)(1) and §482.22(a)(2).

In granting privileges to telemedicine physicians and practitioners, the hospital’s governing body has the option of considering hospital medical staff recommendations that rely, in accordance with §482.22(a)(3) and §482.22(a)(4), upon the credentialing and privileging decisions of the distant-site hospital or telemedicine entity. With respect to the decisions of a distant-site telemedicine entity, the regulation states that this streamlined privileging option is available to the hospital for physicians and practitioners “**employed**” by the distant-site telemedicine entity. We are interpreting “employed” in this context to mean “utilized by” the distant-site telemedicine entity to provide telemedicine services to the hospital under an agreement. Since it is common for telemedicine entities to contract with, rather than employ, the physicians and practitioners it utilizes to provide telemedicine services, it would not be reasonable or consistent with the regulatory intent to interpret “employed” to mean that the physicians or practitioners are employees of the distant-site telemedicine entity.

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When the hospital’s governing body exercises the option to grant privileges based on its medical staff recommendations that rely upon the privileging decisions of a distant-site telemedicine hospital or entity, it may, but is not required to, maintain a separate file on each telemedicine physician and practitioner, or may instead have a file on all telemedicine physicians and practitioners providing services at the hospital under each agreement with a distant-site hospital or telemedicine entity, indicating which telemedicine services privileges the hospital has granted to each physician and practitioner on the list.

Relying upon the credentialing and privileging decisions of the distant-site hospital or telemedicine entity is an option available to the hospital’s governing body, not a requirement. A governing body may, if it so chooses, require its medical staff to independently review the credentials of and make privileging recommendations for each telemedicine physician and practitioner in accordance with §482.22(a)(1) and §482.22(a)(2), rather than permit its medical staff to rely upon the privileging decisions of the distant-site hospital or telemedicine entity.

The agreement with the distant-site hospital or telemedicine entity may not require the hospital to rely upon the distant-site organization’s privileging decisions.

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01.01.09 Not Applicable.

01.01.10 Governing Body Periodically Consults with the Medical Staff.

The governing body must:

- *Consult directly with the individual assigned the responsibility for the organization and conduct of the hospital's medical staff, or his or her designee.*
- *At a minimum, this direct consultation must occur periodically throughout the fiscal or calendar year and include discussion of matters related to the quality of medical care provided to patients of the hospital.*
- *For a multi-hospital system using a single governing body, the single multi-hospital system governing body must consult directly with the individual responsible for the organized medical staff (or his or her designee) of each hospital within its system in addition to the other*

In accordance with §482.22(b)(3), there must be an individual member of the hospital's medical staff who is assigned responsibility for the organization and conduct of the medical staff (the "leader" of the medical staff). §482.12(a)(10) requires that the governing body consult with this individual, or with someone the leader of the medical staff has designated.

"Direct consultation" means that the governing body, or a subcommittee of the governing body, meets with the leader(s) of the medical staff(s) either face-to-face or via a telecommunications system permitting immediate, synchronous communication. (79 FR 27113, May 12, 2014)

This regulation does not preclude a hospital from having a member of the medical staff serve as a member of the hospital's governing body. However, membership on the governing body by a medical staff member is not sufficient per se to satisfy the requirement for periodic consultation. In such a situation the hospital meets the consultation requirement only if the medical staff member serving on the governing body is the leader of the medical staff, or his or her designee, and only if such membership includes meeting with the board periodically throughout the fiscal or calendar year and discussing matters related to the quality of medical care provided to patients of the hospital.

INTERVIEW AND DOCUMENT REVIEW

1. Ask the hospital's CEO how the hospital complies with the requirement for periodic consultations by the governing body with the leader(s) of the hospital's medical staff, or the leader's designee. Can the CEO provide evidence that such consultations have occurred, e.g., meeting agendas and lists of attendees, meeting minutes, etc.
2. Ask the CEO whether the hospital tracks these consultations by the calendar year or its fiscal year; ask to see a copy of the policy that establishes this.
 - Is there evidence that the consultations were "direct?"
 - Is there evidence that the governing body met with the medical staff leader or designee at least twice during the previous year?
 - Is there evidence that the discussion concerned matters related to the quality of medical care in the hospital?

- 1 = Compliant
- 2 = Not Compliant

This standard is not met as evidenced by:

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<p><i>requirements of this paragraph (a) in 42 CFR 482.12.</i></p> <p>§482.12(a)(10)</p>	<p>If there were a change in the medical staff leadership or his or her designee, and the bylaws governing terms and conditions of governing body membership did not allow for substitution of the new leader of the medical staff (or his or her designee) on the governing body, then the governing body would be expected to engage in direct consultation with the individual newly responsible for the organization and conduct of the medical staff, or his or her designee.</p> <p>It should be noted that if a hospital chooses to have the leader of the medical staff, or his or her designee, serve on the governing body, there is nothing in the regulation which prohibits the hospital from also including other medical staff members on the governing body in addition to the leader of the medical staff, or his or her designee.</p> <p>In the case of a multi-hospital system that has one single governing body, the governing body must consult with each separately certified hospital's medical staff leader, or his/her designee.</p> <ul style="list-style-type: none"> • The consultations do not have to be separate. • For example, the system governing body could periodically have a meeting that includes the leaders of the medical staff, or his/her designee, from each hospital within the system, so long as there is discussion of matters related to the quality of medical care provided to the patients of each hospital. 	<p>3. Ask the leader of the hospital's medical staff whether he or she has had meetings with either the whole governing body or a subcommittee of it to discuss the quality of medical care in the hospital.</p> <ul style="list-style-type: none"> • Has the leader ever requested a meeting in addition to those regularly scheduled, to discuss a matter of urgent concern to the medical staff? If yes, did the governing body respond by setting up a meeting? • If the hospital shares a unified medical staff with other separately certified hospitals in a multi-hospital system, the interview with the leader of the medical staff, or designee, may have to be conducted by telephone. Ask the leader how he/she gathers information about the concerns/views of members of the medical staff practicing at the hospital being surveyed about the quality of medical care provided at that hospital. 	

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If the medical staff members at separately certified hospitals in a multi-hospital system and the hospital system’s governing body also have opted to have a unified medical staff (see guidance for §482.22(b)(4)) for some or all of the hospitals in the system, then the governing body must consult with the leader of the unified medical staff or his/her designee. In this case, the leader of the unified medical staff, or the designee, as applicable, is expected to be aware of the concerns/views of members of the medical staff practicing at each separately certified hospital using the unified medical staff.

It is up to the governing body as to whether the leader of the medical staff must make the designation in writing when he or she chooses to designate another individual for these periodic consultations, or whether the leader of the medical staff may make informal, ad hoc designations.

It is also up to the governing body as to whether it wishes to establish minimum advance notice of a designation from the leader of the medical staff to the governing body.

The requirement for the governing body to consult periodically throughout the year leaves some flexibility for the governing body to determine how often during the year its consultations with the leader of the medical staff or designee would occur, but it is expected that consultations occur at least twice during either a calendar or fiscal year.

- (“Fiscal year” refers to the Medicare cost-

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reporting year for the hospital; in the case of a hospital system with multiple, separately certified hospitals that have one single governing body and a unified medical staff, it is possible that individual hospitals have separate fiscal years. In this case, it would be more practical for the governing body to use a calendar year basis for determining the frequency of consultation.)

The governing body is expected to determine the number of consultations needed based on various factors specific to one or more of the hospitals within a multi-hospital system. These factors include, but are not limited to, the scope and complexity of hospital services offered, specific patient populations served by a hospital, and any issues of patient safety and quality of care that a hospital's quality assessment and performance improvement program might periodically identify as needing the attention of the governing body in consultation with its medical staff.

The hospital must also provide evidence that the governing body is appropriately responsive to any periodic and/or urgent requests from the leader of the medical staff or designee for timely consultation on issues regarding the quality of medical care provided to patients of the hospital. (79 FR 27112, May 12, 2014).

The "year" referenced in the regulation may be either the calendar year or the hospital's fiscal year,

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as identified on its Medicare cost report. It is up to the hospital which approach it will take, but it must document the approach selected and consistently apply it. For example, if a hospital chooses to use the calendar year, and had only one consultation during a calendar year, it could not then point out that it had had two meetings during the time period covered by its fiscal year.

The required consultation must include discussion of matters related to the quality of medical care provided to the hospital's patients, or, in the case of a hospital system with one single governing body and a unified medical staff, the quality of medical care provided to each separately certified hospital's patients.

The hospital's governing body must adopt policies and procedures addressing how it implements the requirement for periodic, direct consultation with the leader of the medical staff, or the designee.

The hospital must have evidence that the required consultations do take place, such as meeting agendas and lists of attendees, or minutes taken of the discussion, including who was present, etc., and that matters related to the quality of medical care provided to patients of the hospital were discussed.

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<p>01.01.11 Chief Executive Officer (CEO) Appointment. <i>The governing body must:</i></p> <ul style="list-style-type: none"> • <i>Appoint a chief executive officer who is responsible for managing the hospital.</i> <p>§482.12(b)</p>	<p>The Governing Body must appoint one chief executive officer who is responsible for managing the entire hospital.</p> <p>The CEO is accountable for providing an organizational structure, with appropriate resources including support staff, to effectively implement plans to provide ethical, efficient, effective services.</p> <p>This individual is responsible to governance for day-to-day operations of the entire hospital and is guided by a position description. The position description, with defined management objectives, serves as the basic evaluation criteria for the CEO.</p> <p>The CEO is responsible for insuring that all services provided including those by arrangement, agreement or contract complies with all standards requirements.</p>	<p style="text-align: center;"><u>DOCUMENT REVIEW</u></p> <ol style="list-style-type: none"> 1. Verify that the hospital has only one chief executive officer for the entire hospital. 2. Verify that the governing body has appointed the chief executive officer. 3. Verify that the chief executive officer is responsible for managing the entire hospital. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>
<p>01.01.12 Care of Patients. <i>In accordance with hospital policy, the governing body must ensure that the following requirements are met.</i></p> <p><i>Every Medicare patient is under the care of:</i></p> <p><i>(i) A doctor of medicine or osteopathic medicine. (This provision is not to be construed to limit the authority of a doctor of medicine or osteopathy to</i></p>	<p>Practitioners other than doctors of medicine or osteopathic medicine may join the medical staff if the practitioners are appropriately licensed and medical staff membership is in accordance with State law.</p> <p>Every Medicare or Medicaid patient must be under the care of a licensed practitioner as defined in this requirement.</p>	<p style="text-align: center;"><u>CHART REVIEW</u></p> <ul style="list-style-type: none"> • Verify that Medicare patients are under the care of a licensed practitioner as defined by 482.12(c)(1). 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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	<p><i>delegate tasks to other qualified health care personnel to the extent recognized under State law or a state’s regulatory mechanism.);</i></p> <p><i>(ii) A doctor of dental surgery or dental medicine who is legally authorized to practice dentistry by the State and who is acting within the scope of his or her license;</i></p> <p><i>(iii) A doctor of podiatric medicine, but only with respect to functions which he or she is legally authorized by the State to perform;</i></p> <p><i>(iv) A doctor of optometry who is legally authorized to practice optometry by the State in which he or she practices;</i></p> <p><i>(v) A chiropractor who is licensed by the State or legally authorized to perform the services of a chiropractor, but only with respect to treatment by means of manual manipulation of the spine to correct a subluxation demonstrated by x-ray to exist; and</i></p>		

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(vi) A clinical psychologist as defined in §410.71 of **42 CFR 410.71**, but **only with respect to clinical psychologist services as defined in §410.71 of 42 CFR 410.71** and only to the extent permitted by State law.

§482.12(c)
 §482.12(c)(1); §482.12(c)(1)(i)
 §482.12(c)(1)(ii); §482.12(c)(1)(iii)
 §482.12(c)(1)(iv); §482.12(c)(1)(v)
 §482.12(c)(1)(vi)

01.01.13 State Privilege Requirements.

In accordance with hospital policy, the governing body must ensure that the following requirements are met:

- *Patients are admitted to the hospital only on the recommendation of a licensed practitioner permitted by the State to admit patients to a hospital.*
- *If a Medicare patient is admitted by a practitioner not specified in paragraph (c)(1) [standard*

CMS hospital regulations do permit licensed practitioners (e.g., nurse practitioners, midwives, etc.), as allowed by the State, to admit patients to a hospital, and CMS does not require these practitioners be employed by a Doctor of Medicine/Doctor of Osteopathic Medicine.

- However, CMS regulations **do require** that Medicare and Medicaid patients admitted by these practitioners be under the care of a Doctor of Medicine / Doctor of Osteopathic Medicine.
- Evidence of being under the care of a Doctor of Medicine / Doctor of Osteopathic Medicine must be in the patient’s medical record.

CHART REVIEW

1. Verify that admitting privileges are limited to those categories of practitioners as allowed by State law.
2. Verify that patients are admitted only by those practitioners who are currently licensed and have been granted admitting privileges by the governing body in accordance with State laws and medical staff bylaws.
3. If the hospital grants admitting privileges to these practitioners (midwives), select Medicare and Medicaid patients (select only Medicare patients for midwives) that are

1 = Compliant
 2 = Not Compliant

This standard is not met as evidenced by:

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<p>01.01.15] of 42 CFR 482.12, that patient is under the care of a doctor of medicine or osteopathic medicine.</p> <p>§482.12(c)(2)</p>	<ul style="list-style-type: none"> If a hospital allows these practitioners to admit and care for patients, as allowed by State law, the governing body and medical staff would have to establish policies and bylaws to ensure that the requirements of 42 CFR §482 are met. <p>MIDWIFE PATIENTS</p> <p>42 CFR §482.1(a)(5) states, "Section 1905(a) of the Act provides that 'medical assistance' (Medicaid) payments may be applied to various hospital services. Regulations interpreting those provisions specify that hospitals receiving payment under Medicaid must meet the requirements for participation in Medicare (except in the case of medical supervision of nurse midwife services. See §440.10 and §440.165 42 of this chapter)."</p> <ul style="list-style-type: none"> Midwives are not specified at 42 CFR §482.12(c)(1). <p>Section §482.1(a)(5), when taken together with this requirement (42 CFR §482.12(c)(2)) means that in a State that permits midwives to admit patients (and in accordance with hospital policy and practitioner privileges), CMS requires ONLY Medicare patients of a midwife be under the care of a doctor of medicine or osteopathic medicine.</p> <ul style="list-style-type: none"> CMS DOES NOT require Medicaid or other non-Medicare patients admitted by a midwife to be under the care of a doctor of medicine or osteopathic medicine. 	<p>admitted to the hospital by these practitioners.</p> <p>4. Determine if the patient is/was under the care of a Doctor of Medicine/Doctor of Osteopathic Medicine.</p>	

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01.01.14 Physician Availability.

The governing body must ensure that the following requirements are met:

- *A doctor of medicine or osteopathic medicine is on duty or on call at all times.*

§482.12(c)(3)

Self-explanatory.

DOCUMENT REVIEW

- Verify the governing body has established and monitors the enforcement of policies that ensure a doctor of medicine or osteopathic medicine is on duty or on call at all times to provide medical care and onsite supervision when necessary.
- Review the “call” register and documents that assure that a doctor of medicine or osteopathic medicine is on duty or on call at all times.

INTERVIEW

- Interview nursing staff. How do they know who is on call? Are they able to call the on-call Doctor of Medicine / Doctor of Osteopathic Medicine and speak with him/her at all times? When appropriate, do on-call Doctor of Medicine / Doctor of Osteopathic Medicine come to the hospital to provide needed care.

- 1 = Compliant
- 2 = Not Compliant

This standard is not met as evidenced by:

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<p>01.01.15 Medical Staff Oversight. <i>The governing body must ensure that the following requirements are met:</i></p> <p><i>A doctor of medicine or osteopathic medicine is responsible for the care of each Medicare patient with respect to any medical or psychiatric problem that—</i></p> <p><i>(i) Is present on admission or develops during hospitalization; and</i></p> <p><i>(ii) Is not specifically within the scope of practice of a doctor of dental surgery, dental medicine, podiatric medicine, or optometry; a chiropractor; or clinical psychologist, as that scope is—</i></p> <p><i>(A) Defined by the medical staff;</i></p> <p><i>(B) Permitted by State law; and</i></p> <p><i>(C) Limited, under paragraph (c)(1)(v) of 42 CFR 482.12, with respect to chiropractors.</i></p> <p>§482.12(c)(4)</p>	<p>CMS hospital regulations do permit licensed practitioners (i.e., doctors of dental surgery, dental medicine, podiatric medicine, or optometry; chiropractors; or clinical psychologists), as allowed by the State, to admit patients to a hospital.</p> <p>However, CMS <u>does require</u> that Medicare and Medicaid patients who are admitted by a doctor of dental surgery, dental medicine, podiatric medicine, or optometry; a chiropractor; or clinical psychologist be under the care of a Doctor of Medicine / Doctor of Osteopathic Medicine with respect to any medical or psychiatric problem that is present on admission or develops during hospitalization that is outside the scope of practice of the admitting practitioner.</p> <p>If a hospital allows a doctor of dental surgery, dental medicine, podiatric medicine, or optometry, a chiropractor or a clinical psychologist to admit and care for patients, as allowed by State law, the governing body and medical staff must establish policies and bylaws to ensure that the requirements of 42 CFR §482 are met.</p> <p>As applicable, the patient’s medical record must demonstrate Doctor of Medicine / Doctor of Osteopathic Medicine responsibility / care.</p>	<p style="text-align: center;">CHART REVIEW</p> <ol style="list-style-type: none"> 1. Verify that an assigned doctor of medicine or osteopathic medicine is responsible for and is monitoring the care of each Medicare or Medicaid patient with respect to all medical or psychiatric problems during the hospitalization. 2. If non-Doctor of Medicine / Doctor of Osteopathic Medicine admit patients, verify that every Medicare / Medicaid patient is being monitored by a Doctor of Medicine / Doctor of Osteopathic Medicine who is responsible for any medical or psychiatric problem outside the scope of practice of the admitting practitioners. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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<p>01.01.16 Institutional Plan & Budget. <i>The institution must have an overall institutional plan that meets the following conditions:</i></p> <p>(1) <i>The plan must include an annual operating budget that is prepared according to generally accepted accounting principles.</i></p> <p>(2) <i>The budget must include all anticipated income and expenses. This provision does not require that the budget identify item by item the components of each anticipated income or expense.</i></p> <p>(3) <i>The plan must provide for capital expenditures for at least a 3-year period, including the year in which the operating budget specified in paragraph (d)(2) of 42 CFR 482.12 is applicable.</i></p> <p>(4) <i>The plan must include and identify in detail the objective of, and the anticipated sources of financing for, each anticipated capital expenditure in excess of \$600,000 (or a lesser amount that is established, in accordance with section 1122(g)(1) of the Act (Social Security Act), by the State in which</i></p>	<p>Self-explanatory.</p>	<p align="center"><u>DOCUMENT REVIEW</u></p> <ul style="list-style-type: none"> Verify that an institutional plan and budget exist, includes items 1-4, and complies with all items in this standard. Do not review the specifics or format in the institutional plan or the budget. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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the hospital is located) that relates to any of the following:

- (i) Acquisition of land.*
- (ii) Improvement of land, building, and equipment.*
- (iii) The replacement, modernization, and expansion of the buildings and equipment.*

§482.12(d); §482.12(d)(1);
 §482.12(d)(2); §482.12(d)(3);
 §482.12(d)(4)(i); §482.12(d)(4)(ii);
 §482.12(d)(4)(iii)

01.01.17 Plan Submission.

The plan must be submitted for review to the planning agency designated in accordance with section 1122(b) of the Social Security Act (the Act), or if an agency is not designated, to the appropriate health planning agency in the state (See part 100 of this title.)

Self-explanatory.

*A capital expenditure is not subject to section 1122 review of the Act (**Social Security Act**) if 75 percent of the healthcare facility's patients who are*

DOCUMENT REVIEW

- Determine that the hospital's plan for capital expenditures has been submitted to the planning agency designated to review capital expenditures. In certain cases facilities used by HMO and CMP patients are exempt from the review process.

- 1 = Compliant
- 2 = Not Compliant

This standard is not met as evidenced by:

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*expected to use the service for which the capital expenditure is made are individuals enrolled in a health maintenance organization (HMO) or competitive medical plan (CMP) that meets the requirements of section 1876(b) of the Act (**Social Security Act**), and if the Department determines that the capital expenditure is for services and facilities that are needed by the HMO or CMP in order to operate efficiently and economically and that are not otherwise readily accessible to the HMO or CMP because-*

- (i) The facilities do not provide common services at the same site.*

- (ii) The facilities are not available under a contract of reasonable duration.*

- (iii) Full and equal medical staff privileges in the facilities are not available.*

- (iv) Arrangements with these facilities are not administratively feasible.*

- (v) The purchase of these services is more costly than if the HMO or CMP provided the service directly.*

§482.12(d)(5)

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01.01.18 Plan Review & Update.

The plan must be reviewed and updated annually.

Self-explanatory.

DOCUMENT REVIEW

- Verify that the plan and budget are reviewed and updated annually.

- 1 = Compliant
 2 = Not Compliant

§482.12(d)(6)

This standard is not met as evidenced by:

01.01.19 Plan Preparation.

The plan must be prepared—

- (i) Under the direction of the governing body; and*
- (ii) By a committee consisting of representatives of the governing body, the administrative staff, and the medical staff of the institution.*

Self-explanatory.

DOCUMENT REVIEW

- Verify that the governing body, administrative staff, and medical staff have participated in the development of the institutional plan and budget.

- 1 = Compliant
 2 = Not Compliant

This standard is not met as evidenced by:

§482.12(d)(7)
 §482.12(d)(7)(i)
 §482.12(d)(7)(ii)

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<p>01.01.20 <u>Oversight of the Physical Environment.</u> The governing body must be responsible for providing a physical environment that is constructed, arranged, maintained, equipped, and staffed to meet the needs and services required for patients.</p>	<p>The governing body shall receive and review periodic written reports from appropriate internal and external sources regarding the adequacy and deficiencies of the physical environment to assure the well-being of patients.</p> <p>These reports:</p> <ul style="list-style-type: none"> • Summarize issues relating to the physical environment, construction, equipment, and staffing needs. • Are typically prepared at least quarterly and aggregated into an annual evaluation. <p>The leadership:</p> <ul style="list-style-type: none"> • Provides resources and support necessary for staff to perform their duties and • Holds staff accountable to their assigned responsibilities. 	<p style="text-align: center;"><u>DOCUMENT REVIEW</u></p> <ol style="list-style-type: none"> 1. Assess leadership’s role in evaluating the staff’s accountability in performing their duties. 2. Determine the governance has received physical plant and equipment reports. 3. Determine the governance has acted upon these reports, as necessary. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>
<p>01.01.21 <u>Oversight of the QAPI Program.</u> The governing body shall be responsible for a hospital-wide Quality Assessment Performance Improvement program that reflects all hospital departments and services.</p>	<p>The QAPI Plan reflects final approval of the governing body either by date and signature or by notation as to the date that governance minutes will document such approval.</p> <p>Hospital staff prepares aggregate summaries for reporting to governance; these separate findings, as appropriate, for staff and other providers of care and</p>	<p style="text-align: center;"><u>DOCUMENT REVIEW</u></p> <p>Determine that governance has:</p> <ol style="list-style-type: none"> 1. Approved the QAPI plan within the last twelve months. 2. Received and acted upon summary findings at least quarterly for both Staff and other providers. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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The QAPI plan and its findings are shared with and reviewed by the governance.

- service.
- Such reports are typically documented at least quarterly and aggregated into an annual evaluation.
 - Report formats may vary to include narration, statistical charts, diagrams, and "story" boards.

3. Received and acted upon an annual QAPI evaluation for both staff and other providers.
4. If the hospital is subject to "open meetings" requirements due to ownership by a governmental agency, or otherwise, the QAPI reports may be noted in detail in a governance subcommittee such as Joint Conference with action being taken by the full governance in open session.

01.01.22 Contracted Services.
The governing body must be responsible for services furnished in the hospital whether or not they are furnished under contracts.

The governing body must ensure that a contractor of services (including one for shared services and joint ventures) furnishes services that permit the hospital to comply with all applicable conditions of participation and standards for the contracted services.

§482.12(e)

The QAPI Plan addresses a broad scope and includes any clinical or clinical support services provided under contractual arrangement.

The governing body has the responsibility for assuring that hospital services are provided in compliance with the Medicare Conditions of Participation and according to acceptable standards of practice, irrespective of whether the services are provided directly by hospital employees or indirectly by contract.

Consequently, a list of all contracted services, with the scope and nature of such service, is maintained.

- The governing body must take actions through the hospital's QAPI program to:
- assess the services furnished directly by hospital

DOCUMENT REVIEW

- Ascertain that all contractor services provided in the hospital are in compliance with the Conditions of Participation for hospitals.

- 1 = Compliant
- 2 = Not Compliant

This standard is not met as evidenced by:

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staff and those services provided under contract,

- identify quality and performance problems,
- implement appropriate corrective or improvement activities, and
- to ensure the monitoring and sustainability of those corrective or improvement activities. (See §482.21 QAPI.)

01.01.23 Contractor Quality Monitoring.

The governing body must ensure that the services performed under a contract are provided in a safe and effective manner.

§482.12(e)(1)

Indirect arrangements may take into consideration services provided through formal contracts, joint ventures, informal agreements, shared services, or lease arrangements.

The patient care services, and all other services, provided under contract are subject to the same hospital-wide quality assessment and performance improvement (QAPI) evaluation as other services provided directly by the hospital.

DOCUMENT REVIEW

1. Determine if the hospital has a mechanism to evaluate the quality of each contracted service and ensures that each contracted service is provided in a safe and effective manner.
2. Review the QAPI plan to ensure that every contracted service is evaluated.

- 1 = Compliant
- 2 = Not Compliant

This standard is not met as evidenced by:

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01.01.24 List of Contracted Services.
The hospital must maintain a list of all contracted services, including the scope and nature of the services provided.

§482.12(e)(2)

Self-explanatory.

DOCUMENT REVIEW

- Determine that a current list of all contractual providers (including shared service or joint venture) of service is maintained. The list must include the scope and nature of the services provided.

- 1 = Compliant
 2 = Not Compliant

This standard is not met as evidenced by:

01.01.25 Policy and Procedure Review and Approval.

All administrative policies and procedures shall have the final approval of the CEO or designee triennially and reflect current practice, policy changes necessitated by identified problems, and standards changes. The chief of staff shall sign off clinical policies and procedures.

Department policies and procedures shall be reviewed, updated, and signed every three (3) years or triennially by department heads and also must reflect required changes consistent with current practice, problem resolution and standards changes.

Triennial review may be used if it complies with state law.

DOCUMENT REVIEW

1. Review policy and procedure manuals. Verify that department heads, chief of staff, and CEO have reviewed and approved these at least every three (3) years.
2. Review policies for required changes due to practice changes, problem identification, and changes in standards.

- 1 = Compliant
 2 = Not Compliant

This standard is not met as evidenced by:

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01.01.26 Medically-Related Patient Care Services.

The hospital shall have an ongoing plan, consistent with available community and hospital resources, to provide or make available social work, psychological, and educational services to meet the medically related needs of its patients.

The hospital should have policies and procedures to **provide or make available medical related services to meet** the needs of patients regarding:

1. Social work
2. Psychological, and
3. Educational services.

DOCUMENT REVIEW

1. Review the hospital’s plan for providing medically related social work, psychological and educational needs of its patients.
2. Review the documentation of the agreements (e.g., contracts, memorandum of understanding, or letters of agreement) to assure that services are available to all patients needing them.

- 1 = Compliant
 2 = Not Compliant

This standard is not met as evidenced by:

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<p>01.02.01 Emergency Services. <i>The hospital must ensure the emergency services requirements are met.</i></p> <p>§482.12(f)</p>	<p>Self-explanatory.</p>	<ul style="list-style-type: none"> • Score compliance based on the outcome of scoring Chapter 20, Emergency Services if an emergency department is present. • If there is no Emergency Department / Services, score compliance based on standards 01.02.03 and / or 01.02.04. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>
<p>01.02.02 Emergency Services Compliance with Federal Laws. <i>If emergency services are provided at the hospital, the hospital must comply with the requirements of §482.55.</i></p> <p>§482.12(f)(1)</p>	<p>Self-explanatory.</p>	<ul style="list-style-type: none"> • Score based on the outcome of scoring in Chapter 20, Emergency Services. • If there is no Emergency Department / Services, score this as “not applicable”. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant <input type="checkbox"/> NA=Not Applicable if facility has NO Emergency department</p> <p>This standard is not met as evidenced by:</p>
<p>01.02.03 Policies Regarding Emergency Care When Services Are Not Provided. <i>If emergency services are not provided at the hospital, the governing body must assure that the medical staff has written policies and procedures for appraisal of emergencies, initial treatment, and referral when appropriate.</i></p> <p>§482.12(f)(2)</p>	<p>This requirement applies hospital-wide (all on-campus and off-campus locations) to hospitals that do not provide emergency services.</p> <p>Hospitals without emergency departments must have appropriate policies and procedures in place for addressing individual’s emergency care needs 24 hours per day and 7 days per week, including the following:</p> <p>Appraisal of Persons with Emergencies</p>	<p style="text-align: center;"><u>DOCUMENT REVIEW</u></p> <ol style="list-style-type: none"> 1. Verify that the medical staff has adopted written policies and procedures for the management of medical emergencies. 2. Review emergency care policies and procedures. Are they consistent with the expectations articulated above for appraisal, initial treatment, and referral? Do they address emergency procedures for all on-campus and off-campus locations? 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant <input type="checkbox"/> NA=Not Applicable if facility HAS an Emergency Department</p> <p>This standard is not met as evidenced by:</p>

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	<p>A hospital must have medical staff policies and procedures for conducting appraisals of persons with emergencies. The policies and procedures must ensure that:</p> <ul style="list-style-type: none"> • As required by <u>42 CFR §482.23(b)</u>, an RN is immediately available, as needed, to provide bedside care to any patient and that, • Among such RN(s) who are immediately available at all times, there must be an RN(s) who is/are qualified, through a combination of education, licensure, and training, to conduct an assessment that enables them to recognize the fact that a person has a need for emergency care. <p>The policies and procedures for appraisal should provide that the Doctor of Medicine/Doctor of Osteopathic Medicine (on-site or on-call) would directly provide appraisals of emergencies or provide medical direction of on-site staff conducting appraisals.</p> <p>Initial Treatment</p> <p>A hospital must have medical staff policies and procedures for providing the initial treatment needed by persons with emergency conditions.</p> <p>Among the RN(s) who must be available at all times in a hospital as required by <u>42 CFR §482.23(b)</u> [see 16.00.04], there must be RN(s) who are qualified, through a combination of education, licensure, and training, to provide initial treatment to a person</p>	<p style="text-align: center;"><u>INTERVIEW</u></p> <ul style="list-style-type: none"> • Interview hospital staff at various locations. Can they state their duties and what they are to do if an individual seeks or needs emergency care at their location? 	

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experiencing a medical emergency. The on-site or on-call physician could provide initial treatment directly or provide medical oversight and direction to other staff. This requirement, taken together with other hospital regulatory requirements, suggests that a prudent hospital would evaluate the patient population the hospital routinely cares for in order to anticipate potential emergency care scenarios and develop the policies, procedures, and staffing that would enable it to provide safe and adequate initial treatment of an emergency.

Referral when Appropriate

A hospital must have medical staff policies and procedures to address situations in which a person's emergency needs may exceed the hospital's capabilities.

The policies and procedures should be designed to enable hospital staff members who respond to emergencies to:

- (a) recognize when a person requires a referral or transfer, and
- (b) assure appropriate handling of the transfer.

This includes arrangement for appropriate transport of the patient.

Further, in accordance with the Discharge Planning CoP at [42 CFR §482.43\(d\)](#), the hospital must transfer patients to appropriate facilities, i.e., those with the appropriate capabilities to handle the patient's condition.

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The regulation also requires that necessary medical information be sent along with the patient being transferred. This enables the receiving hospital to treat the medical emergency more efficiently.

Patient Transportation and Emergency Medical Services (EMS)

A hospital may arrange transportation of the referred patient by several methods, including using the hospital's own ambulance service, the receiving hospital's ambulance service, a contracted ambulance service, or, in extraordinary circumstances, alerting EMS via calling 9-1-1. There is no specific Medicare prohibition on a hospital with or without an emergency department calling 9-1-1 in order to obtain transport of a patient to another hospital. Use of 9-1-1 to obtain transport does not, however, relieve the hospital of its obligation to arrange for the patient's transfer to an appropriate facility and to provide the necessary medical information along with the patient.

A hospital policy or practice that relies on calling 9-1-1 in order for EMS to substitute its emergency response capabilities for those the hospital is required to maintain, as described above, is not consistent with the Medicare CoPs. For example, a hospital may not rely upon 9-1-1 to provide appraisal and initial treatment of medical emergencies that occur at the hospital. Such policy or practice should be considered as condition-level non-compliance with the applicable CoP, 42 CFR §482.55 or 42 CFR §482.12(f).

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<p>01.02.04 Off-Site Emergency Care. <i>If emergency services are provided at the hospital but are not provided at one or more off-campus departments of the hospital, the governing body of the hospital must assure that the medical staff has written policies and procedures in effect with respect to the off-campus department(s) for appraisal of emergencies and referral when appropriate.</i></p> <p>§482.12(f)(3)</p>	<p>This requirement applies to any off-campus hospital department / location that does not qualify as a dedicated emergency department in accordance with <u>42 CFR §489.24(b)</u> and is part of a hospital that provides emergency services. Such departments / locations must have and must implement medical staff policies and procedures for the appraisal of emergencies and referral when appropriate.</p> <p>Appraisal of Persons with Emergencies A hospital must have medical staff policies and procedures for conducting appraisals of persons with emergencies at off-campus departments / locations that are not dedicated emergency departments.</p> <p>The policies and procedures must ensure that clinical personnel -- who are qualified, through a combination of education, licensure, and training, to conduct an assessment that enables them to recognize the fact that a person has a need for emergency care -- are available during all hours of operation at the off-campus department / location.</p> <p>Referral when Appropriate A hospital must have medical staff policies and procedures to address situations in which a person's emergency needs may exceed the capabilities of the off-campus departments / locations that are not dedicated emergency departments.</p> <p>The policies and procedures should be designed to enable staff members at such locations to:</p> <p style="margin-left: 20px;">(a) recognize when a person requires a referral</p>	<p style="text-align: center;">DOCUMENT REVIEW</p> <ul style="list-style-type: none"> • Review emergency care policies and procedures. Determine if they address emergency procedures for all off-campus locations. <p style="text-align: center;">INTERVIEW</p> <ul style="list-style-type: none"> • Interview off-campus hospital department staff. Can they state their duties and what they are to do if an individual seeks emergency care? 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant <input type="checkbox"/> NA=Not Applicable if facility has NO off-campus departments.</p> <p>This standard is not met as evidenced by:</p>

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or transfer, and
 (b) assure appropriate handling of the transfer.

This includes arrangement for appropriate transport of the patient along with the transfer of the patient's medical information so that the receiving hospital may treat the medical emergency more efficiently.

Initial Treatment

Although there is no specific regulatory requirement for such off-campus departments or locations to provide initial treatment of emergencies, nevertheless they are expected to provide treatment and stabilization consistent with the complexity of services, the type and qualifications of clinical staff, and the resources available at that location.

This expectation is based on the requirements of the Outpatient Services CoP that hospital outpatient services meet the needs of the patients in accordance with acceptable standards of practice, outpatient services must be appropriately organized and integrated with inpatient services, and outpatient services must have appropriate professional and nonprofessional personnel available. For example, an off-campus cardiac rehabilitation clinic would be expected to have the appropriate qualified staff, equipment (such as a crash cart), and policies and procedures in place to appropriately provide appraisal, initial interventions, and referral of a patient who experiences a cardiac emergency.

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A hospital policy or practice that relies on calling 9-1-1 in order for EMS to substitute its emergency response capabilities for those the hospital is required to maintain at its off-campus departments / locations, as described above, is not consistent with the Medicare CoPs. However, given the more limited emergency capabilities that may be present in some off-campus departments or locations, calling 9-1-1 to respond to an emergency might be appropriate. See the hospital emergency services CoP ([42 CFR §482.55](#)) for the emergency requirements for the hospital's locations that provide emergency services.

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FOR FUTURE USE

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<p>03.00.00 Condition of Participation: Medical Staff. <i>The hospital must have an organized medical staff that operates under bylaws approved by the governing body, and which is responsible for the quality of medical care provided to patients by the hospital.</i></p> <p>§482.22</p>	<p>The hospital may have only one medical staff for the entire hospital (including all campuses, provider-based locations, satellites, remote locations, etc.).</p> <p>For example, a multi-campus hospital may not have a separately organized medical staff for each campus. On the other hand, in the case of a hospital system, it is permissible for the system to have a unified medical staff for multiple, separately certified hospitals.</p> <p>The medical staff must be organized and integrated as one body that operates under one set of bylaws approved by the governing body. These medical staff bylaws must apply equally to all practitioners within each category of practitioners at all locations of the hospital and to the care provided at all locations of the hospital.</p> <p>The single medical staff is responsible for the quality of medical care provided to patients by the hospital.</p>	<p><u>DOCUMENT REVIEW AND INTERVIEW</u> Score based on the results of scoring for ONLY the 482.22 standards and sub-standards listed within this chapter.</p>	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>
<p>03.00.01 Eligibility and Process for Appointment to the Medical Staff. <i>The medical staff must be composed of doctors of medicine or osteopathy. In accordance with State law, including scope-of-practice laws, the medical staff may also include other categories of physicians (as listed at</i></p>	<p>The hospital’s governing body has the responsibility, consistent with State law, including scope-of-practice laws, to determine which types/categories of physicians and, if it so chooses, non-physician practitioners or other licensed healthcare professionals (collectively referred to in this guidance as “practitioners”) may privileged to provide care to hospital patients.</p>	<p><u>DOCUMENT REVIEW</u></p> <ol style="list-style-type: none"> 1. Ask the hospital and medical staff leadership to describe the categories of practitioners who are members of the medical staff or who may be granted medical staff privileges. <ul style="list-style-type: none"> • Ask for documentation that supports their response. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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<p><i>§482.12(c)(1) and non-physician practitioners who are determined to be eligible for appointment by the governing body.</i></p> <p>§482.22(a)</p>	<ul style="list-style-type: none"> • All practitioners who require privileges in order to furnish care to hospital patients must be evaluated under the hospital’s medical staff privileging system before the hospital’s governing body may grant them privileges. • All practitioners granted hospital privileges must function under the bylaws, regulations and rules of the hospital’s medical staff. • The privileges granted to an individual practitioner must be consistent with State scope-of-practice laws. <p>PHYSICIANS</p> <p>The medical staff must at a minimum be composed of physicians who are doctors of medicine or doctors of osteopathic medicine. In addition, the medical staff may include other healthcare professionals included in the definition in Section 1861(r) of the Social Security Act of a “physician”:</p> <ul style="list-style-type: none"> • Doctor of dental surgery or of dental medicine; • Doctor of podiatric medicine; • Doctor of optometry; and a • Chiropractor. <p>In all cases the healthcare professionals included in the definition of a physician must be legally authorized to practice within the State where the hospital is located and providing services within their authorized scope of practice. In addition, in certain</p>	<ul style="list-style-type: none"> 2. If the hospital grants medical staff privileges and/or membership to physicians who are not MDs/DOs or to non-physician practitioners, ask the hospital and medical staff leadership to describe the process the hospital uses to ensure that any privileges granted are consistent with State law. <ul style="list-style-type: none"> • Ask for documentation that supports their response. • How has the facility verified that appointment to the medical staff is consistent with State law and regulations for non-physician practitioners? 3. Ask the hospital and medical staff leadership to describe the process by which they exercise oversight of practitioners granted privileges only. 	

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instances the Social Security Act and regulations attach further limitations as to the type of hospital services for which healthcare professionals may be considered to be a “physician.” See §482.12(c)(1) for more detail on these limitations.

The governing body has the flexibility to determine, **consistent with State law**, whether **practitioners** included in the definition of a physician, other than a doctor of medical or osteopathic medicine are eligible for appointment to the medical staff.

**For Information Only –
Not Required/ Not to be Cited**

CMS expects that all physician practitioners granted privileges are also appointed as members of the medical staff. However, if State law limits the composition of the hospital’s medical staff to certain categories of practitioners, e.g., only MDs or DOs, there is nothing in the CoPs that prohibits hospitals and their medical staffs from establishing certain practice privileges for other categories of physician practitioners excluded from medical staff membership under State law, or from granting those privileges to individual practitioners in those categories, as long as such privileges are recommended by the medical staff, approved by the governing body, and in accordance with State law. (79 FR 27114 - 27115, May 12, 2014)

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For physician practitioners granted privileges only, the hospital’s governing body and its medical staff must exercise oversight, such as through credentialing and competency review, of those other physician practitioners to whom it grants privileges, just as it would for those practitioners appointed to its medical staff.

NON-PHYSICIAN PRACTITIONERS

The governing body ensures that any privileges granted to non-physician practitioners must be in accordance with State law, regulations, and scope of practice.

Furthermore, the governing body has the authority, in accordance with State law, to appoint non-physician practitioners to the medical staff. **The regulation allows hospitals and their medical staffs to take advantage of the expertise and skills of all types of practitioners who practice at the hospital when making recommendations and decisions concerning medical staff privileges and membership.**

<p style="text-align: center;">For Information Only – Not Required/ Not to be Cited</p> <p>CMS expects that all practitioners granted privileges are also appointed as members of the medical staff. However, if State law limits the composition of the hospital’s medical staff to certain categories of practitioners, e.g., only physician practitioners, there is nothing in the</p>

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CoPs that prohibits hospitals and their medical staffs from establishing certain practice privileges for those specific categories of non-physician practitioners excluded from medical staff membership under State law, or from granting those privileges to individual practitioners in those categories, as long as such privileges are recommended by the medical staff, approved by the governing body, and in accordance with State law. (79 FR 27114 - 27115, May 12, 2014)

For non-physician practitioners granted privileges only, the hospital’s governing body and its medical staff must exercise oversight, such as through credentialing and competency review, of those non-physician practitioners to whom it grants privileges, just as it would for those practitioners appointed to its medical staff.

Practitioners are described in Section 1842(b)(18)(C) of the Act as any of the following:

- Physician assistant (as defined in Section 1861(aa)(5) of the Act);
- Nurse practitioner (as defined in Section 1861(aa)(5) of the Act);
- Clinical nurse specialist (as defined in Section 1861 (aa)(5) of the Act);
- Certified registered nurse anesthetist (as defined in Section 1861 (bb)(2) of the Act);
- Certified nurse-midwife (as defined in Section 1861(gg)(2) of the Act);

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- Clinical Social Worker (as defined in Section 1861(hh)(1) of the Act);
- Clinical psychologist (as defined in 42 CFR §410.71 for purposes of Section 1861 (ii) of the Act);
- Anesthesiologist’s Assistant (as defined in §410.69); or
- Registered dietitian or nutrition professional.

Other types of licensed healthcare professionals have a more limited scope of practice and are generally not eligible for hospital medical staff privileges, unless their permitted scope of practice in their State makes them more comparable to the above types of **non-physician** practitioners.

Some examples of types of such licensed healthcare professionals who might be eligible for medical staff privileges depending on State law and medical staff bylaws, rules and regulations include, but are not limited to:

- Physical Therapist (as defined at §410.60 and §484.4);
- Occupational Therapist (as defined at §410.59 and §484.4); and
- Speech Language Therapist (as defined at §410.62 and §484.4).

Furthermore, some States have established a scope of practice for certain licensed pharmacists who are permitted to provide patient care services that make them more like the above types of non-physician

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practitioners, including the monitoring and assessing of patients and ordering medications and laboratory tests.

- In such States, a hospital may grant medical staff privileges to such pharmacists and/or appoint them as members of the medical staff. There is no standard term for such pharmacists, although they are sometimes referred to as “clinical pharmacists.”

Practitioners may be granted active, courtesy, emergency, temporary, etc. membership or privileges in accordance with state law and as specified in the medical staff bylaws, rules, and regulations.

03.00.02 Periodic Appraisal of Members.

The Medical Staff must periodically conduct appraisals of its members.

§482.22(a)(1)

The medical staff must at regular intervals appraise the qualifications of all practitioners appointed to the medical staff / granted medical staff privileges. In the absence of a State law that establishes a timeframe for periodic reappraisal, a hospital’s medical staff must conduct a periodic appraisal of each practitioner. CMS recommends that an appraisal be conducted at least every 24 months for each practitioner.

The purpose of the appraisal is for the medical staff to determine the suitability of continuing the medical staff membership or privileges of each individual practitioner, to determine if that individual practitioner’s membership or privileges should be continued, discontinued, revised, or otherwise changed.

DOCUMENT REVIEW

1. Determine whether the medical staff has a system in place that is used to reappraise each of its current members and their qualifications at regular intervals, or, if applicable, as prescribed by State law.
2. Determine whether the medical staff by-laws identify the process and criteria to be used for the periodic appraisal.
3. Determine whether the criteria used for reevaluation comply with the requirements of this section, State law and hospital bylaws, rules, and regulations.

- 1 = Compliant
- 2 = Not Compliant

This standard is not met as evidenced by:

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	<p>The medical staff appraisal procedures must evaluate each individual practitioner’s qualifications and demonstrated competencies to perform each task or activity within the applicable scope of practice or privileges for that type of practitioner for which he/she has been granted privileges. Components of practitioner qualifications and demonstrated competencies would include at least: current work practice, special training, quality of specific work, patient outcomes, education, maintenance of continuing education, adherence to medical staff rules, certifications, appropriate licensure, and currency of compliance with licensure requirements.</p> <ul style="list-style-type: none"> • In addition to the periodic appraisal of members, any procedure / task / activity / privilege requested by a practitioner that goes beyond the specified list of privileges for that particular category of practitioner requires an appraisal by the medical staff and approval by the governing body. • The appraisal must consider evidence of qualifications and competencies specific to the nature of the request. It must also consider whether the activity / task / procedure is one that the hospital can support when it is conducted within the hospital. • Privileges cannot be granted for tasks / procedures / activities that are not conducted within the hospital, regardless of the individual 	<ol style="list-style-type: none"> 4. Determine whether the medical staff has a system to ensure that practitioners seek approval to expand their privileges for tasks/activities/procedures that go beyond the specified list of privileges for their category of practitioner. 5. Determine how the medical staff conducts the periodic appraisals of any current member of the medical staff who has not provided patient care at the hospital or who has not provided care for which he/she is privileged to patients at the hospital during the appropriate evaluation time frames. Is this method in accordance with State law and the hospital’s written criteria for medical staff membership and for granting privileges? 	

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practitioner’s ability to perform them.

- After the medical staff conducts its reappraisal of individual members, the medical staff makes recommendations to the governing body to continue, revise, discontinue, limit, or revoke some or all of the practitioner’s privileges, and the governing body takes final appropriate action.

A separate credentials file must be maintained for each medical staff member.

- The hospital must ensure that the practitioner and appropriate hospital patient care areas / departments are informed of the privileges granted to the practitioner, as well as of any revisions or revocations of the practitioner’s privileges.
- Furthermore, whenever a practitioner’s privileges are limited, revoked, or in any way constrained, the hospital must, in accordance with State and / or Federal laws or regulations, report those constraints to the appropriate State and Federal authorities, registries, and/or data bases, such as the National Practitioner Data Bank.

03.00.03 Not Applicable.

03.00.04 Not Applicable.

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<p>03.00.05 Responsibilities of Credentialed Professionals. The responsibilities for all credentialed practitioners must include:</p> <p>A. Participating in Medical Staff functions, committee activity, educational, and Quality Assessment and Performance Improvement (QAPI) activities.</p> <p>B. Abiding by Medical Staff Bylaws, Rules and Regulations.</p> <p>C. Adhering to ethical practice guidelines.</p>	<p>Self-explanatory.</p>	<p><u>DOCUMENT REVIEW</u> Review Medical Staff Bylaws, Rules and Regulations and policies to determine compliance.</p> <p><u>FILE REVIEW</u> Review a select sampling of files to verify practitioners attest to these responsibilities at appointment / reappointment.</p>	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>
<p>03.00.06 Recommendation for Appointment to Governance. <i>The medical staff must examine the credentials of all eligible candidates for medical staff membership and make recommendations to the governing body on the appointment of these candidates in accordance with State law, including scope-of-practice laws, and the medical staff bylaws, rules, and regulations.</i></p>	<p>There must be a mechanism established to examine credentials of individual prospective members (new appointments or reappointments) by the medical staff. The individual’s credentials to be examined must include at least:</p> <ul style="list-style-type: none"> • A request for clinical privileges; • Evidence of current licensure; • Evidence of training and professional education; • Documented experience; and • Supporting references of competence. 	<p><u>DOCUMENT REVIEW, FILE REVIEW, AND INTERVIEW</u></p> <ol style="list-style-type: none"> 1. Determine whether the medical staff bylaws identify the process and criteria to be used for the evaluation of candidates for medical staff membership / privileges. 2. Determine whether the criteria used for evaluation comply with the requirements of this section, State law, and hospital bylaws, rules, and regulations. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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<p><i>A candidate who has been recommended by the medical staff and who has been appointed by the governing body is subject to all medical staff bylaws, rules, and regulations, in addition to the requirements contained in 42 CFR 482.22.</i></p> <p>§482.22(a)(2)</p>	<p>The medical staff may not make its recommendation solely on the basis of the presence or absence of board certification, but must consider all of the elements above. However, this does not mean that the medical staff is prohibited from requiring in its bylaws board certification when considering a Doctor of Medicine / Doctor of Osteopathic Medicine for medical staff membership or privileges; only that such certification may not be the only factor that the medical staff considers.</p> <p>The medical staff makes recommendations to the governing body for each candidate for medical staff membership / privileges that are specific to type of appointment and extent of the individual practitioner’s specific clinical privileges, and then the governing body takes final appropriate action.</p> <p>Each practitioner who is a member of the medical staff or who holds medical staff privileges is subject to the medical staff’s bylaws, rules, and regulations, in addition to all the requirements of the Medical Staff Condition of Participation.</p> <p>The medical staff and the governing body must enforce its medical staff requirements and take appropriate actions when individual members or other practitioners with privileges do not adhere to the medical staff’s bylaws, regulations, or rules.</p> <p>They must likewise afford all members/ practitioners who hold privileges the protections and due process</p>	<ol style="list-style-type: none"> 3. Determine whether the medical staff has a system to ensure that practitioners seek approval to expand their privileges for tasks / activities / procedures that go beyond the specified list of privileges for their category of practitioner. 4. Ask the leadership of the medical staff what methods are used to ensure that all medical staff members and non-member practitioners who hold privileges adhere to the medical staff bylaws, rules and regulations and are afforded the due protections and process rights provided for under the bylaws, rules and regulations. <ul style="list-style-type: none"> • Ask for specific examples of actions taken. 5. When interviewing practitioners during the survey, ask how they are made aware of their rights and responsibilities with respect to medical staff bylaws, rules and regulations. 	

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rights provided for in the bylaws, rules and regulations.

A separate credentials file must be maintained for each individual medical staff member or applicant.

The hospital must ensure that the practitioner and appropriate hospital patient care areas / departments are informed of the privileges granted to the practitioner.

03.00.07 Duties & Responsibilities to Patients.

The duties and privileges for all credentialed practitioners shall include:

- A. Provision of continuous care / supervision of his / her patients; and
- B. Calling for, or responding to, consultations when required by patient condition or hospital requirement.

DOCUMENT REVIEW & FILE REVIEW

Review credentialing documentation to determine that duties and obligations for all credentialed provider categories are descriptive of these requirements.

- 1 = Compliant
- 2 = Not Compliant

This standard is not met as evidenced by:

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<p>03.00.08 Telemedicine Privileging Provisions Through Distant-Site Hospital Agreement. <i>When telemedicine services are furnished to the hospital's patients through an agreement with a distant-site hospital, the governing body of the hospital whose patients are receiving the telemedicine services may choose, in lieu of the requirements in paragraphs (a)(1) and (a)(2) of 42 CFR 482.22, to have its medical staff rely upon the credentialing and privileging decisions made by the distant-site hospital when making recommendations on privileges for the individual distant-site physicians and practitioners providing such services, if the hospital's governing body ensures, through its written agreement with the distant-site hospital, that all of the following provisions are met:</i></p> <p>(i) <i>The distant-site hospital providing the telemedicine services is a Medicare participating hospital.</i></p> <p>(ii) <i>The individual distant-site physician or practitioner is privileged at the distant-site hospital providing the telemedicine services, which provides a current list of the distant-site physician's or</i></p>	<p>This standard is only applicable if the hospital utilizes telemedicine services through an agreement with a distant-site hospital.</p> <p>The hospital's governing body has the option, when considering granting privileges to telemedicine physicians and practitioners, to have the hospital's medical staff rely upon the credentialing and privileging decisions of the distant-site hospital for these physicians and practitioners. This process would be in lieu of the traditional process required under §482.22(a)(1) and §482.22(a)(2), whereby the hospital's medical staff conducts its own review of each telemedicine physician's or practitioner's credentials and makes a recommendation based on that individualized review.</p> <p>In order to exercise this alternative credentialing and privileging option, the hospital's governing body must ensure through its written agreement with the distant-site hospital that all of the following requirements are met:</p> <ul style="list-style-type: none"> • The distant-site hospital participates in the Medicare program. If the distant-site hospital's participation in Medicare is terminated, either voluntarily or involuntarily, at any time during the agreement, then, as of the effective date of the termination, the hospital may no longer receive telemedicine services under the agreement; 	<p>DOCUMENT REVIEW</p> <p>If the hospital provides telemedicine services to its patients under an agreement with a <u>distant-site hospital</u>, ask whether the hospital's governing body has exercised the option to have the medical staff rely upon the credentialing and privileging decisions of the distant-site hospital in making privileging recommendations on telemedicine physicians and practitioners. If yes, ask to see:</p> <ol style="list-style-type: none"> 1. The written agreement with the distant-site hospital. Does the agreement address the required elements concerning the distant-site hospital's Medicare participation, licensure of telemedicine physicians and practitioners, current list of telemedicine physicians and practitioners with privileges, and review by the hospital of the telemedicine physicians' and practitioners' services and provision of information based on its review to the distant-site hospital? 2. The list provided by the distant-site hospital of the telemedicine physicians and practitioners, including their current privileges and pertinent licensure information. 3. Evidence that the hospital reviews the services provided by the telemedicine physicians and practitioners, including any 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant <input type="checkbox"/> NA=Not Applicable</p> <p>This standard is not met as evidenced by:</p>

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<p><i>practitioner’s privileges at the distant-site hospital.</i></p> <p>(iii) <i>The individual distant-site physician or practitioner holds a license issued or recognized by the State in which the hospital whose patients are receiving the telemedicine services is located.</i></p> <p>(iv) <i>With respect to a distant-site physician or practitioner, who holds current privileges at the hospital whose patients are receiving the telemedicine services, the hospital has evidence of an internal review of the distant-site physician’s or practitioner’s performance of these privileges and sends the distant-site hospital such performance information for use in the periodic appraisal of the distant-site physician or practitioner. At a minimum, this information must include all adverse events that result from the telemedicine services provided by the distant-site physician or practitioner to the hospital’s patients and all complaints the hospital has received about the distant-site physician or</i></p>	<ul style="list-style-type: none"> • The distant-site hospital provides to the hospital a list of all its physicians and practitioners covered by the agreement, including their privileges at the distant-site hospital. The list may not include any physician or practitioner who does not hold privileges at the distant-site hospital. The list must be current, so the agreement must address how the distant-site hospital will keep the list current; • Each physician or practitioner who provides telemedicine services to the hospital’s patients under the agreement holds a license issued or recognized by the State where the hospital (not the distant-site hospital) is located. States may have varying requirements as to whether they will recognize an out-of-state license for purposes of practicing within their State, and they may also vary as to whether they establish different standards for telemedicine services. The licensure requirements governing in the State where the hospital whose patients are receiving the telemedicine services is located must be satisfied, whatever they may be; and • The hospital has evidence that it reviews the telemedicine services provided to its patients and provides feedback based on 	<p>adverse events and complaints, and provides feedback to the distant-site hospital.</p> <p style="text-align: center;"><u>FILE REVIEW</u></p> <ul style="list-style-type: none"> • Review telemedicine credentialing files for evidence of compliance with credentialing process as outlined in the agreement and governing body bylaws. 	

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practitioner.
 §482.22(a)(3)
 §482.22(a)(3)(i)
 §482.22(a)(3)(ii)
 §482.22(a)(3)(iii)
 §482.22(a)(3)(iv)

this review to the distant-site hospital for the latter’s use in its periodic appraisal of each physician and practitioner providing telemedicine services under the agreement. At a minimum, the hospital must review and send information to the distant-site hospital on all adverse events that result from a physician or practitioner’s provision of telemedicine services under the agreement and on all complaints it has received about a telemedicine physician or practitioner covered by the agreement.

NOTE: Please refer to standards 03.00.02 for reference to §482.22 (a)(1) and 03.00.06 for reference to §482.22(a)(2), as mentioned above.

03.00.09 Telemedicine Privileging Provisions Through Distant-Site Telemedicine Entity Agreement.

*When telemedicine services are furnished to the hospital’s patients through an agreement with a distant-site telemedicine entity, the governing body of the hospital whose patients are receiving the telemedicine services may choose, in accordance with the requirements at §482.22(a)(1) and §482.22(a)(2) of **42 CFR 482.22**, to have its medical staff rely upon the credentialing and privileging decisions*

This standard is only applicable if the hospital utilizes telemedicine services through an agreement with a distant-site telemedicine agreement.
 NOTE: Please refer to standards 03.00.02 for reference to §482.22 (a)(1) and 03.00.06 for reference to §482.22(a)(2), as mentioned above.

For the purposes of this rule, a distant-site telemedicine entity is defined as an entity that –

- 1. Provides telemedicine services;**
- 2. Is not a Medicare-participating hospital; and**
- 3. Provides contracted services in a manner that enables a hospital using its services to meet all applicable Conditions of Participation,**

DOCUMENT REVIEW

If the hospital provides telemedicine services to its patients under an agreement with a one or more distant-site telemedicine entities, ask whether the hospital’s governing body has exercised the option to have the medical staff rely upon the credentialing and privileging decisions of the distant-site telemedicine entity in making privileging recommendations on telemedicine physicians and practitioners. If yes, ask to see:

- 1. The written agreement(s) with the distant-site telemedicine entity (ies). Does each**

- 1 = Compliant
- 2 = Not Compliant
- NA=Not Applicable

This standard is not met as evidenced by:

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<p><i>made by the distant-site telemedicine entity when making recommendations on privileges for the individual distant-site physicians and practitioners providing such services, if the hospital's governing body ensures, through its written agreement with the distant-site telemedicine entity, that the distant-site telemedicine entity furnishes services that, in accordance with §482.12(e), permit the hospital to comply with all applicable conditions of participation for the contracted services.</i></p> <p><i>The hospital's governing body must also ensure, through its written agreement with the distant-site telemedicine entity, that all of the following provisions are met:</i></p> <p><i>(i) The distant-site telemedicine entity's medical staff credentialing and privileging process and standards at least meet the standards at §482.12(a)(1) through (a)(7) and §482.22(a)(1) through (a)(2).</i></p> <p><i>(ii) The individual distant-site physician or practitioner is privileged at the distant-site</i></p>	<p>particularly those requirements related to the credentialing and privileging of practitioners providing telemedicine services to the patients of a hospital.</p> <p>A distant-site telemedicine entity would include a distant-site hospital that does not participate in the Medicare program that is providing telemedicine services to a Medicare-participating hospital. (See 76 FR 25553, May 5, 2011)</p> <p>The hospital's governing body has the option, when considering granting privileges to telemedicine physicians and practitioners, to have the hospital's medical staff rely upon the credentialing and privileging decisions of the distant-site hospital for these physicians and practitioners. This process would be in lieu of the traditional process required under §482.22(a)(1) and §482.22(a)(2), whereby the medical staff conducts its own review of each telemedicine physician's or practitioner's credentials and makes a recommendation based on that individualized review.</p> <p>In order to exercise this alternative credentialing and privileging option, the hospital's governing body must ensure through its written agreement with the distant-site hospital that all of the following requirements are met:</p> <ul style="list-style-type: none"> The distant-site telemedicine entity utilizes a medical staff credentialing and privileging process and standards that at least meets the 	<p>agreement address the required elements concerning the distant-site telemedicine entity's utilization of a medical staff credentialing and privileging process that meets the requirements of the hospital CoPs, appropriate licensure of telemedicine physicians and practitioners, current list of telemedicine physicians and practitioners specifying their privileges, and written review by the hospital of the telemedicine physicians' and practitioners' services and provision of information based on its review to the distant-site hospital?</p> <ol style="list-style-type: none"> The list provided by the distant-site telemedicine entity of the telemedicine physicians and practitioners covered by the agreement, including their current privileges and pertinent licensure information. Evidence that the hospital reviews the services provided by the telemedicine physicians and practitioners, including any adverse events and complaints, and provides written feedback to the distant-site telemedicine entity. Ask the hospital how it verifies that the telemedicine entity employs a credentialing and privileging process that meets or exceeds what is required for hospitals under the Medicare CoPs? (Surveyors do not 	

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<p><i>telemedicine entity providing the telemedicine services, which provides the hospital with a current list of the distant-site physician's or practitioner's privileges at the distant-site telemedicine entity.</i></p> <p>(iii) <i>The individual distant-site physician or practitioner holds a license issued or recognized by the state in which the hospital whose patients are receiving such telemedicine services is located.</i></p> <p>(iv) <i>With respect to a distant-site physician or practitioner, who holds current privileges at the hospital whose patients are receiving the telemedicine services, the hospital has evidence of an internal review of the distant-site physician's or practitioner's performance of these privileges and sends the distant-site telemedicine entity such performance information for use in the periodic appraisal of the distant-site physician or practitioner. At a minimum, this information must include all</i></p>	<p>standards for the medical staff of a hospital established at §482.12(a)(1) through (a)(7) and §482.22(a)(1) through (a)(2);</p> <ul style="list-style-type: none"> • The distant-site telemedicine entity provides a list to the hospital of all physicians and practitioners covered by the agreement, including their privileges at the distant-site telemedicine entity. The list may not include any physician or practitioner who does not hold privileges at the distant-site telemedicine entity. The list must be current, so the agreement must address how the distant-site telemedicine entity will keep the list current; • Each physician or practitioner who provides telemedicine services to the hospital's patients under the agreement holds a license issued or recognized by the State where the hospital (not the distant-site hospital) is located. States may have varying requirements as to whether they will recognize an out-of-state license for purposes of practicing within their State, and they may also vary as to whether they establish different standards for telemedicine services. The licensure requirements governing in the State where the hospital whose patients are receiving the telemedicine services is located must be satisfied, whatever they may be; and • The hospital has evidence that it reviews the telemedicine services provided to its patients 	<p>attempt to independently verify whether or not the distant-site telemedicine entity's credentialing and privileging process fulfills the regulatory requirements. Surveyors focus only on whether the hospital takes steps to ensure that the distant-site telemedicine entity complies with the terms of the written agreement.)</p>	

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<p><i>adverse events that result from the telemedicine services provided by the distant-site physician or practitioner to the hospital's patients, and all complaints the hospital has received about the distant-site physician or practitioner.</i></p> <p>§482.22(a)(4) §482.22(a)(4)(i) §482.22(a)(4)(ii) §482.22(a)(4)(iii) §482.22(a)(4)(iv)</p>	<p>and provides a written copy of this review to the distant-site telemedicine entity for the latter's use in its periodic appraisal of the physicians and practitioners providing telemedicine services under the agreement. At a minimum, the hospital must review and send information to the distant-site telemedicine entity on all adverse events that result from a physician or practitioner's provision of telemedicine services and on all complaints it has received about a telemedicine physician or practitioner.</p>		
<p>03.00.10 Medical Staff Responsibilities to the Governing Body.</p> <p>(1) <i>The Medical Staff must be well organized and accountable to the governing body for the quality of the medical care provided to the patients. The medical staff must be organized in a manner approved by the governing body.</i></p> <p>(2) <i>If the medical staff has an executive committee, a majority of</i></p>	<p>The conditions of participation create a system of checks and balances within an overall framework of collaboration between the governing body and the medical staff (and, to a certain degree, also between an individual practitioner and the hospital's medical staff and governing body). Each has its own areas of authority.</p> <p>The medical staff has oversight of all practitioners practicing in the hospital through processes such as peer review and making recommendations concerning privileging and re-privileging.</p>	<p>DOCUMENT REVIEW AND INTERVIEW</p> <ol style="list-style-type: none"> 1. Verify that the medical staff has a formal, organized structure reflected in the medical staff bylaws, rules and regulations and that functions and responsibilities within the medical staff and with respect to the governing body and other parts of the hospital are reflected. 2. If there is active medical staff executive committee, verify that a majority of the members are doctors of medicine or 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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<p><i>the members of the committee must be doctors of medicine or osteopathic medicine.</i></p> <p>(3) <i>The responsibility for organization and conduct of the medical staff must be assigned only to one of the following:</i></p> <p>(i) <i>An individual doctor of medicine or osteopathic medicine.</i></p> <p>(ii) <i>A doctor of dental surgery or dental medicine, when permitted by State law of the State in which the hospital is located.</i></p> <p>(iii) <i>A doctor of podiatric medicine, when permitted by State law of the State in which the hospital is located.</i></p> <p>§482.22(b) §482.22(b)(1) §482.22(b)(2) §482.22(b)(3) §482.22(b)(3)(i) §482.22(b)(3)(ii) §482.22(b)(3)(iii)</p>	<p>The governing body has the authority to establish the categories of healthcare professionals (regardless of the terms used to describe those categories) who are eligible for privileges and medical staff appointment.</p> <p>However, the governing body must rely on the medical staff to apply the criteria for privileging and appointment to those eligible candidates and to make their recommendations before the governing body makes a final decision to appoint or not appoint a practitioner to the medical staff. (77 FR 29042 May 16, 2012).</p> <p>If the hospital uses a unified medical staff that it shares with other hospitals that are part of a multi-hospital system, this does not change the requirement for the medical staff to be well organized and accountable to the system’s governing body for the quality of care in each separately certified hospital.</p> <p><u>Leadership of the Medical Staff</u> The members of the hospital’s medical staff must select, in accordance with the medical staff bylaws, rules or regulations approved by the governing body, a single individual to lead the medical staff and be responsible for the organization and conduct of the medical staff.</p> <ul style="list-style-type: none"> This individual must be a doctor of medicine or osteopathy, or, if permitted by State law where the hospital is located, a doctor of 	<p>osteopathic medicine.</p> <ol style="list-style-type: none"> Verify that an individual doctor of medicine or osteopathic medicine, or if permitted by State law, a doctor of dental surgery, dental medicine, or podiatric medicine, selected by the medical staff, is responsible for the conduct and organization of the medical staff. Ask the CEO and medical staff leadership to describe the mechanisms by which the medical staff fulfills its responsibility to be accountable for the quality of medical care in the hospital. Interview several members of the medical staff, including both practitioners who hold leadership or executive committee positions and ones who do not. <ul style="list-style-type: none"> Ask them what their medical staff duties and responsibilities are and how they perform them. Ask them to describe how the medical staff is accountable for the quality of medical care provided to patients. 	

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dental surgery, dental medicine, or podiatric medicine.

- Removal of the leader of the medical staff may only occur in accordance with medical staff bylaws, rules or regulations.
- If the hospital uses a unified medical staff, only one individual may be responsible for the organization and conduct of the unified medical staff; that individual may or may not hold privileges and practices at the hospital being surveyed.
- When the individual does not practice at the hospital being surveyed and it is necessary to interview this individual as part of a survey, a telephone interview must be arranged.

Executive Committee

The medical staff bylaws, rules and regulations may provide for the members of the medical staff to select a smaller executive committee to which it delegates many of the functions of the medical staff, in order to increase the efficiency of its operations.

If the medical staff has an executive committee, the majority of the voting members must be doctors of medicine (MDs) or osteopathy (DOs).

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*For Information Only – Not Required/
Not to be Cited*

A hospital is not required to have an executive committee. However, use of an executive committee may facilitate efficient and effective functioning of the medical staff in hospitals systems that use a unified medical staff, particularly if the executive committee includes members from each hospital that shares the unified medical staff.

Accountability of the Medical Staff

The medical staff must be accountable to the hospital’s governing body for the quality of medical care provided to the patients.

The medical staff demonstrates its accountability through its exercise of its duties related to appointment of members of the medical staff, its conduct of reappraisals, including peer reviews, its approval of policies and procedures as required under other conditions of participation and its leadership participation in the organization and implementation of the hospital’s quality assessment and performance improvement program required in accordance with §482.21.

If the hospital uses a unified medical staff, the medical staff continues to be accountable for the quality of care in each separately certified hospital

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that uses the unified medical staff.

The medical staff must be accountable to the hospital’s governing body for the quality of medical care provided to the patients. The organization of the medical staff must comply with these requirements.

This will include:

- A. Acting on the reports of services, departments, and committees of the Medical Staff;
- B. Direct reporting to governance regarding Medical Staff appointments, reappointments, and privilege delineations;
- C. Direct reporting to governance regarding Medical Staff behaviors resulting in suspension, or other corrective action, and any fair hearing results;
- D. Direct reporting to governance of organizational proposals including revisions in Bylaws, Rules and Regulations and Medical Staff officers;
- E. Accountability to governance for the findings from ongoing evaluation of the clinical work of the Medical Staff; and
- F. Collaborating with administration and governance regarding institutional planning, budgeting and appropriate utilization of available resource.

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<p>03.00.11 <u>Multiple-Hospital Systems: Unified and Integrated Medical Staff.</u> <i>If a hospital is part of a hospital system consisting of multiple separately certified hospitals and the system elects to have a unified and integrated medical staff for its member hospitals, after determining that such a decision is in accordance with all applicable State and local laws, each separately certified hospital must demonstrate that...</i></p> <p>§482.22(b)(4)</p>	<p><u>MULTI- HOSPITAL SYSTEM</u> A hospital that is part of a system consisting of multiple separately-certified hospitals may use a single unified and integrated medical staff (hereafter referred to as a “unified medical staff”) that is shared with one or more of the other hospitals in the system. In other words, as long as the requirements of §482.22(b)(4) are met, it is not necessary for each separately-certified hospital within the system to have its own distinct medical staff organization and structure, including hospital-specific medical staff bylaws, rules and requirements, hospital-specific medical staff leadership, hospital-specific credentialing and peer review, etc.</p> <p>Instead, it may use one medical staff organization and structure for multiple hospitals, so long as all of the requirements of this section are met.</p> <p>However, separately certified hospitals which share a single unified and integrated medical staff must also share a system governing body, in accordance with the provisions of §482.12, since only one governing body may carry out the governing body’s medical staff responsibilities for a unified medical staff.</p> <p><u>MULTI-CAMPUS HOSPITAL</u> Note that a multi-campus hospital that has several inpatient campuses that are provider-</p>	<p><u>DOCUMENT REVIEW</u></p> <ol style="list-style-type: none"> 1. Ask the hospital and medical staff leadership if the hospital is part of a multi-hospital system of separately certified hospitals. <ul style="list-style-type: none"> • If no, it is not necessary to assess compliance with this regulation. • If yes, ask if the hospital also shares its governing body and medical staff with one or more other separately-certified hospitals in the system. If yes: 2. Does the use of the unified medical staff predate July 11, 2014? <ul style="list-style-type: none"> • If yes, ask for documentation of the governing body’s determination that use of a unified medical staff does not conflict with State or local law. 3. Did the use of the unified medical staff start after July 11, 2014? <ul style="list-style-type: none"> • If yes, ask for documentation of the governing body’s decision to elect use of a unified medical staff and of its determination that use of a unified medical staff does not conflict with State or local law. • Can the hospital produce documentation that practitioners who practice at the hospital have been 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant <input type="checkbox"/> Not Applicable for non-system hospitals</p> <p>This standard is not met as evidenced by:</p>

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	<p>based, remote locations of the hospital is not a multi-hospital system.</p> <p>A multi-campus hospital is one certified hospital, NOT several separately certified hospitals.</p> <ul style="list-style-type: none"> • A multi-campus hospital may not have separate medical staffs at each campus, since each hospital must have no more than one medical staff. • A multi-campus hospital with one medical staff separate from that of other certified hospitals is not employing a unified medical staff as that term is used in this regulation. • However, a multi-campus hospital that is part of a hospital system consisting of multiple separately certified hospitals may share a unified medical staff with other separately certified hospitals within the system. <p>It should be noted that a hospital system that includes certain types of hospitals, i.e., Hospitals-within-Hospitals or Hospital Satellites, that are being paid under a Medicare payment system other than the Hospital Inpatient Prospective Payment System (IPPS) might jeopardize the Medicare payment status of those excluded hospitals if it owns both the tenant and host hospitals and uses a unified medical staff for both. This is the case even if the requirements of</p>	<p>granted privileges by the hospital’s governing body that specify the practitioner’s privileges apply to specific hospital(s), which include the hospital being surveyed?</p>	

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§482.22(b)(4) are met. However, surveyors do not assess compliance with or enforce the Medicare payment regulations that govern Hospitals-within-Hospitals or Hospital Satellites.

When granting practitioners privileges to provide patient care, a hospital's governing body must specify those hospitals in the system where the privileges apply, since, in addition to the qualifications of individual practitioners, the services provided at each hospital must be considered when granting privileges.

- For example, psychiatric hospitals do not offer surgical services, labor and delivery services, nuclear medicine, etc., so it would not be appropriate for practitioners practicing in these areas to hold privileges at psychiatric hospitals in a multi-hospital system that uses a unified medical staff.
- Likewise if a multi-hospital system covers a wide geographic area, many of its practitioners may have no interest in practicing on site at hospitals that are distant from their usual practice location(s).
- In addition, in order for the approval or opt-out provisions of §482.22(b)(4)(i) and (ii) to be workable, privileges must be granted on a hospital-specific basis to practitioners who actually practice or are likely to practice at the hospital.

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MULTI – HOSPITAL SYSTEM

The governing body in a multi-hospital system must elect to exercise this option.

Since a number of hospital systems interpreted the Medical Staff CoP to permit a unified and integrated medical staff prior to publication of the final rule at §482.22(b)(4) on May 12, 2014 or its effective date on July 11, 2014, the existence of a unified medical staff prior to July 11, 2014 is considered evidence of the hospital’s governing body’s election of this option.

- This does not relieve the governing body of the responsibility to conduct a review of all applicable State and local laws, including regulations, and make a determination that use of a unified medical staff that is shared by multiple hospitals does not conflict with those laws.
- The hospital must maintain documentation of this determination by its governing body.
- Nor does it relieve the governing body of the obligation to inform the medical staff of the right to vote to opt out of a unified medical staff arrangement. (See discussion of §482.22(b)(4)(ii), which requires notification of all members of this right. Failure to comply would be cited under the tag for §482.22(b)(4)(ii).)

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If a hospital is part of a multi-hospital system that wishes to establish a unified medical staff for some or all of its separately certified hospitals after the July 11, 2014 effective date of the final rule at §482.22(b)(4), then the hospital’s system governing body must document in writing its decision to elect to use the unified medical staff option, conditioned upon acceptance of a unified medical staff by the hospital’s medical staff in accordance with §482.22(b)(4)(i).

- The governing body must also document its determination that such election does not conflict with State or local laws, including regulations.

Surveyors

Surveyors are not expected, as part of their assessment of compliance with the Medicare CoPs, to evaluate whether the governing body’s determination of compliance with State and local law is accurate. This would be handled by the appropriate State or local authorities, or, if the State Survey Agency is the appropriate authority, under its State licensure or other authority and not as part of a Federal survey.

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<p>03.00.12 <u>Voting Requirements for Separately Certified Hospitals.</u> <i>If a hospital is part of a hospital system consisting of multiple separately certified hospitals and the system elects to have a unified and integrated medical staff for its member hospitals, after determining that such a decision is in accordance with all applicable State and local laws, each separately certified hospital must demonstrate that:</i></p> <p><i>(i) The medical staff members of each separately certified hospital in the system (that is, all medical staff members who hold specific privileges to practice at that hospital) have voted by majority, in accordance with medical staff bylaws, either to accept a unified and integrated medical staff structure or to opt out of such a structure and to maintain a separate and distinct medical staff for their respective hospital;</i></p> <p>§482.22(b)(4) §482.22(b)(4)(i)</p>	<p>The decision for a particular certified hospital in a multi-hospital system to use a unified medical staff is a joint one arrived at by the:</p> <ul style="list-style-type: none"> • Election of the unified medical staff option by the hospital’s governing body; and • Acceptance by a majority of the medical staff members who hold privileges to practice at that particular hospital, voting in accordance with the medical staff bylaws. <p>The medical staff of each hospital also has the option to opt out of an existing unified medical staff, when a majority of the medical staff members who hold privileges to practice at that particular hospital, voting in accordance with the medical staff bylaws, vote to do so.</p> <ul style="list-style-type: none"> • For purposes of voting on whether to use or opt out of a unified medical staff, the term “privileges to practice at that particular hospital” is interpreted to mean only those practitioners who hold privileges to practice on-site at the hospital. • Practitioners who hold only telemedicine privileges at a hospital are not included when identifying which practitioners are not eligible to vote nor what constitutes a majority of the practitioners holding privileges at the hospital. 	<p><u>DOCUMENT REVIEW</u></p> <p>Assess compliance with this regulation only if the hospital uses a unified medical staff. (See survey procedures for §482.22(b)(4) above.)</p> <ol style="list-style-type: none"> 1. If the hospital uses a unified medical staff, ask the hospital’s leadership when it began to do so. <ul style="list-style-type: none"> • Is there any documentation to support the response? 2. If the hospital began using a unified medical staff <u>after</u> July 11, 2014, is there evidence that a majority of the medical staff holding privileges at the hospital voted in favor of using a unified medical staff? 3. If the hospital uses a unified medical staff, do the bylaws clearly describe a process by which a vote to opt out of using a unified medical staff may be requested and conducted? <ul style="list-style-type: none"> • Are there provisions that are described in the guidance above unduly limiting the rights of medical staff members to vote on whether to accept or opt out of the unified medical staff? 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant <input type="checkbox"/> Not Applicable for non-system hospitals</p> <p>This standard is not met as evidenced by:</p>

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	<p>A hospital that is part of a hospital system is expected to have medical staff bylaws, rules and requirements that address the regulatory requirements of §482.22(b)(4)(i) – (iv) related to using a unified medical staff, including the processes under the bylaws for voting to accept or opt out of a unified medical staff.</p> <ul style="list-style-type: none"> This is the case even if the hospital currently does not use a unified medical staff. <p>If the hospital uses a unified medical staff, depending on State law requirements, the unified medical staff bylaws, rules and requirements required at §482.22(b)(4)(ii) may substitute for hospital-specific medical staff bylaws, rules and requirements.</p> <p>However, CMS recognizes that the process of amending bylaws can be a lengthy one. Hospitals that were part of a hospital system using a unified medical staff as of July 11, 2014 are expected to have initiated the process before December 31, 2014 to effect the necessary amendments, even if the process is not completed until after that date.</p> <p>Likewise, when a hospital is acquired by a system but maintains separate participation in Medicare, if the hospital’s governing body elects to use a unified medical staff and the medical staff accepts such election, the hospital is</p>	<ul style="list-style-type: none"> If there are requirements in the voting process that appear to limit opt-out voting, ask the medical staff leadership to explain why the limitations are reasonable and not unduly restrictive. <p>4. Ask the hospital and members of the medical staff whether there has ever been a vote on the question of opting out.</p> <ul style="list-style-type: none"> If yes, ask the hospital to produce evidence that a majority of the practitioners holding privileges at the hospital voted against opting out. <p>5. Can the hospital readily identify the members of the unified medical staff who are eligible to vote to approve or to opt out of a unified medical staff?</p>	

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expected to initiate the necessary changes to its medical staff bylaws, rules and requirements no later than six months after the effective date of its acquisition.

In establishing medical staff bylaws governing medical staff voting on the questions of acceptance of, or opting out of, a unified medical staff, the medical staff and the governing body, which must approve the revised bylaws in accordance with §482.12(a)(4), have the flexibility to determine the details of the voting process,

- such as how an acceptance or opt-out vote can be requested;
- whether all categories of members holding privileges to practice on-site at the hospital are afforded medical staff voting rights;
- whether voting will be in writing and open or by secret ballot, etc.
- However, a hospital may not set up bylaws that unduly restrict the rights of medical staff members when voting on the issue of accepting or opting out of a unified medical staff structure.

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For example:

- Hospitals may not establish different criteria as to which categories of medical staff members have voting rights with respect to a vote to accept or opt out of a unified medical staff than are used for other amendments to the medical staff’s bylaws, except as required under the regulation at §482.22(b)(4) that only members holding privileges to practice at the hospital may vote. (See also the discussion below concerning delegation of authority to the medical staff executive committee.)

- Hospitals may not require as a condition for holding an opt-out vote that there be a petition signed by the same number of voting members as would be required for a successful vote to opt out.

- Hospitals may require for a successful acceptance or opt-out vote a “supermajority”, that is, a majority that is greater than a simple majority of more than fifty percent of the medical staff members with voting rights holding privileges to practice at the hospital, so long as the same type of supermajority is otherwise generally required to amend the medical staff’s bylaws, rules and requirements.

- In the case where a hospital system has a

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unified medical staff and members of the staff at a hospital in the system exercise their right to hold a vote on the question of opting out, the hospital may not permit delegation of an opt-out decision to the unified medical staff’s executive committee.

- This is the case even when the executive committee is otherwise delegated authority to amend unified medical staff bylaws, rules and requirements that it recommends for approval to the governing body.
- In cases where the bylaws permit such delegation to the unified medical staff’s executive committee for other purposes, a “majority” for purposes of conducting a vote on whether to opt out of a unified medical staff consists of a simple majority, that is, any number which is greater than fifty percent, of the medical staff members practicing at the hospital who have voting privileges.
- On the other hand, in the case where a hospital that is part of a hospital system but has a separate medical staff is holding a vote on

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	<p>whether to accept participating in a unified medical staff, a hospital may permit a vote by members of the hospital's medical staff executive committee only, if this is consistent with the hospital's medical staff bylaws governing amendments in effect at the time of the vote.</p> <ul style="list-style-type: none"> A hospital may establish a minimum interval between acceptance or opt-out votes, such as not permitting a vote more than once every two years. However, a minimum interval between votes longer than two years might unduly restrain the rights of the members of the medical staff and would not be permissible. <p>It is not expected that the medical staff bylaws, rules and requirements that were in effect as of July 11, 2014 would address the issue of a unified medical staff, nor the process of voting by medical staff members at each hospital to accept or opt out of a unified medical staff.</p> <ul style="list-style-type: none"> Although it is expected that the medical staff bylaws, rules and requirements of hospitals that are part of a hospital system will be amended in a timely fashion as discussed above, this does not mean that a vote to accept or opt 		

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out of a unified medical staff may not take place prior to enactment of such amendments.

Voting is governed by the hospital’s medical staff bylaws in effect at the time of the vote, except that only voting members of the medical staff who hold privileges to practice on-site at that hospital may participate in the vote.

- With respect to what constitutes a “majority,” the provisions of the bylaws governing voting rights and voting procedures at the time of the vote apply. However, as discussed above, in the case of a vote to opt-out of a unified medical staff, the vote may not be delegated to the executive committee of the unified medical staff.

Since a number of hospital systems interpreted the Medical Staff CoP to permit a unified medical staff prior to publication of the final rule at §482.22(b)(4) on May 12, 2014 or its effective date of July 11, 2014, in the case of a hospital’s use of a unified medical staff which began prior to the latter date, it is not necessary for the hospital to hold a vote among the members of the medical staff who hold privileges at that hospital to determine whether the majority accepts the continued use of a unified medical staff.

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- However, the governing body is expected to formally notify the medical staff practicing at each hospital of its preference to continue using a unified medical staff arrangement, as well as of the right of the medical staff holding privileges at each hospital to vote to opt out of the unified medical staff.

If the system governing body of a hospital that is part of the multi-hospital system but which has a separate medical staff elects after July 11, 2014 to create a system unified medical staff structure and/or to include the hospital’s medical staff in an already existing unified medical staff structure, the hospital must arrange for a vote by medical staff members, in accordance with the medical staff bylaws, on whether or not to accept use of a unified medical staff for their hospital.

- The hospital may not use a unified medical staff unless a majority of its medical staff members holding voting rights vote, in accordance with the hospital’s medical staff bylaws, to accept a unified medical staff.

Even if a majority of a hospital’s medical staff has voted to use a unified medical staff in the past, the members of the unified medical staff with voting rights and holding privileges to practice

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on-site at that hospital still retain the right to hold a vote to opt out of the unified medical staff structure at a future date.

- If a majority of the staff with voting rights and holding privileges at that hospital vote, in accordance with the unified medical staff’s bylaws, to opt out, then the hospital must establish a separate medical staff.

**03.00.13 Medical Staff:
Bylaws of the Unified Medical Staff.**

If a hospital is part of a hospital system consisting of multiple separately certified hospitals and the system elects to have a unified and integrated medical staff for its member hospitals, after determining that such a decision is in accordance with all applicable State and local laws, each separately certified hospital must demonstrate that:

(ii) The unified and integrated medical staff has bylaws, rules, and requirements that describe its processes for self-governance, appointment, credentialing, privileging, and oversight, as well

One Set of Bylaws, Rules and Requirements

A hospital that uses a unified medical staff must ensure that the unified medical staff has one set of bylaws, rules and requirements that describe the medical staff’s processes for self-governance, appointment, credentialing, privileging, oversight, peer review, and due process rights guarantees.

- Consistent with the requirements for a system governing body in §482.12, the documentation of the bylaws, rules and requirements that apply to the unified medical staff must identify each separately certified hospital that has elected to use a unified medical staff and which, therefore, is covered by the unified medical staff bylaws, rules and regulations.

DOCUMENT REVIEW

Assess compliance with this regulation only if the hospital uses a unified medical staff. (See survey procedures for §482.22(b)(4) above)

1. Ask the hospital’s leadership for evidence that the unified medical staff’s bylaws, rules and requirements are readily available, and that it is clear that they apply to that hospital.
2. Ask the hospital’s leadership to provide evidence that the unified medical staff bylaws, rules or requirements address the rights of members holding privileges at the hospital to vote by majority to opt out of using the unified medical staff, including notification of these rights.

- 1 = Compliant
- 2 = Not Compliant
- Not Applicable for non-system hospitals

This standard is not met as evidenced by:

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<p><i>as its peer review policies and due process rights guarantees, and which include a process for the members of the medical staff of each separately certified hospital (that is, all medical staff members who hold specific privileges to practice at that hospital) to be advised of their rights to opt out of the unified and integrated medical staff structure after a majority vote by the members to maintain a separate and distinct medical staff for their hospital.</i></p> <p>§482.22(b)(4)(ii)</p>	<ul style="list-style-type: none"> • Depending on State law requirements, the unified medical staff bylaws, rules and requirements may be in addition to or instead of hospital-specific medical staff bylaws, rules and requirements. • The unified medical staff bylaws, rules and regulations must not conflict with any of the specific requirements for medical staff found elsewhere in §482.12 or §482.22, or under any other hospital CoPs which assign responsibilities to the hospital’s medical staff. <p>The unified medical staff’s bylaws, rules and requirements addressing its self-governance processes must provide for a process by which members of the unified medical staff holding privileges to practice on site at each separately certified hospital are advised that they have the right to vote on whether to opt out of participation in the unified medical staff, and that if a majority vote to opt out, then the hospital must establish a separate medical staff.</p> <ul style="list-style-type: none"> • At a minimum, the hospital must advise medical staff members in writing of their right to vote by majority to opt out when medical staff membership is first granted, and when it is renewed. 	<ol style="list-style-type: none"> 3. Ask how the unified medical staff bylaws define a majority for the purpose of an opt-out vote. If the unified medical staff bylaws require a super-majority, ask for evidence that this is consistent with the way “majority” is defined for other amendments to the bylaws. 4. Do the bylaws, rules or requirements clearly describe how and when members holding privileges at the hospital will be advised of their rights? 5. Can the hospital readily identify the members of the unified medical staff who are eligible to vote to opt out and therefore must be advised of their rights? 6. Do the credentialing and privileging files of members of the medical staff have any evidence of their being notified of their right to vote by majority to opt out? 7. Interview several members of the medical staff to determine if they recall being notified of their right to vote by majority to opt out. 	

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The bylaws must address the process by which a vote to opt out of the unified medical staff is conducted. In establishing the unified medical staff bylaws governing opting out, the unified medical staff, and the system governing body, which must approve the medical staff’s bylaws, rules or regulations in accordance with §482.12(a)(4), have the flexibility to determine the details of the voting process, such as how an acceptance or opt-out vote can be requested; whether all categories of members holding privileges to practice on-site at the hospital are afforded medical staff voting rights; whether voting will be in writing and open or by secret ballot, etc.

- However, the unified medical staff and system governing body may not set up bylaws that unduly restrict the rights of medical staff members at each separately certified hospital to vote whether to accept or opt out of a unified medical staff structure.

For example:

- The bylaws, rules and requirements may not establish different criteria as to which categories of medical staff members have voting rights with respect to a vote to accept or opt out of a unified medical staff than are used for any other type of voting the medical staff engages in, except as required under the regulation at §482.22(b)(4) that only members holding privileges to practice

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at the hospital may vote. (See also the discussion below concerning delegation of authority to the medical staff executive committee.)

- The bylaws, rules and requirements may not require as a condition for holding an opt-out vote that there be a petition signed by the same number of voting members as would be required for a successful vote to opt out.
- The bylaws, rules and requirements may require for a successful acceptance or opt-out vote a “super-majority,” that is, a majority that is greater than a simple majority of more than fifty percent of the medical staff members with voting rights holding privileges to practice at the hospital, so long as the same type of supermajority is otherwise required to amend the unified medical staff’s bylaws, rules and requirements.
- In the case where a hospital system has a unified medical staff and members of the staff at a hospital in the system exercise their right to hold a vote on the question of opting out, the unified medical staff bylaws may not permit delegation of an opt-out decision to the unified medical staff’s executive committee. This is the case even when the executive committee is otherwise

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delegated authority to amend unified medical staff bylaws, rules and requirements that it recommends for approval to the governing body. In cases where the bylaws permit such delegation to the unified medical staff’s executive committee for other purposes, a “majority” for purposes of conducting a vote on whether to opt out of a unified medical staff consists of a simple majority, that is, any number which is greater than fifty percent of the medical staff members practicing at the hospital who have voting privileges.

- The bylaws, rules and requirements may establish a minimum interval between acceptance or opt-out votes, such as not permitting a vote more than once every two years. However, minimum interval between votes longer than two years might unduly restrain the rights of the members of the medical staff and would not be permissible.

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<p>03.00.14 Multiple-Hospital Systems: Unique Circumstances. <i>If a hospital is part of a hospital system consisting of multiple separately certified hospitals and the system elects to have a unified and integrated medical staff for its member hospitals, after determining that such a decision is in accordance with all applicable State and local laws, each separately certified hospital must demonstrate that:</i></p> <p><i>(iii) The unified and integrated medical staff is established in a manner that takes into account each member hospital's unique circumstances and any significant differences in patient populations and service.</i></p> <p>§482.22(b)(4)(iii)</p>	<p>SEPARATELY CERTIFIED HOSPITALS</p> <p>The separately certified hospitals belonging to a multi-hospital system and using a single unified medical staff may be very different from each other, presenting different needs and challenges for the medical staff.</p> <p>As a result, the unified medical staff is expected to take these differences into account rather than using a one-size-fits-all approach for all of its policies and procedures.</p> <p>For example, a multi-hospital system may:</p> <ol style="list-style-type: none"> 1. Consist of a mixture of different types of hospitals, such as short-term acute care hospitals, psychiatric hospitals, rehabilitation hospitals, children's hospitals, and long-term care hospitals. As a result, they would offer different types of services to different patient populations. <ul style="list-style-type: none"> • This could have implications for medical staff functions such as the periodic review of credentials and privileges and ongoing peer review of the quality of medical care. • It could also have implications for other responsibilities the medical staff has under various CoPs. 	<p>DOCUMENT REVIEW</p> <p>Assess compliance with this regulation only if the hospital uses a unified medical staff. (See survey procedures for §482.22(b)(4) above)</p> <ol style="list-style-type: none"> 1. Ask the hospital's and medical staff's leadership to describe the other types of hospitals in the system with which it shares a unified medical staff, and how the hospital's unique circumstances are addressed. <p>For example, how does the unified medical staff assure that:</p> <ol style="list-style-type: none"> a. Standing orders it has approved are also approved by the nursing and pharmacy leadership in each separately certified hospitals? (see §482.24(c)(3)(i)); b. Policies and procedures developed by the medical staff to minimize drug errors, if this function has not been delegated to the hospital's pharmaceutical service, take into account any unique hospital circumstances? (see §482.25); c. The formulary system established by the medical staff takes into account any unique hospital circumstances? (See §482.25(b)(9)); 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant <input type="checkbox"/> Not Applicable for non-system hospitals</p> <p>This standard is not met as evidenced by:</p>

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	<ul style="list-style-type: none"> • For example, the medical staff has a key role in the development and oversight of the use of standing orders/protocols, but these orders/protocols must be specific to each hospital, reflecting the types of services a hospital offers and its patient population; <ol style="list-style-type: none"> 2. Consist of hospitals that differ in size, ranging from comparatively small hospitals in rural areas, or which provide specialized rehabilitation or long term care hospital services, to very large short term acute care service hospitals. Such differences could have implications for various medical staff requirements, such as on-call requirements. 3. Consist of hospitals that differ as to whether they are teaching hospitals or not, which would have implications for policies concerning the roles and supervision of residents. 4. Consist of hospitals that are located in different states which have different licensure requirements affecting the organization and composition of the medical staff. For example, in one state it might be permissible for non-physician practitioners to be members of the medical staff, while in another the medical staff is limited to 	<ol style="list-style-type: none"> d. The medical staff's specification of procedures and treatments requiring a properly executed informed consent reflects any unique hospital circumstances? (see §482.24(c)(4)(v)); e. The medical staff carries out its joint responsibility with the CEO and Director of nursing for ensuring that hospital-specific infection control problems identified by the hospital's infection control officer(s) are addressed in the hospital's QAPI and training programs? (see §482.42(b)); f. The medical staff fulfills its joint executive responsibilities, along with the hospital's governing body and administrative officials, for ensuring that the hospital-specific QAPI program is: <ul style="list-style-type: none"> • Ongoing, defined, implemented and maintained; • Addresses hospital-specific priorities for improved quality of care and patient safety, and that all improvements are evaluated; • Establishes clear expectations for safety in the hospital; 	

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	<p>physicians.</p> <p>On the other hand, a multi-hospital system may have a conscious strategy of having hospitals that are very similar to each other in terms of size, services, patient populations served, and type of location. In this case, the unified medical staff would have fewer challenges in addressing the needs of each hospital, and might have more policies that are uniform across the medical staff.</p> <p><u>Hospital Leadership</u> In all cases the hospital’s leadership and the medical staff leadership must be able to explain how the way in which the unified medical staff is organized and functions takes account of and responds to the unique circumstances of the hospital that is being surveyed.</p>	<ul style="list-style-type: none"> • Allocates adequate resources for the hospital-specific QAPI program; and • Determines annually the number of distinct improvement projects conducted in the hospital? (See §482.21(e)) <p>g. Medical staff policies governing ordering of outpatient services address any unique hospital circumstances? (See §482.54(c)(4))</p> <p>h. Medical staff policies and recommendations governing which practitioners may be authorized to write orders and be responsible for the care of the patient conform to State law, including scope of practice law, for the State in which the hospital is located? (multiple citations in various CoPs)</p>	

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<p>03.00.15 <u>Medical Staff: Policies of the Unified Medical Staff.</u> <i>If a hospital is part of a hospital system consisting of multiple separately certified hospitals and the system elects to have a unified and integrated medical staff for its member hospitals, after determining that such a decision is in accordance with all applicable State and local laws, each separately certified hospital must demonstrate that:</i></p> <p><i>(iv) The unified and integrated medical staff establishes and implements policies and procedures to ensure that the needs and concerns expressed by members of the medical staff, at each of its separately certified hospitals, regardless of practice or location, are given due consideration, and that the unified and integrated medical staff has mechanisms in place to ensure that issues localized to particular hospitals are duly considered and addressed.</i></p> <p>§482.22(b)(4)(iv)</p>	<p><u>MEDICAL STAFF POLICIES</u> The hospital’s unified medical staff must have written policies and procedures that address how it considers and addresses needs and concerns expressed by members who practice at the hospital.</p> <ul style="list-style-type: none"> • This provision is <u>not</u> about an individual medical staff member’s concerns with privileges granted or not granted to him/her, peer review results, due process issues, etc., since these matters are addressed under the requirements at §482.22(a) and (c) as well as §482.22(b)(4)(ii). • Instead, this provision addresses a requirement for the unified medical staff to consider and address concerns that practitioners have concerning their own hospital’s needs. • For example, physicians practicing in a children’s hospital may have concerns about having protocols for medication administration that reflect specific pediatric patient concerns, or physicians practicing in a small rural hospital may have concerns about how to get timely telemedicine consults from their colleagues in urban areas. <p>The medical staff has flexibility in establishing its written policies and procedures for addressing</p>	<p><u>DOCUMENT REVIEW</u> Assess compliance with this regulation only if the hospital uses a unified medical staff. (See survey procedures for §482.22(b)(4) above)</p> <ol style="list-style-type: none"> 1. Determine that the unified medical staff has policies and procedures addressing how members can raise local concerns and needs. <ul style="list-style-type: none"> • Do the written policies and procedures cover the minimum elements? 2. Ask the hospital and the medical staff leadership whether any members practicing at the hospital have raised concerns or needs. <ul style="list-style-type: none"> • If yes, ask for documentation on how the concern/need was considered and addressed by the unified medical staff. 3. Ask members of the medical staff if they are aware they can raise local concerns or needs with the leadership of the unified medical staff. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant <input type="checkbox"/> Not Applicable for non-system hospitals</p> <p>This standard is not met as evidenced by:</p>

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these local concerns, but at a minimum they must cover the following:

1. A process by which members who practice at a hospital can raise their local concerns and needs with the unified medical staff's leadership;
2. How members are informed of the process by which they can raise their local concerns and needs;
3. A process for referring the concerns and needs raised to the appropriate committee or other group within the medical staff for due consideration; and
4. Documentation of the outcome of the medical staff's review of the concerns and needs raised.

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<p>03.01.01 <u>Medical Staff Bylaws.</u> <i>The medical staff must adopt and enforce bylaws to carry out its responsibilities.</i></p> <p>§482.22(c)</p>	<p>The medical staff must regulate itself by bylaws that are consistent with the requirements of this and other CoPs that mention medical staff bylaws, as well as State laws.</p> <p>The bylaws must be enforced and revised as necessary.</p>	<p><u>DOCUMENT REVIEW</u></p> <ol style="list-style-type: none"> 1. Verify that the medical staff has bylaws that comply with the CoPs and State law. 2. Verify that the bylaws describe a mechanism for ensuring enforcement of its provisions along with rules and regulations of the hospital. 3. Verify that the medical staff enforces the bylaws. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>
<p>03.01.02 <u>Medical Staff Bylaws: Approval by Governance.</u> <i>The bylaws must:</i></p> <ul style="list-style-type: none"> • <i>Be approved by the governing body.</i> <p>§482.22(c)(1)</p>	<p>Medical staff bylaws and any revisions of those bylaws must be submitted to the governing body for approval.</p> <p>The governing body has the authority to approve or disapprove bylaws suggested by the medical staff.</p> <p>The bylaws and any revisions must be approved by the governing body before they are considered effective.</p>	<p><u>DOCUMENT REVIEW</u></p> <p>Verify that the medical staff bylaws have been approved by the medical staff and the governing body.</p>	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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03.01.03 Medical Staff Bylaws: Categories, Duties, & Responsibilities of the Medical Staff.

The bylaws must:

- *Include a statement of the duties and privileges of each category of medical staff (e.g., active, courtesy, etc.).*

§482.22(c)(2)

The medical staff bylaws must state the duties and scope of medical staff privileges each category of practitioner may be granted. Specific privileges for each category must clearly and completely list the specific privileges or limitations for that category of practitioner. The specific privileges must reflect activities that the majority of practitioners in that category can perform competently and that the hospital can support.

Although the medical staff bylaws must address the duties and scope for each category of practitioner, this does not mean that each individual practitioner within the category may automatically be granted the full range of privileges.

It cannot be assumed that every practitioner can perform every task / activity / privilege that is specified for the applicable category of practitioner.

The individual practitioner’s ability to perform each task / activity / privilege must be individually assessed.

DOCUMENT REVIEW

- Determine whether the bylaws specify the duties and scope of medical staff privileges for each category of practitioner eligible for medical staff membership or privileges.

- 1 = Compliant
- 2 = Not Compliant

This standard is not met as evidenced by:

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<p>03.01.04 <u>Medical Staff Bylaws: Organization of the Medical Staff.</u> <i>The bylaws must:</i></p> <ul style="list-style-type: none"> Describe the organization of the medical staff. <p>§482.22(c)(3)</p>	<p>The medical staff bylaws must describe the organizational structure of the medical staff, and lay out the rules and regulations of the medical staff to make clear acceptable standards of patient care for all diagnostic, medical, surgical, and rehabilitative services.</p>	<p><u>DOCUMENT REVIEW</u></p> <ol style="list-style-type: none"> Verify that the bylaws specify the organization and structure of the medical staff, and a mechanism that delineates accountability to the governing body. Verify that the bylaws describe who is responsible for regularly scheduled review and evaluation of the clinical work of the members of the medical staff and describe the formation of medical staff leadership. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>
<p>03.01.05 <u>Attestation Statements in Bylaws.</u> The Medical Staff demonstrates high standards of ethical conduct; its Bylaws provide for:</p> <p>A. Corrective action;</p> <p>B. A fair hearing mechanism; and</p> <p>C. Physician adherence to the Code of Ethics prescribed by his/her profession.</p>	<p>Ethical conduct of the Medical Staff organization is demonstrated in its stated expectations and mechanisms for placing these into operation.</p> <p>The Bylaws make provision for each of these elements.</p> <p>Codes of Ethics may include AOA, AMA, ADA, or APMA.</p>	<p><u>DOCUMENT REVIEW AND OBSERVATION</u></p> <ol style="list-style-type: none"> Verify that the Medical Staff Bylaws include all elements described. Determine compliance with the standard. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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<p>03.01.06 <u>Medical Staff Bylaws: Process for Application, Reapplication, & Criteria for Membership.</u> <i>The bylaws must:</i></p> <ul style="list-style-type: none"> Describe the qualifications to be met by a candidate in order for the medical staff to recommend that the candidate be appointed by the governing body. <p>§482.22(c)(4)</p>	<p>The medical staff bylaws must describe the qualifications to be met by a candidate for medical staff membership / privileges in order for the medical staff to recommend the candidate be approved by the governing body.</p> <p>The bylaws must describe the privileging process to be used in the hospital. The process articulated in the medical staff bylaws must include criteria for determining the privileges that may be granted to individual practitioners and a procedure for applying the criteria to individual practitioners that considers:</p> <ul style="list-style-type: none"> Individual character; Individual competence; Individual training; Individual experience; and Individual judgment. <p>The medical staff may not rely solely on the fact that a Doctor of Medicine / Doctor of Osteopathic Medicine is, or is not, board-certified in making a judgment on medical staff membership. This does not mean that the medical staff is prohibited from requiring board certification when considering a Doctor of Medicine / Doctor of Osteopathic Medicine for medical staff membership; only that such certification is not the only factor that the hospital considers. After analysis of all of the criteria, if all criteria are met except for board certification, the medical staff has the discretion to not recommend that individual for medical staff membership / privileges.</p>	<p style="text-align: center;"><u>DOCUMENT REVIEW</u></p> <ol style="list-style-type: none"> Verify that the medical staff bylaws describe the qualifications such as licensure, specific training, experience, current competence, judgment, character, and health status to be met by an individual candidate for the medical staff to recommend appointment or reappointment. Verify that the process for granting of privileges is clearly defined. Verify that all practitioner categories are included in the process. Verify that there are written criteria for appointments to the medical staff and granting of medical staff privileges. Verify that granting of medical staff membership or privileges, is based upon an individual practitioner’s meeting the medical staff’s membership/privileging criteria. Verify that at a minimum, criteria for appointment to the medical staff / granting of medical staff privileges are individual character, competence, training, experience, and judgment. Verify that written criteria for appointment to the medical staff and granting of medical staff 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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<p>03.01.07 Medical Staff Bylaws: History & Physical Requirement. <i>The bylaws must include a requirement that:</i></p> <p>(i) <i>A medical history and physical be completed and documented for each patient no more than 30 days before or 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia services. The medical history and physical examination must be completed and documented by a physician (as defined in section 1861 (r) of the Act) (Social Security Act), an oromaxillofacial surgeon, or other qualified licensed individual in accordance with state law and hospital policy.</i></p> <p>§482.22(c)(5)(i)</p>	<p>The bylaws must apply equally to all practitioners in each professional category of practitioners. The medical staff then recommends individual candidates that meet those requirements to the governing body for appointment to the medical staff.</p> <p>The purpose of a medical history and physical examination (H&P) is to determine whether there is anything in the patient's overall condition that would affect the planned course of the patient's treatment, such as a medication allergy, or a new or existing co-morbid condition that requires additional interventions to reduce risk to the patient.</p> <p>The Medical Staff bylaws must include a requirement that an H&P be completed and documented for each patient no more than 30 days prior to or 24 hours after hospital admission or registration, but prior to surgery or a procedure requiring anesthesia services.</p> <p>The H&P may be handwritten or transcribed, but always must be placed within the patient's medical record within 24 hours of admission or registration, or prior to surgery or a procedure requiring anesthesia services, whichever comes first.</p> <p>An H&P is required prior to surgery and prior to procedures requiring anesthesia services, regardless of whether care is being provided on an inpatient or</p>	<p>privileges are not dependent solely upon certification, fellowship, or membership in a specialty body or society.</p> <p>FILE REVIEW</p> <ul style="list-style-type: none"> Verify compliance with the standard. <p>DOCUMENT REVIEW</p> <ol style="list-style-type: none"> Review the medical staff bylaws to determine whether they require that a physical examination and medical history be done for each patient no more than 30 days before or 24 hours after admission or registration by a physician (as defined in section 1861(r) of the Act), an oromaxillofacial surgeon, or other qualified licensed individual in accordance with State law and hospital policy. Verify whether the bylaws require the H&P be completed prior to surgery or a procedure requiring anesthesia services. Review the hospital's policy, if any, to determine whether other qualified licensed individuals are permitted to conduct H&Ps to ensure that it is consistent with the State's scope of practice law or regulations. Verify that non-physicians who perform H&Ps within the hospital are qualified and have been credentialed and privileged in 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p> <p>*Score chart review deficiencies at Standard 10.01.07</p>

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	<p>outpatient basis. (71 FR 68676) An H&P that is completed within 24 hours of the patient’s admission or registration, but after the surgical procedure, procedure requiring anesthesia, or other procedure requiring an H&P would not be in compliance with this requirement.</p> <p>The medical history and physical examination must be completed and documented by a physician (as defined in section 1861(r) of the Act), oromaxillofacial surgeon, or other qualified licensed individual in accordance with State law and hospital policy.</p> <p>Section 1861(r) defines a physician as a:</p> <ul style="list-style-type: none"> • Doctor of medicine or osteopathic medicine; • Doctor of dental surgery or of dental medicine; • Doctor of podiatric medicine; • Doctor of optometry; or a • Chiropractor. <p>In all cases the practitioners included in the definition of a physician must be legally authorized to practice within the State where the hospital is located and providing services within their authorized scope of practice. In addition, in certain instances the Social Security Act attaches further limitations as to the type of hospital services for which a practitioner is considered to be a “physician.” For example, a chiropractor is considered a physician only with respect to treatment by means of manual manipulation of the spine (to correct a subluxation).</p>	<p>accordance with the hospital’s policy.</p> <p>4. Determine that hospital policies (including Medical Staff Rules / Regulations) address the use of physician extenders in documenting admission assessment data for the physician's H&P.</p> <p style="text-align: center;">CHART REVIEW Score chart review deficiency at Standard 10.01.07.</p> <p>Review a sample of inpatient and outpatient medical records that include a variety of patient populations undergoing both surgical and non-surgical procedures to verify that:</p> <ul style="list-style-type: none"> • There is an H&P that was completed no more than 30 days before or 24 hours after admission or registration, but, in all cases, prior to surgery or a procedure requiring anesthesia services; and • The H&P was performed by a physician, an oromaxillofacial surgeon, or other qualified licensed individual authorized in accordance with State law and hospital policy. 	

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Other qualified licensed individuals are those licensed practitioners who are authorized in accordance with their State scope of practice laws or regulations to perform an H&P and who are also formally authorized by the hospital to conduct an H&P. Other qualified licensed practitioners could include nurse practitioners and physician assistants.

More than one qualified practitioner can participate in performing, documenting, and authenticating an H&P for a single patient. When performance, documentation, and authentication are split among qualified practitioners, the practitioner who authenticates the H&P will be held responsible for its contents. (71 FR §68675)

A hospital may adopt a policy allowing submission of an H&P prior to the patient’s hospital admission or registration by a physician who may not be a member of the hospital’s medical staff or who does not have admitting privileges at that hospital, or by a qualified licensed individual who does not practice at that hospital but is acting within his / her scope of practice under State law or regulations. Generally, this occurs where the H&P is completed in advance by the patient’s primary care practitioner. (71 FR 68675)

When the H&P is conducted within 30 days before admission or registration, an update must be completed and documented by a licensed practitioner who is credentialed and privileged by the hospital’s medical staff to perform an H&P. (71 FR 68675) (See

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discussion of H&P update requirements at 42 CFR §482.22(c)(5)(ii).)

Surveyors should cite noncompliance with the requirements of 42 CFR §482.22(c)(5) for failure by the hospital to comply with any of this standard's components.

03.01.08 Medical Staff Bylaws: History & Physical Prior to Admission.
The bylaws must include a requirement that:

II. An updated examination of the patient, including any changes in the patient's condition, be completed and documented within 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia services, when the medical history and physical examination are completed within 30 days before admission or registration.

The updated examination of the patient, including any changes in the patient's condition, must be completed and documented by a physician (as defined in section 1861 (r) of the Act) (Social Security Act), an oromaxillofacial surgeon, or other qualified licensed

The Medical Staff bylaws must include a requirement that when a medical history and physical examination has been completed within 30 days before admission or registration, an updated medical record entry must be completed and documented in the patient's medical record within 24 hours after admission or registration.

The examination must be conducted by a licensed practitioner who is credentialed and privileged by the hospital's medical staff to perform an H&P. In all cases, the update must take place prior to surgery or a procedure requiring anesthesia services.

The update note must document an examination for any changes in the patient's condition since the patient's H&P was performed that might be significant for the planned course of treatment. The physician or qualified licensed individual uses his/her clinical judgment, based upon his/her assessment of the patient's condition and co-morbidities, if any, in relation to the patient's planned course of treatment to decide the extent of the update assessment needed as well as the information to be included in the update

DOCUMENT REVIEW

1. Review the medical staff bylaws to determine whether they include provisions requiring that, when the medical history and physical examination was completed within 30 days before admission or registration, an updated medical record entry documenting an examination for changes in the patient's condition was completed and documented in the patient's medical record within 24 hours after admission or registration.
2. Determine whether the bylaws require that, in all cases involving surgery or a procedure requiring anesthesia services, the update to the H&P must be completed and documented prior to the surgery or procedure.

- 1 = Compliant
- 2 = Not Compliant

This standard is not met as evidenced by:

***Score chart review deficiencies at Standard 10.01.07**

CHART REVIEW

Score chart review deficiency at Standard 10.01.07.

In the sample of medical records selected for review, look for cases where the medical history and physical examination was completed within

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<p><i>individual in accordance with state law and hospital policy.</i></p> <p>§482.22(c)(5)(ii)</p>	<p>note in the patient’s medical record.</p> <p>If, upon examination, the licensed practitioner finds no change in the patient's condition since the H&P was completed, he/she may indicate in the patient's medical record that the H&P was reviewed, the patient was examined, and that "no change" has occurred in the patient's condition since the H&P was completed (71 FR 68676).</p> <ul style="list-style-type: none"> Any changes in the patient’s condition must be documented by the practitioner in the update note and placed in the patient’s medical record within 24 hours of admission or registration, but prior to surgery or a procedure requiring anesthesia services. Additionally, if the practitioner finds that the H&P done before admission is incomplete, inaccurate, or otherwise unacceptable, the practitioner reviewing the H&P, examining the patient, and completing the update may disregard the existing H&P, and conduct and document in the medical record a new H&P within 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia. 	<p>30 days before admission or registration.</p> <ol style="list-style-type: none"> Verify that an updated medical record entry documenting an examination for any changes in the patient's condition was completed and documented in the patient's medical record within 24 hours after admission or registration. Verify that in all cases involving surgery or a procedure requiring anesthesia services, the update was completed and documented prior to the surgery or procedure. 	

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<p>03.01.09 Medical Staff Bylaws: Granting of Privileges. <i>The bylaws must:</i></p> <ul style="list-style-type: none"> <i>Include criteria for determining the privileges to be granted to individual practitioners and a procedure for applying the criteria to individuals requesting privileges.</i> <p><i>For distant-site physicians and practitioners requesting privileges to furnish telemedicine services under an agreement with the hospital, the criteria for determining privileges and the procedure for applying the criteria are also subject to the requirements in §482.12(a)(8) and (a)(9), and §482.22(a)(3) and (a)(4).</i></p> <p>§482.22(c)(6)</p>	<p>All patient care is provided by or in accordance with the orders of a physician or practitioner who meets the medical staff criteria and procedures for the privileges granted, who has been granted privileges in accordance with those criteria by the governing body, and who is working within the scope of those granted privileges.</p> <p>Privileges are granted by the hospital's governing body to individual practitioners based on the medical staff's review of that individual practitioner's qualifications and the medical staff's recommendations for that individual practitioner to the governing body.</p> <p>However, in the case of telemedicine physicians and practitioners providing telemedicine services under an agreement, the governing body has the option of having the medical staff rely upon the credentialing and privileging decisions of the distant-site hospital or telemedicine entity with which the hospital has entered into an agreement. When the governing body has exercised this option, the medical staff's bylaws must include a provision allowing the medical staff to rely upon the credentialing and privileging decisions of a distant-site hospital or telemedicine entity when that distant-site hospital or entity is required under the terms of its agreement with the hospital to employ a credentialing and privileging process that conforms to the provisions of §482.12(a)(8) and (a)(9), and §482.22(a)(3) and (a)(4).</p>	<p style="text-align: center;"><u>DOCUMENT REVIEW</u></p> <ol style="list-style-type: none"> Verify that the medical staff bylaws contain criteria for granting, withdrawing, and modifying clinical privileges to individual practitioners of the medical staff and that a procedure exists for applying these criteria. In the case of telemedicine physicians and practitioners providing telemedicine services under an agreement with the hospital where the hospital's governing body has opted to have the medical staff rely upon the credentialing and privileging decisions of the distant-site hospital or telemedicine entity, verify that the bylaws include a provision permitting such reliance. <p style="text-align: center;"><u>FILE REVIEW</u></p> <ul style="list-style-type: none"> Verify that physicians and practitioners who provide care to patients are working within the scope of the privileges granted by the governing body. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>For chart review deficiency: Score at Standard 10.01.07.</p> <p>This standard is not met as evidenced by:</p>

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<p>03.01.10 <u>Medical Staff Policies & Procedures.</u> Policies of the Medical Staff shall be supportive of and congruent with the Medical Staff Bylaws, Rules and Regulations.</p>	<p>Policies of the Medical Staff are not in conflict with Medical Staff Bylaws, Rules and Regulations.</p>	<p style="text-align: center;"><u>DOCUMENT REVIEW</u></p> <p>Review the Medical Staff Bylaws for conflicting position statements. A statement in the bylaws of congruency of all medical staff policies to the bylaws would be acceptable.</p>	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>
<p>03.01.11 <u>Medical Staff Bylaws: Periodic Review.</u> The Medical Staff Bylaws, Rules and Regulations shall be reviewed and updated as necessary to assure congruence with Medical Staff practice, and contain a mechanism for review at least every three (3) years.</p>	<p>The Medical Staff Bylaws contain a provision for their periodic review.</p> <p>Processes are in place that ensures the Governing Body approves all changes to the Medical Staff Bylaws.</p>	<p style="text-align: center;"><u>DOCUMENT REVIEW</u></p> <ol style="list-style-type: none"> 1. The provision for periodic review is present in the Medical Staff Bylaws. 2. The Medical Staff Bylaws have been reviewed within the last three (3) years. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>
<p>03.01.12 <u>Uniform Application of Membership Criteria.</u> Criteria for membership and/or privileging shall be uniformly applied to all applicants for initial appointment and reappointment.</p>	<p>There are to be no “waivers” to the criteria for membership and/or privileging; this includes the period of initial (associate / provisional) appointment.</p>	<p style="text-align: center;"><u>FILE REVIEW & INTERVIEW</u></p> <p>Determine that the document(s) provide for uniform application of criteria and provisional periods for appointments and privileging for ALL providers, not just medical staff.</p>	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>
<p>03.01.13 <u>Not Applicable.</u></p>			

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<p>03.01.14 <u>Nondiscrimination in Application of Membership Criteria.</u> Criteria shall not include:</p> <ul style="list-style-type: none"> • Sex • Race • Creed • National origin • Handicap or other considerations not impacting the applicant's ability to discharge the privileges for which he/she has applied. 	<p>The Medical Staff Bylaws, or the credentials manual, contain a statement of nondiscrimination.</p>	<p style="text-align: center;"><u>DOCUMENT REVIEW</u></p> <ul style="list-style-type: none"> • Determine that the Medical Staff Bylaws or the credentials manual contains a statement of nondiscrimination. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>
<p>03.01.15 <u>Required Application and Reapplication: Information to be Reviewed.</u> Information covering each of the following areas must be reviewed for each applicant / reapplicant during the review and approval process.</p> <p>A. <u>Licensure History:</u> current license(s), licensure sanction(s), state(s) of current practice or intended practice, and all previous licenses held.</p> <p>B. <u>Medical Education and Postgraduate Training:</u></p>	<p>Evaluation of performance for application / reapplication.</p>	<p style="text-align: center;"><u>FILE REVIEW</u></p> <p>Using no fewer than ten (10) files, determine that the credentialing criteria were consistently applied in the recommendations for membership and privilege delineations.</p> <p>The following evidence / documents should be provided for review to verify compliance with the standards.</p> <p>Professional credentialing organizations such as a CVO may be used to perform the primary source verification function for a hospital, but the process for credentialing by the organization must reflect the requirements as stated in the applicable standards.</p>	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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<p>C. <u>Malpractice Insurance and History:</u> 5-year history.</p> <p>D. <u>Specialty Board Status:</u> (if applicable).</p> <p>E. <u>Sanctions or Disciplinary Actions:</u> actions taken by healthcare facilities, specialty boards, federal or state agencies, malpractice carriers.</p> <p>F. <u>Criminal History: felony convictions / criminal history (7-10 years).</u></p> <p>G. <u>Healthcare Employment History:</u> healthcare related employment / appointment history (work history).</p> <p>H. <u>Professional References:</u> current competence and peer recommendations / references, ability to perform privileges requested (health status). <u>For physicians seeking reapplication, peer references include:</u> peers familiar with their practice of medicine, reviews under the hospital's peer review activities, reviews by the hospital's</p>		<p>A. Primary Source Verification (PSV) from State Licensing Agency(ies) and query from the National Practitioner Data Bank (NPDB).</p> <ul style="list-style-type: none"> • Information regarding previously successful and/or currently pending (if available) challenges to any license, and/or voluntary or involuntary relinquishment of his/her license. • Results from search of Federation of State Medical Boards (FSMB) Disciplinary Action Databank or Fraud and Abuse Control Information Systems (FACIS). • If telemedicine is utilized, review the process for validation of licensure and validate it is being enforced. <p>B. Primary Source Verification (PSV) includes AMA Physicians Profile, AOA Official Osteopathic Physician Profile, and Educational Commission for Foreign Medical Graduates (ECFMG), as applicable; documentation regarding training and education sufficient to support requested privileges; evidence of continuing educational activities every two years may be requested.</p> <p>C. Evidence of professional liability insurance including current certificates showing amount insurance; malpractice litigation history from</p>	

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<p>Credentials Committee, Department Chair, or Medical Executive Committee.</p> <p>I. <u>Clinical Activity</u>: procedure logs with outcomes to support privilege requests for procedures not attested to in postgraduate references.</p> <p>J. <u>Information Verified for Comparison</u>: comparison of applicant - provided information and verified information.</p> <p>K. <u>Meeting attendance is consistent with requirements established in the medical staff bylaws.</u></p>		<p>insurance carrier; National Practitioner Data Bank (NPDB) query on professional liability actions resulting in final settlements or judgments within the past 5 years.</p> <p>D. Documentation regarding specialty board status.</p> <ul style="list-style-type: none"> • If certified by a member of board ABMS, verify with ABMS; and/or • If certified by a specialty board of AOA, verify with AOA Official Osteopathic Physician Profile. <p>E. The application requests information regarding:</p> <ol style="list-style-type: none"> 1. Disciplinary actions taken or investigations pending by hospitals or other healthcare facilities, specialty boards, Medicare / Medicaid; 2. Actions against the Federal Drug Enforcement Agency (DEA) certificate or state Controlled Dangerous Substances (CDS) certificate; and 3. Actions listed in the National Practitioner Data Bank (NPDB). <p>F. The application request information regarding any criminal history. The hospital conducts criminal background investigation based on information provided in the application or as required by federal and state regulations.</p>	

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- G. Information regarding other facilities where the applicant has or had privileges, other clinical / medical staff appointments, etc. Verification of this information, including a confirmation of the applicant’s appointment and privilege history, and any pending investigations of disciplinary actions, voluntary resignations, or relinquishments of membership / clinical privileges / contracts.

- H. References from at least one peer, one of which shall be an individual with the same professional credential as the applicant / re-applicant. If someone with the same professional credential is not available, then a person in the same practice area who can speak to the applicant / re-applicant’s professional competence and ethical standards may be used as a reference. Include a statement relative to the physician’s physical and mental health in relation to privileges requested.

REAPPLICANTS DO NOT NEED TO PROVIDE LETTERS OF REFERENCE.

1. For re-applicants, peer review via routine review (e.g., clinical peer review, medical records review, credentials function, Medical Executive Committee) will suffice.

2. However, clinical competence review must be a component of re-credentialing.

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- I. Applicants must provide documentation regarding clinical activity (from residency or from facilities where the applicant has been practicing medicine) and competency for consideration of privileges requested.
- J. Re-applicants must provide recommendations from the department in which privileges are sought; (if volume is low, this may require review of procedure logs / competency from other institutions to verify competency) including:
 - Scope of specific privileges based upon recent experience and
 - Recommendations from quality assurance committee and/or other staff committees based upon peer review findings.
- K. The application / reapplication, including all verified information, is reviewed, evaluated, and then summarized by credentialing professionals. The summary provides a clear report of the review of all submitted information (both application information and verified information). **Meeting attendance is evaluated at time of reappointment against the requirements of the Medical Staff Bylaws.**
- L. Discrepancies or unusual or problematic areas are reviewed and discussed by

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committee members and appropriate members of the Medical Staff leadership. Appropriate physician leaders, committees, as well as the Governing Body review the summary.

- M. Verify that practitioners who provide care to patients are working within the scope of the privileges granted by the governing body.

03.01.16 Not Applicable.

03.01.17 Emergency Privileges.

Medical Staff Bylaws shall provide for the granting of emergency privileges.

The Medical Staff Bylaws provide for a Medical Staff chief and/or the CEO to grant emergency privileges to a practitioner to accomplish life saving procedures, within the scope of his/her license, during such times that reasonably suggest that a staff member who is a credentialed practitioner with appropriate privileges is not available.

This practice is generally limited to circumstances within an overwhelming disaster; it is not utilized to “cover” a practitioner who has failed to follow Medical Staff guidelines in applying for privileges.

DOCUMENT REVIEW

- Determine that the Medical Staff Bylaws, or credentialing procedures manual, describe mechanisms to grant emergency privileges per the standard.

FILE REVIEW

- Verify that the process is followed.

1 = Compliant
 2 = Not Compliant

This standard is not met as evidenced by:

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STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>03.01.18 Temporary Privileges. Medical Staff Bylaws provide for the granting of temporary privileges:</p> <ul style="list-style-type: none"> • During review and consideration of application, but only after completion of the process for files waiting to go to Medical Executive Committee and the Board for final approval, • For care of specific patient(s); • For locum tenens; and • For times of emergency and/or disaster. <p>Upon the recommendation of the chief / chair of a department or service, the chief executive officer of the hospital or his designee who is acting on behalf of the Governing Body and adhering to State law.</p> <p>All such actions are time limited and taken only when sufficient evidence exists that the granting of temporary privileges is prudent.</p>	<p>The granting of temporary privileges is not precipitous, and occurs after:</p> <ol style="list-style-type: none"> (1) Verification of licensure, Drug Enforcement Administration (DEA) certificate, insurance, and (2) At least one recent reference from a previous hospital, chief or department chair. <p>Limits to the number of “specific patients” which may be cared for are identified.</p> <p>Locum tenens privileges may be granted for specific periods of time, which are not typically sequential so as to bypass the need for application for provisional appointment.</p> <p>The hospital should have a plan for dealing with clinical volunteers during times of emergency and/or disaster. This plan should provide for primary source identification from the volunteer’s hospital. (A documented phone call is acceptable.) The hospital should use such volunteers as appropriate within the scope of their license or certification.</p>	<p><u>DOCUMENT REVIEW</u></p> <ul style="list-style-type: none"> • Determine that the Medical Staff Bylaws, or credentials manual, describe mechanisms for the granting of temporary privileges in the four (4) described situations. <p><u>FILE REVIEW</u></p> <ul style="list-style-type: none"> • Review at least one (1) file where temporary privileges were granted to verify the process was followed. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>03.01.19 <u>Suspension of Privileges.</u> Provision for corrective action(s) with suspension of privileges shall occur where appropriate.</p> <p>03.01.20 <u>Fair Hearing Process.</u> The hospital shall have a fair hearing plan for members of the medical staff. Individuals involved in Peer Review activities shall be impartial peers and shall not have an economic interest in and/or a conflict of interest with the subject of the Peer Review activity.</p> <p>Impartial peer would also exclude individuals with blood relationships, employer / employee relationships, or</p>	<p><u>Automatic Suspension</u> of privileges is invoked for:</p> <ul style="list-style-type: none"> • Lapsed professional liability coverage; • Suspensions, revocations, or limitations imposed on the insurance coverage or license or narcotic certificate of the practitioner; and • In congruence with Medical Staff rules regarding delinquent medical records. <p><u>Summary Suspension</u> of privileges is to be invoked in a situation wherein there is real potential danger to a patient due to the behavior or condition of a practitioner. The corrective action mechanism shall address the disruptive and/or impaired practitioner.</p> <p>The fair hearing plan outlines the circumstances under which a practitioner may request (or waive) this mechanism:</p> <ul style="list-style-type: none"> • Denial • Modification or changes in appointment / reappointment category • Initial or re-granting of privileges with final review / action by the Governing Body 	<p><u>DOCUMENT REVIEW</u></p> <p>Review the Medical Staff Bylaws to determine that the provisions for corrective action include:</p> <ul style="list-style-type: none"> • Automatic suspension for each of the described elements; and • Summary suspension. <p>Determine that definitions, with correlating Medical Staff activities, exist for disruptive and impaired practitioners; and, that these are consistent with any state regulations regarding impaired licensees.</p> <p><u>INTERVIEW</u></p> <p>Interview medical staff leadership to validate the process is in place and that the defined process is followed.</p> <p><u>DOCUMENT REVIEW</u></p> <ul style="list-style-type: none"> • Determine that the fair hearing mechanism is descriptive of the required elements. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p> <p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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other potential conflicts that might prevent the individual from giving an impartial assessment, or give the appearance for the potential of bias for or against the subject of the Peer Review.

03.01.21 Medical Staff Bylaws: Definition of a Clinical Emergency.
The Medical Staff, in their Rules and Regulations, defines what constitutes an emergency.

Clear definitions, which distinguish urgent from emergent, are to be noted.

DOCUMENT REVIEW & OBSERVATION
Verify that the definitions have been determined and promulgated.

- 1 = Compliant
- 2 = Not Compliant

This standard is not met as evidenced by:

03.01.22 Not Applicable.

03.01.23 Medical Staff Bylaws: Meeting Frequency & Attendance.
Medical Staff Bylaws outline the requirements for meeting frequency and attendance. Such requirements may be more stringent for provisional (associate) and active staff than for other categories. If there are departments and services, separate requirements are outlined. Meeting attendance is considered as one parameter in the credentialing process.

Active staff should be expected to attend staff, department / service, and committee meetings.

The Medical Staff Bylaws should address the definition of a quorum for the various meetings.

Staff membership, with resulting privileging, carries obligations to reasonably participate in Medical Staff self governance.

DOCUMENT REVIEW
Review the Medical Staff Bylaws and summaries of medical staff attendance rosters to determine conformance with attendance requirements.

- Is a quorum defined?
- Were actions taken without a quorum present?

- 1 = Compliant
- 2 = Not Compliant

This standard is not met as evidenced by:

FILE REVIEW
Was attendance considered in the reappointment files reviewed in credentialing / recredentialing?

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<p>03.01.24 Medical Staff Bylaws: Clinical Department Structure. Medical Staff Bylaws may provide for the organization of clinical departments or services. When such exist, the Medical Staff Bylaws provide for the organizational requirements of:</p> <p>A. Structure – officers and meeting frequency;</p> <p>B. No fewer than three physician on active status to organize a separate department service;</p> <p>C. The criteria for membership; and</p> <p>D. The duties and obligations of departments or services. (a) Selection of chair person; and (b) Duties and responsibilities of chair.</p>	<p>The optimal balance between the benefits of and organizational energies required to maintain two, or more, the Medical Staff considers departments or services.</p> <p>Smaller facilities often operate effectively as non-departmentalized to reduce the incremental meeting attendance requirements, which accompany departmentalization.</p> <p>When a department is maintained with only three (3) members, it often becomes difficult to achieve a quorum.</p> <p>When departments / services exist, they are accountable to the Medical Executive Committee (MEC) and the full Medical Staff, for their portion of the responsibilities outlined above.</p>	<p><u>OBSERVATION & INTERVIEW</u></p> <ul style="list-style-type: none"> Determine that if departments or services exist, the functions are effectively accomplished for each listed department or service. <p><u>DOCUMENT REVIEW</u></p> <ol style="list-style-type: none"> Determine that the Bylaws accurately reflect the organizational structure of the Medical Staff. The Medical Staff, which functions as a “staff of the whole” with Medical Staff Bylaws describing a non-departmentalized organization, is scored as “full compliance.” 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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03.02.01 Autopsies.

The medical staff should attempt to secure autopsies in all cases of unusual deaths and of medical-legal and educational interest. The mechanism for documenting permission to perform an autopsy must be defined.

There must be a system for notifying the medical staff, and specifically the attending practitioner, when an autopsy is being performed.

§482.22(d)

The process for obtaining autopsy, notification of the attending practitioner, and documentation requirements are established in the medical bylaws, rules and regulations, or medical staff policy.

DOCUMENT REVIEW

- Verify that the medical staff has policies requiring the practitioners to attempt to secure permission to perform autopsies, that the mechanism for documenting permission to perform an autopsy is defined, and that there is a system for notifying the medical staff, specifically the attending practitioner, when an autopsy is performed.

- 1 = Compliant
- 2 = Not Compliant

This standard is not met as evidenced by:

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REQUIRED COMMITTEES

There are three required committees:

1. Medical Executive Committee;
2. Utilization Review Committee; and
3. Utilization of Osteopathic Methods & Concepts Committee. (Only required for hospitals with ten or more Doctor of Osteopathic Medicine who admit patients and provide direct patient care.)

OTHER REQUIRED ACTIVITIES

The Medical Staff shall be structured in such a way as to provide to the Governing Board assurance that appropriate care has been provided to the patients.

Although no other committees are required beyond these three (3), all accredited hospitals must establish either a committee or a function of another committee at the determination of the medical staff for the purpose of doing the work of the following:

- (1) Credentials Committee
- (2) Mortality Review Committee
- (3) Infection Control Committee
- (4) Transfusion Committee
- (5) Pharmacy and Therapeutics Committee (P&T Committee)

In small hospitals, designated members of the professional staff or the staff serving as a committee-of-the-whole may perform these functions.

In all instances, these functions shall be performed and recorded by the active staff.

Not Scored

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STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>03.03.01 <u>Medical Executive Committee.</u> The Medical Staff Bylaws require, even if the Medical Staff functions as a “committee of the whole,” a Medical Executive Committee function or process shall be accomplished.</p> <p>The determination of the meeting frequency and attendance requirements for the Medical Executive Committee shall be responsibility of the hospital.</p>	<p>When the Medical Staff functions as a “committee of the whole,” there is a provision to enter executive session with at least one member of administration present in order to act with a degree of freedom in order to address extremely sensitive issues of self-governance.</p>	<p><u>DOCUMENT REVIEW</u></p> <ul style="list-style-type: none"> Determine that the Medical Staff Bylaws provide for a Medical Executive Committee (MEC) (function) or process when as a “committee of the whole,” which meets the requirements of this standard. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>
<p>03.03.02 <u>Medical Executive Committee Scope.</u> The Medical Executive Committee (MEC) is empowered to act on behalf of the Medical Staff when the Medical Staff cannot be assembled or between their regular meetings.</p>	<p>When the Medical Staff functions as a committee of the whole, there shall be a mechanism to convene between meetings; this may be accomplished by <i>ad hoc</i> meetings of an identified MEC when the entire active Medical Staff is unable to be assembled, or, for executive session.</p>	<p><u>DOCUMENT REVIEW</u></p> <ul style="list-style-type: none"> Determine that the Medical Staff Bylaws indicate that the MEC is empowered to act on behalf of the Medical Staff. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>03.04.00 Condition of Participation: Utilization Review. <i>The hospital must have in effect a utilization review (UR) plan that provides for review of services furnished by the institution and by members of the Medical Staff to patients entitled to benefits under the Medicare and Medicaid program.</i></p> <p>§482.30</p>	<p>If the hospital does not satisfy one of the exception criteria at §482.30(a), it must have a UR plan in effect which provides for review of services provided to Medicare and Medicaid beneficiaries.</p> <p>The hospital UR plan should include a delineation of the responsibilities and authority for those involved in the performance of UR activities.</p> <p>It should also establish procedures for the review of the medical necessity of admissions, the appropriateness of the setting, the medical necessity of extended stays, and the medical necessity of professional services.</p>	<p style="text-align: center;"><u>DOCUMENT REVIEW</u></p> <ol style="list-style-type: none"> 1. The manner and degree of noncompliance with one or more of the UR standards is considered when determining whether there is condition-level compliance or non-compliance. 2. Determine that the hospital has a utilization review plan for those services furnished by the hospital and its medical staff to Medicare and Medicaid patients. 3. Determine the Utilization Review Plan has been approved by the Medical Staff within the past three (3) years or more often as needed for updates. 4. Verify through review of records and reports, and interviews with the UR chairman and/or members that UR activities are being performed as described in the hospital UR plan. 5. Review the minutes of the UR committee to verify that they include dates, members in attendance, extended stay reviews with approval or disapproval noted in a status report of any actions taken. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>03.04.01 Applicability. <i>The provisions 42 CFR 482.30 apply except in either of the following circumstances:</i></p> <p>1) <i>A Utilization and Quality Control Quality Improvement Organization (QIO) has assumed binding review for the hospital.</i></p> <p>2) <i>CMS has determined that the UR procedures established by the State under title XIX of the Act (Social Security Act) are superior to the procedures required in this section, and has required hospitals in that State to meet the UR plan requirements under §456.50 through §456.245 of 42 CFR 456.</i></p> <p>§482.30(a) §482.30(a)(1) §482.30(a)(2)</p>	<p>The regulation permits two exceptions to the requirement for a hospital UR plan:</p> <p>(1) where the hospital has an agreement with a QIO under contract with the Secretary to assume binding review for the hospital or;</p> <p>(2) where CMS has determined that UR procedures established by the State under Medicaid are superior to the UR requirements for the Medicare program <u>and</u> has required hospitals in that State to meet the UR requirements for the Medicaid program at 42 CFR §456.50 through §456.245.</p> <p>According to the regulation at 42 CFR §476.86(e), QIO review and monitoring activities fulfill the requirements for compliance activities of State Survey Agencies under §1861(k) of the Social Security Act (Act). The statutory requirements for utilization review at §1861(k) of the Act are reiterated in the UR CoP at 42 CFR §482.30. Therefore, a hospital meets the exception requirements of 42 CFR §482.30 if a QIO has assumed binding review for the hospital. (The hospital may not make requests for work to be performed by the QIO that goes beyond the scope of the QIO’s contract with the Secretary.)</p> <p>The regulation at 42 CFR §489.20(e) requires a hospital to maintain an agreement with a QIO to review the admissions, quality, appropriateness, and diagnostic information related to inpatient services for Medicare patients, if there is a QIO with a contract</p>	<p style="text-align: center;">DOCUMENT REVIEW</p> <p>State survey agencies should survey deemed hospitals for compliance with the UR CoP as part of full surveys following a complaint survey with conditions out, or validation surveys. Compliance determinations for all other hospitals should be made during recertification surveys.</p> <p>Surveyors are to verify either that the hospital:</p> <ol style="list-style-type: none"> Has its own UR plan in place and that it meets the regulatory requirements; or If it does not have its own UR plan, that it has an agreement with the QIO that provides for binding UR review. Surveyors should ask to see the signed, dated agreement. If the hospital has an agreement with a QIO, it is not necessary for surveyors to assess the remaining UR standards. <p>It is not necessary for SAs to conduct routine surveys for compliance with the provider agreement requirement to have a QIO agreement. However, a hospital that does not satisfy the UR CoP through either its own program or a QIO agreement may be cited for violating the UR CoP at the condition.</p>	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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with CMS in the area where the hospital is located.

CMS anticipates that most hospitals comply with the UR CoP by means of the QIO exception.

With regard to the second exception, CMS would have to determine that UR procedures established by a State under Medicaid are superior to the UR requirements for Medicare.

Currently no UR plans established by a State under Medicaid have been approved as exceeding the requirements under Medicare and required for hospital compliance with the Medicare UR CoP within that State. In the event that CMS approves a State’s Medicaid UR process for compliance with the Medicare UR CoP, CMS will advise the affected State Survey Agency.

03.04.02 Composition of the UR Committee.

(A) UR committee consisting of two or more practitioners must carry out the UR function. At least two of the members of the committee must be doctors of medicine or osteopathic medicine. The other members may be any of the other types of practitioners specified in §482.12(c)(1).

Under Medicare, a QIO shall perform UR functions for a hospital. The hospital must have a contract with their QIO to perform UR functions.

Under Medicaid, the State shall undertake review of UR activities in participating facilities either directly or optionally by a QIO or other contractor.

- If a QIO contract exists the State Plan shall comply with 42 CFR §431.630. (For risk management purposes many facilities choose to accomplish their own Utilization Review in addition to that

DOCUMENT REVIEW

1. Determine the composition of the UR committee.
2. Determine that the governing body has delegated to the UR committee the authority and responsibility to carry out the UR function.
3. Verify that small hospitals delegate the UR function to an outside group if it is

- 1 = Compliant
 2 = Not Compliant

This standard is not met as evidenced by:

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STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>(1) <i>Except as specified in paragraphs (b)(2) and (3) of 42 CFR 482.30, the UR committee must be one of the following:</i></p> <p>(i) <i>A staff committee of the institution;</i></p> <p>(ii) <i>A group outside the institution-</i></p> <p>(A) <i>Established by the local medical society and some or all of the hospitals in the locality;</i> <i>or</i></p> <p>(B) <i>Established in a manner approved by CMS</i></p> <p>(2) <i>If, because of the small size of the institution, it is impracticable to have a properly functioning staff committee, the UR committee must be established as specified in paragraph (b)(1)(ii) of 42 CFR 482.30.</i></p> <p>(3) <i>The committee or group’s reviews may not be conducted by any individual who—</i></p> <p>(i) <i>Has a direct financial</i></p>	<p>accomplished by the QIO).</p>	<p>impractical to have a staff committee.</p> <p>4. Ascertain that committee members are not financially involved in the hospital (ownership of 5 percent or greater) nor participants in the development or execution of the patient’s treatment plan.</p>	

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interest (for example, an ownership interest) in that hospital; or

(ii) Was professionally involved in the care of the patient whose case is being reviewed.

- §482.30(b)
- §482.30(b)(1)
- §482.30(b)(1)(i)
- §482.30(b)(1)(ii)
- §482.30(b)(1)(ii)(A)
- §482.30(b)(1)(ii)(B)
- §482.30(b)(2)
- §482.30(b)(3)
- §482.30(b)(3)(i)
- §482.30(b)(3)(ii)

03.04.03 UR Review Requirements.

(1) The UR plan must provide for review for Medicare and Medicaid patients with respect to the medical necessity of:

- (i) Admissions to the institution;*
- (ii) The duration of stays;*

Admissions may be reviewed before, during, or after hospital admission as stated in the hospital’s UR plan.

Reviews may be conducted on a sample basis, except for reviews of extended stay cases.

In an Inpatient Prospective Payment System (IPPS) hospital, to determine outlier review compliance, “reasonably assumes” is a good faith test. The question to ask is whether the hospital is reviewing

DOCUMENT REVIEW

1. Examine the UR plan and other documentation to determine that the medical necessity for Medicare and Medicaid patients is reviewed with respect to admission, duration of the stay, and the professional services furnished.
2. Determine if the hospital is reimbursed under IPPS. This requirement does not apply to IPPS

- 1 = Compliant
- 2 = Not Compliant
- NA=Not Applicable

This standard is not met as evidenced by:

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STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>(iii) <i>Professional services furnished including, drugs and biologicals.</i></p> <p>(2) <i>Review of admissions may be performed before, at, or after hospital admission.</i></p> <p>(3) <i>Except as specified in paragraph (e) of this section, reviews may be conducted on a sample basis.</i></p> <p>(4) <i>Hospitals that are paid for inpatient hospital services under the prospective payment system set forth in Part 412 of 42 CFR 412 must conduct review of duration of stays and review of professional services as follows:</i></p> <p>(i) <i>for duration of stays, these hospitals need review only cases that they reasonably assume to be outlier cases based on extended length of stay, as described in §412.80(a)(1)(i) of 42 CFR 412.80; and</i></p> <p>(ii) <i>for professional services, these hospitals need review only cases that they reasonably assume to be</i></p>	<p>outlier cases.</p> <p>In instances where there was no other review of outlier cases, the question is whether it was reasonable for the hospital not to have known that the cases were in fact outliers. Some medical judgment might be required to determine whether it is reasonable for the hospital to have assumed that a patient fell into a DRG other than the one eventually assigned by the intermediary. This would be an issue in long stay outlier cases where the hospital did not review because the hospital erroneously assumed that the patient was in a DRG under which the case would not have been an outlier.</p>	<p>excluded hospitals or units.</p> <p>3. Verify that in a IPPS hospital the following are being reviewed:</p> <ul style="list-style-type: none"> • Duration of stay in cases reasonably assumed to be outlier cases; and • Professional services in cases reasonably assumed to be outlier cases. 	

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outlier cases based on extraordinarily high costs. as described in §412.80(a)(1)(ii) of 42 CFR 412.80.

§482.30(c)
 §482.30(c)(1); §482.30(c)(1)(i)
 §482.30(c)(1)(ii); §482.30(c)(1)(iii)
 §482.30(c)(2); §482.30(c)(3)
 §482.30(c)(4); §482.30(c)(4)(i)
 §482.30(c)(4)(ii)

03.04.04 Determination Regarding Admissions or Continued Stays.

1. *The determination that an admission or continued stay is not medically necessary –*
 - i. *May be made by one member of the UR committee, if the practitioner or practitioners responsible for the care of the patient as specified of §482.12(c) concur with the determination or fail to present their views when afforded the opportunity; and*
 - ii. *Must be made by at least two members of the UR Committee in all other cases.*

When other than a doctor of medicine or osteopathic medicine makes an initial finding that the written criteria for extended stay are not met, the case must be referred to the committee, or subgroup thereof which contains at least one physician.

If the committee or subgroup agrees after reviewing the case that admissions, or extended stay is not medically necessary or appropriate, the attending physician is notified and allowed an opportunity to present his views and any additional information relating to the patient’s needs for admissions or extended stay.

- When a physician member of the committee performs the initial review instead of a non-physician reviewer, and he finds that admissions or extended stay is not necessary no referral to the committee or subgroup is necessary and he

DOCUMENT REVIEW

Review a sample of “medically unnecessary” decisions involving admissions or continued stay that are not medically necessary and determine that these decisions are made by:

1. One member of the UR committee, if the practitioner(s) responsible for the patient’s care concurs with the determination or fails to present his/her views. The practitioner must be one of those specified in §482.12(c), or
2. At least two members of the UR committee in all cases not qualified under the above.
3. Review a sample of “medically unnecessary” decisions and verify that the physician or practitioners, as specified in §482.12(c), were informed of the committees expected

- 1 = Compliant
 2 = Not Compliant

This standard is not met as evidenced by:

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STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>2. <i>Before making a determination that an admission or continued stay is not medically necessary, the URC must consult the practitioner or practitioners responsible for the care of the patient as specified in §482.12(c), and afford the practitioner or practitioners the opportunity to present their views.</i></p> <p>3. <i>If the committee decides that admission to or continued stay in the hospital is not medically necessary, written notification must be given, no later than 2 days after the determination, to the hospital, the patient, and the practitioner or practitioners responsible for the care of the patient.</i></p> <p>§482.30(d) §482.30(d)(1) §482.30(d)(1)(i) §482.30(d)(1)(ii) §482.30(d)(2) §482.30(d)(3)</p>	<p>may notify the attending practitioner directly.</p> <ul style="list-style-type: none"> • If the attending practitioner does not respond or does not contest the findings of the committee or subgroup or those of the physician who performed the initial review, then the findings are final. • If the attending physician contests the committee or subgroup findings, or if he presents additional information relating to the patient’s need for extended stay, at least one additional physician member of the committee must review the case. • If the two physician members determine that the patient’s stay is not medically necessary or appropriate after considering all the evidence, their determination becomes final. • Written notification of this decision must be sent to the attending physician, patient (or next of kin), facility administrator, and the single State agency (in the case of Medicaid) no later than 2 days after such final decision and in no event later than 3 working days after the end of the assigned extended stay period. <p>There are only 5 working days in a given week.</p> <p>Normally these days are Monday through Friday; however, the institution has the option to establish 5 other days as working days. When a holiday falls on a</p>	<p>decision and were given an opportunity to comment.</p> <p>4. Review a sample of “medically unnecessary” cases and verify that all involved parties are notified of the decision that care is medically not necessary no later than two days following the decision.</p>	

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working day, that day is not counted as a working day. In no case may a non-physician make a final determination that a patient's stay is not medically necessary or appropriate.

If, after referral of a questioned case to the committee or subgroup thereof, the physician reviewer determines that an admission or extended stay is justified, the attending physician shall be so notified and an appropriate date for subsequent extended stay review will be selected and noted on the patient's record.

Written notification of this final determination must be sent to the attending physician, the patient (or next of kin), the facility administrator and the single State agency (in the case of Medicaid) no later than 2 days after such final determination and in no event later than 3 working days after the end of the assigned extended stay period.

Where possible, the written notification should be received by all involved parties within the stated time period. Where appropriate and desired, verbal notification may precede written notification.

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STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>03.04.05 Utilization Review Scope in Non-PPS Hospitals: Extended Stay Review.</p> <p>1. <i>In hospitals that are not paid under the prospective payment system, the UR committee must make a periodic review, as specified in the UR plan, of each current inpatient receiving hospital services during a continuous period of extended duration.</i></p> <p><i>The scheduling of the periodic reviews may –</i></p> <p style="padding-left: 40px;"><i>(i) be the same for all cases or</i> <i>(ii) differ for different classes of cases.</i></p> <p>2. <i>In hospitals paid under the prospective payment system, the UR committee must review all cases reasonably assumed by the hospital to be outlier cases because of the extended length of stay exceeding the threshold criteria for diagnosis. The hospital is not required to review an extended stay that does not exceed the outlier threshold for the diagnosis.</i></p> <p>3. <i>The Utilization Review committee</i></p>	<p>A written Utilization Review Plan is in place and includes a definition of an extended stay.</p>	<p><u>INTERVIEW & DOCUMENT REVIEW</u></p> <p>Review the facility’s definition of extended stay in the UR plan.</p> <ol style="list-style-type: none"> 1. Verify that the hospital’s UR plan requires a periodic review of each current Medicare / Medicaid inpatient receiving hospital services of extended duration and that the review is carried out at the specified time stated in the facility’s UR plan. 2. The review may be the same for all cases or be different for different classes of care. 3. If the committee uses a different number of days for different diagnosis or functional categories for the period of extended stay, the surveyor must verify that there is a written list with lengths of stay designated for each diagnosis of functional category. 4. Determine if the hospital is under IPPS. Hospitals under IPPS need only review cases reasonably assumed to be outlier cases, and extended stay that exceeds the outlier threshold for the diagnosis. 5. Review minutes of the UR committee. Determine that the periodic reviews of extended stay are carried out on or before the expiration of the stated period or no later than 7 days after the day required in the hospital’s plan. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant <input type="checkbox"/> NA=Not Applicable</p> <p>This standard is not met as evidenced by:</p>

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*must make the periodic review **no** later than 7 days after the day required in the UR plan.*

- §482.30(e)
- §482.30(e)(1)
- §482.30(e)(1)(i)
- §482.30(e)(1)(ii)
- §482.30(e)(2)
- §482.30(e)(3)

03.04.06 Review of Professional Services.

The committee must review professional services provided, to determine medical necessity and to promote the most efficient use of available health facilities and services.

§482.30(f)

“Professional” services mean the services provided by practitioners, including both physicians and non-physician practitioners.

The review includes medical necessity and efficient use of available health facilities and services. Examples of topics a committee may review are:

- Availability and use of necessary services - underused, overuse, appropriate use.
- Timeliness of scheduling of services - operating room, diagnostic.
- Therapeutic procedures.

INTERVIEW & DOCUMENT REVIEW

1. Professional service includes the aspects of care rendered by laboratory personnel, physical therapists, nurses, and others, as well as services provided by Doctor of Medicine / Doctor of Osteopathic Medicine.
2. The review includes medical necessity and efficient use of available health facilities and services. Examples of topics a committee may review are:
 - Availability and use of necessary services—underused, overuse, and appropriate use;
 - Timeliness of scheduling of services—operating room, diagnostic services;
 - Therapeutic procedures

- 1 = Compliant
- 2 = Not Compliant

This standard is not met as evidenced by:

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- Determine that the committee performs a review of professional services.

03.04.07 The Utilization Review Committee Meeting Frequency & Attendance.

Meetings shall have written minutes reflecting the activities of the committee. Determination of the meeting frequency and attendance requirements for the Utilization Review Committee shall be the responsibility of the hospital.

Self-explanatory.

DOCUMENT REVIEW

Review UR Committee minutes. Review hospital requirements for meeting attendance / frequency.

- 1 = Compliant
- 2 = Not Compliant

This standard is not met as evidenced by:

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STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>03.05.01 Utilization of Osteopathic Methods & Concepts Committee (OMCC). Only required for hospitals with ten or more Doctors of Osteopathic Medicine who admit and manage patients.</p> <p>Participants shall consist of at least two (2) osteopathic physicians on the active staff; if possible, one osteopathic physician from each of the organized departments should serve on the committee.</p> <p>This requirement shall be waived if the hospital does not have ten (10) osteopathic physicians on the active staff that admit and manage patient. It is automatically reinstated if the hospital obtains ten (10) osteopathic physicians on the active staff who admits and manages patients.</p>	<p>The purposes of the committee are as follows:</p> <ol style="list-style-type: none"> 1. To promote the most effective methods for osteopathic diagnosis and treatment for comprehensive patient care; 2. To improve recording of osteopathic musculoskeletal findings, diagnosis, and management on patient charts; 3. To provide for the ongoing need of continuing education in osteopathic principles and practice; and 4. To provide a clinical environment for osteopathic diagnosis and treatment, which will assure quality, care in HFAP Accredited Health Care Facilities. <p>The hospital is exempt from this requirement if:</p> <ul style="list-style-type: none"> • It does not have ten (10) or more Doctor of Osteopathic Medicine with admitting privileges who manage patients. (For example, pathologists, and radiologists, emergency medicine physicians, or Doctor of Osteopathic Medicine with courtesy privileges would not be included.) 	<p>DOCUMENT REVIEW & INTERVIEW</p> <p>Determine if the hospital meets the criteria for requiring a process to review the Utilization of Osteopathic Methods and Concepts.</p> <ul style="list-style-type: none"> • If it does, determine if this committee has been established in the Medical Staff Bylaws and is functioning as appropriate. • If it does not apply to this hospital, then score as “not applicable.” 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant <input type="checkbox"/> NA=Not Applicable</p> <p>This standard is not met as evidenced by:</p>

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03.05.02 OMCC Functions.

The functions of the Osteopathic Methods and Concepts Committee (OMCC) shall include:

1. Recommendations to improve utilization of osteopathic principles and practice, to record osteopathic findings, describe osteopathic manipulative treatment and to apply such modalities as part of the comprehensive care received by patients;
2. Establishing and recording retrospective and current audits of patient charts relating the application of osteopathic principles and practice to patient diagnosis and treatment; and
3. Informing osteopathic physicians of the evaluations of patient charts done by the committee to improve utilization of osteopathic principles and practices.

Self-explanatory.

DOCUMENT REVIEW

Review minutes of the committee to determine if all functions are being performed.

- 1 = Compliant
- 2 = Not Compliant
- NA=Not Applicable

This standard is not met as evidenced by:

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STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>03.05.03 <u>OMCC Documentation & Meeting Frequency & Attendance Requirements.</u> Meetings shall have written minutes reflecting the activities of the committee.</p> <p>Determination of the meeting frequency and attendance requirements for the utilization of osteopathic methods and concepts activity shall be the responsibility of the hospital.</p>	<p>Self-explanatory.</p>	<p><u>DOCUMENT REVIEW</u> Review committee minutes. Review hospital requirements for meeting attendance / frequency. Verify requirements are met.</p>	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant <input type="checkbox"/> NA=Not Applicable</p> <p>This standard is not met as evidenced by:</p>
<p>03.06.01 <u>Credentials Committee (function).</u> The Credentials Committee (function) reviews as an investigative and recommending body.</p>	<p>Self-explanatory.</p>	<p><u>DOCUMENT REVIEW</u> Review minutes of the Credentials Committee (function) or Medical Staff minutes if it meets as a committee-of-the-whole.</p>	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>
<p>03.06.02 <u>Credentials Committee Responsibility.</u> The Credentials Committee (function) makes recommendations to the executive committee on applications received for staff membership and requests for privileging for members and non-members.</p>	<p>Self-explanatory.</p>	<p><u>DOCUMENT REVIEW</u> Review minutes of the Credentials Committee (function) or Medical Staff minutes if it meets as a committee-of-the-whole.</p>	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>03.06.03 <u>Credentials Committee Scope.</u> The Credentials Committee (function) recommends expansion or limitation of privileges of staff members and all categories of credentialed staff based on a thorough review of credentials.</p> <p>(See Standards 03.01.06, 03.01.09 AND 03.01.15 for required credentialing and privileging criteria.)</p>	<p>The Credentials Committee (function) is responsible for credentialing the medical staff as well as non-physician practitioners who provide a medical level of care, as applicable.</p>	<p><u>DOCUMENT REVIEW</u> Review minutes of the Credentials Committee (function) or Medical Staff minutes if it meets as a committee-of-the-whole.</p>	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>
<p>03.06.04 <u>Not Applicable.</u></p>			
<p>03.06.05 <u>Not Applicable.</u></p>			
<p>03.06.06 <u>Incomplete Applications.</u> The Credentials Committee (function) members shall return incomplete applications to the applicant for corrections before consideration.</p>	<p>Self-explanatory.</p>	<p><u>DOCUMENT REVIEW</u> Review minutes of the Credentials Committee (function) or Medical Staff minutes to insure applications are complete.</p>	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>
<p>03.06.07 <u>Not Applicable.</u></p>			

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STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>03.06.08 <u>Time Frame for Processing of Applications.</u> A recommendation shall be made to the Medical Executive Committee (MEC) within 60 days of receipt of completed application.</p> <p>The recommendations of the Credentials Committee (function) will be based on individual practitioner’s qualifications and competency at the time the privileges are requested.</p>	<p>All recommendations to the Medical Executive Committee (MEC) shall contain a delineation of the privileges to be extended to the applicant.</p>	<p><u>DOCUMENT REVIEW</u></p> <p>Review the Credentials Committee minutes or Medical Executive Committee (MEC) minutes to determine if recommendations are:</p> <ol style="list-style-type: none"> 1. Made to the governing body, 2. Within the required timeframe, and 3. Based on individual practitioner qualifications and competency. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>
<p>03.06.09 <u>Meeting Frequency & Attendance.</u> The hospital shall determine the meeting frequency and attendance requirements for the Credentials Committee.</p>	<p>Self-explanatory.</p>	<p><u>DOCUMENT REVIEW</u></p> <p>Review Credentials Committee minutes. Review hospital requirements for meeting attendance / frequency.</p>	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>
<p>03.07.01 <u>Not Applicable.</u></p>			
<p>03.08.01 <u>Not Applicable.</u></p>			
<p>03.08.02 <u>Not Applicable</u></p>			
<p>03.09.01 <u>Not Applicable.</u></p>			

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Mortality Review Committee (function). The responsibilities of the Mortality Review Committee are defined in Standards 03.10.01 through 03.10.06.

03.10.01 Mortality Review Committee Scope.
The Mortality Review Committee (**or function**) shall review all mortalities in the hospital monthly. This review, if more feasible, may be performed by organized departments, or in smaller hospitals, by the entire staff.

Self-explanatory.

DOCUMENT REVIEW

Review the Mortality Review Committee (**or function**) minutes or the Medical Staff minutes when it acts as a committee-of-the-whole.

- 1 = Compliant
- 2 = Not Compliant

This standard is not met as evidenced by:

03.10.02 Mortality Review Committee Responsibility: Appropriateness of Care.
The Mortality Review Committee (**or function**) shall determine whether all cases had appropriate evaluation and care.

Self-explanatory.

DOCUMENT REVIEW

Review the Mortality Review Committee (**or function**) minutes or the Medical Staff minutes when it acts as a committee-of-the-whole.

- 1 = Compliant
- 2 = Not Compliant

This standard is not met as evidenced by:

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STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>03.10.03 Mortality Review Committee Responsibility: Attending Physician Involvement. The Mortality Review Committee (or function) shall evaluate to see if the attending physician was aware of the critical nature of the case as noted in the physician’s orders, laboratory procedures ordered, and timeliness of consultation orders.</p>	<p>A mortality review process is in place to determine whether:</p> <ol style="list-style-type: none"> 1. The attending physician was aware of the critical nature of the case as noted in the physician’s orders; 2. Laboratory procedures ordered; and 3. Timeliness of consultation orders. 	<p>DOCUMENT REVIEW Review the Mortality Review Committee (or function) minutes or the Medical Staff minutes when it acts as a committee-of-the-whole.</p>	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>
<p>03.10.04 Mortality Chart Review. The Mortality Review Committee (or function) shall review and analyze the supervision of mortalities beginning with early recognition of complications, reevaluation based on clinical and laboratory studies, and modification of the therapeutic regime in accordance with the changing condition of the patient to determine if the diagnosis can be supported.</p>	<p>A Mortality Review process is in place to review and analyze the supervision of mortalities:</p> <ol style="list-style-type: none"> 1. Beginning with early recognition of complications; 2. Reevaluation based on clinical and laboratory studies; and 3. Modification of the therapeutic regime in accordance with the changing condition of the patient to determine if the diagnosis can be supported. 	<p>DOCUMENT REVIEW Review the Mortality Review Committee (or function) minutes or the Medical Staff minutes when it acts as a committee-of-the-whole.</p>	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>
<p>Data collected through this review will be included in the QAPI Program.</p>			
<p>03.10.05 Not Applicable.</p>			

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03.10.06 Meeting Frequency & Attendance.

The hospital shall determine the meeting frequency and attendance requirements for the mortality review committee.

Self-explanatory.

DOCUMENT REVIEW

Review committee minutes. Review hospital requirements for meeting attendance / frequency.

- 1 = Compliant
- 2 = Not Compliant

This standard is not met as evidenced by:

03.11.01 Not Applicable.

03.12.01 Availability of Professional Literature.

The healthcare facility shall assure that the professional staff has access to professional and medical knowledge based resources. This can be accomplished with access to printed materials and/or the availability of electronic information. The medical executive committee will be responsible for directing the identification of resource needs, will evaluate resource availability on an annual basis, and make appropriate recommendations as a result.

The extent of the library facilities and materials may vary depending upon such things as the size and complexity of the healthcare facility, Medical Staff, the patient mix, complexity of the procedures performed, and whether the healthcare facility is a teaching facility for interns and residents as well as other professional disciplines.

The medical library should include computer workstation facilities.

OBSERVATION & INTERVIEW

View the library facilities and materials available within the healthcare facility.

Determine if the facilities are satisfactory to primary staff users.

- 1 = Compliant
- 2 = Not Compliant

This standard is not met as evidenced by:

03.13.01 Not Applicable.

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Transfusion Review Committee (function).

The responsibilities of the Transfusion Review Committee (**or function**) are defined in Standards 03.14.01 through 03.14.03.

03.14.01 Transfusion Committee Responsibilities.

The Transfusion Review Committee (**or function**) shall establish policies governing all transfusions of blood and blood derivations, systems for reporting transfusion reactions and evaluate such policies and practices at regular intervals.

Transfusion reactions will be considered adverse medical events and will be reported in the QAPI program.

Transfusion of blood and blood product policies are reviewed at least every three (3) years and updated more frequently, as necessary.

DOCUMENT REVIEW

1. Review minutes of the Transfusion Review Committee or the Medical Staff minutes when it acts as a committee-of-the-whole.
2. Review transfusion of blood and blood product related polices to determine these are in place and reviewed at least every three (3) years.
3. Verify that transfusion reactions are reported through the QAPI program. Are identified issues being resolved?

- 1 = Compliant
- 2 = Not Compliant

This standard is not met as evidenced by:

03.14.02 Scope of the Transfusion Review Committee.

The Transfusion Review Committee (**or function**) shall investigate all transfusion reactions occurring in the hospital.

A process is in place to review all transfusion reactions.

If a screening tool is used, the medical staff has approved the tool.

DOCUMENT REVIEW

Review minutes of the Transfusion Review Committee or the Medical Staff minutes when it acts as a committee-of-the-whole.

- 1 = Compliant
- 2 = Not Compliant

This standard is not met as evidenced by:

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STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>03.14.03 Performance Improvement. The Transfusion Review Committee (or function) shall recommend improvement in transfusion procedures.</p> <p>The medical staff has a process to review all transfusions administered in the hospital to determine appropriateness of the treatment.</p> <p>This review, if more feasible, may be performed by organized departments, or in smaller hospitals, by the entire staff.</p>	<p>The medical staff shall adopt blood and blood products administration practices based on current national guidelines.</p> <p>The medical staff determines appropriateness of blood and blood products administered to determine appropriateness of treatment and opportunities for improvement.</p>	<p>DOCUMENT REVIEW</p> <p>Review minutes of the Transfusion Review Committee or the Medical Staff minutes when it acts as a committee-of-the-whole.</p> <ul style="list-style-type: none"> Determine the medical staff has a process to review blood transfusions to ensure appropriateness of treatment. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>
<p>03.15.01 Ongoing Professional Practice Evaluation. Ongoing professional practice evaluation (OPPE) information is factored into the decision to maintain existing privilege(s), to revise existing privilege(s), and/or to revoke an existing privilege prior to or at the time of renewal.</p>	<p>The Medical Staff must have a process to monitor the competency of its members. Through an ongoing review of performance measurements, negative trends are tracked and trended in a manner that allows the leadership to identify performance issues and implement strategies that will effect change. Prospective and real-time evaluation is important to ensure the delivery of safe and competent care.</p> <p>The Medical Staff develop an ongoing professional practice evaluation plan that is applicable to all practitioners with privileges granted by the governing body.</p>	<p>DOCUMENT & FILE REVIEW</p> <ol style="list-style-type: none"> The Medical Staff Bylaws address the ongoing professional practice evaluation process. The Medical Staff have identified and approved performance measures. Credential files reflect the ongoing professional practice evaluation is performed at least three (3) times during the two-year appointment cycle. This quality data is reviewed as part of the reappointment process. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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The plan for the evaluation of each practitioner’s professional practice is clearly defined. This medical staff approved plan addresses each of the following:

1. Reasons for ongoing professional practice performance evaluations
2. Identification of performance indicators specific to each department of the medical staff
3. Data collection methods
4. Individual(s) responsible for data collection
5. Sources of data, e.g., medical records
6. Frequency of data collection
7. Methods for evaluation and analysis of data
8. Confidentiality and security of data
9. Individuals that may access individual practitioner’s professional practice data
10. Explanation that data will be used as a measure of competency and will be reviewed at time of reappointment to determine eligibility
11. Evaluation of low volume practitioners
12. Triggers for additional, focused monitoring

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Processes are established to ensure the confidentiality and security of the ongoing professional practice evaluation data. The medical staff identify individuals that may access and review the data, for example:

- Respective department chair
- Credentials committee
- Medical Executive Committee (MEC)
- Special committees
- Chief of Staff
- Chief Medical Officer / Vice President of Medical Affairs (VPMA)
- Personnel working in the Medical Staff Office, Quality Department, or Medical Records Department

Data will be collected on an ongoing basis and summarized at least three (3) times during each two-year appointment cycle. It is recommended that individual data reports be distributed to the practitioners.

When possible, data collection systems that are currently in place should be accessed to measure individual practitioner outcomes. Electronic billing data, for example, often provides information according to the admitting and attending physician, primary surgeon, consultants and other practitioners. Billing data, however, may have limited usefulness for the **non-physician** providers, as traditional coding practices may not identify this group of practitioners.

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At least every two (2) years, the Medical Staff identify and approve performance measurements that are specific to the services provided by the practitioners.

- **At least two (2) performance measures shall be an Administrative indicator in order to evaluate compliance with medical staff bylaws, rules and regulations, and hospital policies.**
- **At least two (2) performance measures shall be a clinical indicator in order to evaluate current competence of privileges granted.**

Examples of performance measures include:

1. Administrative Data

- # Admissions
- # Consultations
- # Weeks on Surgery Suspension List
- Medical record delinquency rate
- **Compliance with bylaws, rules and regulations, and policies**

2. Clinical Indicators

- Core measures (Heart Failure, Acute Myocardial Infarction, Pneumonia, Stroke, and etc.)
- SCIP (Surgical Care Improvement Project)
- Returns to surgery
- Surgical infection rate
- Procedural complication data
- Administration of corticosteroids within 24 hours of admission for asthma
- Cesarean section births, not medically

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- necessary
- Turnaround time for simple / complicated autopsy reports

The Medical Staff determine data to be collected for the **non-physician** practitioners (e.g., **nurse practitioners, physician assistants, certified nurse anesthetists, and certified nurse midwives**) granted **privileges** that are relevant to their practice.

03.15.02 Focused Professional Practice Evaluation.

The organized medical staff defines the circumstances requiring additional, focused monitoring and evaluation of a practitioner’s professional performance.

The focused professional practice evaluation (FPPE) process is designed to be a fair, balanced, and educational approach to ensure the competency of the staff. Focused professional practice evaluation (FPPE) is consistently implemented in accordance with the criteria and requirements defined by the organized medical staff.

The Medical Staff Bylaws address:

1. The period of focused professional practice evaluation (FPPE) implemented for all new privileges granted by the Board either upon initial appointment or for requests for additional privileges.
2. The criteria for evaluating the performance of practitioners when issues affecting the provision of safe, high-quality patient care are identified.

The Medical Staff Bylaws clearly define the

DOCUMENT AND FILE REVIEW

1. The Medical Staff Bylaws address the focused professional practice evaluation process.
2. The Medical Staff Bylaws clearly defines the triggers requiring a focused review, as well as indications for an external reviewer.
3. Credential files reflect the period of focused professional practice evaluation.

- 1 = Compliant
- 2 = Not Compliant

This standard is not met as evidenced by:

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Professional Practice Evaluation process and addresses each of the following:

- Criteria (triggers) for conducting focused performance monitoring
- Methods for determining the duration of focused performance monitoring
- Indications for an external reviewer

The department chair is responsible to assign the focused evaluation. The focused evaluation may be defined as either a period of time (e.g., six months) or a specific number of cases. The focused evaluation may be extended, as defined in the Bylaws.

Data sources for the focused evaluation are defined and may include:

- Chart review
- Direct observation
- Simulation
- Discussion with others involved in the care of each patient

The Medical Staff Bylaws define the unacceptable levels of performance that trigger the need for focused performance monitoring. *Triggers may be a single incident or evidence of a clinical practice trend.*

Examples of performance triggers include:

- # adverse events
- # peer review events with adverse determination
- Infection rates higher than most practitioners
- Sentinel events

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- Low volume admissions/ procedures over an extended period of time
- Increased length of stay(LOS)
- Increased number of returns to surgery
- Frequent / repeat readmission for same issue
- Patterns of unnecessary diagnostic testing / treatments
- Failure to follow approved clinical practice guidelines
- Patient, family, or staff complaints

The Medical Staff Bylaws define the methods to be implemented to resolve performance issues. The measures employed to resolve performance issues are consistently implemented and may include:

- Necessary education
- Proctoring / assisting for defined privilege
- Counseling
- Physician / practitioner assistance programs
- Suspension of specific privileges
- Revocation of specific privileges

The improvement plan must be documented and include the requirements, who is accountable, and how the improvement will be measured and documented.

The outcome of FPPE is to be documented and analyzed. Processes are developed to allow the practitioner to review findings and submit opinions.

The Medical Staff leadership is responsible to submit

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recommendations to the Governing Body regarding:

- The need to continue the FPPE
- Continuation or limiting of the privilege

HUMAN RESOURCES MANAGEMENT

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>04.00.01 Governance Responsibility for Staffing. The hospital Governance Plan is supported by a written description of the “Plan for the Delivery of Care and Services.” This plan describes the mechanisms to provide appropriate staffing for these services.</p>	<p>The plan for staffing addresses the recruitment and retention of qualified persons to provide services.</p> <p>The plan also addresses staffing patterns by department and by shift. Processes and mechanisms for determining the need for staffing adjustments are also defined. "Appropriate staffing" is impacted by both quantity and quality of persons providing care and those supporting direct care providers.</p>	<p>DOCUMENT REVIEW</p> <p>Determine that the “Plan for the Delivery of Care and Services” document addresses staffing, mechanisms and processes for determining staffing adjustments based on need and type of staffing available, recruitment and retention.</p>	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>COMMENTS:</p>
<p>04.00.02 Licensure. The hospital must verify that all employees meet licensure and all other applicable standards for employment.</p> <p>This includes certification, minimum qualifications, training and education requirements, and permits (such as food handlers permits).</p> <p>This standard applies to contract or agency staff as well as hospital employees.</p>	<p>Mechanisms are established to verify with the appropriate licensing agency, all initial and renewal licenses and certificates required to conform to State practice acts.</p> <p>Practice in a facility by an individual without appropriate state license or certification is grounds for loss of accreditation by the facility.</p>	<p>INTERVIEW</p> <p>Determine that there is mail, electronic or telephonic verification with the appropriate licensing authority for all new personnel and for licensure or certificate renewals.</p> <p>This will include all disciplines defined in the State Practice Acts or Association standards which demand certification / licensure / registration for facility employment.</p> <p>Verify that the hospital has established a policy and follows procedures for determining that all personnel required to be licensed, certified and/or permitted by the state are properly licensed and also meet the basic requirements for the positions they hold.</p>	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>COMMENTS:</p>

HUMAN RESOURCES MANAGEMENT

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FILE REVIEW

Review a sampling of personnel files. Verify that all required information is current.

Review administrative and supervisory personnel as well as direct care personnel. Also sample contract and agency staff files.

04.00.03 For Future Use.

04.00.04 License Pending & Lapse or Restriction of Licensure / Certification.

New graduate providers provide services within the scope of their Practice Acts. If the state or territory permits new graduates to function as "license pending," all mandated provisions are enforced.

Providers whose licensure, certification or registration lapses or is placed under revocation, suspension, stipulation, etc., conform to all such provisions.

The facility retains the authority while delegating to the department or service manager the accountability for assuring that all such mandated provisions are enforced.

Typically, nonpayment, late payment, and registration lapses result in prohibition of providing service, as does failure to "pass" the licensing examination.

A copy of State licensing or Practice Act is available to those responsible.

DOCUMENT REVIEW & INTERVIEW

Licensure and registration are not the same as certification.

Determine that facility policy is explicit regarding actions to be taken with examination failures and registration lapses / revocations / suspensions / stipulations.

- 1 = Compliant
- 2 = Not Compliant

COMMENTS:

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<p>04.00.05 <u>Competency.</u> The facility develops policies and procedures identifying those patient care and/or diagnostic procedures, which requires staff to have evidence of specific competence. Some of these may result in external or internal mechanisms for certification. Maintenance of such competence is considered in the design of these policies and procedures.</p>	<p>Hospital policies identify required certifications such as ACLS or Basic Life Support (BLS) certification versus "basic CPR" or rescue training.</p> <p>External certifications may be indicated by subspecialty such as for operating room, emergency room, psychiatric, or critical care nursing, etc; or, may be technique specific such as "chemotherapy," "mammography," etc.</p> <p>Internal certifications may include processes for minimal sedation, moderate sedation (conscious sedation), deep anesthesia, Monitored Anesthesia Care (MAC) or fetal scalp electrode placement.</p>	<p><u>DOCUMENT REVIEW</u></p> <p>Determine that the staffing protocols outline those positions or processes for which the facility has determined that external or internal certification is required. If such exist, determine that there are mechanisms to maintain current skill competence. Job descriptions may be a source for this information</p>	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>COMMENTS:</p>
<p>04.00.06 <u>Federal Employment Regulations.</u> Hospital wide policies and procedures identify adherence to Federal, State and Local requirements. Statements of facility compliance are posted regarding Fair Labor practices, Equal Employment Opportunity standards, and etc. Employee handbooks, human resource manuals, and other documents outline facility standards regarding nondiscrimination practices with concomitant personnel expectations.</p>	<p>These documents are accessible and applicable to all providers (Medical Staff, employee, contractual and volunteer).</p> <p>Detailed explanations may be reserved for department / service managers to share with staff upon their need. Summary formats are made available upon hire or initial orientation for all categories of staff.</p> <p>Disciplinary and grievance mechanisms are outlined and may be impacted by existing labor organization contracts.</p>	<p><u>OBSERVATION & INTERVIEW</u></p> <p>Determine that all appropriate documents are accessible to all providers.</p> <p>Determine that staff is oriented to specific mechanisms regarding discipline and grievance with specific emphasis on discrimination (sexual, ethnic harassment, etc.).</p> <p>Determine that policies and procedures regarding the workday / week and overtime are enforced. Interview managers to test their knowledge of nondiscriminatory policies.</p>	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>COMMENTS:</p>

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<p>04.00.07 <u>Staffing Plans.</u> Hospital and service specific policies and procedures identify basic / core staffing for usual patient care needs and reflect mechanisms for altering these levels for changes in the volume, complexity or intensity of services.</p>	<p>Staffing assignment policies for each department / service identify the principles of matching the mix of skills possessed by the staff to the identified patient needs, or for the specific task, relating to:</p> <ul style="list-style-type: none"> • Physical care; • Equipment / technology / environment; • Emotional support; and • Education for the procedure and / or self-care. <p>The mechanisms for non-nursing providers may be similar to the nursing department, yet not as complex. (Refer to Nursing Department - Assignment of Care for more information.)</p>	<p style="text-align: center;"><u>DOCUMENT REVIEW</u></p> <p>Determine that staffing policies address basic / core staffing with criteria based modifications for changing / augmenting that level.</p> <p style="text-align: center;"><u>INTERVIEW</u></p> <p>Interview managers and selected staff to determine if policies are implemented and that there is sufficient numbers of qualified staff to provide the care, treatment and services required.</p>	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>COMMENTS:</p>
<p>04.00.08 <u>Staffing Assignment Criteria.</u> Staffing policies and procedures identify any constraints regarding assignment to certain types of patients or processes, which require specific skill from a provider. Providers do not provide services beyond their capability; this does not preclude provision of such services under formal preceptorship / supervision within licensure / registration parameters.</p>	<p>Note the requirements in standard 04.00.05 above regarding skill, competence and certifications.</p> <p>Staffing shall be sufficient in numbers and qualification so that individuals are not providing care, treatment or services beyond their education, experience, or training.</p>	<p style="text-align: center;"><u>DOCUMENT REVIEW</u></p> <p>Review assignment mechanisms and interview sufficient numbers of managers and staff to determine that patient care is not jeopardized.</p>	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>COMMENTS:</p>

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<p>04.00.09 <u>Evaluation of Competence.</u> Staff is competent in knowledge, skills and ability to perform their responsibilities. An objective process for assessing and evaluating the competence of all employees is performed at defined intervals.</p> <p>Competency assessment is an ongoing process. The facility will define the competencies to be assessed annually and those competencies to be assessed at shorter defined time intervals.</p>	<p>Prior to beginning the relationship with the facility the applicant provides information about education, training, and skills relevant to the desired position.</p> <p>During the initial phase of affiliation with the facility there is a period of observation and training as needed to document the competencies required.</p> <p>Written criteria are utilized for such evaluations. Such criteria include those noted in the facility and service Quality Assessment Performance Improvement plan.</p> <p>Evaluation is repeated at specified intervals; this may be upon the discretion of the facility but is at least on an annual basis.</p>	<p style="text-align: center;"><u>DOCUMENT REVIEW</u></p> <p>Determine that there are criteria based mechanisms for assessing competency:</p> <ol style="list-style-type: none"> 1. Pre-affiliation (Prior to orientation); 2. Initial phase of affiliation (during orientation); and 3. At specified periods thereafter, but at least annually. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>COMMENTS:</p>
<p>04.00.10 <u>New Employee Orientation.</u> Providers of care or service who are new in their affiliation are provided an orientation to the facility and their job responsibilities.</p> <p>The period of orientation is documented and may vary according to the classification of the professional, support staff, agency or contractual, volunteer, student, etc., including prior experience(s).</p> <p>The documents related to new orientation are readily retrievable.</p>	<p>Written documentation is maintained for each employee (including contracted employees) to verify that orientation to the facility and role has been accomplished.</p> <p>The documentation may be located in the human resources department, in each department or service, or may be located within the official file for each provider.</p>	<p style="text-align: center;"><u>FILE REVIEW</u></p> <p>Determine that orientation is available and provided to all categories of personnel.</p> <p>Determine that mechanisms exist to readily retrieve the documentation.</p>	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>COMMENTS:</p>

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<p>04.00.11 Required Orientation Curriculum. The orientation curriculum addresses specific information about the processes expected of the individual (scope of service, the written job description and evaluation tools). Facility wide, department / service and job specific components include:</p> <ol style="list-style-type: none"> 1. Infection control, including blood borne pathogens and airborne pathogens; 2. Quality Assessment / Performance Improvement (QAPI); 3. Life safety; 4. Equipment / device safety; 5. Hazardous waste and materials safety; 6. Information Management including confidentiality, computer access, and medical records confidentiality; 7. Patient Rights; and 8. Restraint use if applicable to the job type. 	<p>An effective process is in place. The standard does not mandate an "education department."</p> <p>All components of the orientation are included for all categories of personnel; in some instances this may be via video or booklet material reviewed off-site (such as for agency or student providers).</p> <p>The orientation program is significantly enhanced when there is documentation of knowledge via post testing of the employee.</p> <p>The facility may wish to consider the review of falls, incidents, medical errors, etc. within its department / service and job specific reviews.</p>	<p style="text-align: center;"><u>DOCUMENT REVIEW</u></p> <p>Review curriculum content for various providers and affiliates.</p> <p>Determine that the orientation program is comprehensive and includes:</p> <ol style="list-style-type: none"> 1. Role expectations 2. Evaluation mechanisms 3. The eight (8) required elements 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>COMMENTS:</p>

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<p>04.00.12 Annual Required Competencies. The facility provides for ongoing training and education to maintain and improve the competency and knowledge of staff.</p> <p>Annual retraining in the eight (8) areas noted in standard 04.00.11 is documented.</p>	<p>Ongoing training and education for all providers in addition to the mandated areas are related to the identified learning needs of the provider in accomplishing the job related duties expected by the facility.</p> <p>Training may be provided directly by the facility or from external sources.</p> <p>Learning needs may be determined from results of:</p> <ul style="list-style-type: none"> • Staff survey; • The findings from Quality Assessment Performance Improvement (QAPI) activities; or • The implementation of new or revised technology or practices. <p>This element does not require a facility to provide training for staff to advance to a new career(s) although some facilities may provide tuition assistance without regard to correlation to the present job.</p>	<p>FILE REVIEW</p> <p>Determine that each provider (staff or contractual) has a record of ongoing training that document:</p> <ol style="list-style-type: none"> 1. Completion of the required EIGHT (8) elements for annual retraining; 2. Education relating to the findings from QAPI activities; and 3. Education related to the implementation of new or revised technology or practices. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>COMMENTS:</p>

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<p>04.00.13 <u>Employee Identification System.</u> Hospital staff and contracted personnel shall be issued and required to wear an identification badge.</p> <p>Hospital policy defines the information to be provided on the identification badge. Minimally, the badge should include:</p> <ul style="list-style-type: none"> • First name • Job title <p>Other information to consider include:</p> <ul style="list-style-type: none"> • Credentials • Department • Photo 	<p>All care providers including physicians and agency personnel are expected to wear an identification badge in order to:</p> <ol style="list-style-type: none"> 1. Comply with the patient’s right to know the names of their care providers, and 2. To identify employees and allow access to work areas during an emergency or disaster situation. <p>Hospital policy specifies the specific information to be displayed on the identification badge.</p>	<p><u>OBSERVATION AND DOCUMENT REVIEW</u></p> <ol style="list-style-type: none"> 1. Review the Human Resource policy to determine that the requirement was met. 2. Observe employees when touring the facility to determine that the requirement is met. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>COMMENTS:</p>

FOR FUTURE USE

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
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THIS CHAPTER IS FOR FUTURE USE

FOR FUTURE USE

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THIS CHAPTER IS FOR FUTURE USE

INFECTION CONTROL

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>07.00.00 Condition of Participation: Infection Control. <i>The hospital must provide a sanitary environment to avoid sources and transmission of infections and communicable diseases.</i></p> <p><i>There must be an active program for the prevention, control, and investigation of infections and communicable diseases.</i></p> <p>§482.42</p>	<p>The hospital infection control program must be hospital-wide, include all locations, all campuses, all departments and services.</p> <p>This regulation requires the hospital to develop, implement, and maintain an active, hospital-wide program for the prevention, control, and investigation of infections and communicable diseases.</p> <p>The National Institute of Allergy and Infectious Diseases defines an infectious disease as a change from a state of health to a state in which part or all of a host’s body cannot function normally because of the presence of an infectious agent or its product. An infectious agent is defined by the NIAID as a living or quasi-living organism or particle that causes an infectious disease, and includes bacteria, viruses, fungi, protozoa, helminthes, and prions. NIAID defines a communicable disease as a disease associated with an agent that can be transmitted from one host to another (NIAID website glossary).</p> <p>According to the Centers for Disease Control and Prevention (CDC), healthcare-associated infections, i.e., infections that patients acquired during the course of receiving treatment for other conditions within a healthcare setting are one of the top ten leading causes of death in the United States. The CDC estimates that there are 1.7 million healthcare-associated infections in American hospitals each year, with 99,000 associated deaths. (CDC website,</p>	<p><u>DOCUMENT REVIEW, OBSERVATION, & INTERVIEW</u></p> <ol style="list-style-type: none"> Survey of the Infection Control Condition of Participation (CoP) should be coordinated by one surveyor. However, each surveyor should assess the hospital’s compliance with the Infection Control CoP as he/she conducts his/her survey assignments. Determine whether there are hospital-wide policies and procedures for preventing, identifying, reporting, investigating, and controlling infections and communicable diseases of patients and hospital personnel, including contract personnel and volunteers. Determine whether the infection control program can identify all hospital locations and that the policies and procedures take the various hospital locations into account. Determine whether the policies and procedures have been implemented correctly in an active infection control program. Determine whether the program is hospital-wide and program specific in gathering and assessing infection and communicable disease data. Review the parameters of the active surveillance program to determine whether it is consistent with infection control 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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	<p>Estimates of Healthcare-Associated Infections, date last modified May 30, 2007)</p> <p>The hospital must provide and maintain a sanitary environment to avoid sources and transmission of infections and communicable diseases. All areas of the hospital must be clean and sanitary. This includes all hospital units, campuses and off-site locations. The infection prevention and control program must include appropriate monitoring of housekeeping, maintenance (including repair, renovation and construction activities), and other activities to ensure that the hospital maintains a sanitary environment.</p> <p>Examples of areas to monitor would include: food storage, preparation, serving and dish rooms, refrigerators, ice machines, air handlers, autoclave rooms, venting systems, inpatient rooms, treatment areas, labs, waste handling, surgical areas, supply storage, equipment cleaning, etc.</p> <p>The hospital’s program for prevention, control and investigation of infections and communicable diseases should be conducted in accordance with nationally recognized infection control practices or guidelines, as well as applicable regulations of other federal or state agencies. Examples of organizations that promulgate nationally recognized infection and communicable disease control guidelines, and/or recommendations include: the Centers for Disease Control and Prevention (CDC), the Association for Professionals in Infection Control and Epidemiology (APIC), the Society</p>	<p>standards of practice and suitable to the scope and complexity of the hospital’s services.</p> <p>6. Throughout the hospital, observe the sanitary condition of the environment of care, noting the cleanliness of patient rooms, floors, horizontal surfaces, patient equipment, air inlets, mechanical rooms, food service activities, treatment and procedure areas, surgical areas, central supply, storage areas, etc.</p> <p>7. Determine whether the hospital’s infection prevention and control program is integrated into its hospital-wide QAPI program.</p>	

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for Healthcare Epidemiology of America (SHEA), and the Association of periOperative Registered Nurses (AORN). The U.S. Occupational Health and Safety Administration (OSHA) also issues federal regulations applicable to infection control practices.

In order to prevent, control and investigate infections and communicable diseases, the hospital’s program must include an active surveillance component that covers both hospital patients and personnel working in the hospital. Surveillance includes infection detection, data collection and analysis, monitoring, and evaluation of preventive interventions.

The hospital must conduct surveillance on a hospital-wide basis in order to identify infectious risks or communicable disease problems at any particular location. This does not imply “total hospital surveillance,” but it does mean that hospitals must have reliable sampling or other mechanisms in place to permit identifying and monitoring infections and communicable diseases occurring throughout the hospital’s various locations or departments. The hospital must document its surveillance activities, including the measures selected for monitoring, and collection and analysis methods. Surveillance activities should be conducted in accordance with recognized infection control surveillance practices, such as, for example, those utilized by the CDC’s National Healthcare Safety Net (NHSN).

The hospital must develop and implement appropriate

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infection control interventions to address issues identified through its detection activities, and then monitor the effectiveness of interventions through further data collection and analysis.

The hospital’s infection prevention and control program must be integrated into its hospital-wide Quality Assurance and Performance Improvement (QAPI) program. (See 42 CFR 482.42(b)(1).)

SPECIAL CHALLENGES IN INFECTION CONTROL

MULTI-DRUG RESISTANT ORGANISMS (MDROs)

According to the Centers for Disease Control’s (CDC) publication, Management of Multi-drug Resistant Organisms in Healthcare Settings 2006, <http://www.cdc.gov/ncidod/dhqp/pdf/ar/mrdoGuideline2006.pdf>, MDROs are microorganisms that are resistant to one or more antimicrobial agents. Options for treating patients with MDRO infections are very limited, resulting in increased mortality, as well as increased hospital length of stay and costs. During the last several decades the prevalence of MDROs in hospitals has increased steadily. Hospitals are encouraged to have mechanisms in place for the early identification of patients with targeted MDROs prevalent in their hospital and community, and for the prevention of transmission of such MDROs. When ongoing transmission of targeted MDROs in the hospital is identified, the infection prevention and control program should use this event to identify potential breaches in infection control practice.

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AMBULATORY CARE

The ambulatory care setting, including emergency departments, presents unique challenges for infection control, because: patients remain in common areas, often for prolonged periods of time, until they can be seen by a healthcare practitioner; examination or treatment rooms are turned around quickly with minimal cleaning; and infectious patients may not be recognized immediately. Furthermore, immunocompromised patients may receive treatments in rooms among other patients who pose risks of infection.

The hospital's infection prevention and control program should be designed with these ambulatory care setting challenges in mind. After assessing the likely level of risk in its various ambulatory care settings, including off-site settings, a hospital might identify particular settings, such as the emergency department, where it would be appropriate to employ measures for screening individuals with potentially contagious diseases during their initial patient encounter, and taking appropriate control measures for those individuals who may present risk for the transmission of infectious agents by the airborne or droplet route. Guidelines promulgated by the CDC's Healthcare Infection Control Practices Advisory Committee (HICPAC) are a resource for hospitals in developing their infection control program for ambulatory care.

For example, when potentially infectious individuals

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are identified, prevention measures should include prompt physical separation wherever possible, implementation of respiratory hygiene / cough etiquette protocols, and / or appropriate isolation precautions based on the routes of transmission of the suspected infection.

COMMUNICABLE DISEASE OUTBREAKS

Community-wide outbreaks of communicable diseases (such as measles, SARS, or influenza) present many of the same issues and require many of the same considerations and strategies as other hospital infectious disease threats. If a communicable disease outbreak occurs, an understanding of the epidemiology, likely modes of transmission, and clinical course of the disease is essential for responding to and managing the event.

Among the infection control issues that may need to be addressed are:

- Preventing transmission among patients, healthcare personnel, and visitors;
- Identifying persons who may be infected and exposed;
- Providing treatment or prophylaxis to large numbers of people; and
- Logistics issues (staff, medical supplies, resupply, continued operations, and capacity).

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Pandemics, or very widespread and clinically serious outbreaks of an infection, present additional challenges due to the widespread effect on the availability of back-up resources that would typically be available to address an outbreak confined to a smaller geographic area. Additionally, the duration of a pandemic may present special challenges for staffing, supplies, resupply, etc. Hospitals should work with local, State, and Federal public health agencies to identify likely communicable disease threats and develop appropriate preparedness and response strategies.

BIOTERRORISM

Healthcare facilities would confront a set of issues similar to naturally occurring communicable disease threats when dealing with a suspected bioterrorism event. The required response is likely to differ based on whether exposure is a result of a biological release or person-to-person transmission.

A variety of sources offer guidance for the management of persons exposed to likely agents of bioterrorism, including Federal agency websites (e.g.,

- http://www.ahrq.gov/prep;
- http://www.usamrid.army.mil/publications/index.html; <http://www.bt.cdc.gov>)

Because of the many similarities between man-made and naturally occurring threats, an all-hazards approach to developing emergency response plans is

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preferred, and hospitals are encouraged to work with their State and local emergency response agencies to develop their plans.

The hospital must be in compliance with the Occupational Health and Safety Administration’s Bloodborne Pathogens regulation at 29 CFR 1910.1030.

07.01.01 Infection Control Officer (ICO).

A person or persons must be designated as Infection Control Officer (ICO) or officers to develop and implement policies governing control of infections and communicable diseases.

§482.42(a)

Hospital infection control officers are often referred to as “hospital epidemiologists (HEs),” “infection control professionals (ICPs)” or “infection preventionists.” CDC has defined “infection control professional” as “a person whose primary training is in either nursing, medical technology, microbiology, or epidemiology and who has acquired specialized training in infection control.”

The hospital must designate in writing an individual or group of individuals as its infection control officer or officers. In designating infection control officers hospitals should assure that the individuals so designated are qualified through education, training, experience, or certification (such as that offered by the Certification Board of Infection Control and Epidemiology Inc. (CBIC), or by the specialty boards in adult or pediatric infectious diseases offered for physicians by the American Board of Internal Medicine (for internists) and the American Board of Pediatrics (for pediatricians)). Infection control officers should maintain their qualifications through ongoing

DOCUMENT REVIEW AND FILE REVIEW

1. **Determine whether** an Infection Control Officer(s) is designated and has the responsibility for the infection **prevention and control** program.
2. Determine whether the infection control officer(s) have developed and implemented hospital infection control policies.
3. Review the personnel file of the infection control officer(s) to determine whether he/she is qualified through ongoing education, training, experience, or certification to oversee the infection control program.

- 1 = Compliant
- 2 = Not Compliant

This standard is not met as evidenced by:

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education and training, which can be demonstrated by participation in infection control courses, or in local and national meetings organized by recognized professional societies, such as APIC and SHEA.

CMS does not specify either the number of infection control officers to be designated or the number of infection control officer hours that must be devoted to the infection prevention and control programs. However, resources must be adequate to accomplish the tasks required for the infection control program. A prudent hospital would consider patient census, characteristics of the patient population, and complexity of the healthcare services it offers in determining the size and scope of the resources it commits to infection control. The CDC’s HICPAC as well as professional infection control organizations such as the APIC and the SHEA publish studies and recommendations on resource allocation that hospitals may find useful.

The infection control officer(s) must develop and implement policies governing the control of infections and communicable diseases. Infection control policies should address the roles and responsibilities for infection control within the hospital; how the various hospital committees and departments interface with the infection control program; and how to prevent infectious / communicable diseases; and how to report infectious / communicable diseases to the infection control program.

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<p>07.01.02 Infection Prevention. <i>The infection control officer or officers must develop a system for identifying, investigating, reporting and preventing spread of infections among patients and personnel.</i></p> <p>§482.42(a)</p>	<p>The infection control officer or officers must develop, implement and evaluate measures governing the identification, investigation, reporting, prevention and control of infections and communicable diseases within the hospital, including both healthcare–associated infections and community-acquired infections. Infection control policies should be specific to each department, service, and location, including off-site locations, and be evaluated and revised when indicated.</p> <p>The successful development, implementation and evaluation of a hospital-wide infection prevention and control program requires frequent collaboration with persons administratively and clinically responsible for inpatient and outpatient departments and services, as well as, non-patient-care support staff, such as maintenance and housekeeping staff.</p> <p>Implicit in the infection control officer(s)' responsibility for measures to identify, investigate, report, prevent and control infections and communicable diseases are the following activities:</p> <ol style="list-style-type: none"> 1. Maintenance of a sanitary hospital environment; 2. Development and implementation of infection control measures related to hospital personnel; hospital staff, for infection control purposes, includes all hospital staff, contract workers (e.g., agency nurses, housekeeping staff, etc), and volunteers; 	<p style="text-align: center;"><u>INTERVIEW & DOCUMENT REVIEW</u></p> <p>Determine whether the hospital has an active, hospital-wide infection control program reflecting the infection control officer responsibilities specified in the interpretive guidelines.</p> <p>Specifically, surveyors should determine whether the hospital:</p> <ol style="list-style-type: none"> 1. Maintains a sanitary environment; 2. Develops and implements infection control measures related to hospital personnel; 3. Mitigates risks associated with patient infections present upon admission; 4. Mitigates risks contributing to healthcare-associated infections (for example, observe whether staff exhibit good hand washing hygiene); 5. Conducts active surveillance; 6. Monitors compliance with all infection control program requirements; 7. Evaluates the infection control program regularly and revises it, when indicated; 8. Coordinates as required by law with federal, state, and local emergency preparedness and health authorities to address communicable 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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	<p>3. Mitigation of risks associated with patient infections present upon admission;</p> <p>4. Mitigation of risks contributing to healthcare-associated infections;</p> <p>5. Active surveillance;</p> <p>6. Monitoring compliance with all policies, procedures, protocols and other infection control program requirements;</p> <p>7. Program evaluation and revision of the program, when indicated;</p> <p>8. Coordination as required by law with federal, state, and local emergency preparedness and health authorities to address communicable disease threats, bioterrorism, and outbreaks;</p> <p>9. Complying with the reportable disease requirements of the local health authority.</p> <p>A hospital with a comprehensive hospital-wide infection control program should have and implement policies and procedures, based as much as possible on national guidelines, that address the following:</p> <p><u>Maintenance of a Sanitary Physical Environment:</u></p> <p>1. Ventilation and water quality control issues, including measures taken to maintain a safe environment during internal or external</p>	<p>disease threats, bioterrorism, and outbreaks; and</p> <p>9. Complies with the reportable disease requirements of the local health authority.</p>	

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construction / renovation;

2. Maintaining safe air handling systems in areas of special ventilation, such as operating rooms, intensive care units, and airborne infection isolation rooms;
3. Techniques for food sanitation;
4. Techniques for cleaning and disinfecting environmental surfaces, carpeting and furniture;
5. Techniques for textiles reprocessing, storage and distribution;
6. Techniques for disposal of regulated and non-regulated waste; and
7. Techniques for pest control.

Hospital Staff-Related Measures:

1. Measures – and authority - for evaluating hospital staff immunization status for designated infectious diseases, as recommended by the CDC and its Advisory Committee on Immunization Practices (ACIP);
2. Policies articulating the authority and circumstances under which the hospital screens hospital staff for infections likely to cause significant infectious disease or other risk to the exposed individual, and for reportable diseases, as

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required under local, state, or federal public health authority;

3. Policies articulating when infected hospital staff are restricted from providing direct patient care and/or are required to remain away from the healthcare facility entirely;
4. New employee and regular update training in preventing and controlling healthcare-associated infections and methods to prevent exposure to and transmission of infections and communicable diseases;
5. Measures to evaluate staff and volunteers exposed to patients with infections and communicable disease.

Mitigation of Risks Associated With Patient Infections

Present Upon Admission:

1. Measures for the early identification of patients who require isolation in accordance with CDC guidelines;
2. Appropriate use of personal protective equipment including gowns, gloves, masks and eye protection devices;
3. Use and techniques for “isolation” precautions as recommended by the CDC.

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Mitigation of Risks Contributing To Healthcare-Associated Infections:

A. Surgery-related infection risk mitigation measures:

1. Implementing appropriate prophylaxis to prevent surgical site infection (SSI), such as a protocol to assure that antibiotic prophylaxis to prevent surgical site infection for appropriate procedures is administered at the appropriate time, done with an appropriate antibiotic, and discontinued appropriately after surgery;
2. Addressing aseptic technique practices used in surgery and invasive procedures performed outside the operating room, including sterilization of instruments.

B. Other Hospital Healthcare-Associated Infection Risk Mitigation Measures:

1. Promotion of hand-washing hygiene among staff and employees, including utilization of alcohol-based hand sanitizers;
2. Measures specific to prevention of infections caused by organisms that are antibiotic-resistant;
3. Measures specific to prevention of device-associated bloodstream infection (BSI), such as a protocol for reducing infections of central venous catheters specifying aseptic

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- precautions for line insertions, care of inserted lines, and prompt removal when a line is no longer needed;
4. Measures specific to prevention of other device-associated infections, e.g., those associated with ventilators, tube feeding, indwelling urinary catheters, etc.;
 5. Isolation procedures and requirements for highly immuno-suppressed patients who require a protective environment;
 6. Care techniques for tracheostomy care, respiratory therapy, burns and other situations that reduce a patient's resistance to infection;
 7. Requiring disinfectants, antiseptics, and germicides to be used in accordance with the manufacturers' instructions;
 8. Appropriate use of facility and medical equipment, including negative and positive pressure isolation room equipment, portable air filtration equipment, treatment booths and enclosed beds, UV lights, and other equipment used to control the spread of infectious agents;
 9. Adherence to nationally recognized infection prevention and control precautions, such as

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current CDC guidelines and recommendations, for infections / communicable diseases identified as present in the hospital; and

10. Educating patients, visitors, caregivers, and staff, as appropriate, about infections and communicable diseases and methods to reduce transmission in the hospital and in the community.

C. Active Surveillance:

The hospital is expected to identify and track infections and communicable diseases in any of the following categories occurring throughout the hospital, whether in patients or staff (patient care staff and non-patient care staff, including employees, contract staff and volunteers).

Hospitals are not required to organize their surveillance according to these categories. The categories are:

1. **Healthcare-associated infections selected by the hospital’s Infection Prevention and Control Program as part of a targeted surveillance strategy based on nationally recognized guidelines and periodic risk assessment;**
2. **Patients or staff with identified communicable diseases that local, State, or**

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- Federal health agencies require be reported;**
3. **Patients identified by laboratory culture as colonized or infected with multi-drug-resistant organisms (MDROs), as defined by the hospital’s Infection Prevention and Control Program;**
 4. **Patients who meet CDC criteria for requiring isolation precautions (other than “Standard Precautions” or a protective environment) during their hospitalization;**
 5. **Patients or staff with signs and symptoms that have been requested be reported or recorded by local, State, or Federal health agencies; and**
 6. **Staff or patients who are known or suspected to be infected with epidemiologically-significant pathogens that are identified by the hospital or local, State, or Federal health agencies.**
 7. Provisions to monitor compliance with all policies, procedures, protocols and other infection control program requirements;
 8. Provision for program evaluation and revision of the program, when indicated;
 9. Policies and procedures developed in

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coordination with federal, state, and local emergency preparedness and health authorities to address communicable disease threats, bioterrorism, and outbreaks; and

10. Procedures for meeting the reporting requirements of the local health authority.

07.01.03 Not Applicable.

07.01.04 Responsibilities of Chief Executive Officer, Medical Staff, & Director of Nursing Services.

The Chief Executive Officer, Medical Staff, and the Director of Nursing Services must:

1. *Ensure that the hospital-wide quality assessment and performance improvement (QAPI) program and training programs address problems identified by the infection control officer(s).*
2. *Be responsible for the implementation of successful corrective action plans in affected problem areas.*

The chief executive officer (CEO), the medical staff and the director of nursing (DON) must ensure that the hospital-wide Quality Assessment and Performance Improvement (QAPI) program and staff in-service training programs address problems identified through the infection prevention and control program.

To reflect the importance of infection control the regulations specifically require that the hospital’s QAPI and training programs must be involved in addressing problems identified by the infection control program, and hold the CEO, medical staff and DON jointly responsible for linking the infection control program with the QAPI and training programs. Requirements for the hospital’s QAPI program are found at 42 CFR 482.21.

These hospital leaders are also held explicitly responsible for implementing successful corrective

INTERVIEW & DOCUMENT REVIEW

1. Determine whether the hospital’s QAPI program and staff in-service training programs address problems identified by the infection control officer(s).
2. Determine whether infection control problems identified are reported to the Medical Staff, CEO and DON. Verify that hospital leadership takes steps to assure that corrective actions are implemented and successful.

- 1 = Compliant
- 2 = Not Compliant

This standard is not met as evidenced by:

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§482.42(b)
 §482.42(b)(1)
 §482.42(b)(2)

action plans. In order to accomplish this, hospital leaders must monitor adherence to corrective action plans, as well as assess the effectiveness of actions taken, with implementation of revised corrective actions as needed.

Education on the principles and practices for preventing transmission of infectious agents within the hospital should be provided to anyone who has an opportunity for contact with patients or medical equipment, e.g., nursing and medical staff; therapists and technicians, such as those involved in respiratory, physical, and occupational therapy and radiology and cardiology services; phlebotomists; housekeeping and maintenance staff; volunteers; and all students and trainees in healthcare professions.

07.01.05 Not Applicable.

07.01.06 Not Applicable.

07.01.07 Corrective Action.

The ICO shall be responsible for developing corrective action plans for problem areas identified through surveillance activities conducted.

Self-explanatory.

INTERVIEW & DOCUMENT REVIEW

Review corrective action plans developed and implemented to resolve identified issues.

- 1 = Compliant
- 2 = Not Compliant

This standard is not met as evidenced by:

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<p>07.01.08 <u>Classification of Infections.</u> There is a means of classifying infections into community acquired and healthcare acquired.</p>	<p>Definitions of healthcare acquired and community-acquired infections are based upon current CDC criteria and are applicable to both patient and staff infections.</p>	<p style="text-align: center;"><u>DOCUMENT REVIEW</u></p> <p>Review definitions utilized by the hospital. The current CDC guidelines should be evident.</p>	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>
<p>07.01.09 <u>Infection Clusters.</u> There is a mechanism for investigating infections, particularly those occurring in clusters.</p>	<p>Clustering is to be reported to the appropriate local or state health agency in conformance with local, state or federal law.</p> <p>Mechanisms are in place to investigate causes of infection.</p>	<p style="text-align: center;"><u>DOCUMENT REVIEW AND INTERVIEW</u></p> <p>Review culture summaries. Interview the infection control officer to determine actions taken regarding potential clusters of infections.</p>	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>
<p>07.01.10 <u>Infection Control Precautions.</u> Effective means are in place for preventing / controlling the transmission of infection among patients and personnel.</p>	<p>Standard precautions are appropriately employed throughout the hospital.</p> <p>The facility has adopted isolation precautions based on current CDC recommendations, for example:</p> <ul style="list-style-type: none"> • Standard precautions • Airborne precautions • Droplet precautions • Contact precautions 	<p style="text-align: center;"><u>INTERVIEW AND OBSERVATION</u></p> <ol style="list-style-type: none"> 1. Review the program and interview the ICO to assess the use of standard, airborne, droplet, and contact precautions. 2. Observe for compliance with use of standard, airborne, droplet, and contact precautions in all clinical areas. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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<p>07.01.11 Staff Orientation. The ICO contributes to the hospital-wide orientation and it's Service Education Program.</p>	<p>Infection Control information is presented upon orientation, reorientation, and on an as needed basis thereafter. The ICO presents this information and/or oversees the content presented.</p>	<p style="text-align: center;"><u>FILE REVIEW AND INTERVIEW</u></p> <ol style="list-style-type: none"> 1. See also 04.00.11. As infection control content is mandatory for clinical caregivers and highly encouraged for support staff, this content is to be noted in the orientation and reorientation curricula. 2. Interview staff to verify content is covered in orientation and during annual education programs. 	<p style="text-align: right;"> <input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant </p> <p style="text-align: right;">This standard is not met as evidenced by:</p>
<p>07.01.12 State & Local Reporting. The ICO cooperates with the disease control activities of the local (or state) health authorities.</p>	<p>In addition to the reporting of clusters (07.01.06 above) the ICO is knowledgeable regarding the reporting of other required communicable / infectious diseases.</p>	<p style="text-align: center;"><u>DOCUMENT REVIEW</u></p> <p>Review the Communicable Disease Log to determine reporting in the various categories, e.g., sexually transmitted, childhood, viral, food borne, and etc.</p>	<p style="text-align: right;"> <input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant </p> <p style="text-align: right;">This standard is not met as evidenced by:</p>
<p>07.01.13 Committee / Function Structure. The chairperson of the infection control committee (function) is a physician (Doctor of Medicine / Doctor of Osteopathic Medicine) member of the active Medical Staff.</p> <p>Other members of the professional staff are active in the infection control function.</p>	<p>Physician members of the function should be representative of the Medical Staff.</p> <p>Minimum attendance will include the following:</p> <ol style="list-style-type: none"> 1. Doctor of Medicine / Doctor of Osteopathic Medicine program coordinator 2. Infection Control Officer (ICO) 3. Administration 4. Medical staff participation by department, as 	<p style="text-align: center;"><u>DOCUMENT REVIEW</u></p> <ol style="list-style-type: none"> 1. Determine the appointments and attendance of physicians for this function. Is a pathologist or an infection disease specialist available for consult to the Medical Staff? 2. Does the committee have representation across the facility? 	<p style="text-align: right;"> <input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant </p> <p style="text-align: right;">This standard is not met as evidenced by:</p>

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The hospital shall determine the meeting frequency and attendance requirements for the Infection Control Committee. The committee must meet, at a minimum, quarterly.

appropriate.

5. Appropriate clinical staff (OB, ICU, etc)
6. Microbiology department representation
7. Housekeeping department representation
8. Central / sterile supply representation
9. Surgery department management and/or clinical representative
10. Other appropriate clinical departments as identified

One person may represent more than one area, but the areas represented must be reflected in the minutes.

07.01.14 Infection Control Plan.

The Infection Control Committee shall develop and implement an infection control plan for the hospital. The **annual** Infection Control Plan shall include the following:

- A. The plan shall encompass all departments and patient services located within the hospital. The combination of plans of all the departments / services may serve as the infection control manual for the hospital.
- B. Development of policies and

The facility has an annual Infection Control Plan approved by the Infection Control Committee (function).

DOCUMENT REVIEW

1. Review the Infection Control Committee minutes or the Medical Staff minutes when it acts as a committee-of-the-whole.
2. **Determine that the facility has an annual infection control plan.**

- 1 = Compliant
 2 = Not Compliant

This standard is not met as evidenced by:

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procedures in each department / service relative to infection prevention and control with assistance and approval of the infection control committee.

- C. Provision for cleaning and care of all equipment including a formula for every mixture prepared in the department / service for use in the cleaning procedures. Each solution shall have a proven effective spectrum of germicidal action.

07.01.15 Reporting Requirements.
Activity reports of the infection control function are discussed by the professional medical staff at least quarterly.

The infection control findings are noted in Medical Staff minutes, either as a separate or combined committee.

DOCUMENT REVIEW

Access the Medical Staff minutes to determine the frequency that infection control issues are presented.

- 1 = Compliant
- 2 = Not Compliant

This standard is not met as evidenced by:

07.01.16 Periodic Review of the Plan.
The Infection Control Committee shall review and make revisions when necessary, the hospital's Infection Control Plan at least annually.

Self-explanatory.

DOCUMENT REVIEW

1. Review minutes of the Infection Control Committee or the Medical Staff minutes when it acts as a committee-of-the-whole.
2. **Determine that the annual infection control plan has been approved by the infection**

- 1 = Compliant
- 2 = Not Compliant

This standard is not met as evidenced by:

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07.01.17 Healthcare-Associated Infections (HAI).

The Infection Control Committee (**function**) shall review at each meeting healthcare-associated infections.

- A. Establish techniques of discovering and reporting infections and tracing sources of infection of patients and hospital personnel.
- B. Establish techniques for prevention, handling, and control of institutional infections.
- C. Review findings of conditions within the hospital.

The Infection Control minutes memorialize discussions of the required elements conducted at meetings.

The infection control committee (functions) reviews healthcare-associated infections, as a subset of the hospital-wide infection report.

Observations of proper hand hygiene practices and appropriate use of alcohol-based hand rub.

control committee (function).

DOCUMENT REVIEW

1. Review the Infection Control Committee minutes or the Medical Staff minutes when it acts as a committee-of-the-whole.
2. **A review of the Infection Control minutes demonstrates the required elements have been addressed at each meeting.**

- 1 = Compliant
- 2 = Not Compliant

This standard is not met as evidenced by:

07.01.18 Quality Improvement Priorities.

The Professional Medical Staff analyzes the reports of infections in patients and staff, makes the final determination as to hospital / community linkage, and determines if there are quality improvement opportunities.

The "action" includes determinations as to linkages and for quality opportunities with assigned responsibility for follow-up.

DOCUMENT REVIEW & INTERVIEW

Determine that the actions include linkage determination and responsibility assignment for follow up on quality actions.

- 1 = Compliant
- 2 = Not Compliant

This standard is not met as evidenced by:

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07.01.19 Prevention of Infections

Central Venous Catheters.

The organization adopts nationally recognized clinical practice standards that are identified as effective in improving patient safety through the prevention of infection:

- The prevention of central venous catheter-related infections

The organization adheres to effective methods of preventing central venous catheter-related blood stream infections.

Organizational policies and procedures reflect evidence-based strategies for infection reduction and processes to monitor compliance and infection rates.

PATIENT SAFETY INITIATIVE

Vascular catheter-related infections are the leading cause of hospital-associated blood stream infections and are associated with significant morbidity in critically ill patients.

Most central venous catheter-related infections are considered preventable. Evidence shows that most central venous catheter-related infections are caused by organisms that colonize the skin at the insertion site and migrate down the extraluminal surface of the catheter through the transcutaneous tract created at the time of insertion.

Approaches for implementation are:

- 1. Before Insertion Practices, including:**
 - a. Use of aseptic technique during central line insertion.**
 - b. Disinfecting skin with an appropriate antiseptic before catheter insertion and at the time of dressing changes—preferably with a 2% chlorhexidine-based preparation; alternatively use tincture of iodine, and iodophor or 70% alcohol.**
- 2. After Insertion Practices, including:**
 - a. Disinfection of catheter hubs and injection ports before accessing the ports**
 - b. The prompt removal of the catheter as soon as it is no longer essential.**

DOCUMENT REVIEW

- 1. Verify the facility has taken actions to prevent central line-associated bloodstream infection by implementing evidence-based practices.**
2. Review the policy for central catheter insertion and care. It must reflect:
 - A. Evidence-based strategies for infection reduction, and
 - B. Define a process to monitor compliance and infection rates.

CHART REVIEW

Review patient records to determine compliance with the policy.

- 1 = Compliant
- 2 = Not Compliant

This standard is not met as evidenced by:

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<p>07.01.20 Surgical Site Infections. The organization adopts nationally recognized clinical practice guidelines that are identified as effective in improving patient safety through the prevention of infection:</p> <ul style="list-style-type: none"> • The reduction of surgical site infections (SSI's). <p>The organization ensures the evaluation of each preoperative patient in light of his or her planned surgical procedure for the risk of SSI, and implements appropriate antibiotic prophylaxis and other preventive measures based on that evaluation.</p> <p>Explicit organizational policies and procedures are in place regarding the prevention of SSI's, including selection, timing, and discontinuation of antibiotics.</p>	<p style="text-align: center;"><u>PATIENT SAFETY INITIATIVE</u></p> <p>Surgical site infections (SSI) account for 14% of hospital-acquired infections. Studies estimate that SSI's on average increase the hospital length of stay by seven days. Death may occur from sepsis secondary to SSI.</p> <p>Strategies to reduce infection in certain patients who have an increased risk of SSI include controlling blood glucose levels in diabetic patients to avoid preoperative hyperglycemia, encouraging tobacco cessation for 30 days pre-operatively, and treating infections remote from the surgical site before performing elective surgery.</p> <p>Many surgical procedures have shown a reduction in SSI's through the use of prophylactic antibiotics that are given prior to surgery in order to establish tissue levels at the time of incision and that are maintained throughout the operation. The medical literature regularly publishes recommendations and updates for prophylactic antibiotics for various surgical procedures.</p> <p>Antibiotic prophylaxis should be given for the duration of the operation only. Bowel preparation for elective colorectal surgery is also recommended. Feedback to the surgical team and OR staff of surgical infection rates is important for ongoing infection-reduction efforts.</p> <p style="text-align: center;">Approaches recommended by the National Quality</p>	<p style="text-align: center;"><u>DOCUMENT REVIEW</u></p> <ol style="list-style-type: none"> 1. Verify the facility has taken actions to prevent surgical-site infection by implementing evidence-based practices. 2. Review the organizational policies on prevention of surgical site infections for content. The policies should, at a minimum, address the elements described below. <ol style="list-style-type: none"> A. Evidence-based strategies for infection reduction, and B. Define a process to monitor compliance and infection rates. <p style="text-align: center;"><u>CHART REVIEW</u></p> <p>Review inpatient and outpatient surgical records to determine if:</p> <ol style="list-style-type: none"> 1. The risk assessment for SSI was completed; and 2. The appropriate plan of care and intervention was documented as completed. 	<p> <input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant </p> <p>This standard is not met as evidenced by:</p>

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Forum include:

1. Identify and treat all infections remote to the surgical site before elective surgery and postpone elective operations until the infection has resolved.

2. Utilize mechanical and intraluminal antibiotic bowel preparation for patients undergoing elective colorectal surgery.

3. Remove hair from the incision site only if the hair interferes with the operation by clipping (not shaving) immediately before the operation.

4. Administer prophylactic antimicrobial agent to patients based on published guidelines and recommendations targeting the most common pathogens for the planned procedure.

5. Utilize an intravenous route to administer the prophylactic antimicrobial agent and to administer the antibiotic so that a bactericidal concentration is established in serum and tissues when the incision is made (except for Cesarean delivery, when antibiotics should be administered after cord clamp).

6. Maintain therapeutic levels of the agent in serum and tissues throughout the operation and until, at most, a few hours after the incision is closed.

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7. Regularly calculate operation-specific SSI rates and report these rates to surgical team members.
8. Utilize other surgical infection prevention methods in accordance with the patient's specific clinical situation.

07.01.21 Hand-Washing Guidelines.

The hospital adopts nationally recognized clinical practice guidelines that are identified as effective in improving patient safety through the prevention of infection:

- Prevention of person-to-person transmission of infections.

Explicit organizational policies and procedures are in place regarding hand decontamination and the prevention of nosocomial infections which include:

- A. Use of alcohol-based hand rubs.
- B. Surgical hand antisepsis.
- C. Elimination of the use of artificial nails for ALL staff working in intensive care units and operating rooms.

PATIENT SAFETY INITIATIVE

Up to 10% of hospitalized patients suffer from an infection acquired while they are in the hospital. Many of these infections are transmitted via the hands of healthcare workers. Pathogenic gram-negative bacilli may survive on the hands for over two hours. The increase in antibiotic-resistant pathogens makes prevention of person-to-person transmitted infections especially important.

Although hand washing has been shown to be highly effective in preventing the transmission of pathogens within a hospital, studies have repeatedly shown that hand washing compliance rates are generally less than 50%. Studies suggest that healthcare-acquired infections are the primary cause of about 1% of in-hospital deaths and are a significant contributing factor to another 3% of deaths in hospitals.

The burden of nosocomial infection adds dramatically to morbidity resulting from the underlying diseases and generally increases hospital costs because of

DOCUMENT REVIEW

1. Verify the facility has taken actions to prevent infection by implementing evidence-based hand hygiene practices, preferably those established by the Centers for Disease Control and Prevention.
2. Review the organizational policies on hand hygiene to ensure they include, at a minimum, elements A-E.

- 1 = Compliant
 2 = Not Compliant

This standard is not met as evidenced by:

OBSERVATION

Observe hand hygiene technique throughout the organization in all areas where patient care is delivered to determine if organization policies are being followed.

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D. Natural nail tips limited to ¼ inch in length.	extended hospital stays. Although most studies of hand washing have been performed in hospital settings, nosocomial infections remain a problem in all healthcare settings.		
E. Required glove use and glove changing requirements.	The Centers for Disease Control and Prevention (CDC) “Guideline for Hand Hygiene in Health-Care Settings” recommendations are the standards of practice that serve as the template for development of organizational standards of practice.		

07.01.22 Environmental Surveillance.
In addition to reports of actual infections and communicable diseases, the ICO submits reports to the Professional Medical Staff, Safety Committee, and the Infection Control Committee / function the following:

- **Environmental surveillance activities**

The ICO conducts "walking rounds" to assess conformance with standard precautions and aseptic principles. **Environmental surveillance** reports are submitted to the Professional Medical Staff, Safety Committee, and Infection Control Committee / function for review.

Environmental surveillance reports are communicated to clinical areas, as appropriate.

Collecting cultures of the environment is discouraged unless a specific problem is being monitored.

DOCUMENT REVIEW

1. The review of minutes includes evidence that summaries of such surveillance have been discussed.
2. Environmental surveillance activities are included in the hospital wide QAPI program.

- 1 = Compliant
- 2 = Not Compliant

This standard is not met as evidenced by:

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<p>07.01.23 <u>Employee Health.</u> In addition to reports of actual infections and communicable diseases, the ICO submits reports to the Professional Medical Staff and the Infection Control Committee / function the following:</p> <ul style="list-style-type: none"> • Employee health activities 	<p>The Employee Health Plan identifies the reports to be collected and submitted quarterly for review by the Medical Staff and the Infection Control Committee / function.</p> <p>These employee health reports include:</p> <ul style="list-style-type: none"> • work days lost, • immunization rate, • employee screening, etc. <p>A process is in place to:</p> <ol style="list-style-type: none"> 1. Record employee injuries and illnesses using the OSHA mandated Form 300 “Log of Work-Related Injuries and Illnesses.” 2. Complete and post the annual OSHA Form 300A “Summary of Work-Related Injuries and Illnesses report,” per OSHA instructions. 3. Complete OSHA Form 301 “Injury and Illness Incident Report.” 	<p style="text-align: center;"><u>DOCUMENT REVIEW</u></p> <p>The review of minutes indicates:</p> <ol style="list-style-type: none"> 1. At least quarterly review of Employee Health statistics with action taken as appropriate; and 2. OSHA mandated records are maintained in accordance with OSHA requirements. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>
<p>07.01.24 <u>Employee Health Policies.</u> The Infection Control Committee shall establish and evaluate employee health policies.</p>	<p>The annual Employee Health Plan is approved by the Infection Control Committee (function).</p>	<p style="text-align: center;"><u>DOCUMENT REVIEW</u></p> <ol style="list-style-type: none"> 1. Review the Infection Control Committee minutes or the Medical Staff minutes when it acts as a committee-of-the-whole. 2. Verify the facility has an Employee Health Plan, approved annually by the Infection Control Committee (function). 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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07.01.25 Employee Health-Influenza Vaccine.

Healthcare workers **should** be vaccinated against influenza to protect both themselves and patients from influenza.

Influenza vaccinations will be made available to all healthcare workers. The vaccination status of all employees will be maintained; employees refusing vaccination shall have such refusal noted.

Explicit employee health policies and procedures will be in place to address these issues.

PATIENT SAFETY INITIATIVE

Many high-risk elderly patients do not receive influenza vaccinations or are incompletely immunized from the vaccine because of weakened immune systems. Influenza, and the pneumonia that often follows it, are major problems in institutional care settings where the number of frail elderly people creates an environment that is likely to allow the rapid spread of such infections.

Influenza causes at least 20,000 deaths each year in the United States. Healthcare workers in close contact with high-risk patients may be infected with influenza and spread the infection to other workers or patients. Vaccination of healthcare workers can prevent worker infection and worker-mediated transmission of disease among patients, but evidence shows that only about one-third of hospital workers have current vaccinations against influenza.

The National Quality Forum recommends compliance with CDC guidelines which include:

- 1. Implement the CDC Advisory Committee on Immunization Practices annual recommendations for influenza prevention and control**
- 2. Education of healthcare personnel on the benefits of the influenza vaccination and the potential health consequences of influenza illness for themselves, family members, and**

DOCUMENT REVIEW

Verify the facility has taken actions to prevent influenza by implementing evidence-based practices, preferably those established by the Centers for Disease Control and Prevention.

Review employee health policies and procedures to ensure the required components are in place. Verify:

1. Influenza vaccinations are made available to all healthcare workers.
2. The vaccination status of all employees is maintained.
3. Employees refusing vaccination is documented.

FILE REVIEW

Review employee health files. Verify:

1. All employees have been offered the influenza vaccination.
2. Employee refusal has been documented.

- 1 = Compliant
- 2 = Not Compliant

This standard is not met as evidenced by:

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patients;

- 3. Offer the influenza vaccine annually to all eligible healthcare workers
- 4. Monitor influenza vaccination coverage and declination rates during the influenza season

07.01.26 Annual Report.

The ICO prepares an annual summary of improvements in care / services resulting from the infection control program; this summary highlights activities associated with Risk Reduction.

The annual summary is dually reported to the infection control function and to QAPI. Emphasis on efficiencies in care and improvements in service are essential.

DOCUMENT REVIEW

- The review of minutes reveals the annual summary of **improvements resulting from the infection control program**. One of the actions being "to forward to QAPI".

- 1 = Compliant
- 2 = Not Compliant

This standard is not met as evidenced by:

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<p>07.02.00 Central Supply. The actions taken by the hospital to decontaminate and / or sterilize (as well as provide sterile) products meet or exceed the guidelines set forth the Centers for Disease Control and the Occupational Health and Safety Administration.</p>			<p>Scoring deferred.</p>
<p>07.02.01 Decontamination & Sterilization. There are written policies and procedures for the decontamination and sterilization techniques performed in any location of the facility approved by the infection control committee / function.</p>	<p>Policies and procedures shall be written for all types of activities relating to decontamination of supplies and equipment and protect the staff and visitors. The Infection Control committee / function shall - periodically approve these policies.</p>	<p>DOCUMENT REVIEW There is evidence that the infection control committee has reviewed the departmental policies or the chairman of the infection control committee / function with ongoing revisions consistent with CDC guidelines, OSHA, state and local laws.</p>	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>
<p>07.02.02 Required Policies. The approved policies relate to at least the following: A. Decontamination and Sterilization B. Decontamination of Reusable Items and Reuse of Single Use Devices C. Preparing, Assembling, Wrapping, Storage of, and Distribution of Sterile Equipment and Supplies</p>	<p>There shall be policies for the following functions and each shall be in compliance with established codes and / or guidelines.</p> <p>All policies shall be approved by the Infection Control Committee / Function minimally every three (3) years, or more often, as needed. The hospital shall comply with these policies.</p>	<p>The standard is scored under sections 07.02.03 through 07.02.11.</p>	<p>Scoring deferred.</p>

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- D. Monitoring Devices
- E. Sterilization Data Requirements
- F. Shelf Life
- G. Cold Sterilization
- H. Load Control Numbers
- I. Recall Process
- J. Environmental Requirements in Decontamination Rooms

07.02.03 Decontamination of Reusable Items & Reuse of Single Use Devices.

Reuse of single use devices is a decision of the hospital.

However, if reuse is approved within the organization, the FDA Reuse of Single Use Devices Guidelines must be followed. There are approved policies for the collecting, receiving, decontaminating, cleaning, disinfecting, and sterilizing of reusable instruments.

Steam sterilization may be provided via a contracted vendor.

Reuse of single use devices must be in compliance with the FDA Reuse of Single Use Devices Guidelines.

If the hospital decides to reuse single use items, its policies and practices should identify and document how the hospital assures:

1. The device can be adequately cleaned and sterilized;
2. The physical characteristics or quality of the device will not be adversely affected by reprocessing; and

DOCUMENT REVIEW & OBSERVATION

Verify:

1. Policies and procedures for the collection, receipt, and sterilization of reusable instruments are enforced.
2. Policies demonstrate and document consideration of all three processes consistent with FDA guidelines regarding reuse of single use items, if applicable.
3. Through observation and discussion with staff that the reuse policy is implemented.

- 1 = Compliant
- 2 = Not Compliant

This standard is not met as evidenced by:

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	3. The device will remain safe and effective for its intended use.		
<p>07.02.04 <u>Preparing, Assembling, Wrapping, Storage of, & Distribution of Sterile Equipment & Supplies.</u> There are approved policies for the preparing, assembly, wrapping, storage, and distribution of sterile equipment and supplies.</p>	<p>The distribution of sterile equipment policies would address the process for obtaining supplies after normal working hours.</p>	<p style="text-align: center;"><u>DOCUMENT REVIEW, OBSERVATION, & INTERVIEW</u></p> <p>Verify:</p> <ol style="list-style-type: none"> 1. Policies are in place describing all five processes. 2. Policies are enforced. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>
<p>07.02.05 <u>Monitoring Devices.</u> Policies and/or procedures govern the use of key monitoring devices, including the following:</p> <ol style="list-style-type: none"> 1. Bacteriologic spore tests are used at least weekly in all steam sterilizers; 2. Bacteriologic spore tests are used in every load of any type of pressurized gas or liquid sterilization process; and 3. Chemical indicators are used with each package which has gone through a sterilizer cycle. 	<p>Policies and procedures are developed consistent with manufacturer’s instructions and national guidelines such as CDC, CDC-HICPAC, AORN, AAMI, and etc.</p> <p>Testing is accomplished, whether or not a load is processed, to document unit capacity.</p> <p>Gas or liquid sterilization is defined as ethylene oxide, carbon dioxide, hydrogen peroxide, or any other non-steam sterilization process.</p> <p>Chemical indicators can be any of several types to demonstrate the product has gone through a sterilization process.</p> <p>Vendor contracts specify the quality controls used.</p>	<p style="text-align: center;"><u>DOCUMENT REVIEW & OBSERVATION</u></p> <ol style="list-style-type: none"> 1. Verify that policies are in place. 2. Logs are maintained for each type of quality control mechanism. 3. Review the logs to assure that frequencies are within the guidelines. 4. Determine the facility utilizes IUSS guidelines. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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<p>07.02.06 <u>Sterilization Data Requirements.</u> Temperature and pressure readings are recorded and maintained for every sterilized load.</p>	<p>A policy describes that for each sterilizer load either automatically printed values or hand written readings are maintained.</p>	<p style="text-align: center;"><u>DOCUMENT REVIEW</u></p> <p>Verify:</p> <ol style="list-style-type: none"> 1. Policy addresses requirements. 2. Implementation in the quality control logs. 	<p> <input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant </p> <p>This standard is not met as evidenced by:</p>
<p>07.02.07 <u>Shelf Life.</u> There is identification of the shelf life for each type of sterilized product used on or around any hospital patient or in or around any product or equipment that is used for patient care.</p>	<p>Time related or event related dates do not have to exist but some form of declaration shall be made for employees to understand the hospital's decision of whether the instruments are sterile for a limited amount of time or until the package / barrier is compromised.</p>	<p style="text-align: center;"><u>DOCUMENT REVIEW AND OBSERVATION</u></p> <ol style="list-style-type: none"> 1. The policy describes how long each type of package is considered sterile. It addresses commercially prepared products as well as products sterilized in the hospital. 2. Observe for compliance in all patient care areas. 	<p> <input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant </p> <p>This standard is not met as evidenced by:</p>
<p>07.02.08 <u>Cold Sterilization.</u> Descriptions exist for cold sterilization procedures utilized in the hospital.</p>	<p>A policy delineates the steps of any cold sterilization processes used in the hospital.</p>	<p style="text-align: center;"><u>DOCUMENT REVIEW AND OBSERVATION</u></p> <ol style="list-style-type: none"> 1. Verify that a policy delineates the procedures and precautions for any cold sterilization processes used. 2. Verify compliance with the policy. 	<p> <input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant </p> <p>This standard is not met as evidenced by:</p>

INFECTION CONTROL

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>07.02.09 <u>Load Control Numbers.</u> Load control numbers are used to designate the equipment used, the sterilization cycle, and date for each sterilized item.</p>	<p>There is a written procedure used to track sterilized items to a specific sterilizer load.</p>	<p style="text-align: center;"><u>OBSERVATION</u></p> <p>Verify the load control mechanism.</p>	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>
<p>07.02.10 <u>Recall Process.</u> There is a process for the recall and disposal / or reprocessing of outdated or contaminated patient care supplies / equipment.</p>	<p>If products are recalled due to ineffective sterilization, a process exists:</p> <ol style="list-style-type: none"> 1. To notify the physician(s) of patients for whom these supplies may have been used. 2. To remove the products from patient care. 	<p style="text-align: center;"><u>DOCUMENT REVIEW & INTERVIEW</u></p> <p>Review policies related to the product recall mechanism.</p> <p>Verify the policy addresses:</p> <ol style="list-style-type: none"> 1. The provision for physician notification. 2. The removal of products from patient care. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>
<p>07.02.11 <u>Environmental Requirements in Decontamination Rooms.</u> The physical environment for areas used for final decontaminating, cleaning, and / or sterilizing equipment or supplies provides for the following:</p> <ol style="list-style-type: none"> 1. Adequate space; 2. A double sink; 3. Air flow in the direction from the clean area toward the dirty area; 	<p>The facilities provided for the functions of conducting normal sterile processing activities shall not pose an undue risk to adequacy of the process or generate harm to staff or patients.</p>	<p style="text-align: center;"><u>OBSERVATION</u></p> <p>Verify:</p> <ol style="list-style-type: none"> 1. Traffic patterns, space allocation, air patterns and exchanges; and, 2. Safety monitors and protections for staff. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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and

4. An air exchange rate of at least six (6) in the clean area and at least ten (10) in the dirty area.

07.02.12 Immediate Use Steam Sterilization (IUSS) in Surgical Settings.

Immediate use sterilization (IUSS) practices are based on current nationally recognized infection control guidelines and standards of practice.

Surgical disinfection and sterilization procedures are expected to be consistent with accepted standards of practice to prevent the transmission of infectious disease and protect the health and safety of patients.

Nationally recognized organizations with expertise in infection prevention and control and instrument sterilization processes, and other professional organizations recommend abandoning the use of the term “flash” sterilization, which is now considered outmoded, and replacing it with the term “IUSS.” This change in terminology and practice should be addressed in the facility’s Infection Control Plan and implemented throughout the facility, as appropriate.

CHANGE IN TERMINOLOGY: “FLASH” STERILIZATION VS. “IUSS”

Surgical disinfection and sterilization procedures are expected to be consistent with accepted standards of practice to prevent the transmission of infectious disease and protect the health and safety of patients. The technology and terminology in this area can be a source of confusion when assessing sterilization procedures during surveys. IUSS was formerly known as “flash sterilization.”

The term “flash sterilization” is now considered by multiple organizations nationally recognized for their expertise in infection prevention and control and

DOCUMENT REVIEW AND CHART REVIEW

- A. Review the Infection Control Plan to determine that the infection prevention and control program is consistent with the national standards of practice.
- B. Determine that the Infection Control Plan has:
 - replaced the use of “flash sterilization” and
 - has adopted the term “Immediate Use Steam Sterilization” (IUSS).

If the answer to any of the following questions is “no”, a citation under the appropriate infection control CoP/CfC is warranted.

1. Is IUSS reserved for immediate use needs (e.g., used only emergently), when a needed instrument has been contaminated and there is no sterile replacement available, or for a patient care item that cannot be packaged, sterilized and stored before use)?
2. Is there a process in place to ensure IUSS is

- 1 = Compliant
 2 = Not Compliant

This standard is not met as evidenced by:

INFECTION CONTROL

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
	<p>sterilization practices and other professional organizations to be an outmoded term that should be replaced with the term “Immediate Use Steam Sterilization” (IUSS). These organizations have also recently described professionally acceptable standards of practice with respect to the use of IUSS.</p> <p>BACKGROUND INFORMATION: “FLASH” STERILIZATION VS. “IUSS” Surgical instruments must ordinarily be sterilized using terminal sterilization cycles within rigid sterilization containers, wrappers, or primary packaging designed to maintain the instruments’ sterility and which allow the devices to be stored for later use (“terminal sterilization”).</p> <p>“Flash sterilization” is a term that was traditionally used to describe steam sterilization cycles where medical instruments and devices:</p> <ul style="list-style-type: none"> • are generally not packaged in preparation for sterilization; • are subjected to an abbreviated steam exposure time and no or minimal drying time; and • are used promptly (i.e., without being stored). <p>POSITION PAPER A 2011 position paper¹ adopted by the Association for the Advancement of Medical Instrumentation (AAMI), Accreditation Association for Ambulatory Health Care (AAHC), Association of periOperative Registered Nurses (AORN), Association for Professionals in Infection Control and Epidemiology</p>	<p>not used for implants (in most circumstances, as described above); instruments used on patients with known or suspected CJD or similar disorders; devices or loads not validated with the specific cycle; and single-use devices?</p> <ol style="list-style-type: none"> 3. Are instrument(s) to undergo IUSS first cleaned and disinfected following the manufacturer’s IFU? 4. Is there evidence that all of the personnel who perform IUSS: <ul style="list-style-type: none"> • Have the necessary time, equipment, supplies and facilities readily available; • Have been trained and are able to correctly follow the manufacturer’s IFU(s) regarding IUSS with respect to each instrument, , sterilizer(s), and container(s) and cleaning supplies they are using for IUSS; and • Have had their competency initially verified before they undertake IUSS, and periodically thereafter? 5. Can personnel provide evidence that the sterilizer cycle being used for IUSS is indicated in the device manufacturer’s IFU? 	

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	<p>(APIC), ASC Quality Collaboration, Association of Surgical Technologists (AST), and International Association of Healthcare Central Service Materiel Management (IAHCSMM) (“Position Paper”) recommended that the term “flash sterilization” be abandoned and replaced by the term IUSS.</p> <p>NEW TERMINOLOGY The new term, IUSS, is still used to describe the process for steam sterilizing an instrument that is needed immediately, not intended to be stored for later use, and which allows for minimal or no drying after the sterilization cycle. ² IUSS is now the preferred term, because “flash” does not adequately convey the fact that sufficient time and a number of steps and safeguards are required to accomplish pre-cleaning procedures that are necessary to ensure sterilization.</p> <p>OLD TERMINOLOGY The old terminology is also not necessarily consistent with current recommendations for the length of cycles needed for IUSS and/or the need to use rigid sterilization containers designed specifically for IUSS. ^{3,4}</p> <p>It should be noted that IUSS is not equivalent to “short cycle” sterilization. Regardless of the cycle duration, correct use of a sterilization cycle for a wrapped/contained load that meets the device manufacturer’s instructions for use (IFU) is the equivalent of terminal sterilization and is not IUSS if</p>	<p>6. Are physical monitors used documented to record that cycle parameters are met for each load?</p> <p>7. Is there evidence that the sterilizer is being maintained as required by the manufacturer’s IFU?</p> <p>8. Is the rigid sterilization container/packaging, or tray used in a particular cycle consistent with how it is labeled by the manufacturer?</p> <p>9. Is the rigid sterilization container being used for the load consistent with its manufacturer’s recommendations for IUSS (e.g. load weight, configuration of instruments)?</p>	

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it includes use of a dry time and is packaged in a wrap or rigid sterilization container intended to be stored for later use.

PROFESSIONALLY ACCEPTED IUSS STANDARDS OF PRACTICE

Consistent with standards of practice previously articulated by national associations with expertise in infection prevention, the availability of IUSS is not considered an appropriate substitute for maintaining a sufficient inventory of instruments.^{5,6,7,8}

While IUSS will accomplish sterilization *if all of the steps before, during, and after the process are performed correctly*, and used in compliance with specific device manufacturer’s; sterilization manufacturer’s; and, if applicable, container manufacturer’s validated written instructions for use (IFU). Practices associated with the outmoded term “flash” sterilization have been implicated in surgical site infections and are considered to pose an increased risk of complications because of potential barriers to thorough completion of all necessary reprocessing steps.^{9,10,11,12,13}

IUSS also entails an increased risk of inadvertent contamination during transfer to the sterile field and damage to the instruments,¹⁴ as well as risks related to wet instruments and the potential for burns.¹⁵ Therefore use of IUSS, even when all steps are performed properly, should be limited to situations in which there is an urgent need and insufficient time

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to process an instrument by using terminal sterilization.^{16,17}

PHYSICAL MONITORS USED WITH IUSS CYCLES

Policies are designed based on device manufacturer’s written instructions for reprocessing any reusable device must be followed. The cycle parameters required to achieve sterilization are determined by the design of an instrument, the characteristics of the load, the sterilizer capabilities and the packaging.

The facility adopts policies regarding the parameters required to achieve sterilization including the physical monitoring of each IUSS cycle, including;

1. Adherence to manufacturer’s instructions for sterilization.

2. Identification of devices that are NOT compatible with IUSS.

3. The facility identifies for each IUSS cycle, the appropriate PHYSICAL MONITORS (time, temperature, pressure).

4. The policy identifies:
 - the indications for use of a Chemical Indicator (CI)

 - the indications for use of a Biological Indicator (BI),

 - the sterilization procedure,

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- use of labels, and
- frequency for testing.

07.03.00 Housekeeping.

There are policies and procedures approved by the Infection Control Committee relating to the description of the scope and practices of House-keeping, Linen Services and the hospital’s environment.

The current approved practices are available to the staff.

Housekeeping polices are reviewed and approved by the Infection Control Committee (function) at least every three (3) years.

These should include, but are not limited, to the following.

1. Cleaning Products Inventory
2. High Risk Cleaning Procedures
3. Air Supply and Return Grills
4. Maintenance of Ceilings
5. Hand-washing Sinks
6. Maintenance of Housekeeping and Laundry Equipment
7. Waste Disposal
8. Use of Personal Protective Equipment

DOCUMENT REVIEW

1. Determination shall be made as to whether the policies meet the current accepted practices of the industry and have been approved by the infection control committee.
2. **Housekeeping policies have been approved by the Infection Control Committee (function) at least every three (3) years.**

- 1 = Compliant
- 2 = Not Compliant

This standard is not met as evidenced by:

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STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>07.03.01 <u>Cleaning Products Inventory.</u> The Infection Control Committee approves the selection of cleaning products.</p>	<p>The facility maintains a current inventory / list of all cleaning products used in the organization. The list is updated as new products are introduced into the facility.</p> <p>The Infection Control Committee approves all cleaning products and dilution ratios used in the hospital. New cleaning products are approved for use prior to implementation.</p>	<p style="text-align: center;"><u>DOCUMENT REVIEW</u></p> <ol style="list-style-type: none"> 1. The Infection Control Committee minutes reflect approval of all cleaning products with the associated dilution ratios. 2. All cleaning products and dilution ratios have been reviewed and approved. 3. A cleaning product inventory is in place and is current. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>
<p>07.03.02 <u>High-Risk Cleaning Procedures.</u> There are policies and procedures for the cleaning of areas in the hospital deemed as high risk due to their special functions. These would include, but are not limited to:</p> <ol style="list-style-type: none"> 1. Surgery 2. Labor and Delivery 3. Cardiac Catheterization Lab 4. Bone Marrow Rooms 5. Central Sterile Processing 6. Newborn Nursery 7. Linen processing and etc. 	<p>Policies are accessible to staff for the proper tasks, cleaning solutions, frequencies, and tools sufficient to disinfect and reduce the spread of microbes and communicable diseases.</p>	<p style="text-align: center;"><u>DOCUMENT REVIEW & OBSERVATION</u></p> <ol style="list-style-type: none"> 1. Review of policies and observation of operations will determine if acceptable techniques are being used. 2. High-risk cleaning policies have been approved by the Infection Control Committee (function) at least every three (3) years. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

INFECTION CONTROL

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>07.03.03 <u>Air Supply & Return Grills.</u> Air supply and return grills are clean.</p>	<p>The HVAC grills do not have a build up of dust or debris.</p>	<p style="text-align: center;"><u>OBSERVATION</u></p> <p>Observation of the facilities will determine if adequate cleaning is being accomplished to prevent the build up of dust / debris on the grills. (Special care is taken to observe in the ICU, Operating Room (OR), Delivery Room, food preparation areas, etc.)</p>	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>
<p>07.03.04 <u>Maintenance of Ceilings.</u> Ceilings do not have openings to areas which cannot be cleaned regularly. Ceiling tiles do not have moisture stains/mildew.</p>	<p>Care is taken to reduce the potential that dust and other contaminants may fall from ceiling spaces into food service or patient care areas.</p> <p>Ceiling tiles are exchanged when they are moistened to minimize the potential for bacterial growth.</p>	<p style="text-align: center;"><u>OBSERVATION</u></p> <p>Observe in the sensitive areas, noted above, to determine the risk of contamination from the ceilings.</p> <ol style="list-style-type: none"> 1. Determine the ceiling tiles are clean with no evidence of dust or other contaminants. 2. Ceiling tiles are not stained. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>
<p>07.03.05 <u>Hand-Washing Sinks.</u> Each hand-washing sink has a soap dispenser and a method for hand drying.</p>	<p>Communal use of bar soap is prohibited.</p> <p>The Infection Control Committee approves the hand washing soap.</p> <p>Paper towels are preferred over blowers. Mechanisms exist to protect paper towels from surface contamination.</p>	<p style="text-align: center;"><u>OBSERVATION</u></p> <ul style="list-style-type: none"> • Determine that approved hand washing soap is readily available for staff use. • Determine that paper towels are not lying on an area where they can become contaminated. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

INFECTION CONTROL

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>07.03.06 <u>Maintenance of Housekeeping & Laundry Equipment.</u> Policies and procedures govern the care and cleaning of housekeeping and laundry equipment.</p>	<p>There are written procedures describing processes for decontaminating cleaning equipment. These include, but are not limited to:</p> <ol style="list-style-type: none"> 1. The frequency the equipment is cleaned. 2. The cleaning products used on each type of equipment. 3. Where and how the equipment is to be stored to reduce re-contamination. 	<p style="text-align: center;"><u>OBSERVATION</u></p> <p>Review of policies and observation of techniques will determine whether the hospital is following current accepted practices of the industry.</p>	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>
<p>07.03.07 <u>Waste Disposal.</u> Policies and procedures govern the proper storage and disposal of waste including biomedical and infectious.</p>	<p>There are written procedures which describe methods of holding, handling, transporting, storage, and disposal of all types of waste.</p>	<p style="text-align: center;"><u>OBSERVATION</u></p> <p>Review of policies and observation of operations will determine if acceptable methods are being used in the hospital for trash storage and disposal.</p>	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>
<p>07.03.08 <u>Use of Personal Protective Equipment.</u> Policies and procedures govern the use of personal protective equipment and hygiene of the staff conducting housekeeping and laundry functions in the hospital.</p>	<p>Individuals assuming the tasks of providing for clean facilities and linens use proper attire and personal hygiene practices to reduce the potential transmittal of diseases.</p> <p>Personal protective equipment is made available and consistently used in all departments by all personnel, per hospital policy, when exposure to biohazardous or infectious waste is possible.</p> <p>Personnel wear impervious gloves and gowns when</p>	<p style="text-align: center;"><u>OBSERVATION</u></p> <p>Review of policies and observation of staff practices meet the current accepted practices of the industry.</p>	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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appropriate to the task in order to protect skin and clothing from exposure to waste products, especially employees:

1. Working in the laundry.
2. Responsible for trash / waste removal.

07.04.01 Laundry.

Contaminated linen will be placed and stored in hampers or other holding devices which reduce the potential for particles becoming airborne and / or liquids from dripping from or absorption into the holding device.

Contaminated linen collection bags or containers will be labeled and/or color coded to communicate that the contents contain infectious materials.

Soiled linen containers will not be used for storage or transport of clean linen.

The clean portion of the laundry has positive pressure to prevent airborne contamination, in accordance with state and federal guidelines for healthcare laundry facilities.

Grossly soiled linen is stored in covered devices which are nonabsorbent in both patient care areas and non-patient care areas.

OBSERVATION

Observe operations to determine whether approved methods are consistently used for handling and storage of contaminated linen. (See 07.03.02 above.)

Contaminated containers are sanitized before use to transport clean linen.

- 1 = Compliant
- 2 = Not Compliant

This standard is not met as evidenced by:

07.04.02 Not Applicable.

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STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>07.04.03 <u>Clean Linen Storage.</u> Clean linen is stored in the hospital in a manner which reduces the potential for airborne or surface contamination.</p>	<p>Clean linen is stored in enclosed areas or in enclosed packaging.</p> <p>Clean inventory is transported in a manner to prevent the spread of dust and soil onto clean linen from transport carts and/or wheels.</p> <p>The lowest shelf of the clean linen storage and transportation carts cannot have open grates.</p>	<p style="text-align: center;"><u>OBSERVATION & INTERVIEW</u></p> <p>Observe for the storage and transport of clean linen.</p> <p>Verify:</p> <ol style="list-style-type: none"> 1. Transport carts are enclosed. 2. Clean linen storage shelves and transportation carts should not have open grating as the lowest shelf. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>
<p>07.05.01 <u>Pest Control.</u> All openings to the outside of the physical hospital shall be protected to effectively reduce the potential of the entrance of pests into the hospital.</p>	<p>Measures are taken to reduce the opportunities for insects and other pests to have access into the facilities. Outside doors have self-closing devices. Windows are permanently closed or have sufficient screening. Air intakes are sufficiently filtered. Exhaust air ducts have controlled air current.</p>	<p style="text-align: center;"><u>OBSERVATION</u></p> <p>Observe the hospital to determine whether sufficient measures have been taken to prevent pest entry.</p>	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>
<p>07.05.02 <u>Extermination Program.</u> There is a pest extermination program to control the presence and reproduction of pests. The pest control program must be safe for use around patients and staff. Use of poisons is not considered appropriate due to the potential of exposure to decomposing carcasses as well as the poison. Traps must not present a hazard to patients or staff.</p>	<p>There is an ongoing pest extermination process within the hospital. This can be provided by hospital employees or by a contracted outside service.</p>	<p style="text-align: center;"><u>OBSERVATION</u></p> <ol style="list-style-type: none"> 1. Review records of pest control. 2. Observe the availability of MSDS precautions for any chemicals. 3. Observe for exposure of patients and staff to hazardous conditions. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

MATERIALS MANAGEMENT

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>08.00.01 <u>Inventory.</u> An appropriate inventory of non-expired supplies is provided to support the services offered to the patients.</p> <p>A process is in place to assure that outdated / expired supplies are not used.</p>	<p>The purchasing service orders and stocks supplies in a manner so as to reduce the potential of inventory outage or backorder for essential commodities.</p> <p>The use of out-dated / expired supplies should not occur.</p>	<p><u>OBSERVATION AND INTERVIEW</u></p> <p>Observe supply carts, cabinets, and storeroom(s) and interview staff.</p> <ol style="list-style-type: none"> Determine if there are out-dated / expired supplies present. Determine if there are shortages, frequent back orders, or inappropriate substitutions of essential supplies. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>
<p>08.00.02 <u>Supplies for Patient Care.</u> The commodities supplied to the patient care and support services meet the needs of each group.</p>	<p>The supplies are of the sizes and quantities needed to accommodate the requirements of the procedures / tasks to be performed.</p>	<p><u>OBSERVATION AND INTERVIEW</u></p> <p>Observe supply carts, cabinets, and storeroom(s) and interview staff.</p> <ul style="list-style-type: none"> Determine the availability of the necessary variety of supplies. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>
<p>08.00.03 <u>Safe Storage of Supplies.</u> The commodities supplied to the patient care and support services are stored in such a manner so as to protect them from damage or loss from moisture, thermal change, rodents, vermin, or theft.</p>	<p>The supplies are off floor surfaces by at least four (4) inches.</p> <p>Supplies are grouped / segregated by type.</p> <p>Hazardous chemicals are not stored with food products, dressings or medications.</p> <p>Supplies requiring special temperature ranges are identified and stored accordingly.</p>	<p><u>OBSERVATION</u></p> <p>Observe supply carts, cabinets, and storeroom(s) for these conditions.</p> <ul style="list-style-type: none"> Determine supplies are off the floor and stored in a manner so as to protect them from damage and theft. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

MATERIALS MANAGEMENT

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>08.00.04 Policies on Supply Availability. A policy and procedure is in place that specifies the type of supply products to be purchased or to be kept in stock.</p>	<p>The policies and procedures are approved by administration and represent sound practices for the acquisition, storage and delivery of materials to the facility.</p> <p>Emergency and contingency plans are formally documented and known by both material management personnel and supervisory staff.</p>	<p>DOCUMENT REVIEW</p> <p>Review policies and procedures. Determine the facility has policies pertaining to materials including:</p> <ul style="list-style-type: none"> • Acquisition • Delivery • Storage • Emergency acquisition 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>
<p>08.00.05 Special Storage Requirements. Supply storage will consider and accommodate the special needs of flammable and hazardous materials to protect both patients and staff from exposure to fire and/or hazardous conditions and materials.</p> <p>Storage issues that require special consideration may include, but is not limited to bulk alcohol storage, poisons, gas tank storage, formalin, etc.</p>	<p>Self- explanatory.</p>	<p>OBSERVATION & BUILDING TOUR</p> <p>Observe for safe storage of hazardous and flammable materials.</p> <ul style="list-style-type: none"> • Consider the volume of materials being stored as well as accessibility to patients, including pediatric patient or pediatric visitor access, to hazardous materials. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

MATERIALS MANAGEMENT

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>08.00.06 Product Recall. Processes, policies and procedures are in place to provide for an effective product recall system that include the following:</p> <ol style="list-style-type: none"> 1. Receipt and distribution of recall notices. 2. Identification of product availability within the hospital. 3. Notification of recalls to appropriate departments / staff. 4. Verification of recall of all available products. 	<p>Self-explanatory.</p>	<p><u>DOCUMENT REVIEW, OBSERVATION & INTERVIEW</u></p> <ol style="list-style-type: none"> 1. Verify the facility has a policy with all required elements in place. 2. Verify that the policy for product recall has been implemented. 3. Verify staff are aware of the process for notification and recall of products. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

EMERGENCY MANAGEMENT

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>Planning.</p> <p>09.00.01 Emergency Operations Plan. A written Emergency Operations Plan (EOP) is developed, maintained, and available to the staff for crisis preparation and response.</p> <p>The organization reviews the EOP on an annual basis and makes adjustments based on lessons learned during actual emergency events and during planned exercises.</p> <p>The EOP is based on the priorities established in the annual Hazard Vulnerability Analysis (HVA), and the EOP is reviewed with the community's emergency response agencies to synchronize responses to common emergency events.</p> <p>The EOP is reviewed with the community emergency preparedness agency.</p>	<p>Emergency preparedness is necessary to ready the hospital for possible and probable emergency events that may affect the patient care processes and normal hospital operations.</p> <p>There shall be a written Emergency Operations Plan (EOP) and associated procedures for possible situations to be followed by each department and/or service within the hospital and for each building utilized for patient treatment and/or housing. The organization may choose to have one EOP that is inclusive for all of their facilities where patients are treated and housed, or they may choose to have individual EOPs for each location.</p> <p>The hospital uses its annual Hazard Vulnerability Analysis (HVA) as a foundation for the Emergency Operations Plan to determine the activities designed to reduce the risk associated with emergency events. The hospital shares the details of the EOP with the community's emergency response agencies. The hospital assesses the community's abilities to meet the needs of the hospital during an emergency event. This involvement with the community and the assessment of the community's abilities is documented.</p> <p>The Emergency Operations Plan must be integrated into the facility-wide Quality Assurance Performance Improvement (QAPI) plan.</p> <p>When creating the EOP, consideration should be given</p>	<p style="text-align: center;"><u>DOCUMENT REVIEW AND INTERVIEW</u></p> <ul style="list-style-type: none"> • Review the Emergency Operations Plan to determine its applicability with the potential emergencies identified in the Hazard Vulnerability Analysis (HVA). • Was the EOP reviewed with local authorities? • Does the hospital share their plans and abilities with the local authority in community emergency preparedness during the planning phase as well as the implementation phase? <p>Verify:</p> <ul style="list-style-type: none"> • Emergency Management is integrated into the facility-wide QAPI Plan. • Emergency Management related data is collected and utilized to improve the quality of patient care and patient safety. Improvements are monitored to insure improvement in outcomes / results. • Review documentation to ensure the EOP was shared with local authorities and reviewed with the community emergency preparedness & response plan. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>COMMENTS:</p>

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to the four phases of Emergency Management:

- Mitigation
- Preparedness
- Response
- Recovery

Refer to NFPA 99 (2012 edition), Health Care Facilities, **Chapter 12** for guidance on the development of the EOP, development of the committee with oversight on emergency management, including setting up an incident command system and designation of incident commander in an all hazards approach. When creating the EOP, emergency response considerations should be given to special populations within the hospital, which include pediatric, ICU and Neonatal patients.

The EOP includes a plan for the influx or a surge of patients, and must be **reviewed by the** community's emergency response **agency**.

A reference for use in creating the EOP:

[U.S. Department of Health and Human Services / Assistant Secretary for Preparedness and Response \(ASPR\), Medical Surge Capacity and Capability <http://www.phe.gov/PREPAREDNESS/PLANNING/MS/CC/Pages/default.aspx>](http://www.phe.gov/PREPAREDNESS/PLANNING/MS/CC/Pages/default.aspx)

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<p>09.00.02 Emergency Hazard Vulnerability Analysis (HVA). The Emergency Operations Plan provides for an assessment to ascertain conceivable threats and disasters that could affect the ability to operate the facilities of the organization, or to provide services to their patients, and the probability of those events occurring.</p> <p>The hospital’s Hazard Vulnerability Analysis (HVA) must be shared with the community’s emergency response agencies. The hospital must identify likely hazards for their community service area (e.g., natural disaster, bioterrorism threats, disruption of utilities such as water, sewer, electrical communications, fuel, nuclear accidents, industrial accidents, and other likely mass casualties, etc.) and develop appropriate responses that will assure that safety and wellbeing of patients.</p> <p>The Hazard Vulnerability Analysis (HVA) is documented and reviewed by the oversight committee on emergency management for relevancy and accuracy on an annual basis.</p>	<p>The hospital may choose to create a single Hazard Vulnerability Analysis (HVA) that applies to all of the sites of the hospital, or an individual Hazard Vulnerability Analysis (HVA) for each of their locations.</p> <p>All facilities where patient care and treatment is provided are required to have an assessment conducted for hazards, including facilities which the hospital may not own but where they provide treatment for their patients. Some remote locations may have different hazards and therefore a separate Hazard Vulnerability Analysis (HVA) would be appropriate.</p> <p>Hospitals must prioritize the potential hazards to their organization, and these priorities are documented in the Hazard Vulnerability Analysis (HVA). The hospital shares their HVA with their community partners to help set priorities with the Hazard Vulnerability Analysis (HVA).</p> <p>Community partners may include:</p> <ul style="list-style-type: none"> • The department of public health • The department of public safety • The department of public works • Local municipality representatives • Other government agencies • Community organizations • Vendors • Other health care organizations 	<p style="text-align: center;">DOCUMENT REVIEW</p> <ul style="list-style-type: none"> • Verify that the Hazard Vulnerability Analysis (HVA) is reviewed by the organization and updated annually. • Confirm that the hospital shared their HVA with one or more community partners. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>COMMENTS:</p>

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Response & Recovery

09.01.01 Emergency Safety & Security.

The Emergency Operations Plan provides for a comprehensive process to provide for the safety and security of the patients, staff and visitors during an emergency event.

During an emergency event, patients, visitors and staff must be protected from threats concerning security. Policies, procedures and systems must be developed to monitor and reduce adverse outcomes. The organization identifies and implements a process on how supplemental security resources are obtained in the event of a disaster.

The Emergency Operations Plan must address the following:

1. The differing needs of each location where the hospital operates;
2. The special needs of patient populations treated at the hospital (e.g., patients with psychiatric diagnoses, patients on special diets, newborns, etc.);
3. Security of patients and walk-in patients;
4. Security of supplies from misappropriation;
5. Pharmaceuticals, food, other supplies and equipment that may be needed during emergency / disaster situations;
6. Communication to external entities if telephones and computers are not operating or become overloaded (e.g., ham radio operators, community officials, other healthcare facilities if

DOCUMENT REVIEW

- Review the Emergency Operations Plan (EOP) to verify that the hospital has developed and implemented a comprehensive plan to ensure that the safety and wellbeing of patients are assured during emergency situations.
- Review Emergency Operations Plan to determine how supplemental emergency forces are obtained.
- Determine if policies, procedures and systems are in place to provide emergency safety and security services. Review documents to determine if the emergency security program is effective.

- 1 = Compliant
- 2 = Not Compliant

COMMENTS:

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	transfer of patients is necessary, etc.);		
	7. Communication among staff within the hospital itself;		
	8. Qualifications and training needed by personnel including healthcare staff, security staff, and maintenance staff, to implement and carry out emergency procedures;		
	9. Identification, availability and notification of personnel that are needed to implement and carry out the hospital's emergency plans;		
	10. Identification of community resources, including lines of communication and names and contact information for community emergency preparedness coordinators and responders;		
	11. Provisions if gas, water, and/or electricity supply is shut off to the community;		
	12. Transfer or discharge of patients to home, other healthcare settings, or other hospitals;		
	13. Transfer of patients with hospital equipment to another hospital or healthcare setting;		
	14. Managing volunteers and convergent responders;		
	15. Methods to evaluate repairs needed and to secure various materials and supplies to effectuate repairs.		

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<p>09.01.02 Emergency Supplies. The Emergency Operations Plan provides for a plan and a process to ensure supplies and equipment are stored, maintained, and ready for immediate use in the event of an emergency.</p> <p>The plan provides for how the hospital will replenish the supplies and equipment after the emergency event begins.</p> <p>All supplies and equipment designated for emergency response are documented, and reviewed and updated semi-annually.</p>	<p>During an emergency event, the availability of supplies needed at the beginning of the event is critical for an effective response.</p> <p>The Office of the Assistant Secretary for Preparedness and Response (ASPR) states that organizations should be prepared to “stand on their own” for at least 72 hours before an organized Federal response can effectively relieve the situation. That benchmark must be considered when identifying the supplies and equipment that are required to shelter in place or effect an orderly evacuation.</p> <p>The amount and type of emergency supplies and equipment is left to the individual facility to determine but must be based on the reality of their EOP.</p> <p>Emergency supplies and equipment must be maintained to ensure an acceptable response at the beginning of an event. This would require the supplies and equipment are stored in such a manner to ensure their safety (protection against theft or damage, contamination, or deterioration) and availability when needed.</p> <p>The hospital identifies in writing the supplies it will need to potentially meet the needs of patients in an emergency situation.</p> <p>The hospital makes provisions to ensure the availability of those supplies when needed.</p> <p>The hospital identifies the equipment it will require to</p>	<p><u>INTERVIEW AND DOCUMENT REVIEW</u></p> <ul style="list-style-type: none"> Interview the person in charge of Emergency Management and determine if there are supplies identified and stored for the first response phase of an emergency. Determine if the organization has reviewed and updated the emergency supply list on a semi-annual basis. Review the Emergency Operations Plan to ensure the EOP provides for the supplies and equipment needed in the initial phase of an emergency event. Has the hospital identified supplies and equipment that are likely to be needed in emergency situations? Has the hospital made adequate provisions to ensure the availability of those supplies and equipment when needed? 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>COMMENTS:</p>

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meet the patients’ needs for an emergency situation.

The hospital makes adequate provisions to ensure the availability of that equipment when needed.

The hospital must have a plan to protect these limited emergency supplies and must have a plan for prioritizing their use until replacement supplies are available. The plan must also address the events of a disruption in the supply chain for these emergency utilities, such as a disaster involving the entire surrounding community.

09.01.03 Emergency Utilities.

The Emergency Operations Plan provides for the continuation of emergency power, fuel, medical air, gas, and vacuum, and potable water during an emergency event.

*There **must** be facilities for emergency gas and water supply.*

§482.41(a)(2)

The hospital must ensure the continuation of operation of strategic utilities during an emergency event, including:

- emergency power;
- fuel for generators and boilers;
- medical air, gas and vacuum; and
- potable water.

The hospital needs to document what areas of the facility are served by emergency power, and what areas are not.

The hospital must have written agreements which are updated annually with vendors, suppliers, or others to provide for the following utilities during an emergency event:

- Service and repairs for the generators
- Replenishment of fuel for generators and boilers
- Portable cylinders of medical air and medical

DOCUMENT REVIEW AND INTERVIEW

- Verify that the utility supplies for emergency power, fuel, medical air, gas and vacuum, potable water, and non-potable water is appropriate for the size of the hospital operations, the services provided and the number of staff and inpatients.
- Verify the written agreements to replenish the supplies for the emergency utilities are updated annually.
- Review the plan used to determine the quantity of potable water meets the needs of all the staff and inpatients during an emergency event.

- 1 = Compliant
- 2 = Not Compliant

COMMENTS:

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- gas
- Portable vacuum
- Drinking water
- Non-potable water for processing

The hospital shall determine the quantity of fuel supply to have on hand for the emergency generators and boilers. This quantity is based on the circumstances of the hospital and the availability of replacement fuel.

At a minimum, the quantity of fuel maintained for the emergency generators must be at least a 26 hour supply, as required by NFPA 72 (2010), for the fire alarm system. For installations in seismic areas, compliance for maintenance of fuel supply for generators must comply with NFPA 110 (2010 edition).

Whatever quantity of fuel is maintained, consideration must be given to its capability to replenish the fuel supply before it is exhausted.

Documentation

The hospital shall maintain documentation of its fuel supply needs and its procedures for fuel replenishment in times of emergency. If the hospital uses the same fuel supply for multiple uses, (heating, hot water, generator, etc.) the hospital must maintain fuel supplies to address its total needs and to address periods where re-supply may be limited (i.e. snow, flooding, transportation disruption, etc.).

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09.01.04 Emergency Decontamination.
For hospitals that receive emergency patients, the Emergency Operations Plan (EOP) provides how the hospital arranges for the chemical, biological and radioactive decontamination.

Decontamination procedures must be in place for internal and external accidents. The hospital designates teams to respond to emergency events and initiate the decontamination procedures. A plan describing the decontamination procedures can be integrated into a single plan or multiple plans.

During an emergency, aspects of the physical environment must contain, neutralize, or destroy potentially harmful materials and wastes. The procedures for the cleanup of spills and accidents must include the notification of the appropriate authorities based on the size and severity of the spill and hospital resources available.

Resources for decontamination planning include:

[OSHA Best Practices for Hospital-Based First Receivers of Victims from Mass Casualty Incidents Involving the Release of Hazardous Substances: https://www.osha.gov/dts/osta/bestpractices/html/hospital_firstreceivers.html](https://www.osha.gov/dts/osta/bestpractices/html/hospital_firstreceivers.html)

US DOL OSHA 29 CFR 1910.120 Hazardous Materials waste operations and emergency response: https://www.osha.gov/pls/oshaweb/owadisp.showdocument?p_table=standards&p_id=9765

This standard does not apply to hospitals that do not receive emergency patients.

DOCUMENT REVIEW AND OBSERVATION

- Review Emergency Operations Plan to ensure decontamination planning activities are addressed.

- 1 = Compliant
- 2 = Not Compliant
- N/A

COMMENTS:

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<p>09.01.05 <u>Emergency Personal Protective Equipment.</u> The Emergency Operations Plan provides how the hospital stores and maintains Personal Protective Equipment, and distributes them during the event of an emergency.</p>	<p>The selection, storage and distribution of the appropriate Personal Protective Equipment (PPE) is dependent on the product, specific Safety Data Sheets (SDS) and the organization’s Hazardous Material and Waste plan.</p> <p>The selection of PPE is not limited to hazardous materials and waste but must include any infectious disease exposures as indicated.</p> <p>The plans for PPE can be integrated into a single procedure or multiple plans. All plans for PPE must be integrated and included into the Emergency Operations Plan.</p> <p>Personal Protective Equipment (PPE) that is stored and maintained is documented and updated semi-annually.</p>	<p style="text-align: center;"><u>OBSERVATION</u></p> <ul style="list-style-type: none"> • Review the Emergency Operations Plan to determine the organization’s selection process of PPE meets the anticipated needs during an emergency. • Review where the PPE is stored to determine if stock meets the anticipated needs during an emergency. • Review the plans for the distribution of PPE during an emergency. • Determine if the hospital updated the PPE list on a semi-annual basis. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>COMMENTS:</p>
<p>09.01.06 <u>Emergency Nutritional Services.</u> The Emergency Operations Plan (EOP) provides for methods to ensure the nutritional needs of patients and personnel during an emergency event.</p>	<p>The Emergency Operations Plan (EOP) describes the strategies for ensuring nutritional needs are met during situations in which hospital services or utilities are disrupted.</p> <p>The plan outlines methods for meeting the nutritional needs of patients, visitors, and personnel while awaiting evacuation or the return to normal hospital operations. During an emergency event, the facility may experience a disruption in one or multiple services, such as:</p> <ol style="list-style-type: none"> 1. Loss of water, gas, fuel, or electricity; 	<p style="text-align: center;"><u>DOCUMENT REVIEW</u></p> <p>Verify that the Emergency Operations Plan addresses methods for ensuring the nutritional needs of patients and personnel are met during emergencies, including major facilities disruption.</p> <p>Review the written agreements with the food suppliers to determine that they have been updated annually.</p>	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>COMMENTS:</p>

EMERGENCY MANAGEMENT

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	<ol style="list-style-type: none"> 2. Equipment failure, e.g., dishwashing machines, pumps, refrigeration, cooking appliances; 3. Disruption with the delivery and grocery and food preparation items. <p>The Emergency Operations Plan anticipates the possible disruptions and prepares strategies, in advance, for ensuring continuity of services, including:</p> <ol style="list-style-type: none"> 1. Alternative methods for heating foods and water used for cooking. 2. A disruption with delivery of food products. <p>The hospital has written agreements with food suppliers for priority grocery delivery. The written agreements are updated on an annual basis.</p> <p>The hospital calculates the volume of food, drinking water, paper products, and utensils needed to feed the patients, staff, and visitors for at least three (3) days. The hospital stores a 3-day inventory of:</p> <ol style="list-style-type: none"> 1. Fresh and frozen foods 2. Dairy products 3. Drinking water 4. Paper products 5. Special dietary requirements, e.g., diabetic, Kosher, and vegetarian diets 		

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<p>09.01.07 Emergency Communications. The Emergency Operations Plan (EOP) provides for written procedures and methods on how the hospital communicates with staff and outside agencies that have a functional role with the hospital’s response and recovery phases during an emergency event.</p> <p>The procedure must include a tiered rapid process for alert and notification of staff in an emergency. This includes staff mobilization and communications call-back processes used at the beginning of an emergency event.</p> <p>The procedure must also include how the hospital will communicate with outside agencies, such as:</p> <ul style="list-style-type: none"> • Emergency response agencies • The community and the media • Suppliers of essential supplies and services • Other healthcare organizations <p>The procedure arranges for the dispensing provision of information by hospital designated spokespersons to the media.</p>	<p>Reliable communication must be maintained by the hospital during an emergency event and through to the recovery phase.</p> <p>Backup technology must be considered and utilized with the consideration that traditional methods of communication may not be available. Alternative methods must be explored and planned for in the written procedure.</p> <p>All hospital units and departments must have a process in place to initiate the call back of staff on each unit. Staff must be able to make external notifications and demonstrate the capability to share information with the incident commander and necessary external partners.</p> <p>The Emergency Operations Plan must include a process for the notification of key personnel who are either at the hospital or away from the hospital whenever the Incident Command System is activated.</p> <p>The staff call-back roster is dated and is updated at least semi-annually. NOTE: Real-time electronic tracking systems of current and former staff members are deemed to meet the requirement for semi-annual updates.</p> <p>The Emergency Operations Plan identifies the location where the media will be briefed.</p>	<p style="text-align: center;"><u>DOCUMENT REVIEW</u></p> <ul style="list-style-type: none"> • Review the emergency communications process and determine that it meets the requirement for communication with staff and outside agencies. • Determine if the staff call-back roster has been updated semi-annually. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>COMMENTS:</p>

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<p>09.01.08 Incident Command Center. The Emergency Operations Plan provides for the identification where the hospital’s incident command center will be located. The EOP ensures essential equipment and support is intact and maintained for use in directing and controlling response and recovery operations. The EOP provides for a process for activation of the incident command center, and how it is operated.</p>	<p>There is a reference in the Emergency Operations Plan to the location of the command center for directing and controlling hospital emergency response functions. The plans and procedures also include or reference a layout diagram; a list of facility equipment (e.g., telephones, displays, fax machines, computers), and the source(s) of backup power (if available).</p>	<p><u>DOCUMENT REVIEW AND OBSERVATION</u></p> <ul style="list-style-type: none"> • Review the Emergency Operations Plan to determine that the command center is identified. • Review the Emergency Operations Plan to determine that the organization’s command center setup process includes instructions and drawings. • Determine if a list of facility equipment and supplies meets the anticipated needs during an emergency. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>COMMENTS:</p>
<p>09.01.09 Emergency Triage. For hospitals that receive emergency patients, the Emergency Operations Plan (EOP) provides for the triaging of victims during an emergency event and includes identification tags, placement of patients, notification of physicians, and preliminary diagnosis of patients.</p>	<p>Where the potential for chemical, biological, radiological, nuclear or explosive (CBRNE) exposure victims apply, the organization must coordinate decontamination activities that meet the needs of the victim. Additional concerns include proper selection of personal protective equipment (PPE) for those performing decontamination, and the prevention of the contamination of the emergency department.</p>	<p style="text-align: center;"><u>DOCUMENT REVIEW</u></p> <ul style="list-style-type: none"> • Review the Emergency Operations Plan (EOP) to determine that the decontamination activities meet the needs of the potential victims. • Interview staff to determine training was conducted for decontamination activities. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant <input type="checkbox"/> N/A</p> <p>COMMENTS:</p>
<p>Where applicable, the Emergency Operations Plan (EOP) must address handling of exposure victims from Chemical, Biological, Radiological, Nuclear and Explosive (CBRNE) incidents.</p>	<p>Recommended guidance can be found at: OSHA Best Practices for Hospital-Based First Receivers of Victims from Mass Casualty Incidents Involving the Release of Hazardous Substances:</p> <p>https://www.osha.gov/dts/osta/bestpractices/html/hospital_firstreceivers.html</p> <p>For communicable disease outbreaks, concerns</p>	<ul style="list-style-type: none"> • Determine if the Emergency Operations Plan (EOP) addresses preparedness and response to CBRNE victims (where applicable), selection of PPE and protection of the first responder when decontaminating patients. 	

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include:

- isolation,
- cross contamination,
- staff exposure,
- prevention of the spread of the disease,
- identification of most likely potential toxic agents,
- pharmacy considerations,
- laboratory considerations, and
- infection control.

Notification of the public health department and other authorities is required whenever an emergency event is declared, and/or whenever the Incident Command system is activated.

The hospital conducts training activities on decontamination of victims. The frequency of this training is determined by the organization, based on the potential for victims that would require decontamination.

The need for a hospital to have decontamination capabilities is not reduced where governmental agencies provide decontamination in the field.

This standard does not apply to hospitals that do not receive emergency patients.

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<p>09.01.10 <u>Emergency Evacuation.</u> The Emergency Operations Plan (EOP) provides for a written Emergency Evacuation Plan which identifies when and how the patients will be evacuated from the facility.</p> <p>The Emergency Evacuation Plan is reviewed by the community emergency response agency.</p>	<p>A written Emergency Evacuation Plan must be created which identifies when and how the hospital will evacuate patients from the hospital when it is no longer safe to provide patient care and treatment services at the facility.</p> <p>The written Emergency Evacuation Plan must be reviewed with the local community emergency response agency.</p> <p>Additional evacuation procedures for specialty patient care units must be developed and incorporated into the Emergency Evacuation Plan.</p>	<p><u>DOCUMENT REVIEW AND OBSERVATION</u></p> <ul style="list-style-type: none"> • Review the Emergency Operations Plan to determine if it provides for the Emergency Evacuation Plan. • Review documentation from the local authorities to determine if the Emergency Evacuation Plan was reviewed by the local community emergency response agency. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>COMMENTS:</p>
<p>09.01.11 <u>Volunteer Management.</u> For hospitals that receive emergency patients, the Emergency Operations Plan (EOP) provides for a volunteer management plan that assigns, trains, and supervises volunteers during an emergency event.</p> <p>The hospital shall review the volunteer management plan with other local hospitals and healthcare systems and local emergency management agencies.</p>	<p>The facility must have a plan to verify each volunteer's identity, license, credentials, certifications, and hospital privileges, within 72 hours of activating the Incident Command Center, when possible. Federal, local or state-based systems shall be utilized to verify the identity and credentials of health professionals, when possible.</p> <p>Any special issues, such as spontaneous non-medical volunteers, stress management for volunteers, and legal issues, such as workers' compensation, insurance, and safety are addressed in advance and included in the EOP.</p> <p>Recommended guidance can be found at: http://www.phe.gov/esarvhp/Pages/faqs.aspx</p>	<p><u>DOCUMENT REVIEW</u></p> <ul style="list-style-type: none"> • Review the Emergency Operations Plan (EOP) to determine if it includes a volunteer management program. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant <input type="checkbox"/> N/A</p> <p>COMMENTS:</p>

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The hospital develops and implements volunteer management planning and response training. The hospital provides training for each volunteer team member. This training and education is documented.

This standard does not apply to hospitals that do not receive emergency patients.

09.01.12 Business Continuity.

The Emergency Operations Plan includes a continuity planning component which identifies key clinical and business functions and the strategies required to recover them with minimal disruption to clinical operations during the recovery phase of an emergency.

The hospital conducts a business impact analysis to identify time-sensitive or critical business functions and the resources that support them. The hospital must identify, document, and implement processes to recover critical business functions and processes.

The hospital develops a business continuity plan to manage clinical and business disruption. Emergency exercises conducted by the hospital evaluate the effectiveness of the recovery strategies in the business continuity plan.

DOCUMENT REVIEW

- Review the Emergency Operations Plan (EOP) to determine that the business continuity plan and associated implementation procedures are included.
- Review the emergency exercises to ensure recovery strategies from the business continuity plan are evaluated.

- 1 = Compliant
- 2 = Not Compliant

COMMENTS:

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Exercises & Education

09.02.01 Emergency Exercises.

For all healthcare occupancy and ambulatory healthcare occupancy facilities that provide patient care, the Emergency Operations Plan (EOP) provides for separate emergency exercises to be performed twice per year. At least one of the exercises shall include the community.

For business occupancy buildings that provide patient care, the Emergency Operations Plan (EOP) provides for separate emergency exercises to be performed once per year.

Each exercise is to be planned by the oversight committee on emergency management and implemented to build competencies in staff. Each exercise must be based on one of the identified priorities in the Hazard Vulnerability Analysis (HVA).

Every emergency exercise must include the activation of the hospital’s Incident Command System. At least one emergency exercise per year shall include the community and have substitute patients (actors or paper descriptions of the injuries). Responses to real emergencies may be used if separated by at least four months from the last emergency or exercise.

Each implementation (either actual emergency or an exercise) shall be evaluated by several trained observers located in strategic areas to record the responses of the staff and the processes being followed. The emergency management committee uses this information to improve the hospital’s capability to respond to emergencies, and to make improvements to the Emergency Operations Plan. The emergency committee submits reports to hospital leadership, and as appropriate, state and Federal entities.

Table-top drills, while useful in the planning phase, are not an acceptable substitute for these exercises.

Buildings classified as healthcare and/or ambulatory healthcare occupancies are required to conduct two exercises within the past calendar year.

Buildings classified as business occupancies and provide patient care activities are required to perform one drill within the past calendar year.

DOCUMENT REVIEW

- Review the evaluation records of the emergency exercises.
- Assure that all after-action plan items have been documented in the oversight committee on emergency management meeting minutes and the Quality Assurance Performance Improvements (QAPI) minutes.
- Ensure that each exercise is based on one of the identified Hazard Vulnerability Analysis (HVA) hazards.
- **Ensure that buildings classified as healthcare occupancy or ambulatory healthcare occupancy each receives at least two drills within the past calendar year.**
- **Ensure that buildings classified as business occupancies and provide patient care activities each receives at least one drill within the past calendar year.**

- 1 = Compliant
- 2 = Not Compliant

COMMENTS:

EMERGENCY MANAGEMENT

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>09.02.02 Emergency Education. The Emergency Operations Plan (EOP) provides for an educational program on activities, assignments and duties each staff member is responsible for during an emergency event.</p> <p>The hospital shall integrate the Emergency Education program within all hospital departments.</p>	<p>The hospital develops and implements specialized emergency response teams and provides annual training and education on responsibilities for each team member.</p> <p>This training and education is documented.</p> <p>Incident Command Management training must be provided to the appropriate staff members as described in the National Incident Management System (NIMS) Implementation Activities for Hospitals and Healthcare Systems:</p> <p>http://www.fema.gov/pdf/emergency/nims/imp_hos.pdf</p>	<p><u>DOCUMENT REVIEW AND FILE REVIEW</u></p> <ul style="list-style-type: none"> Review the Emergency Operations Plan to determine if an education program is part of the emergency management process. Review the education program to determine if it is implemented for all staff in all departments. Verify by interview that staff and physicians have been trained. Review employee files to verify disaster preparedness education has been provided annually. This education must include basic emergency preparedness and response procedures for the employee’s specific area of responsibility. Based on National Incident Management System, certain identified members of the staff must have Incident Command Management training as designated by Federal guidance for hospitals and healthcare systems. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>COMMENTS:</p>

EMERGENCY MANAGEMENT

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
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MEDICAL RECORDS (HEALTH INFORMATION) SERVICES

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>10.00.00 Condition of Participation: Medical Record Services. <i>The hospital must have a medical record service that has administrative responsibility for medical records.</i></p> <p><i>A medical record must be maintained for every individual evaluated or treated in the hospital.</i></p> <p>§482.24</p>	<p>The facility should have an organizational plan, which shows the responsible person for medical records (health information) of every individual treated at the facility.</p> <p>The term “hospital” includes <u>all locations of the hospital</u>.</p> <p>The hospital must have <u>one unified</u> medical record service that has administrative responsibility for all medical records, both inpatient and outpatient records.</p> <p>The hospital must create and maintain a medical record for every individual, both inpatient and outpatient, evaluated or treated in the hospital.</p> <p>The term “medical records” includes at least written documents, computerized electronic information, radiology film and scans, laboratory reports and pathology slides, videos, audio recordings, and other forms of information regarding the condition of a patient.</p>	<p align="center"><u>DOCUMENT REVIEW AND INTERVIEW</u></p> <ol style="list-style-type: none"> Review the organizational structure and policy statements. Interview the person responsible for the medical record (health information) service to determine that it is structured appropriately to meet the needs of the facility and the patients. <p align="center"><u>CHART REVIEW</u></p> <p>Review a sample of active and closed medical records for completeness and accuracy in accordance with Federal and State laws and regulations and hospital policy.</p> <ul style="list-style-type: none"> The sample should be 10 percent of the average daily census and be no less than 30 records. Additionally, select a sample of outpatient records in order to determine compliance in outpatient departments, services, and locations. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>
<p>10.00.01 <u>Not Applicable.</u></p>			

MEDICAL RECORDS (HEALTH INFORMATION) SERVICES

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>10.00.02 Organization & Staffing. <i>The organization of the medical record service must be appropriate to the scope and complexity of the service performed.</i></p> <p><i>The hospital must employ adequate personnel to ensure prompt completion, filing, and retrieval of records.</i></p> <p>§482.24(a)</p>	<p>The medical records service must be organized, equipped, and staffed in accordance with the scope and complexity of the hospital’s services and in such a manner as to comply with the requirements of this regulation and other Federal and State laws and regulations.</p> <p>There must be an established medical record system that is organized and employs adequate personnel to ensure prompt:</p> <ul style="list-style-type: none"> • Completion of medical records; • Filing of medical records; and • Retrieval of medical records. <p>The term “employs adequate personnel” includes:</p> <ol style="list-style-type: none"> 1. That medical record personnel are employees of the hospital; 2. That the hospital employs an adequate number of medical record personnel, employs adequate types of medical record personnel, and employs personnel who possess adequate education, skills, qualifications and experience to ensure the hospital complies with requirements of this regulation and other Federal and State laws and regulations. 	<p style="text-align: center;"><u>INTERVIEW</u></p> <ol style="list-style-type: none"> 1. Determine that there is an established system in place that addresses the following activities of the medical record service: <ol style="list-style-type: none"> a) timely processing of records; b) coding / indexing of records; c) record retrieval; d) protecting confidentiality of medical information; and e) retrieval and compilation of data of quality assurance activities. 2. Verify that the system is reviewed and revised as needed. 3. Interview staff, if needed, review written job descriptions and staffing schedules to determine if staff is carrying out all designated responsibilities. 4. Verify that the hospital employs adequate medical record personnel as previously described. 5. Are medical records promptly completed in accordance with State law and hospital policy? <p style="text-align: center;"><u>DOCUMENT REVIEW</u></p> <p>Select a sample of past patients of the hospital (inpatient and/or outpatient). Request those patients’ medical records. Can the hospital promptly retrieve those records?</p>	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

MEDICAL RECORDS (HEALTH INFORMATION) SERVICES

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>10.00.03 Retention of Medical Records. <i>The hospital must maintain a medical record for each inpatient and outpatient.</i></p> <p><i>Medical records must be accurately written, promptly completed, properly filed and retained, and accessible.</i></p> <p><i>The hospital must use a system of author identification and record maintenance that ensures the integrity of the authentication and protects the security of all record entries.</i></p> <p>§482.24(b)</p>	<p>The hospital must maintain a medical record for each inpatient and outpatient evaluated or treated in any part or location of the hospital.</p> <p>All medical records must be accurately written. The hospital must ensure that all medical records accurately and completely document all orders, test results, evaluations, care plans, treatments, interventions, care provided and the patient’s response to those treatments, interventions and care.</p> <p>All medical records must be promptly completed.</p> <p>Every medical record must be complete with:</p> <ul style="list-style-type: none"> • All documentation of orders, diagnosis, evaluations, treatments • Test results • Care plans • Discharge plans • Consents • Interventions • Discharge Summary • Clinical evaluation information obtained from post-discharge follow-up telephone calls (excluding patient satisfaction calls) • Care provided along with the patient’s response to those treatments and interventions. <p>The record must be completed promptly after discharge in accordance with State law and hospital policy but no later than 30 days after discharge.</p>	<p>CHART REVIEW, INTERVIEW, & OBSERVATION</p> <ol style="list-style-type: none"> 1. Determine the location(s) where medical records are maintained. 2. Verify that a medical record is maintained for each person treated or receiving care. The hospital may have a separate record for both inpatients and outpatients. However, when two different systems are used they must be appropriately cross referenced and accessible. 3. Verify that procedures ensure the integrity of authentication and protect the security of patient records. 4. Verify that medical records are stored and maintained in locations where the records are secure, that protects them from damage, flood, fire, etc.; access is limited to only authorized individuals. 5. Verify that records are accurate, completed promptly, easily retrieved and readily accessible, as needed, in all locations where medical records are maintained. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

MEDICAL RECORDS (HEALTH INFORMATION) SERVICES

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
	<p>The medical record must be properly filed and retained.</p> <p>The hospital must have a medical record system that ensures the prompt retrieval of any medical record, of any patient evaluated or treated at any location of the hospital within the past 5 years.</p> <p>NOTE: §482.24(b)(1) addresses the 5 year medical record retention requirement.</p> <p>The medical record must be accessible.</p> <p>The hospital must have a medical record system that allows the medical record of any patient, inpatient or outpatient, evaluated and/or treated at any location of the hospital within the past 5 years to be accessible by appropriate staff, 24 hours a day, 7 days a week, whenever that medical record may be needed.</p> <p>Medical records must be properly stored in secure locations where they are protected from fire, water damage and other threats.</p> <p>Medical information such as consultations, orders, practitioner notes, x-ray interpretations, lab test results, diagnostic test results, patient assessments and other patient information must be accurately written, promptly completed and properly filed in the patients' medical record, and accessible to the physicians or other care providers when needed for use in making assessments of the patient's condition, decisions on the provision of care to the patient, and</p>		

MEDICAL RECORDS (HEALTH INFORMATION) SERVICES

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
	<p>in planning the patient’s care. This requirement applies to the medical records of current inpatients and outpatients of the hospital.</p> <p>The hospital must have a system of author identification and record maintenance that ensures the integrity of the authentication and protects the security of all record entries. The medical record system must correctly identify the author of every medical record entry and must protect the security of all medical record entries.</p> <p>The medical record system must ensure that medical record entries are not lost, stolen, destroyed, altered, or reproduced in an unauthorized manner. Locations where medical records are stored or maintained must ensure the integrity, security and protection of the records. These requirements apply to both manual and electronic medical record systems.</p>		
<p>10.00.04 Record Security & Retention Requirements. <i>Medical records must be retained in their original or legally reproduced form for a period of at least 5 years.</i></p> <p>§482.24(b)(1)</p>	<p>All medical records are retained in their original or legally reproduced form in hard copy, microfilm, computer memory banks, or other electronic storage media.</p> <p>The hospital must be able to promptly retrieve the complete medical record of every individual evaluated or treated in any part or location of the hospital within the last 5 years.</p>	<p>INTERVIEW, OBSERVATION, AND CHART REVIEW</p> <ol style="list-style-type: none"> Determine that medical records are retained for at least five (5) years, or more, as required by state or local laws. Determine that the medical records are stored in a secured manner. Select a sample of patients, both inpatient and outpatient who were patients of the 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

MEDICAL RECORDS (HEALTH INFORMATION) SERVICES

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
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In accordance with Federal and State law and regulations, certain medical records may have retention requirements that exceed 5 years (for example: FDA, OSHA, EPA).

hospital between the previous 48-60 months. Request their medical record. Include both hospital campus and off campus locations.

Determine the medical record:

- 1) Is promptly retrieved?
- 2) Is complete?
- 3) Is in original or in a legally reproduces form?

10.00.05 Coding & Indexing.

The hospital must have a system of coding and indexing medical records. The system must allow for timely retrieval by diagnosis and procedure, in order to support medical care evaluation studies.

The facility has an efficient, organized system for coding and indexing medical records that allows for the timely retrieval of information.

INTERVIEW & DOCUMENT REVIEW

- Verify that the facility uses a coding and indexing system that permits timely retrieval of medical records by diagnosis procedure.

- 1 = Compliant
- 2 = Not Compliant

This standard is not met as evidenced by:

§482.24(b)(2)

MEDICAL RECORDS (HEALTH INFORMATION) SERVICES

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>10.00.06 Security of Medical Information. <i>The hospital must have a procedure for ensuring the confidentiality of patient records.</i></p> <p><i>Information from or copies of records may be released only to authorized individuals, and the hospital must ensure that unauthorized individuals cannot gain access to or alter patient records.</i></p> <p><i>Original medical records must be released by the hospital only in accordance with Federal or State laws, court orders, or subpoenas.</i></p> <p>§482.24(b)(3)</p>	<p><u>RELEASE OF INFORMATION or COPIES OF RECORDS</u> The hospital must have a procedure to ensure the confidentiality of each patient’s medical record, whether it is in paper or electronic format, or a combination of the two, from unauthorized disclosure.</p> <p>Confidentiality applies wherever the record or portions thereof are stored, including but not limited to central records, patient care locations, radiology, laboratories, record storage areas, etc.</p> <p>A hospital is permitted to disclose medical record information, without a patient’s authorization, in order to provide patient care and perform related administrative functions, such as payment and other hospital operations.</p> <p>1. Payment operations include hospital activities to obtain payment or be reimbursed for the provision of health care to an individual.</p> <p>2. Health care operations are administrative, financial, legal, and quality improvement activities of a hospital that are necessary to conduct business and to support the core functions of treatment and payment. These activities include, but are not limited to:</p> <ul style="list-style-type: none"> • Quality assessment and improvement activities, • Case management and care coordination; 	<p><u>DOCUMENT REVIEW, INTERVIEW AND OBSERVATION</u></p> <p>1. Verify that policies are in place that limits access to, and disclosure of, medical records to permitted users and uses, and that require written authorization for other disclosures. Are the policies consistent with the regulatory requirements?</p> <p>2. Observe whether patient records are secured from unauthorized access at all times and in all locations.</p> <p>3. Ask the hospital to demonstrate what precautions are taken to prevent physical or electronic altering of content previously entered into a patient record, or to prevent unauthorized disposal of patient records.</p> <p>4. Verify that patient medical record information is released only as permitted under the hospital’s policies and procedures.</p> <p>5. Conduct observations and interview staff to determine what safeguards are in place or precautions are taken to prevent unauthorized persons from gaining physical access or electronic access to information in patient records.</p> <p>6. If the hospital uses electronic patient records, is access to patient records controlled through standard measures, such</p>	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

MEDICAL RECORDS (HEALTH INFORMATION) SERVICES

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
	<ul style="list-style-type: none"> • Competency assurance activities, conducting or arranging for medical reviews, audits, or legal services, including fraud and abuse detection and compliance programs; • Business planning, development, management, and administration and certain hospital-specific fundraising activities. <p>POLICIES AND PROCEDURES</p> <p>The hospital must develop policies and procedures that reasonably limit disclosures of information contained in the patient’s medical record to the minimum disclosure necessary, except when the disclosure is for treatment or payment purposes, or as otherwise required by State or Federal law.</p> <p>When the minimum necessary standard is applied, a hospital may not disclose the entire medical record for a particular purpose, unless it can specifically justify that the whole record is the disclosure amount reasonably required for the purpose.</p> <p>A hospital may disclose information from the medical record electronically, and may also share an electronic medical record system with other health care facilities, physicians and practitioners, so long as the system is designed and operated with safeguards that ensure that only authorized disclosures are made.</p>	<p>as business rules defining permitted access, passwords, etc.?</p> <p>7. Do the hospital’s policies and procedures provide that “original” medical records are retained, unless their release is mandated under Federal or State law, court order or subpoena? Interview staff responsible for medical records to determine if they are aware of the limitations on release of “original” medical records.</p> <p>8. Observe the hospital’s security practices for patient records. Are patient records left unsecured or unattended? Are patient records unsecured or unattended in hallways, patient rooms, nurse’s stations, or on counters where unauthorized persons could gain access to patient records?</p> <p>9. Verify that there is an established system in place that addresses protecting the confidentiality of medical information.</p> <p>10. If the hospital uses electronic patient records, are appropriate security safeguards in place? Is access to patient records controlled?</p> <p>11. Verify that adequate precautions are taken to prevent physical or electronic altering, damaging or deletion / destruction of patient records or information in patient records.</p>	

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The hospital must obtain written authorization from the patient or the patient’s representative for any other disclosure of medical record information.

PREVENTING UNAUTHORIZED ACCESS

The hospital must ensure that unauthorized individuals cannot gain access to patient records. This applies to records in electronic as well as hard copy formats.

Patient records must be secure at all times and in all locations. This includes open patient records for patients who are currently inpatients in the hospital and outpatients in outpatient clinics.

- For hard copy records, techniques such as locked cabinets or file rooms and limiting access to keys or pass codes may be employed.
- For electronic records technical safeguards, such as business rules that limit access based on need to know, passwords, or other control mechanisms must be in place.

When disposing of copies of medical records, physical safeguards might include first shredding documents containing confidential information, taking appropriate steps to erase information from media used to store electronic records, etc.

RELEASE OF ORIGINAL RECORDS

The hospital must not release the original of a

MEDICAL RECORDS (HEALTH INFORMATION) SERVICES

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
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medical record that exists in a hard copy, paper version only, unless it is required to do so in response to a court order, a subpoena, or Federal or State laws.

For electronic records, the hospital must ensure that the media or other mechanism by which the records are stored electronically is not removed in such a way that all or part of the record is deleted from the hospital's medical record system.

The hospital must have policies and procedures that address how it assures that it retains its "original" medical records, unless their release is mandated by law/court order/subpoena.

Patient records must be secure at all times and in all locations. This includes patient records for patients who are currently inpatients in the hospital **as well as** outpatients in outpatient clinics.

Policies are in place that address the organization of the medical records service including:

- Confidentiality
- Release of information
- Retention
- Storage
- Security of medical records in all areas of the inpatient and outpatient areas of the organization.

MEDICAL RECORDS (HEALTH INFORMATION) SERVICES

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>10.01.01 <u>Content of the Record.</u> <i>The medical record must contain information to justify admission and continued hospitalization, support the diagnosis, and describe the patient's progress and response to medications and services.</i></p> <p>§482.24(c)</p>	<p>The medical record must contain information such as notes, documentation, records, reports, recordings, test results, assessments etc., to:</p> <ul style="list-style-type: none"> • Justify admission; • Justify continued hospitalization; • Support the diagnosis; • Describe the patient's progress; • Describe the patient's response to medications; and • Describe the patient's response to services such as interventions, care, treatments, etc. <p>The medical record must contain complete information / documentation regarding evaluations, interventions, care provided, services, care plans, discharge plans, and the patient's response to those activities.</p> <p>Patient medical record information, such as,</p> <ul style="list-style-type: none"> • laboratory reports, • test results, • consults, • assessments, • radiology reports, and • dictated notes, etc., must be promptly filed in the patient's medical record in order to be available to the physician and other care providers to use in making assessments of the patient's condition, to justify continued hospitalization, to support the diagnosis, to describe the patient's progress, and to describe the patient's response to 	<p style="text-align: center;"><u>CHART REVIEW</u></p> <ol style="list-style-type: none"> 1. Review a sample of open (active) and closed medical records for completeness and accuracy in accordance with facility policy. <p>Select charts of patients admitted or housed in the hospital as observation status; exclude ED patients and other outpatients.</p> <ol style="list-style-type: none"> 2. Verify each record contains information to: <ul style="list-style-type: none"> • Justify admission and continued hospitalization; • Support the diagnosis; • Describe patient's progress; and • Response to medications and services. <p style="text-align: center;"><u>DOCUMENT REVIEW</u></p> <ul style="list-style-type: none"> • Verify that medical record documentation issues are identified, reported and action taken to correct deficiencies in a timely manner for all disciplines documenting in the medical record. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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medications, interventions, and services, in planning the patient's care, and in making decisions on the provision of care to the patient.

10.01.02 Information in Medical Records.

The parts of the medical record that are the responsibility of the physician must be authenticated by the physician.

Medical staff policies identify those portions of the medical record, if any, that may be delegated to a non-physician practitioner.

Medical staff policy, consistent with State law defines:

1. The portions of the medical record that may be delegated to non-physician practitioners, such as:

- **Medical History**
- **Physical Examination**
- **Progress Notes**
- **Operative Report**
- **Discharge Summary**

2. The requirements for co-signature and/or authentication, consistent with State law for non-physician practitioners, especially:

- **Nurse Practitioners**
- **Physician Assistants**
- **Certified Registered Nurse Anesthetists (CRNA)**
- **Certified Nurse Midwives**

When **non-physician practitioners** are approved by the medical staff, **for duties such as performing medical histories or physical examinations and documentation of findings**, such information must be reviewed and **authenticated** by the responsible

DOCUMENT REVIEW

1. Determine that medical staff policies and/or rules and regulations indicate what, if any, portions of the medical history, physical examination, progress notes, operative report or discharge summary may be delegated.

2. Determine that **the medical staff rules and regulations or policies define those** entries in the medical record entered by house staff or non-physicians **that** require counter **signature** by supervisory or attending medical staff.

(H&P requires cosignature in all circumstances when not completed by a Doctor of Medicine / Doctor of Osteopathic Medicine.)

CHART REVIEW

- Verify that all records / entries requiring authentication have been authenticated.

- 1 = Compliant
 2 = Not Compliant

This standard is not met as evidenced by:

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	<p>physician within the time frame noted by medical staff policies or rules and regulations, consistent with State law.</p>		
<p>10.01.03 Legible & Complete. <i>All patient medical record entries must be legible, complete, dated, timed, and authenticated in written or electronic form by the person responsible for providing or evaluating the service provided, consistent with hospital policies and procedures.</i></p> <p>§482.24(c)(1)</p>	<p>Entries in the medical record may be made only by individuals as specified in the hospital and medical staff policies.</p> <p>All entries in the medical record must be legible. Orders, progress notes, nursing notes, or other entries in the medical record that are not legible may be misread or misinterpreted and may lead to medical errors or other adverse patient events.</p> <p>All entries in the medical record must be complete. A medical record is considered complete if it contains sufficient information:</p> <ul style="list-style-type: none"> • To identify the patient • Support the diagnosis / condition • Justify the care, treatment, and services • Document the course and results of care, treatment, and services • Promote continuity of care among providers. <p>With these criteria in mind, an individual entry into the medical record must contain sufficient information on</p>	<p style="text-align: center;">CHART REVIEW</p> <p>Review a sample of open and closed medical records.</p> <ol style="list-style-type: none"> 1. Determine whether all medical record entries are legible. Are they clearly written in such a way that they are not likely to be misread or misinterpreted? 2. Determine whether orders, progress notes, nursing notes, or other entries in the medical record are complete. 3. Does the medical record contain sufficient information to identify the patient; <ul style="list-style-type: none"> • Support the diagnosis / condition; • Justify the care, treatment, and services; • Document the course and results of care, treatment, and services; and • Promote continuity of care among providers? 4. Determine whether medical record entries are dated, timed, and appropriately authenticated by the person who is 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

MEDICAL RECORDS (HEALTH INFORMATION) SERVICES

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
	<p>the matter that is the subject of the entry to permit the medical record to satisfy the completeness standard.</p> <p>All entries in the medical record must be dated, timed, and authenticated, in written or electronic form, by the person responsible for providing or evaluating the service provided.</p> <ol style="list-style-type: none"> 1. The time and date of each entry (orders, reports, notes, etc.) must be accurately documented. <p>Timing establishes when an order was given, when an activity happened or when an activity is to take place. Timing and dating entries is necessary for patient safety and quality of care.</p> <p>Timing and dating of entries establishes a baseline for future actions or assessments and establishes a timeline of events. Many patient interventions or assessments are based on time intervals or timelines of various signs, symptoms, or events. (71 FR §68687)</p> <ol style="list-style-type: none"> 2. The hospital must have a method to establish the identity of the author of each entry. This would include verification of the author of faxed orders / entries or computer entries. 3. The hospital must have a method to require that each author takes a specific action to verify that the entry being authenticated is his/her entry or that he/she is responsible for the entry, and that 	<p>responsible for ordering, providing, or evaluating the service provided.</p> <ol style="list-style-type: none"> 5. Determine whether all orders, including verbal orders, are written in the medical record and signed by the practitioner who is caring for the patient and who is authorized by hospital policy and in accordance with State law to write orders. 6. Determine whether the hospital has a means for verifying signatures, both written and electronic, written initials, codes, and stamps when such are used for authorship identification. <ul style="list-style-type: none"> • For electronic medical records, ask the hospital to demonstrate the security features that maintain the integrity of entries and verification of electronic signatures and authorizations. • Examine the hospital’s policies and procedures for using the system, and determine if documents are being authenticated after they are created. 	

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the entry is accurate.

The requirements for dating and timing do not apply to orders or prescriptions that are generated outside of the hospital until they are presented to the hospital at the time of service. Once the hospital begins processing such an order or prescription, it is responsible for ensuring that the implementation of the order or prescription by the hospital is promptly dated, and timed in the patient’s medical record.

PRE-PRINTED ORDER SETS

When a practitioner is using a preprinted order set, the ordering practitioner may be in compliance with the requirement at §482.24(c)(1) to date, time, and authenticate an order if the practitioner accomplishes the following:

- (1) **Last page:**
Sign, date, and time the last page of the orders, with the last page also identifying the total number of pages in the order set.
- (2) **Pages with Internal Selections:**
Sign or initial any other (internal) pages of the order set where selections or changes have been made.
 - The practitioner should initial / sign the top or bottom of the pertinent page(s); and
 - The practitioner should also initial each place in the preprinted order set where changes,

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such as additions, deletions, or strike-outs of components that do not apply, have been made.

- It is not necessary to initial every preprinted box that is checked to indicate selection of an order option, so long as there are no changes made to the option(s) selected.

PRE-ESTABLISHED ELECTRONIC ORDER SET

In the case of a pre-established electronic order set, the same principles would apply, so that the practitioner would date, time and authenticate the final order that resulted from the electronic selection / annotation process, with the exception that pages with internal changes would not need to be initialed or signed if they are part of an integrated single electronic document.

1. Authentication of medical record entries may include written signatures, initials, computer key, or other code.
2. For authentication, in written or electronic form, a method must be established to identify the author.
3. When rubber stamps or electronic authorizations are used for authentication, the hospital must have policies and procedures to ensure that such stamps or authorizations are used only by the individuals whose signature they represent.

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4. There shall be no delegation of stamps or authentication codes to another individual. It should be noted that some insurers and other payers may have a policy prohibiting the use of rubber stamps as a means of authenticating the medical records that support a claim for payment.

5. Medicare payment policy, for example, no longer permits such use of rubber stamps. Thus, while the use of a rubber stamp for signature authentication is not prohibited under the CoPs and analysis of the rubber stamp method per se is not an element of the survey process, hospitals may wish to eliminate their usage in order to avoid denial of claims for payment.

Electronic Medical Record

Where an electronic medical record is in use, the hospital must demonstrate how it prevents alterations of record entries after they have been authenticated. Information needed to review an electronic medical record, including pertinent codes and security features, must be readily available to surveyors to permit their review of sampled medical records while on-site in the hospital.

Countersignature

When State law and/or hospital policy requires that entries in the medical record made by residents or non-physicians be countersigned by supervisory or attending medical staff members, then the medical staff rules and regulations must address counter-signature requirements and processes.

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Auto-authentication

A system of auto-authentication in which a physician or other practitioner authenticates an entry that he or she cannot review, e.g., because it has not yet been transcribed, or the electronic entry cannot be displayed, is not consistent with these requirements.

- There must be a method of determining that the practitioner did, in fact, authenticate the entry after it was created.
- In addition, failure to disapprove an entry within a specific time period is not acceptable as authentication.

The practitioner must separately date and time his/her signature authenticating an entry, even though there may already be a date and time on the document, since the latter may not reflect when the entry was authenticated.

For certain electronically-generated documents, where the date and time that the physician reviewed the electronic transcription is automatically printed on the document, the requirements of this section would be satisfied. However, if the electronically-generated document only prints the date and time that an event occurred (e.g., EKG printouts, lab results, etc.) and does not print the date and time that the practitioner actually reviewed the document, then the practitioner must either authenticate, date, and time this document itself or incorporate an acknowledgment that the document was reviewed into another

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<p>10.01.04 <u>Dating, Timing, & Authentication of Orders.</u> <i>All orders, including verbal orders, must be dated, timed, and authenticated promptly by the ordering practitioner or by another practitioner who is responsible for the care of the patient only if such a practitioner is acting in accordance with State law, including scope-of-practice laws, hospital policies, and medical staff bylaws, rules and regulations.</i></p> <p>§482.24(c)(2)</p>	<p>document (such as the H&P, a progress note, etc.), which would then be authenticated, dated, and timed by the practitioner.</p> <p>This regulation provides that, if State law is silent regarding a specific timeframe for authentication of verbal orders, then the facility is responsible to define in policy the timeframe for the authentication of verbal orders.</p> <p>PROMPTLY AUTHENTICATE ORDERS The hospital must ensure that all orders, including verbal orders, are dated, timed, and authenticated promptly. The Merriam-Webster online dictionary defines “prompt” as performed readily or immediately.</p> <p>Verbal orders are orders for medications, treatments, interventions or other patient care that are transmitted as oral, spoken communications between senders and receivers, delivered either face-to-face or via telephone.</p> <p>The receiver of a verbal order must date, time, and sign the verbal order in accordance with hospital policy.</p> <p>CMS expects hospital policies and procedures for verbal orders to include a read-back and verification process.</p>	<p style="text-align: center;"><u>DOCUMENT REVIEW</u></p> <ol style="list-style-type: none"> 1. Does the hospital have policies and procedures requiring prompt authentication of all orders, including verbal orders, by the ordering practitioner or, if permitted under State law, hospital policy and medical staff bylaws, rules and regulations, another practitioner responsible for the care of the patient? 2. Do the hospital’s policies and procedures for verbal orders include a “read back and verify” process where the receiver of the order reads back the order to the ordering practitioner to verify its accuracy? 3. Determine whether there is a State law that qualifies for the exception to the 48-hour requirement for verbal order authentication. This should be done in consultation with the Regional Office in advance of the survey. <p style="text-align: center;"><u>CHART REVIEW</u></p> <ol style="list-style-type: none"> 1. Review orders, including verbal orders, in a sample of medical records. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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	<p>The prescribing practitioner must verify, sign, date and time the order as soon as possible after issuing the order, in accordance with hospital policy, and State and Federal requirements.</p> <p>Authentication of a verbal order may be written, electronic, or faxed.</p> <ul style="list-style-type: none"> The hospital must have a method for establishing the identity of the practitioner who has given a verbal order, including verification of the author of faxed verbal orders or computer entries. <p>In some instances, the ordering practitioner may not be able to authenticate his or her order, including a verbal order (e.g., the ordering practitioner gives a verbal order which is written and transcribed, and then is “off duty” for the weekend or an extended period of time). In such cases it is acceptable for another practitioner who is responsible for the patient’s care to authenticate the order, including a verbal order, of the ordering practitioner, as long as it is permitted under State law, hospital policies and medical staff bylaws, rules, and regulations.</p> <p>Hospitals may choose in their policies to restrict which practitioners it would authorize to authenticate another practitioner’s orders. For example, a hospital could choose to restrict authentication of orders for pediatric patients to practitioners who are privileged to provide pediatric care. (77 FR 29053, May 16, 2012)</p>	<ol style="list-style-type: none"> Have orders been dated, timed, and authenticated promptly by the ordering practitioner or, if permitted under State law, hospital policy and medical staff bylaws, rules and regulations, another practitioner who is responsible for the care of the patient? Has the receiver of a verbal order, dated, timed, and signed the order according to hospital policy? 	

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- All practitioners responsible for the patient’s care are expected to have knowledge of the patient’s hospital course, medical plan of care, condition, and current status.
- When a practitioner other than the ordering practitioner **authenticates** an order, that practitioner assumes responsibility for the order as being complete, accurate and final.
- A qualified **non-physician** practitioner, such as a physician assistant (PA) or nurse practitioner (NP), **who is responsible for the care of the patient** may authenticate a physician’s or other qualified **non-physician** practitioner’s order only if the order is within his/her scope of practice.

If State law requires that the **ordering** practitioner authenticate **his/her own** orders, **or his/her own verbal orders, then** a practitioner other than the prescribing practitioner would not be permitted to authenticate the verbal order in that State. (71 FR 68682 and 77 FR 29053, May 16, 2012)

NOTE CONCERNING VERBAL ORDERS FOR LABORATORY TESTS:

The requirement to authenticate **promptly** a verbal order applies to verbal orders associated with both inpatients and outpatients.

It is possible that a hospital verbal order for a laboratory test could be authenticated in compliance with the Clinical Laboratory Improvement Amendment (CLIA) regulatory standard of authentication, i.e.,

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<p>10.01.05 Pre-printed Orders, Order Sets & Protocols. <i>Hospitals may use pre-printed and electronic standing orders, order sets, and protocols for patient orders only if the hospital:</i></p> <p>(i) <i>Establishes that such orders and protocols have been reviewed and approved by the medical staff and the hospital's nursing and pharmacy leadership;</i></p> <p>(ii) <i>Demonstrates that such orders and protocols are consistent with</i></p>	<p>within 30 days, but nonetheless be out of compliance with the hospital Medical Records Services requirement for prompt authentication of all orders, including verbal orders. Because CLIA laboratories – even if physically situated in a hospital – are surveyed for compliance only with CLIA regulations, the laboratory would not be cited for a deficiency by a CLIA survey team. However, hospital surveyors conducting a survey would cite the hospital's inpatient or outpatient recordkeeping for deficiencies under the Medical Record Services CoP if the lab order originated for a patient during a hospital inpatient stay or hospital outpatient clinic visit and the order was not authenticated promptly.</p> <p>WHAT IS COVERED BY THIS REGULATION?</p> <p>There is no standard definition of a “standing order” in the hospital community at large (77 FR 29055, May 16, 2012), but the terms “pre-printed standing orders,” “electronic standing orders,” “order sets,” and “protocols for patient orders” are various ways in which the term “standing orders” has been applied.</p> <p>For purposes of brevity, in our guidance we generally use the term “standing order(s)” to refer interchangeably to pre-printed and electronic standing orders, order sets, and protocols.</p> <ul style="list-style-type: none"> • However, we note that the lack of a standard 	<p style="text-align: center;">CHART REVIEW</p> <ol style="list-style-type: none"> 1. Ask the hospital's medical staff and its nursing and pharmacy leadership whether standing orders are used. If yes, ask them to describe how a standing order is developed and monitored, and their role in the process. 2. Ask to see an example of one or more standing orders, including documentation on the development of the order, including: <ol style="list-style-type: none"> a. Reference to the evidence-based national guidelines that support it; 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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<p><i>nationally recognized and evidence-based guidelines;</i></p> <p>(iii) <i>Ensures that the periodic and regular review of such orders and protocols is conducted by the medical staff and the hospital's nursing and pharmacy leadership to determine the continuing usefulness and safety of the orders and protocols; and</i></p> <p>(iv) <i>Ensures that such orders and protocols are dated, timed, and authenticated promptly in the patient's medical record by the ordering practitioner or another practitioner responsible for the care of the patient only if such a practitioner is acting in accordance with State law, including scope-of-practice laws, hospital policies, and medical staff bylaws, rules, and regulations.</i></p> <p>§482.24(c)(3) §482.24(c)(3)(i) §482.24(c)(3)(ii) §482.24(c)(3)(iii) §482.24(c)(3)(iv)</p>	<p>definition for these terms and their interchangeable and indistinct use by hospitals and health care professionals may result in confusion regarding what is or is not subject to the requirements of §482.24(c)(3), particularly with respect to "order sets."</p> <p>NOT CONSIDERED TO BE A STANDING ORDER Not all pre-printed and electronic order sets are considered a type of "standing order" covered by this regulation.</p> <p>Where the order sets consist solely of menus of treatment or care options designed to facilitate the creation of a patient-specific set of orders by a physician or other qualified practitioner authorized to write orders, and none of the treatment choices and actions can be initiated by non-practitioner clinical staff before the physician or other qualified practitioner actually creates the patient-specific order(s), such menu would not be considered "standing orders" covered by this regulation. We note in such cases the menus provide a convenient and efficient method for the physician/practitioner to create an order, but the availability of such menu options does not create an "order set" that is a "standing order" subject to the requirements of this regulation.</p> <p>The physician/practitioner may, based on his/her professional judgment, choose to:</p> <ol style="list-style-type: none"> 1. use the available menu options to create an order; 	<p>b. Participation of medical staff and nursing and pharmacy leadership in the review and approval of the standing order;</p> <p>c. Description of the protocol to be followed when initiating the execution of the order, including description of the roles and responsibilities of various types of staff;</p> <p>d. Description of the process for authenticating the order's initiation by the practitioner responsible for the care of the patient, or another authorized practitioner;</p> <p>e. Evidence of training of personnel on the order's protocol; and</p> <p>f. Evidence of periodic evaluation and, if needed, modification of the standing order, including whether the order remains consistent with current evidence-based national guidelines, staff adherence to the protocol for initiation and execution, and whether there have been any preventable adverse events associated with the order.</p> <p>3. Ask staff providing clinical services in areas</p>	

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	<p>2. not use the menu options and instead create an order from scratch; or</p> <p>3. modify the available menu options to create the order.</p> <p>In each case the physician/practitioner exercises his privileges to prescribe specific diagnosis and/or treatment activities that are to be implemented for a patient.</p> <p>On the other hand, in cases where hospital policy permits treatment to be initiated, by a nurse, for example, without a prior specific order from the treating physician/practitioner, this policy and practice must meet the requirements of this regulation for review of standing orders, regardless of whether it is called a standing order, a protocol, an order set, or something else.</p> <ul style="list-style-type: none"> Such treatment is typically initiated when a patient’s condition meets certain pre-defined clinical criteria. For example, standing orders may be initiated as part of an emergency response or as part of an evidence-based treatment regimen where it is not practical for a nurse to obtain either a written, authenticated order or a verbal order from a physician or other qualified practitioner prior to the provision of care. <p>Hybrids, where a component for non-practitioner-initiated treatment is embedded within a menu of options for the physician or other qualified practitioner, still require compliance with the</p>	<p>of the hospital where standing orders might be typically used, including but not limited to, the emergency department, labor and delivery units, and inpatient units, whether standing orders are used. If they say yes, ask them:</p> <ul style="list-style-type: none"> To describe a typical scenario where a standing order would be used, and what they would do in that case. For a copy of the protocol for that standing order. Does their description conform to the protocol? <p>4. Review a sample of medical records of patients where a nurse-initiated standing order was used and verify that the order was documented and authenticated by a practitioner responsible for the care of the patient.</p>	

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requirements for a standing order for that component.

- For example, if an order set includes a protocol for nurse-initiated potassium replacement, that protocol must be reviewed under the requirements of this regulation before it may become part of a menu of treatment options from which a physician or other qualified practitioner would select treatments for a particular patient.

REQUIREMENTS FOR “STANDING ORDERS”

Hospitals have the flexibility to use standing orders to expedite the delivery of patient care in well-defined clinical scenarios for which there is evidence supporting the application of standardized treatments or interventions.

Appropriate use of standing orders can contribute to patient safety and quality of care by promoting consistency of care, based on objective evidence, when orders may be initiated as part of an emergency response or as part of an evidence-based treatment regimen where it is not practicable for a nurse or other non-practitioner to obtain a verbal or authenticated written order from a physician or other practitioner responsible for the care of the patient prior to the provision of care.

In all cases, implementation of a standing order must be medically appropriate for the patient to whom the order is applied.

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Much of the evidence on the effectiveness of standing orders in hospitals has been narrowly focused on aspects of their use by Rapid Response Teams addressing inpatient emergencies. However, standing orders may also be appropriate in other clinical circumstances, including, but not limited to:

- Protocols for triaging and initiating required screening examinations and stabilizing treatment for emergency department patients presenting with symptoms suggestive of acute asthma, myocardial infarction, stroke, etc. (This does not relieve a hospital of its obligations under the Emergency Medical Treatment and Labor Act (EMTALA) to have qualified medical personnel complete required screening and, when applicable, stabilizing treatment in a timely manner.)
- Post-operative recovery areas.
- Timely provision of immunizations, such as certain immunizations for newborns, for which there are clearly established and nationally recognized guidelines.

Standing orders may not be used in clinical situations where they are specifically prohibited under Federal or State law.

- For example, the hospital patient's rights regulation at §482.13(e)(6) specifically prohibits the use of standing orders for restraint or seclusion of hospital patients.

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When deciding whether to use standing orders, hospitals should also be aware that, although use of standing orders is permitted under the hospital Conditions of Participation, some insurers, including Medicare, may not pay for the services provided because of the use of standing orders. (77 FR 29056)

MINIMUM REQUIREMENTS FOR STANDING ORDERS

Hospitals may employ standing orders only if the following requirements are met for each standing order for a particular well-defined clinical scenario:

1. Each standing order must be reviewed and approved by the hospital’s medical staff and nursing and pharmacy leadership before it may be used in the clinical setting. The regulation requires a multi-disciplinary collaborative effort in establishing the protocols associated with each standing order.
2. The hospital’s policies and procedures for standing orders must address:
 - the process by which a standing order is developed; approved; monitored;
 - initiated by authorized staff; and
 - subsequently authenticated by physicians or other practitioners responsible for the care of the patient.
3. For each approved standing order, there must be

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specific criteria clearly identified in the protocol for the order for a nurse or other authorized personnel to initiate the execution of a particular standing order, for example, the specific clinical situations, patient conditions, or diagnoses by which initiation of the order would be justified. Under no circumstances may a hospital use standing orders in a manner that requires any staff not authorized to write patient orders to make clinical decisions outside of their scope of practice in order to initiate such orders.

Since residents are physicians, this regulation does not require specific criteria for a resident to initiate the execution of a particular standing order. However, there may be State laws governing the practice of residents in hospitals that are more restrictive; if so, the hospital is expected to comply with the State law.

Likewise, the hospital may choose through its policies and medical staff bylaws, rules and regulations to restrict the role of residents with respect to standing orders.

4. Policies and procedures should also address the instructions that the medical, nursing, and other applicable professional staff receive on the conditions and criteria for using standing orders as well as any individual staff responsibilities associated with the initiation and execution of standing orders. An order that has been initiated for a specific patient must be added to the

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patient's medical record at the time of initiation, or as soon as possible thereafter.

- Likewise, standing order policies and procedures must specify the process whereby the physician or other practitioner responsible for the care of the patient acknowledges and authenticates the initiation of all standing orders after the fact, with the exception of influenza and pneumococcal vaccines, which do not require such authentication in accordance with § 482.23(c)(2).

(76 FR 65896, October 24, 2011 & 77 FR 29056, May 16, 2012)

- The hospital must be able to document that the standing order is consistent with nationally recognized and evidence-based guidelines. This does not mean that there must be a template standing order available in national guidelines which the hospital copies, but rather that the content of each standing order in the hospital must be consistent with nationally recognized, evidence-based guidelines for providing care. The burden of proof is on the hospital to show that there is a sound basis for the standing order.

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5. Each standing order must be subject to periodic and regular review by the medical staff and the hospital’s nursing and pharmacy leadership, to determine the continuing usefulness and safety of the orders and protocols.

- At a minimum, an annual review of each standing order would satisfy this requirement.

- However, the hospital’s policies and procedures must also address a process for the identification and timely completion of any requisite updates, corrections, modifications, or revisions based on changes in nationally recognized, evidence-based guidelines. The review may be prepared by the hospital’s QAPI program, so long as the medical staff and nursing and pharmacy leadership read, review, and, as applicable, act upon the final report.

Among other things, reviews are expected to consider:

- Whether the standing order’s protocol continues to be consistent with the latest standards of practice reflected in nationally recognized, evidence-based guidelines;

- Whether there have been any preventable adverse patient events

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	<p>resulting from the use of the standing order, and if so, whether changes in the order would reduce the likelihood of future similar adverse events. Note that the review would not be expected to address adverse events that are a likely outcome of the course of patient’s disease or injury, even if the order was applied to that patient, unless there is concern that use of the standing order exacerbated the patient’s condition; and</p> <ul style="list-style-type: none"> • Whether a standing order has been initiated and executed in a manner consistent with the order’s protocol, and if not, whether the protocol needs revision and/or staff need more training in the correct procedures. <p>6. An order that has been initiated for a specific patient must be added to the patient’s medical record at the time of initiation, or as soon as possible thereafter.</p> <ul style="list-style-type: none"> • The hospital must ensure each standing order that has been executed is dated, timed, and authenticated promptly in the patient’s medical record by the ordering practitioner or another practitioner responsible for the care of the patient. 		

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- Another practitioner who is responsible for the care of the patient may date, time and authenticate the standing order instead of the ordering practitioner, but only if the other practitioner is acting in accordance with State law, including scope of practice laws, hospital policies, and medical staff bylaws, rules and regulations.

The hospital’s standing orders policies and procedures must specify the process whereby the responsible practitioner, or another authorized practitioner, acknowledges and authenticates the initiation of each standing order after the fact, with the exception of standing orders for influenza and pneumococcal vaccines, which do not require such authentication.

Further, the responsible practitioner must be able to modify, cancel, void or decline to authenticate orders that were not medically necessary in a particular situation. The medical record must reflect the physician’s actions to modify, cancel, void or refusal to authenticate a standing order that the physician determined was not medically necessary. (76 FR 65896, October 24, 2011)

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<p>10.01.06 Abbreviations & Symbols. Abbreviations and symbols are utilized sparingly. The following have been developed by the organization:</p> <ol style="list-style-type: none"> 1. A list of standardized abbreviations, symbols, and dose designations; 2. A list of abbreviations, symbols, and dose designation that should never be used; and 3. Explicit organizational policies and procedures regarding the use of only standardized abbreviations and dose designations. <p>A current abbreviations and symbols list, with a legend of their meaning is maintained in the facility for all persons who document in patient medical records. These lists are approved by the Professional Medical Staff.</p> <p>All staff entering data into the medical record will be educated on use of abbreviations. Policy compliance will be monitored.</p>	<p style="text-align: center;"><u>PATIENT SAFETY INITIATIVE</u></p> <p>The use of non-standardized abbreviations and dose designations is a demonstrated cause of medication errors.</p> <p>Although the use of abbreviations and dose designations is reputed to save time and make order writing more efficient, illegible handwriting and the use of abbreviations or dose designations that are unfamiliar or that have multiple meanings may lead to confusion and errors.</p> <ul style="list-style-type: none"> • For example, the use of “U” for “units” is especially problematic because when handwritten, “U” often looks like a zero. <p>Numerous case reports document that errors related to insulin dosage have occurred because of this.</p> <p>Likewise, using handwritten trailing zeros or a leading decimal point without a leading zero are dangerous order writing practices because the decimal point is sometimes not seen, and misinterpretation of such orders can lead to as much as a 10-fold dosing error.</p> <p>Experiential data show that using standardized abbreviations and symbols and standardized phraseology reduces medication and treatment errors.</p>	<p style="text-align: center;"><u>DOCUMENT REVIEW</u></p> <ol style="list-style-type: none"> 1. Review the organizational policies and procedures regarding the use of standardized abbreviations and dose designations. 2. Review the facility’s approved list of: <ol style="list-style-type: none"> a. Abbreviations, symbols, and dose designations, and b. Abbreviations and dose designations that should never be used. 3. Determine the compliance of these by sampling the last 30 discharges. 4. Interview staff to determine awareness of the approved and do not use lists. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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<p>10.01.07 History & Physical Requirements. <i>All records must document the following, as appropriate:</i></p> <p>Evidence of –</p> <ul style="list-style-type: none"> • <i>A medical history and physical examination completed and documented no more than 30 days before or 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia services. The medical history and physical examination must be placed in the patient’s medical record within 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia services.</i> <p>§482.24(c)(4) §482.24(c)(4)(i) §482.24(c)(4)(i)(A)</p>	<p>The medical record must include documentation that a medical history and physical examination (H&P) was completed and documented for each patient no more than 30 days prior to hospital admission or registration, or 24 hours after hospital admission or registration, but in all cases prior to surgery or a procedure requiring anesthesia services.</p> <p>The purpose of an H&P is to determine whether there is anything in the patient's overall condition that would affect the planned course of the patient's treatment, such as an allergy to a medication that must be avoided, or a co-morbidity that requires certain additional interventions to reduce risk to the patient.</p> <p>The H&P documentation must be placed in the medical record within 24 hours of admission or registration, but in all cases prior to surgery or a procedure requiring anesthesia services, including all inpatient, outpatient, or same-day surgeries or procedures. (71 FR §68676)</p> <p>The H&P may be handwritten or transcribed.</p> <p>An H&P that is completed within 24 hours of the patient’s admission or registration, but after surgery or a procedure requiring anesthesia would not be in compliance.</p>	<p style="text-align: center;"><u>CHART REVIEW</u></p> <p>Review a sample of inpatient medical records for various types of patients and outpatient medical records for patients having same day surgery or a procedure requiring anesthesia to determine whether:</p> <ol style="list-style-type: none"> 1. There is an H&P that was done no more than 30 days before or 24 hours after admission or registration, but, for all cases involving surgery or a procedure requiring anesthesia services, prior to the surgery or procedure; 2. The H&P documentation was placed in the medical record within 24 hours after admission or registration, but, for all cases involving surgery or a procedure requiring anesthesia services, prior to the surgery or procedure; or 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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<p>10.01.08 History & Physical Update Requirements. <i>All records must document the following as appropriate:</i></p> <p>Evidence of –</p> <ul style="list-style-type: none"> • <i>An updated examination of the patient, including any changes in the patient’s condition, when the medical history and physical examination are completed within 30 days before admission or registration. Documentation of the updated examination must be placed in the patient’s medical record within 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia services.</i> <p>§482.24(c)(4)(i)(B)</p>	<p>When an H&P is completed within the 30 days before admission or registration, the hospital must ensure that an updated medical record entry documenting an examination for any changes in the patient's condition is placed in the patient's medical record within 24 hours after admission or registration, but, in all cases involving surgery or a procedure requiring anesthesia services, prior to the surgery or procedure.</p> <p>REQUIREMENTS OF THE UPDATED EXAMINATION The examination must be conducted by a practitioner who is credentialed and privileged by the hospital’s medical staff to perform an H&P.</p> <p>The update note must document an examination for any changes in the patient's condition since the time that the patient's H&P was performed that might be significant for the planned course of treatment.</p> <ul style="list-style-type: none"> • The physician, oromaxillofacial surgeon, or qualified licensed individual uses his/her clinical judgment, based upon his/her assessment of the patient’s condition and co-morbidities, if any, in relation to the patient’s planned course of treatment to decide the extent of the update assessment needed as well as the information to be included in the update note in the patient’s medical record. • If, upon examination, the licensed practitioner finds no change in the patient's condition since the H&P was completed, he/she may indicate in the patient's medical record that the H&P was 	<p style="text-align: center;"><u>CHART REVIEW</u></p> <p>In the sample of medical records selected for review, look for cases where the medical history and physical examination was completed within 30 days before admission or registration.</p> <ol style="list-style-type: none"> 1. Determine whether an updated medical record entry documenting an examination for changes in the patient's condition was completed and documented in the patient's medical record within 24 hours after admission or registration. 2. Determine whether, in all cases involving surgery or a procedure requiring anesthesia services, the update was completed and documented prior to the surgery or procedure. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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reviewed, the patient was examined, and that "**no change**" has occurred in the patient's condition since the H&P was completed. (71 FR §68676)
Such statements in the medical record would meet the requirement for documenting the H&P update.

- Any changes in the patient’s condition must be documented by the practitioner in the update note and placed in the patient’s medical record within 24 hours of admission or registration, but prior to surgery or a procedure requiring anesthesia services.
- Additionally, if the practitioner finds that the H&P done before admission is incomplete, inaccurate, or otherwise unacceptable, the practitioner reviewing the H&P, examining the patient, and completing the update may disregard the existing H&P, and conduct and document in the medical record a new H&P within 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia.

10.01.09 Admitting Diagnosis.

All records must document the following, as appropriate:

- *The admitting diagnosis.*

§482.24(c)(4)(ii)

All inpatient medical records must contain the admitting diagnosis.

CHART REVIEW

Verify in a sample of medical records that the patient’s admitting diagnosis is documented.

- 1 = Compliant
- 2 = Not Compliant

This standard is not met as evidenced by:

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<p>10.01.10 <u>Consultative Reports.</u> <i>All records must document the following, as appropriate:</i></p> <ul style="list-style-type: none"> <i>Results of all consultative evaluations of the patient and appropriate findings by clinical and other staff involved in the care of the patient.</i> <p>§482.24(c)(4)(iii)</p>	<p>All patient records, both inpatient and outpatient, must contain the results of all consultative evaluations of the patient and appropriate findings by clinical and other staff involved in the care of the patient.</p> <p>This information must be promptly filed in the patient’s medical record in order to be available to the physician or other care providers:</p> <ul style="list-style-type: none"> to use in making assessments of the patient’s condition, to justify treatment or continued hospitalization, to support or revise the patient’s diagnosis, to support or revise the plan of care, to describe the patient’s progress and to describe the patient’s response to medications, treatments, and services. 	<p align="center"><u>CHART REVIEW</u></p> <p>Review a sample of medical records of patients who have orders for consultative evaluations.</p> <ul style="list-style-type: none"> Are the results / reports and other clinical findings of those consultative evaluations included in the patient’s medical record, consistent with Medical staff policy? 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>
<p>10.01.11 <u>Not Applicable.</u></p>			

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<p>10.01.12 <u>Consultation Requirements.</u> The requests for diagnostic testing, which require professional interpretation (psychometrics, pathology, imaging, etc.) and consultations include sufficient detail to facilitate the interpreter's review.</p>	<p>The professional staff that evaluate the diagnostic tests, and/or provide patient assessment consultations, should logically come to their own conclusions; however, these professionals should not have to search for readily available data, which may enhance their review and findings.</p>	<p><u>DOCUMENT REVIEW AND CHART REVIEW</u></p> <ol style="list-style-type: none"> 1. Determine that policies and Medical Staff Rules and Regulations address the need to provide sufficient information with requested consultations or evaluations. 2. Review charts to determine orders for consultation include sufficient information and consultative testing and reports are available within appropriate timeframes. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>
<p>10.01.13 <u>Not Applicable.</u></p>			
<p>10.01.14 <u>Not Applicable.</u></p>			
<p>10.01.15 <u>Documentation of Complications.</u> <i>All records must document the following, as appropriate:</i></p> <ul style="list-style-type: none"> • <i>Documentation of complications, hospital acquired infections, and unfavorable reactions to drugs and anesthesia.</i> 	<p>All patient medical records, both inpatient and outpatient, must document:</p> <ul style="list-style-type: none"> • Complications; • Hospital-acquired infections; • Unfavorable reactions to drugs; and • Unfavorable reactions to anesthesia. 	<p><u>CHART REVIEW & INTERVIEW</u></p> <ul style="list-style-type: none"> • Through observations, interviews, and review of hospital reports and documentation, determine if patient complications, hospital-acquired infections, and unfavorable reactions to drugs / anesthesia have been documented in the applicable patient's medical record. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

§482.24(c)(4)(iv)

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<p>10.01.16 <u>Informed Consent.</u> All records must document the following, as appropriate:</p> <ul style="list-style-type: none"> • <i>Properly executed informed consent forms for procedures and treatments specified by the medical staff, or by Federal or State law if applicable, to require written patient consent.</i> <p>§482.24(c)(4)(v)</p>	<p style="text-align: center;"><u>PATIENT SAFETY INITIATIVE</u></p> <p>Informed consent is discussed in three locations in the CMS Hospital CoPs. See also the guidelines for 42 CFR §482.13(b)(2) pertaining to patients' rights, and the guidelines for 42 CFR §482.51(b)(2), pertaining to surgical services.</p> <p>The medical record must contain a document recording the patient's informed consent for those procedures and treatments that have been specified as requiring informed consent.</p> <p>Medical staff policies should address which procedures and treatments require written informed consent.</p> <p>There may also be applicable Federal or State law requiring informed consent. The informed consent form contained in the medical record should provide evidence that it was properly executed.</p> <p><u>INFORMED CONSENT FORMS</u></p> <p>A properly executed informed consent form should reflect the patient consent process. Except as specified for emergency situations in the hospital's informed consent policies, all inpatient and outpatient medical records must contain a properly executed informed consent form prior to conducting any procedure or other type of treatment that requires informed consent.</p> <p>An informed consent form, in order to be properly executed, must be consistent with hospital policies as well as applicable State and Federal law or regulation.</p>	<p style="text-align: center;"><u>DOCUMENT REVIEW</u></p> <ol style="list-style-type: none"> 1. Verify that the hospital has assured that the medical staff has specified which procedures and treatments require written patient consent. 2. Verify that the hospital's standard informed consent form contains the elements listed as the minimum elements of a properly executed informed consent. 3. Compare the hospital's standard informed consent form to the hospital's policies on informed consent, to verify that the form is consistent with the policies. If there is applicable State law, verify that the form is consistent with the requirements of that law. <p style="text-align: center;"><u>CHART REVIEW</u></p> <ol style="list-style-type: none"> 1. Review a minimum of six random medical records of patients who have, are undergoing, or are about to under a procedure or treatment that requires informed consent. Verify that each medical record contains informed consent forms. 2. Verify that each completed informed consent form contains the information for each of the elements listed above as the minimum elements of a properly executed informed consent, as well as any additional elements required by State law and/or the hospital's policy. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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A properly executed informed consent form contains the following minimum elements:

1. Name of the hospital where the procedure or other type of medical treatment is to take place;
2. Name of the specific procedure, or other type of medical treatment for which consent is being given;
3. Name of the responsible practitioner who is performing the procedure or administering the medical treatment;
4. Statement that the procedure or treatment, including the anticipated benefits, material risks, and alternative therapies, was explained to the patient or the patient’s legal representative; (Material risks could include risks with a high degree of likelihood but a low degree of severity, as well as those with a very low degree of likelihood but high degree of severity. Hospitals are free to delegate to the responsible practitioner, who uses the available clinical evidence as informed by the practitioner’s professional judgment, the determination of which material risks, benefits and alternatives will be discussed with the patient.)
5. Signature of the patient or the patient’s legal representative; and
6. Date and time the informed consent form is signed by the patient or the patient’s legal

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representative.

If there is applicable State law governing the content of the informed consent form, then the hospital’s form must comply with those requirements.

A well-designed informed consent form might also include the following additional information:

1. Name of the practitioner who conducted the informed consent discussion with the patient or the patient’s representative.
2. Date, time, and signature of the person witnessing the patient or the patient’s legal representative signing the consent form.
3. Indication or listing of the material risks of the procedure or treatment that were discussed with the patient or the patient’s representative;
4. Statement, if applicable, that physicians other than the operating practitioner, including but not limited to residents, will be performing important tasks related to the surgery, in accordance with the hospital’s policies and, in the case of residents, based on their skill set and under the supervision of the responsible practitioner.
5. Statement, if applicable, that qualified medical practitioners who are not physicians who will perform important parts of the surgery or administration of anesthesia will be performing only tasks that are within their scope of practice,

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as determined under State law and regulation, and for which they have been granted privileges by the hospital.

PATIENT SAFETY INITIATIVE

In recent years, informed consent forms have largely become legal documents that protect institutions rather than provide information for shared decision-making. Because an estimated 40 million people in the United States are marginally or functionally illiterate and a much larger number are medically illiterate, policies should be implemented to ensure the use of clear informed consent forms that most patients and their families can readily understand.

Similarly, providing informed consent should be viewed as an interactive process between healthcare providers and patients, not merely a form for which a signature must be obtained.

POLICY

Hospitals must assure that the practitioner(s) responsible for the surgery obtains informed consent from patients in a manner consistent with hospital policy.

The hospital has a policy that describes the informed consent process including:

1. Who may obtain the patient’s informed consent;
2. Which procedures require informed consent;
3. The circumstances under which surgery is

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	<p>considered an emergency and may be undertaken without an informed consent;</p> <p>4. The circumstances when a patient’s legal representative, rather than the patient, may give informed consent for surgery;</p> <p>5. The content of the informed consent form and instructions for completing it;</p> <p>6. The process used to obtain informed consent, including how informed consent is to be documented in the medical record;</p> <p>7. Mechanisms that ensure that the informed consent form is properly executed and is in the patient’s medical record prior to the surgery (except in an emergency); and</p> <p>8. If the informed consent process and informed consent form are obtained outside the hospital, how the properly executed informed consent form is incorporated into the patient’s medical record prior to the surgery.</p> <p>Informed consents will be written in simple sentences (4th grade comprehension level) and in the primary language of the patient.</p> <p>Interpreter services will be provided as need is identified.</p> <p>After the informed consent discussion has occurred,</p>		

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the patient or legal representative will be asked to recount what he or she has been told.

10.01.17 Adequacy of Available Information.

All records must document the following, as appropriate:

- *All practitioners' orders, nursing notes, reports of treatment, medication records, radiology, and laboratory reports, and vital signs and other information necessary to monitor the patient's condition.*

§482.24(c)(4)(vi)

The requirement means that the stated information is necessary to monitor the patient's condition and that this and other necessary information must be in the patient's medical record.

In order for necessary information to be used it must be promptly filed in the medical record so that health care staff involved in the patient's care can access/retrieve this information in order to monitor the patient's condition and provide appropriate care.

The medical record must contain:

1. All practitioner's orders (properly authenticated);
2. All nursing notes (including nursing care plans);
3. All reports of treatment (including complications and hospital-acquired infections);
4. All medication records (including unfavorable reactions to drugs);
5. All radiology reports;
6. All laboratory reports;
7. All vital signs; and

CHART REVIEW

1. **Review INPATIENT RECORDS.**
2. Verify that the patient records contain appropriate documentation of practitioners' orders, interventions, findings, assessments, records, notes, reports and other information necessary to monitor the patient's condition.
3. Is this information included in patient records in a prompt manner so that health care staff involved in the care of the patient has access to the information necessary to monitor the patient's condition?

- 1 = Compliant
 2 = Not Compliant

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8. All other information necessary to monitor the patient’s condition.

10.01.18 Discharge Summary.
The records must document the following, as appropriate:

- *Discharge summary with outcome of hospitalization, disposition of case and provisions for follow-up care.*

§482.24(c)(4)(vii)

All patient medical records must contain a discharge summary. A discharge summary discusses the outcome of the hospitalization, the disposition of the patient, and provisions for follow-up care.

Follow-up care provisions include any post hospital appointments, how post hospital patient care needs are to be met, and any plans for post-hospital care by providers such as home health, hospice, nursing homes, or assisted living.

The Doctor of Medicine / Doctor of Osteopathic Medicine or other qualified practitioner with admitting privileges in accordance with State law and hospital policy, who admitted the patient is responsible for the patient during the patient’s stay in the hospital. This responsibility would include developing and entering the discharge summary.

Other Doctors of Medicine / Doctors of Osteopathic Medicine who work with the patient’s MD/DO and who are covering for the patient’s MD/DO and who are knowledgeable about the patient’s condition, the patient’s care during the hospitalization, and the patient’s discharge plans may write the discharge summary at the responsible MD/DO’s request.

In accordance with hospital policy, and 42 CFR Part §482.12(c)(1)(i) the MD/DO may delegate writing the

CHART REVIEW

Determine that each record contains a discharge summary to assure proper continuity of care.

1. Verify that a discharge summary is included to assure that proper continuity of care is required.
2. Verify that a final diagnosis is included in the discharge summary.
3. For patient stays under 48 hours, the final progress notes may serve as the discharge summary and must contain the outcome of hospitalization, the case disposition, and any provisions for follow-up care.

DISCHARGE SUMMARIES MUST BE COMPLETED WITHIN 7 DAYS OF DISCHARGE. (See standard 10.01.33)

- 1 = Compliant
- 2 = Not Compliant

This standard is not met as evidenced by:

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discharge summary to other qualified health care personnel such as nurse practitioners and MD/DO assistants to the extent recognized under State law or a State’s regulatory mechanism.

Whether delegated or non-delegated, we would expect the person who writes the discharge summary to authenticate, date, and time their entry and additionally for delegated discharge summaries we would expect the MD/DO responsible for the patient during his/her hospital stay to co-authenticate and date the discharge summary to verify its content.

The discharge summary requirement would include outpatient records. For example:

1. The outcome of the treatment, procedures, or surgery;
2. The disposition of the case;
3. Provisions for follow-up care for an outpatient surgery patient or an emergency department patient who was not admitted or transferred to another hospital.

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<p>10.01.19 <u>Medical Record Delinquency.</u> <i>All records must document the following, as appropriate:</i></p> <ul style="list-style-type: none"> <i>Final diagnosis with completion of medical records within 30 days following discharge.</i> <p>§482.24(c)(4)(viii)</p>	<p>All medical records must contain a final diagnosis.</p> <p>All medical records must be complete within 30 days of discharge or outpatient care.</p>	<p align="center"><u>CHART REVIEW</u></p> <p>Select a sample of patients who have been discharged for more than 30 days. Request their medical records.</p> <ol style="list-style-type: none"> Are those records complete? Does each record have the patient’s final diagnosis? 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>
<p>10.01.20 <u>Not Applicable.</u></p>			
<p>10.01.21 <u>Not Applicable.</u></p>			
<p>10.01.22 <u>Not Applicable.</u></p>			

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<p>10.01.23 (For Doctors of Osteopathic Medicine only) Osteopathic Musculoskeletal Exam (OME). An osteopathic musculoskeletal examination is required as an integral part of the history and physical performed by osteopathic physicians unless contraindicated.</p> <p>The reason for omitting the musculoskeletal examination is documented in those cases where this examination is contraindicated.</p>	<p>The scope of the osteopathic musculoskeletal examination is impacted by the nature of the patient needs, the need for inpatient versus outpatient service, and the immediate availability of other supporting assessment data.</p> <p>The scope of the osteopathic musculoskeletal examination is consistent with the patient’s medical condition and tolerance. If a patient is intolerant of an OME, the reason for omitting the exam is documented.</p>	<p style="text-align: center;"><u>DOCUMENT REVIEW</u></p> <p>Verify that Medical Staff Rules and Regulations address this requirement when the history and physical is completed by osteopathic physicians (Doctor of Osteopathic Medicine).</p> <p style="text-align: center;"><u>CHART REVIEW</u></p> <p>Ask the Health Information (Medical Records) Manager for the last ten inpatients (non-obstetric) discharged by a Doctor of Osteopathic Medicine. Examine records to determine that there is evidence of an osteopathic musculoskeletal examination (or documentation reasonably supporting the exemption from same).</p>	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>
<p>10.01.24 Initial Assessments. An initial database is documented by each discipline rendering services to a patient.</p> <p>This data is documented within time frames determined by hospital / service policies and incorporates / findings from other sources while keeping duplication of data to a minimum.</p> <p>The database is inclusive of physical, emotional, educational and social</p>	<p>Initial patient assessments provide the baseline of the patient at the time of admission. From these assessments, the needs of the patient are identified and the plan of care is developed.</p> <p>Direct care providers, such as nursing, nutrition, rehabilitation specialists, respiratory care, social service, etc., each have established policies delineating the data collection process. These policies identify the time frames for beginning and completing the initial assessment, the basic structure (components), and identify who can accomplish the database.</p> <p>Policies are in place describing the scope and content</p>	<p style="text-align: center;"><u>DOCUMENT REVIEW</u></p> <p>Review hospital policies that address initial patient assessments. Verify that policies:</p> <ol style="list-style-type: none"> 1. Are in place describing the initial patient assessment requirements for each listed discipline. 2. The elements and timelines of the initial assessment are identified. <p style="text-align: center;"><u>CHART REVIEW</u></p> <p>Review a minimum of five (5) inpatient and five (5) outpatient records to verify initial assessments by all disciplines are appropriate, complete and</p>	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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findings appropriate to the service setting (inpatient, outpatient, and ambulatory care) and the age and presenting problems of the patient.	of the initial assessment for: <ol style="list-style-type: none"> 1. Medical staff 2. Nursing, general 3. Nursing: Ambulatory care, ambulatory surgery, special care units, obstetrics, emergency department, pediatrics, and other subspecialties 4. Nutrition Services: Screens and full assessment 5. Pharmacy, clinical intervention 6. Rehabilitation: Physical Therapy, Occupational Therapy, Speech Language Pathology, and other rehabilitation, 7. Behavioral 8. Respiratory care 9. Social service 10. Pediatrics and other clinical services provided. 	timely. Verify: <ol style="list-style-type: none"> 1. Initial assessments are completed and within the timelines as established by policy. 	

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<p>10.01.25 Progress Notes. All records shall document reassessments and findings by clinical and other staff involved in the care of patients. Reassessments are entered as progress notes into the clinical record by each discipline providing care to the patient, at the time of the reassessment and at frequencies established within discipline specific standard(s) of practice.</p> <p>Reassessments are documented whenever there is:</p> <ol style="list-style-type: none"> 1. A significant change in the patient’s condition or status; 2. A significant response (desired or undesired) to a procedure / intervention; and 3. At specified time intervals. <p>Progress notes are dated, timed and signed by the author.</p> <p>Minimally, progress notes are authored by:</p> <ol style="list-style-type: none"> 1. Physicians, at least daily; 2. Nurses, with a change of shift or care giver; and 	<p>Hospital policy describes expectations for providing progress notes.</p> <p>Progress notes may be facilitated by the use of "flow" sheets or other checklist forms of documentation.</p>	<p style="text-align: center;"><u>DOCUMENT REVIEW</u></p> <p>Determine that discipline specific standards of practice have been established and address the three required criteria for reassessment.</p> <p style="text-align: center;"><u>CHART REVIEW</u></p> <p>Review medical records. Verify:</p> <ol style="list-style-type: none"> 1. Appropriate assessments and reassessments are completed, timed, dated, and authenticated. 2. Practitioners prepare progress notes at the defined frequency. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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- 3. Other support staff with each observation or, at intervals no less than every five visits or weekly, whichever comes first; and
- 4. For behavioral medicine patients, at least weekly for inpatients and monthly for outpatients.

10.01.26 Multidisciplinary Plan of Care.

Each patient will have a comprehensive, integrated, multidisciplinary plan of care, which is developed from the initial patient assessment. This care plan will include, at a minimum, physician and nursing components.

Each discipline is responsible for being knowledgeable and coordinating with the plan(s) of other disciplines in respect to individual patients.

Although each discipline is ethically and legally accountable for their own actions, this principle does not detract from the fact that a physician is responsible for each patient's medical plan of care.

DOCUMENT REVIEW

Verify that hospital policy supports the development of multidisciplinary plans for patient care.

- 1 = Compliant
- 2 = Not Compliant

This standard is not met as evidenced by:

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<p>10.01.27 <u>Outpatient Problem List.</u> If the hospital provides ongoing ambulatory care to a patient for the same problem(s), the list of problems, needs and diagnoses is developed and included in the medical record by at least the third visit.</p>	<p>Whether this is in freestanding clinics, or via mechanisms in the acute care hospital, the coordination of services for patients with repeating ambulatory care is based upon a common problem list.</p> <p>This list also includes known allergies and all medications (legend and non-legend) taken by the patient in order to assess for potential interactions, interferences and incompatibilities.</p>	<p style="text-align: center;"><u>DOCUMENT REVIEW</u></p> <p>Determine that the hospital provides ongoing ambulatory care (oncology, transfusion, mental health, physical rehabilitation, dialysis, etc.) If so, determine that hospital policy requires the establishment of a multidisciplinary problem list for each patient within the required time frame.</p> <p style="text-align: center;"><u>CHART REVIEW</u></p> <p>Review outpatient records. Verify:</p> <ul style="list-style-type: none"> • A problem list has been initiated by at least third (3rd) visit for patients returning for the same problem and has been appropriately updated. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>
<p>10.01.28 <u>Plan of Care: Assessment & Reassessment.</u> Each patient will have a comprehensive, integrated, multidisciplinary plan of care, which is developed from the initial patient assessment. This care plan will include, at a minimum, physician and nursing components.</p> <p>The plan of care is initiated within time frames established by the hospital.</p> <p>The plan is updated whenever there are significant changes in the list of patient problems, needs and diagnoses. The plans of care focus on:</p>	<p>Initial patient assessments provide the baseline of the patient at the time of admission. From these assessments, the needs of the patient are identified and the plan of care is developed.</p> <p>Individual plans of care are initiated at the time of the initial assessment. Coordinated plans of care <u>may</u> include:</p> <ol style="list-style-type: none"> 1. Clinical or Critical Pathways, which are matched to the patient as soon as the principle diagnoses are known. 2. A Master Treatment Plan (MTP), which is coordinated as soon as at least two disciplines have completed their assessments (with the exception of behavioral medicine in which all 	<p style="text-align: center;"><u>CHART REVIEW</u></p> <p>Review inpatient and outpatient records. The plan of care should be consistent with the observations noted in the progress notes.</p> <p>Verify:</p> <ol style="list-style-type: none"> 1. A plan of care is initiated within the established timeframe. 2. The plan of care is updated whenever there are significant changes in the list of patient problems, needs and diagnosis. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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<p>1. Immediate needs;</p> <p>2. The patient's needs for education regarding the diagnosis, treatment, and continuing management of health care problems and the maintenance of health; and</p> <p>3. Discharge planning.</p> <p>(See also the requirements in the Nursing Process.)</p> <p>When patient re-assessments dictate the need to change the treatment plan, the plan of care is modified.</p>	<p>disciplines shall complete initial assessments in order to develop the MTP by the fifth day.)</p> <p>Individual care providers are knowledgeable of the comprehensive plan of care. Each discipline involved with the care of a patient is responsible to contribute to the plan of care.</p> <p>Staff are expected to review the plan of care at the start of each shift; documentation of this review is not required.</p> <p>Modifications of the plan of care are dated, timed and signed by the author.</p> <p>Updates to the plan of care occur whenever there is:</p> <ol style="list-style-type: none"> 1. A significant change in the patient's condition or status 2. At specified time intervals 	<p style="text-align: center;">CHART REVIEW</p> <ul style="list-style-type: none"> • Examine patient records to verify that complete assessments have been conducted and documented. <p style="text-align: center;">DOCUMENT REVIEW</p> <ul style="list-style-type: none"> • Determine that Medical Staff and hospital policies appropriately identify required content of newborn care records. • Adult Medical Surgical facilities without OB 	<p><input type="checkbox"/> 1 = Compliant</p> <p><input type="checkbox"/> 2 = Not Compliant</p> <p><input type="checkbox"/> Not Applicable</p> <p>This standard is not met as evidenced by:</p>
<p>10.01.29 Newborn Care. Requirements for initial assessment, interventions, and reassessment are clearly defined, approved by the medical staff and implemented in the hospital.</p> <p>Newborn assessment data begins at delivery with the recording of 1 and 5 minute APGAR scores.</p>	<p>Consolidated nursing and medical data sheets include infant cord management and any State mandated ophthalmic prophylaxis.</p> <p>A physician physical assessment is documented for normal newborns at the completion of the "transition" period or prior to discharge.</p> <p>All data points are considered in order to document that the newborn is "at," "small for," or "large for," his calculated gestational / developmental age.</p>	<p style="text-align: center;">CHART REVIEW</p> <ul style="list-style-type: none"> • Examine patient records to verify that complete assessments have been conducted and documented. <p style="text-align: center;">DOCUMENT REVIEW</p> <ul style="list-style-type: none"> • Determine that Medical Staff and hospital policies appropriately identify required content of newborn care records. • Adult Medical Surgical facilities without OB 	<p><input type="checkbox"/> 1 = Compliant</p> <p><input type="checkbox"/> 2 = Not Compliant</p> <p><input type="checkbox"/> Not Applicable</p> <p>This standard is not met as evidenced by:</p>

MEDICAL RECORDS (HEALTH INFORMATION) SERVICES

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>10.01.30 <u>Pediatric / Adolescent Patients.</u> The medical record of pediatric and adolescent patients includes documentation of the achievement of physical, emotional and social developmental markers.</p>	<p>A newborn record, which is separate from that of the mother, is initiated and maintained. This record reflects almost continuous observations during the first hours of transition, from in-utero, until thermostabilization has occurred.</p> <p>Initial data are recorded by nursing including legal identification processes.</p> <p>Hospital policy describes the physical, emotional, and social development criteria to be assessed and documented for pediatric and adolescent patients.</p> <p>Due to the broad range of growth markers there may be multiple kinds of "flow" charts or other mechanisms to facilitate pediatric assessment. Each such assessment should have sufficient content to indicate that there has been an assessment of the developmental processes and nurturing (in order to screen out abuse / neglect).</p> <p>Immunization history is an expected data point.</p> <p>Considerations, in addition to height and weight, may include head circumference and neuromuscular sensory markers in the very young.</p> <ol style="list-style-type: none"> 1. In toddlers, the factors indicating communication, social and dexterity skills may be key. 2. Social values begin to appear in the preschool child and may be altered in the child living in a 	<p>still require these requirements, as there may be precipitous deliveries in the hospital.</p> <p align="center"><u>DOCUMENT REVIEW</u></p> <p>Determine that Medical Staff and hospital policies appropriately identify required developmental markers and nurturing as key data points in pediatric records.</p> <p align="center"><u>CHART REVIEW</u></p> <p>Examine pediatric / adolescent medical records. Verify:</p> <ol style="list-style-type: none"> 1. The completion of age-appropriate physical, emotional, and social development assessments. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant <input type="checkbox"/> Not Applicable</p> <p>This standard is not met as evidenced by:</p>

MEDICAL RECORDS (HEALTH INFORMATION) SERVICES

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dysfunctional setting.

- Peer relationships and competitiveness emerge as strong factors in the early school age child (progress and "getting along" in school). The development of secondary sexual characteristics may be key in ascertaining behavioral issue concerns.

10.01.31 Obstetric Patients.

The office prenatal record is forwarded to the labor rooms, following the visit occurring nearest the 34th - 35th weeks of pregnancy.

Hospital policy describes the expectations relative to forwarding prenatal records and diagnostic test results.

The prenatal record includes information regarding the findings from laboratory data such as CBC, Blood Group - RH screen for irregular antibodies, Rubella Screen (titer), RPR, sexually transmitted diseases, and most recent PAP Smear; UA, and any other testing accomplished.

CHART REVIEW AND INTERVIEW

Review medical records of obstetric patients. Verify:

- When the prenatal record is forwarded to the hospital in advance of admission, the prenatal record is updated by the physician **or non-physician practitioner**, upon admission.
- Determine that obstetric prenatal records **are forwarded to the hospital in a timely manner**, which include all required assessments.

- 1 = Compliant
- 2 = Not Compliant
- Not Applicable

This standard is not met as evidenced by:

MEDICAL RECORDS (HEALTH INFORMATION) SERVICES

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>10.01.32 <u>Actions Taken to Improve Glycemic Control.</u></p> <ol style="list-style-type: none"> Unless a recent hemoglobin A1C (HbA1c) is known, among hospitalized hyperglycemic patients an HbA1c should be obtained upon admission. Both a nutritionist / dietitian and a diabetes nurse educator (nurse, when diabetic nurse educator is not available) are needed to assess compliance with medication, diet, and other aspects of care. At the time of discharge, the diabetes provider must communicate with outpatient care providers about the patient’s regimen and glycemic control, and also, based on information gathered during the admission, to convey any evidence that might support the need for a change of long-term strategy. 	<p align="center"><u>PATIENT SAFETY INITIATIVE</u></p> <p>Implement evidence-based intervention practices that prevent hypoglycemia and optimize the care of patients with hyperglycemia and diabetes.</p> <p>Among patients having known diabetes, an HbA1c elevation on admission may justify intensification of preadmission management at the time of discharge.</p> <p>The event of hospitalization is the ideal “teachable moment” for patients and their caregivers to improve self-care activities.</p>	<p align="center"><u>CHART REVIEW</u></p> <ol style="list-style-type: none"> Review Policy and Procedures. Review a sample of medical records to determine interventions from abnormal glucose levels (at least 2 consecutive glucose readings > 180 mg/dL or the receipt of insulin any time during the hospitalization). Exclude patients with a history of pancreatic transplant, pregnant at the time of admission, receiving hospice or comfort care or receiving insulin for a reason other than glucose management. Review medical record for evidence of assessment by nurse and dietitian. Review medical record for evidence of communication by the attending/discharge physician to the outpatient care provider. <p align="center"><u>PATIENT INTERVIEW</u></p> <p>Speak with patient to determine that evidence of diabetic teaching occurred.</p>	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

MEDICAL RECORDS (HEALTH INFORMATION) SERVICES

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>10.01.33 <u>Discharge Summary.</u> A concise discharge summary must be completed on each patient within seven (7) days of patient discharge.</p>	<p>In order to facilitate the transition of care between providers, it is essential that the discharge summary document is available to the next provider, at a minimum, by the time of the patient’s next appointment. Future care of the patient may depend upon findings / events incurred during the inpatient stay.</p> <p>All tests / diagnostics pending at the time of discharge may be noted as such in the discharge summary. As new results are obtained, relating to the inpatient stay, the document may be amended by the discharging practitioner.</p>	<p><u>OBSERVATION, INTERVIEW, & CHART REVIEW</u></p> <ol style="list-style-type: none"> 1. Observe the discharge process for compliance with standard. 2. Review the patient record for inclusion and completion of the discharge summary within the designated time frame. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>
<p>10.02.01 <u>Not Applicable.</u></p>			
<p>10.02.02 <u>Not Applicable.</u></p>			
<p>10.02.03 <u>Not Applicable.</u></p>			
<p>10.02.04 <u>Not Applicable.</u></p>			
<p>10.02.05 <u>Required Policies.</u> The Medical Records Committee shall recommend policies for medical record maintenance and supervise medical records to ensure proper recording of sufficient data to evaluate patient care.</p>	<p>Self-explanatory.</p>	<p><u>DOCUMENT REVIEW</u> Review the Medical Records Committee minutes.</p>	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

MEDICAL RECORDS (HEALTH INFORMATION) SERVICES

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>10.02.06 <u>Policies on Confidentiality & Release of Records.</u> The Medical Records Committee shall develop policies, with the aid of legal counsel, to guide the medical records administrator, professional staff, and administration in matters of privileged communication and legal release of information.</p> <p>10.02.07 <u>Not Applicable.</u></p>	<p>Medical Records policies are reviewed at least every three (3) years and updated more frequently, as necessary.</p>	<p><u>DOCUMENT REVIEW</u></p> <p>Review the Medical Records Committee minutes.</p> <p>Determine the medical records committee participates in the development of policies on confidentiality and release of medical records.</p> <p>Determine the Medical Records related polices have been reviewed at least every three (3) years.</p>	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

PHYSICAL ENVIRONMENT

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
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General Requirements:

11.00.01 Condition of Participation: Physical Environment.

The hospital must be constructed, arranged, and maintained to ensure the safety of the patient, and to provide facilities for diagnosis and treatment, and for special hospital services appropriate to the needs of the community.

§482.41

This standard applies to all locations of the hospital, all campuses, all satellites, all provider-based activities, and all inpatient and outpatient locations, regardless of occupancy designation.

The hospital's Facility Maintenance and hospital departments or services responsible for the hospital's buildings and equipment (both facility equipment and patient care equipment) must be incorporated into the hospital's QAPI program and be in compliance with the QAPI requirements.

DOCUMENT REVIEW, INTERVIEW, AND OBSERVATION

Review the scores for this chapter with focus on the list of systems identified in 11.00.02 below.

One surveyor should conduct survey of the Physical Environment; however, each surveyor, as he/she conducts his/her survey assignments, should assess the hospital's compliance with this standard.

- 1 = Compliant
- 2 = Not Compliant

This standard is not met as evidenced by:

11.00.02 Required Plans & Performance Standards.

The hospital shall maintain written plans and performance improvement standards for the following areas:

- 01: Building Safety
- 02: Building Security
- 03: Hazardous Materials and Waste
- 04: Fire Safety Control
- 05: Medical Equipment Management
- 06: Utility Systems Management

Plans to be reviewed and approved at least once every 12 months by the organization's committee that oversees safety in the environment. The annual review is documented.

The hospital shall maintain written plans on management procedures to address each of the six (6) areas identified. Performance improvement goals and objectives must be included for each area.

Plans must be reviewed and approved by the organization's committee which oversees safety in the environment. Each area is tracked in a subchapter, **identified in the standard**. Each of the six (6) areas must have an individual(s) identified as to who is responsible for that particular area.

The hospital designates the individual responsible for each subchapter, and documents their qualifications for the responsibility.

DOCUMENT REVIEW, OBSERVATION, AND INTERVIEW

Review the hospital written plans for managing each of the six (6) areas identified. Do written procedures exist which instructs staff on the proper action to take in regards to each of the six (6) areas?

- Do performance improvement goals and objectives exist for each area?
- Is there an identifiable person or department or team responsible for each area to facilitate corrections or improvements as necessary?
- Is there evidence of active monitoring and follow-up for each area?

- 1 = Compliant
- 2 = Not Compliant

This standard is not met as evidenced by:

PHYSICAL ENVIRONMENT

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
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Building Safety:

11.01.01 Periodic Monitoring for Safety Issues.

The physical environment of each facility used for treating or housing patients shall be inspected once every six months in patient care areas, and once every 12 months in non-patient care areas **to identify safety related concerns and issues.**

Inspections must be documented with date, initials or signatures of individuals participating in the inspection, and all deficiencies identified with the **action item** of said deficiencies.

11.01.02 Building Safety.

The condition of the physical plant and the overall hospital environment must be developed and maintained in such a manner that the safety and well-being of patients, visitors, and staff is assured.

§482.41(a)

All patient care areas of the facility are inspected at least once every six months and all non-patient care areas are inspected at least once every 12 months to identify safety related concerns and issues. Special care is given to ensure compliance with applicable codes, standards and regulations related to the physical environment.

Interior and exterior walking surfaces are to be inspected for tripping or slipping hazards. Electrical hazards, ergonomics, corridor clutter, fluid leaks, signage, egress lighting and paths of egress are of particular interest.

The hospital must ensure that the condition of the physical plant and overall hospital environment is developed and maintained in a manner to ensure the safety and well-being of patients, visitors and staff.

Routine and preventative maintenance on medical equipment is scored under 11.05.01, and utility (plant) equipment is scored under 11.06.09.

DOCUMENT REVIEW, INTERVIEW AND OBSERVATION

- Verify that records have been maintained demonstrating safety inspections were conducted once every six months in patient care areas and once every 12 months for non-patient care areas
- Additional facilities associated with the hospital, either owned or leased must also be monitored for safety. Records demonstrating correction of actions should be reviewed. All items identified in the report should be reviewed for **corrective action.**

DOUCUMENT REVIEW AND OBSERVATION

- Verify that the condition of the hospital is maintained in a manner to assure the safety and well-being of patients (e.g., condition or ceilings, walls, and floors, presence of patient hazards, etc.).

- 1 = Compliant
- 2 = Not Compliant

This standard is not met as evidenced by:

- 1 = Compliant
- 2 = Not Compliant

This standard is not met as evidenced by:

PHYSICAL ENVIRONMENT

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>11.01.03 <u>Safety Committee.</u> There is a Safety Committee that is developed to discuss the opportunities to improve all issues related to safety existing within the hospital.</p> <p>Multi-disciplinary membership shall consist of individuals who have knowledge and authority of the operations within their own area / service.</p>	<p>Membership includes a representative from administration, clinical, and support services. This team is responsible for all safety-related policies, procedures, and processes in the hospital.</p> <p>The Safety Committee meets periodically, to review reports, analyze trends, discuss safety related issues in the physical environment, and identify opportunities to resolve physical environment safety issues.</p> <p>The Safety Committee reports appropriate results of monitoring and committee actions and recommendations to leadership, Quality Assessment Performance Improvement (QAPI), and department managers.</p> <p>HFAP does not specify the frequency of Safety Committee meetings, but meeting held less than once every two months require a risk assessment to indicate the effectiveness of less frequent meetings.</p>	<p style="text-align: center;"><u>DOCUMENT REVIEW</u></p> <p>Review the appointment process, composition of, and duties of the Safety Committee and their performance.</p> <p>Review minutes of committee meetings. Determine if recommendations for action were made for specific safety issues.</p> <p>Evaluate the frequency of the Safety Committee meetings. If less frequent than once every two months, then review risk assessment indicating the effectiveness of the less-frequent meetings.</p> <p>Review reports of the Safety Committee to the governing body to determine effectiveness of the committee to make recommendations on physical environment issues.</p>	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>
<p>11.01.04 <u>Safety Committee Chairperson.</u> The Chief Executive Officer of the hospital shall appoint the chairperson of the Safety Committee.</p> <p>The appointment must be documented.</p>	<p>The role of the chairperson is to assure that concerns that are identified by the Safety Committee can receive administrative attention in an expeditious manner.</p> <p>Consideration should be made to limit the appointment of the chairperson to a 1-year term to allow a change in leadership. While this is not a requirement, it is suggested to rotate the chairperson’s role to prevent domination by one individual.</p>	<p style="text-align: center;"><u>INTERVIEW</u></p> <ul style="list-style-type: none"> • Verify the appointment. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

PHYSICAL ENVIRONMENT

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>11.01.05 <u>Safety Officer.</u> An individual is appointed by the chief executive officer to serve as the organization’s Safety Officer with responsibilities to intervene whenever conditions in the environment present a threat to the life and health of the occupants, or threaten damage to the physical environment.</p> <p>This appointment must be documented.</p>	<p>The CEO annually appoints an individual possessing knowledge of safety requirements. This position is responsible for all safety issues not specifically assigned to another member or to a safety committee.</p> <p>Authority to take any action needed relating to situations that pose immediate threat to life, health, and/or property shall be included in the appointment document.</p>	<p><u>DOCUMENT REVIEW</u></p> <ul style="list-style-type: none"> Review the appointment process and content of the appointment document. Verify the appointment has been reaffirmed annually. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>
<p>11.01.06 <u>Not Applicable.</u></p>			
<p>11.01.07 <u>Not Applicable.</u></p>			
<p>11.01.08 <u>Review of Safety Policies / Procedures.</u> The Safety Committee is responsible to evaluate safety policies and procedures as conditions change within the organization or at least once every 36 months.</p>	<p>People, processes, and characteristics change; therefore, all safety policies and procedures shall be reviewed at least once every 36 months and approved for appropriateness by the Safety Committee.</p> <p>The chairperson of the Safety Committee shall sign and date the policies.</p>	<p><u>DOCUMENT REVIEW</u></p> <ul style="list-style-type: none"> Verify that an appraisal has been documented at least once in the past 36 months within the Safety Committee minutes Verify that policies are current. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

PHYSICAL ENVIRONMENT

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>11.01.09 <u>Smoking / Tobacco Products Policy.</u> The hospital shall have, disseminate, and enforce a hospital-wide policy prohibiting the use and sale of tobacco products within the buildings used for treating or housing patients.</p>	<p>Smoking and the use of lighting material for smoking is also a fire hazard. Smoke in a hospital contaminates air in the central air system. Smoking is dangerous around oxygen.</p> <p>Active promotion is to be taken to promote a tobacco free environment in the healthcare hospital.</p> <p>The policy on smoking must address the requirements found in chapter 18/19.7.4 of the 2012 Life Safety Code, including information on:</p> <ul style="list-style-type: none"> • Prohibited areas • Signage • Ashtray construction • Metal containers with lids for ash disposal <p>The policy shall prohibit smoking by patients unless authorized to smoke by the attending physician. If permitted, smoking must be out of doors and away from entrances or air intakes. If permitted indoors, it must be confined to controlled smoking areas which prevent exposure to non-smokers, must not contaminate the central air system, and the smoke from the controlled area must be exhausted to the out of doors. Other <u>patients</u> and <u>staff</u> MUST be protected from exposure.</p>	<p><u>DOCUMENT REVIEW AND OBSERVATION</u></p> <ul style="list-style-type: none"> • Verify policy and observe practice. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>
<p>11.01.10 <u>Eyewash Stations and Emergency Showers.</u> Where the eyes or body of any person may be exposed to injurious corrosive materials, ANSI Z358.1-2014 approved eyewash stations and/or emergency</p>	<p>Where injurious corrosive materials exist, organizations must conduct a risk assessment to determine the need for ANSI Z358.1-2014 approved eyewash stations and/or emergency showers.</p> <p>ANSI Z358.1-2014 is the standard that must be</p>	<p><u>DOCUMENT REVIEW AND OBSERVATION</u></p> <ul style="list-style-type: none"> • In areas where injurious corrosive materials are observed, review the organization’s risk assessment to determine the need for emergency eyewash or shower equipment. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant <input type="checkbox"/> N/A</p> <p>This standard is not</p>

PHYSICAL ENVIRONMENT

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>showers shall be provided within the work area for immediate emergency use.</p>	<p>followed for the proper design, installation and maintenance of emergency eyewash and shower equipment.</p> <p>To purchase your own copy of the ANSI Z358.1-2014 standard, follow this link: http://webstore.ansi.org/</p>	<ul style="list-style-type: none"> • Check logs to ensure plumbed emergency eyewash and shower equipment are activated weekly to verify operation and to ensure the flushing fluid is available. • Examine emergency eyewash and shower equipment to ensure it complies with ANSI Z358.1-2014 standards for installation and operation. 	<p>met as evidenced by:</p>

PHYSICAL ENVIRONMENT

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
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Building Security:

11.02.01 Building Security.

The organization shall have policies and other measures in effect to identify and minimize security risks to patients, visitors, and staff.

Patients, visitors, and staff shall be protected from security concerns. Policies, procedures, and systems shall be developed to monitor and reduce adverse outcomes. Examples of security issues include theft of personal or commercial items, abduction, and assaults of individuals in and outside the facilities.

Security risks must be identified and action taken to minimize the risk to patients, visitors and staff.

DOCUMENT REVIEW AND INTERVIEW

- Determine if policies, procedures and systems are in place. Review documents to determine if the security program is effective or if there are security concerns.
- Review security risk assessments for frequency and thoroughness of assessments, and follow-through on recommended actions.
- Interview staff to determine if security and safety is an issue.

1 = Compliant
 2 = Not Compliant

This standard is not met as evidenced by:

11.02.02 Security Management.

There shall be an individual or department with responsibility for monitoring and addressing security concerns.

Smaller facilities may have full time or part time security staff that reports to an administrative staff person. Larger facilities may have their own security department and security officers.

Consideration should be given how to process supplement security resources in the event of a disaster. This may be accomplished with Memorandums of Understanding (MOU).

The hospital has established a relationship with the local police department to facilitate timely response if external police assistance is required. External support for security is available on a timely basis from the local police department.

INTERVIEW

- Interview various hospital employees to determine if they can identify the person or department responsible for security issues.
- Does adequate staff and supervision exist?
- Review security reports for occurrences of security problems. Are security issues handled quickly and thoroughly? Is follow-up appropriate?

1 = Compliant
 2 = Not Compliant

This standard is not met as evidenced by:

PHYSICAL ENVIRONMENT

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11.02.03 Not Applicable.

11.02.04 Security Sensitive Areas.
 The hospital identifies areas that they believe to be security sensitive and have control systems in place to protect the areas and contents.

These security sensitive areas are documented.

There are many different types of areas in a hospital that can be considered security sensitive, such as nurseries, pharmacies, cashiers box, medical records, etc. The organization must first identify these areas and then have systems in place to control and protect these areas.

Note: Control systems can be physical locks on doors, observation systems, as well as special response plans. **Any locks on doors must comply with the Life Safety Code, 2012 edition.**

The hospital reviews the list of security sensitive areas on an annual basis, to determine accuracy and whether additional locations need to be added.

DOCUMENTATION AND INTERVIEW

- Review list of security sensitive areas. Determine if all sensitive areas are included.
- Determine through interview if security control system is sufficient to protect identified areas.

1 = Compliant
 2 = Not Compliant

This standard is not met as evidenced by:

11.02.05 Security Incident Procedures.
 The hospital has written procedures that they must adhere to in the event of a security incident.

Security incidents may include an infant abduction, VIP visit, civil disobedience, bomb threat, or unruly patient or guest. The hospital must have written procedures that their security staff must follow in the event of a security incident.

DOCUMENTATION

Review list of written procedures for security incidents. Evaluate if the list adequately covers procedures for staff to follow in the event of an incident.

1 = Compliant
 2 = Not Compliant

Interview staff to determine if they received training on Security Incident Procedures.

This standard is not met as evidenced by:

PHYSICAL ENVIRONMENT

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
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Hazardous Materials and Waste.

11.03.01 Hazardous Materials & Waste Program.

There shall be a system to identify, handle, process, and dispose of hazardous materials and wastes. Each service area within the hospital shall develop and maintain a list of the hazardous materials and wastes housed in the area and/or used by staff.

A hazardous material is defined as any substance or material that could adversely affect the safety of the public, handlers or carriers during use, transportation, storage, or disposal.

Aspects of the physical environment are designed and maintained to contain, neutralize, or destroy potentially harmful materials and wastes. Examples of hazardous waste include but are not limited to chemotherapy waste, chemical waste, infectious waste, waste gas, and radioactive waste.

The hospital designates **in writing** an individual to be responsible for the coordination of activities to ensure procedures are written, approved (by the appropriate committee), and implemented for response to spills, accidents, and emergency in-house decontamination for patients of the emergency department.

11.03.02 Storage & Disposal Of Trash.

The hospital must have procedures for the proper routine storage and prompt disposal of trash.

§482.41(b)(4)

The term trash refers to common garbage as well as bio-hazardous waste. The storage and disposal of trash must be in accordance with Federal, State and local laws and regulations (i.e., EPA, OSHA, CDC, State environmental, health and safety regulations).

The procedures for proper routine storage and disposal of trash must be written, and reviewed by the Safety Committee once every 3 years.

DOCUMENT REVIEW AND OBSERVATION

- **Review the** procedures for the processes used in using, storage, transporting and disposal of these materials and wastes are written and updated **once every three years.**
- Observe for appropriate handling storage, processing and disposal of hazardous materials and wastes.
- **Interview staff to determine the effectiveness of hazardous spill training.**

- 1 = Compliant
- 2 = Not Compliant

This standard is not met as evidenced by:

DOCUMENTATION AND OBSERVATION

- Verify that the hospital has developed and implemented policies for the proper storage and disposal of trash.
- Verify through observation that staff adhere to these policies and that the hospital has signage, as appropriate.
- **Verify that the hospital has trained individuals to sign the EPA manifest.**

- 1 = Compliant
- 2 = Not Compliant

This standard is not met as evidenced by:

PHYSICAL ENVIRONMENT

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>11.03.03 Program Minimizes Exposure. The hazardous materials and waste program is organized in a manner, which minimizes potential exposure to patients, visitors, staff, and the surrounding community.</p>	<p>Policies and procedures should address the prevention and response to spills, slips, falls, and accidents.</p>	<p>DOCUMENT REVIEW AND OBSERVATION</p> <ul style="list-style-type: none"> Review hazardous waste plans for various waste products. Determine compliance. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>
<p>11.03.04 Labels, Inventory & SDS. The hospital identifies and documents all hazardous materials and waste used, stored or generated throughout the hospital, and ensures that they are properly labeled.</p>	<p>Hazardous products are appropriately labeled according to regulations and NFPA standards.</p> <p>Safety Data Sheets (SDS) are maintained (or are available within 10 minutes) in an area that is always available to the staff for every hazardous material for which they may come in contact. Hazardous materials that must be included on the inventory are those whose storage, use or handling are regulated by standards or laws.</p> <p>The inventory is updated annually.</p> <p>Safety Data Sheet information may be stored electronically, or obtained through the internet or a fax-back service. However, paper copies of the Safety Data Sheets of all hazardous products must be maintained on the premise of the facility, in the event the electronic copies are not available. Copies of the SDS may be maintained on CDs or flash-drives in lieu of paper copies, provided a battery-operated computer is available to display them.</p>	<p>DOCUMENT REVIEW AND OBSERVATION</p> <ul style="list-style-type: none"> Review the Hazardous Materials and Waste Management Plan. Check hazardous materials during building tour looking for proper labeling, use, disposal and storage. Ask staff to provide you a Safety Data Sheet for random selected materials. Confirm paper copies of the Safety Data Sheets are available to the hospital staff, or copies in CDs or flash-drives provided a battery-operated computer is available to display them. Review inventory of hazardous materials and confirm that it is updated annually. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

PHYSICAL ENVIRONMENT

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>11.03.05 <u>Personal Protective Equipment (PPE).</u> Appropriate Personal Protective Equipment (PPE) is provided, as necessary, to staff to ensure against possible exposure to hazardous materials and wastes.</p>	<p>Personal protective equipment is required to be readily available to the staff to prevent exposure to harmful substances by the Occupational Safety and Health Administration (OSHA). The types of protective equipment can range from gloves to a self-contained breathing apparatus.</p> <p>The types of protective devices needed for handling chemicals are listed on the warning label accompanying a product or on the SDS (Safety Data Sheet).</p>	<p><u>OBSERVATION</u></p> <ul style="list-style-type: none"> Review the hazardous materials and waste program for exposure to risk content. Look for evidence of use of PPE. Is PPE available? 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>
<p>11.03.06 <u>Hazardous Materials – Routine Monitoring.</u> Monitoring of hazardous materials and wastes is conducted to reduce the exposure potential to harmful agents.</p>	<p>Routine inspections of the occupied areas of the hospital shall occur to observe and record how hazardous substances are stored, handled, and organized.</p> <p>Environmental tests are performed for substances that produce harmful vapors to ensure that engineering controls are adequate to provide a safe environment.</p> <p>Policies and procedures have been developed to comply with these Federal regulations.</p>	<p><u>DOCUMENT REVIEW AND OBSERVATION</u></p> <ul style="list-style-type: none"> Review documented routine monitoring of hazardous materials. Observations will be made of the storage containers (which may range from labeling the container to the use of explosion proof cabinets), the availability and use of personal protective equipment, and staff knowledge of the hazardous materials and wastes program. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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Fire Safety Control

11.04.01 Written Fire Control Plans.

The hospital must have written fire control plans that contain provisions for:

- *Prompt reporting of fires*
- *Extinguishing fires*
- *Protection for patients, personnel and guests*
- *Evacuation*
- *Cooperation with fire-fighting authorities*

§482.41(b)(5)

The written fire control plans must describe the roles expected of staff at the area or location of the fire, and in areas and locations away from the fire. Plans must include how and when to activate the alarm, the proper method to contain smoke and fire, the correct method on when and how to use a fire extinguisher and when and where to evacuate patients.

The fire control plan must meet the requirements of chapter 18/19.7.1.1 of the **2012** Life Safety Code, including but not limited to:

- Plan must be made available to all personnel
- Plan must be available at the telephone operator position(s) or the continuously manned security center
- Provide instruction in fire-safety procedures and devices to all staff

The plan must also include instructions on how to evacuate the building when instructed to do so by a person of authority. The term ‘staff’ includes all individuals, whether employees, volunteers, students or contract workers who are performing their job requirements within the facility.

DOCUMENT REVIEW AND INTERVIEW

- Review the hospital’s written fire control plans to verify they contain the provisions identified.
- Verify that hospital staff reported all fires as required.
- Interview staff throughout the hospital to verify their knowledge of their responsibilities during a fire.

- 1 = Compliant
- 2 = Not Compliant

This standard is not met as evidenced by:

PHYSICAL ENVIRONMENT

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>11.04.02 Fire Drills - Quarterly. Fire drills shall be conducted at least quarterly on all shifts in all buildings classified as healthcare occupancy or ambulatory healthcare occupancy.</p> <p>For buildings classified as business occupancy (or other occupancies), fire drills are conducted annually on all shifts.</p> <p>All fire drills are documented.</p>	<p>The fire plan is practiced without prior warning to the occupants of the building(s). Observers document actual reactions to the enactment.</p> <p>Fire drills must meet the following requirements:</p> <ul style="list-style-type: none"> • Simulation of emergency fire conditions • A coded announcement is permitted between 9:00 pm and 6:00 am in lieu of activating the audible notification devices on the fire alarm system, but the fire alarm system still needs to be activated for each drill • Patients are not required to be moved during drills • Evacuation of simulated patients to the nearest smoke compartment barrier door <p>Drills should take into consideration non-customary shifts such as 12-hour shifts and weekend staffing patterns.</p> <p>Staff participates in the drills inasmuch as the hospital’s fire response plan requires their response to fire alarms.</p>	<p style="text-align: center;"><u>DOCUMENT REVIEW</u></p> <ul style="list-style-type: none"> • Participation is based upon staff’s role in accordance with the Fire Control Plan, which may be at the point of alarm and away from the point of alarm. • Review logs to ensure each healthcare occupancy and each ambulatory healthcare occupancy had one drill per shift per quarter. • Review logs to ensure off-site business occupancies have had annual fire drills on each shift. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

PHYSICAL ENVIRONMENT

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>11.04.03 <u>Fire Drill - Critique.</u> Each fire drill shall be evaluated by observers located in strategic areas to record the responses of the staff and the processes being followed.</p> <p>Each fire drill critique is documented.</p>	<p>Detailed documentation of critiquing of the drills shall be maintained. A proper critique must include;</p> <ul style="list-style-type: none"> • the staff’s response to the alarm; • the building’s response to the alarm; and • the fire alarm response. <p>This information is to be used by the Safety Team to improve hospital fire response systems.</p> <p>Actual fire alarms (non-drills) may be used in lieu of planned fire drills provided all areas of response are properly critiqued.</p>	<p style="text-align: center;"><u>DOCUMENT REVIEW</u></p> <ul style="list-style-type: none"> • Review records of the analysis of the fire drill implementations. • Review Safety Team/Committee minutes to determine if they evaluate fire drills to improve the hospital’s fire response. 	<p style="text-align: center;"> <input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant </p> <p>This standard is not met as evidenced by:</p>
<p>11.04.04 <u>Approval by State & Local Fire Agencies.</u> <i>The hospital must maintain written evidence of regular inspection and approval by state or local fire control agencies.</i></p> <p>§482.41(b)(6)</p>	<p>The frequency of inspections by state or local authorities on fire safety should be at the minimum, once per calendar year.</p> <p>Inspection frequencies more than 1-year will be considered if the hospital has historical evidence proving longer frequencies between inspections does not present an unsafe environment for the hospital.</p> <p>Evidence substantiating a safe environment would be consecutive reports indicating no findings or minimal findings.</p> <p>Where state and local fire control authorities refuse to provide inspections, the hospital must have written documents from the state and local fire control authorities indicating their decision not to provide inspections.</p>	<p style="text-align: center;"><u>DOCUMENT REVIEW</u></p> <ul style="list-style-type: none"> • Examine copies of inspection and approval reports from state and local fire control agencies to verify evidence of inspections and correction of any deficiencies. • Examine documentation from state or local fire control authorities where they refuse to provide inspections. 	<p style="text-align: center;"> <input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant </p> <p>This standard is not met as evidenced by:</p>

PHYSICAL ENVIRONMENT

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>11.04.05 <u>Minimize the Risk of Danger from Fire.</u> The hospital shall minimize the risk of danger from fire, smoke and the products of combustion.</p>	<p>The hospital must take a proactive approach to reduce the risk of harm and danger to the occupants of the facility, from the harmful effects from fire, smoke and the products of combustion.</p> <p>This standard does not require the hospital to install fire safety features that are not required by any applicable code, standard or regulation.</p>	<p><u>OBSERVATION</u> During the building tour, identify situations that exist which may present a danger to the occupants from the harmful effects of fire, smoke and the products of combustion.</p>	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>
<p>11.04.06 <u>Fire Response – Staff Training.</u> All staff members, including volunteers, students, physicians, and chaplains in the hospital must be trained and have knowledge on the proper procedure to respond to fire situations, both at the point of the alarm and away from the point of the alarm.</p>	<p>Self-Explanatory.</p>	<p><u>DOCUMENT REVIEW AND INTERVIEW</u></p> <ul style="list-style-type: none"> Review training records to ensure staff receives fire response training. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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Medical Equipment Management.

11.05.01 Medical Equipment & Systems – Maintenance.

There is an established, scheduled preventive maintenance program for medical equipment relating directly or indirectly to patient care, and shall be maintained and tested periodically in accordance with the manufacturer’s recommendations.

As an alternative approach, hospitals may choose to employ alternative maintenance activities and/or schedules provided they develop, implement, and maintain a documented Alternate Equipment Management (AEM) program, to minimize risks to patients and others in the hospital associated with the use of medical equipment.

The definition of ‘medical equipment’ is a device intended to be used for diagnostic, therapeutic, or monitoring of care to a patient in a hospital. All medical equipment (electrical and non-electrical) shall be included in the process for preventive maintenance. There shall be written testing criteria for each type of equipment included in the preventive maintenance system. For hospitals that elect to perform equipment maintenance in accordance with the manufacturer’s requirements, the hospital must maintain documentation of the manufacturer’s recommendations as well as the hospital’s maintenance activities.

The organization may use an alternative method of communication to staff on medical equipment inspections, in lieu of stickers applied to medical equipment identifying the next inspection due date.

Alternate Equipment Management (AEM) Program

A hospital may, under certain conditions, use equipment maintenance activities and frequencies that differ from those recommended by the manufacturer, provided the activities and frequencies do not reduce the safety of the equipment. Hospitals that choose to employ alternate maintenance activities and/or schedules must develop, implement, and maintain a documented AEM program to minimize risks to patients and others in the hospital associated with the use of medical equipment. The

DOCUMENT REVIEW AND INTERVIEW

- Review records and/or equipment for evidence of routine inspections and documentation of the hospital’s biomedical preventive maintenance program.
- Are inspections conducted in a timely manner? Are past-due inspections common or rare?
- Can the staff recognize whether the equipment they are using has been inspected or is due for inspection? **While stickers applied to the medical equipment identifying the next inspection due date are not a requirement of this standard, there must be some form of effective communication to the staff on the current preventive maintenance of that equipment.**
- Is the preventive maintenance process one that alerts the staff to potentially unsafe equipment?

If the hospital is utilizing an AEM program for inspection, testing and maintenance activities, then the following activities need to be reviewed:

- Review the documentation for the AEM program. Determine if it addresses the requirements for equipment to have

- 1 = Compliant
- 2 = Not Compliant

This standard is not met as evidenced by:

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	<p>AEM program must be based on generally accepted standards of practice for medical equipment maintenance, such as ANSI/AAMI EQ 56:1999/(R) 2008, <i>Recommended Practice for a Medical Equipment Management Program</i>.</p> <p>The determination of whether it is safe to perform medical equipment maintenance without following the equipment manufacturer recommendations must be made by qualified personnel, regardless of whether they are hospital employees or contractors. In the case of medical equipment, a clinical or biomedical technician or engineer would be considered qualified.</p> <p>The hospital must maintain records of the qualifications of hospital personnel who make decisions on placing equipment in an AEM program, and must be able to demonstrate how they assure contracted personnel making such decisions are qualified.</p> <p>In determining whether or not to include equipment in an AEM program, and which maintenance strategies to use in developing maintenance activities and frequencies for particular equipment, the hospital must take into account the typical health and safety risks associated with the equipment's use. Note that the risk may vary for the same type of equipment, depending on the patient care setting within the hospital where it is used.</p> <p>A hospital is expected to identify any equipment in its AEM program which is "critical equipment," for which</p>	<p>maintenance activities and frequencies less than the manufacturer's recommendations.</p> <ul style="list-style-type: none"> • Is the determination of the alternative maintenance activities and frequencies being performed by qualified individuals? • Verify that the hospital has documented maintenance activities and frequencies for all equipment included in the AEM program. • Verify the hospital is evaluating the safety and effectiveness of the AEM program on an annual basis. • If the hospital has identified equipment as having such a very low level of risk that it has determined it can use a broad interval range or departmental 'sweeps', ask the hospital for the evidence used to make this determination, and determine if it is reasonable. • Of the critical equipment that is included in the AEM program, ask the hospital to explain how the decision was made to place this critical equipment in the program. • Of the equipment that is included in the AEM program, ask the hospital to describe the methodology for applying maintenance strategies and determining alternative maintenance activities and/or frequencies. 	

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	<p>there is a risk of serious injury or death to a patient or staff person should the equipment fail.</p> <p>Multiple factors must be considered, since different types of equipment present different combinations of severity of potential harm and likelihood of failure. The hospital is expected to be able to demonstrate to a surveyor the factors it considered in its risk assessment for equipment placed in its AEM program.</p> <p>Some equipment may not be eligible for placement in the AEM program, for one or more of the following reasons:</p> <ul style="list-style-type: none"> • Other Federal or State laws that may require the hospital to inspect, test and maintain their equipment strictly in accordance with the manufacturer’s recommendation; • Other CMS Conditions of Participation which require adherence to manufacturer’s recommendations which preclude their inclusion in the AEM program; • Imaging and radiologic equipment, whether used for diagnostic or therapeutic purposes, must be maintained in accordance with the manufacturer’s recommendations; • Medical laser devices; • New equipment for which sufficient maintenance history, either based on the hospital’s own or its contractor’s records, or available publicly from 	<ul style="list-style-type: none"> • If the hospital is utilizing the AEM program, review the annual evaluation to determine they address: <ul style="list-style-type: none"> ○ How the equipment is evaluated ○ How incidents of equipment malfunction are investigated ○ The use of performance data 	

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	<p>nationally recognized sources, is not available to support a risk-based determination, must not be immediately included in the AEM program.</p> <p>The hospital may use one or more maintenance strategies for its AEM program in order to determine the appropriate inspection, testing and maintenance activities and frequencies, based upon the nature of the equipment and the level of risk it presents to patient or staff health and safety. The risk to patient health and safety that is considered in developing alternative maintenance strategies must be explained and documented in the AEM program.</p> <p>In developing AEM maintenance strategies, hospitals may rely upon information from a variety of sources, including, but not limited to:</p> <ul style="list-style-type: none"> • Manufacturer’s recommendations • Nationally recognized expert associations • Hospital’s own experience • Contractor’s own experience • Other materials <p>For each type of equipment subject to the AEM program, there must be documentation indicating:</p> <ul style="list-style-type: none"> • The pertinent types and level of risks to patients or staff health and safety; • Alternative maintenance activities and the differences from the manufacturer’s recommendations when they are known; • The date when AEM program maintenance 		

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activities were performed and what actions, if any, were taken;

- Documentation of equipment failures and identifying if any harm resulted to an individual.

The AEM program must be compliant with these requirements at all times, and must have written policies and procedures that address the effectiveness of the program. The hospital must have a written annual evaluation of the AEM program that addresses the following factors:

- How equipment is evaluated to ensure there is no degradation of performance;
- How incidents of equipment malfunctioning are investigated, including whether or not the malfunction could have been prevented; what steps will be taken to prevent future malfunctions; and how a determination is made whether or not the malfunction resulted from the use of an AEM strategy;
- The process for the removal of equipment from service determined to be unsafe or no longer suitable for its intended application;
- The use of performance data to determine if modifications in the AEM program procedures are required.

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<p>11.05.02 Medical Equipment Inventory. The hospital maintains a written inventory of all medical equipment available for use.</p>	<p>The inventory shall include all medical equipment used directly or indirectly for patient treatment and care.</p> <p>All equipment must be inspected, tested and maintained to ensure safety, availability and reliability. In addition, all equipment, regardless of whether it is leased or owned, and regardless of whether it is maintained in accordance to manufacturer recommendations or is in an AEM program, is listed in an inventory which includes a record of maintenance activities.</p> <p>If the hospital is using an AEM program, the equipment managed through that program must be separately identified on the equipment inventory from that equipment which is managed through the manufacturer’s recommendation program. Critical equipment, whether in an AEM program or not, must also be readily identified as such.</p> <p>To facilitate effective management, a well-designed equipment inventory contains the following information for all equipment included. However, hospitals have the flexibility to demonstrate how alternative means they use are effective in enabling them to manage their equipment.</p> <ul style="list-style-type: none"> • A unique identification number; • The equipment manufacturer; • The equipment model number; • The equipment serial number; • A description of the equipment; • The location of the equipment; • The identity of the department considered 	<p><u>DOCUMENT REVIEW AND OBSERVATION</u></p> <ul style="list-style-type: none"> • Review inventory list. Compare with field observed equipment to ensure all medical equipment is included. • If the hospital utilizes the AEM program, does the inventory for the AEM program contain any equipment which is not eligible for the AEM? 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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- to “own” the equipment;
- Identification of the service provider;
- The acceptance date;
- Additional identification deemed useful.

11.05.03 Patient Call System.

The hospital maintains a means by which patients can summon help.

The hospital maintains a patient call system so patients can summon assistance. A backup system should be available to cover this need during power outages.

Patient call systems are not required in psychiatric nursing units, or psychiatric hospitals that do not serve acute-care patients.

OBSERVATION AND INTERVIEW

- Observe patient care areas to verify that such a system is in place and operational. Verify that there is a backup plan in place for periods of power outage.

- 1 = Compliant
- 2 = Not Compliant

This standard is not met as evidenced by:

11.05.04 Safe Medical Device Act (SMDA).

The hospital has taken actions to comply with the Safe Medical Device Act (SMDA).

Facilities shall demonstrate through the development and implementation of policies and procedures that they have addressed the issues and spirit of this act.

DOCUMENT REVIEW AND OBSERVATION

- Review organization policies and procedures, tracking systems, and their ability to demonstrate compliance.

- 1 = Compliant
- 2 = Not Compliant

This standard is not met as evidenced by:

11.05.05 Medical Equipment Procurement.

The hospital obtains information and opinions when acquiring new medical equipment from the individuals who operate and service the equipment.

Self-explanatory.

DOCUMENT REVIEW AND OBSERVATION

- Review organization policies and procedures, tracking systems, and their ability to demonstrate compliance.

- 1 = Compliant
- 2 = Not Compliant

This standard is not met as evidenced by:

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Utility Systems Management.

11.06.01 Emergency Power & Lighting.

There must be emergency power and lighting in at least the operating, recovery, intensive care, emergency rooms, and stairwells. In all other areas not serviced by the emergency supply source, battery lamps and flashlights shall be available.

§482.41(a)(1)

The hospital must comply with the applicable provisions of the NFPA 101 *Life Safety Code (2012 Edition)* and applicable references, such as NFPA 99 (2012 edition) *Health Care Facilities*, and NFPA 110 (2010 edition) *Standard for Emergency and Standby Power Systems* for emergency lighting and emergency power.

This provision requires emergency lighting for a period of 1½ hours in health care facilities, enabling those inside to move about safely in an emergency.

Facilities are free to expand the coverage of emergency power and lighting based on the size, complexity, and patient care services offered.

DOCUMENT REVIEW AND INTERVIEW

- Determine that the emergency power and lighting cover at least the minimum required areas. Identify how the hospital monitors the readiness of these systems.
- Areas of the hospital that are not serviced by the emergency supply source are equipped with battery lamps and flashlights.

- 1 = Compliant
- 2 = Not Compliant

This standard is not met as evidenced by:

11.06.02 Emergency Power Electrical System.

Hospitals must have a Type I essential electrical system power source powered by a generator set equipped with a transfer switch, in accordance with NFPA 99, (2012 edition).

For all essential electrical systems constructed, modernize or renovated since 1983, the functions of patient

NFPA 99, 2012 edition specifies Type I essential electrical system power source to be classified as Type 10, Class X, Level 1 generator set per NFPA 110 *Standard for Emergency and Standby Power System, 2010 edition.*

The emergency power system is a separate electrical system that is divided into two major systems:

- the emergency system; and
- the equipment system.

INTERVIEW AND OBSERVATION

- Verify that the hospital has a Type I Essential Electrical System powered by generator with an automatic transfer switch
- Verify that there is an emergency power system in place that is subdivided into two branches, the life safety branch and the critical branch for systems installed or modified since January 1, 1984.

- 1 = Compliant
- 2 = Not Compliant

This standard is not met as evidenced by:

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care depending on lighting or appliances that are permitted to be connected to the emergency system are divided into two mandatory branches, the life safety branch and the critical branch, and must comply with NFPA 99.

The emergency system is subdivided into the two branches in accordance with NFPA 99, **2012 edition**:

- 1) The life safety branch.
- 2) The critical branch.

Prior to the development of NFPA 99 standard *Health Care Facilities*, life safety branch and the critical branch were allowed to be one branch and not separated. Therefore, essential electrical systems that were installed, renovated, or modernized after 1983, must comply with NFPA 99 (**2012 edition**) requirements.

Consideration should be given on generator failure solutions, processes for repair, and how to connect external resources during an emergency.

11.06.03 Not Applicable.
(Relocated to 13.05.04)

11.06.04 Not Applicable.
(Relocated to 13.05.05)

11.06.05 Not Applicable.
(Relocated to 13.05.06)

11.06.06 Not Applicable.
(Relocated to 13.05.07)

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<p>11.06.07 Potable Water. Potable water is tested annually and treated as necessary.</p> <p>Test is documented.</p> <p>11.06.08 Not Applicable. (Relocated to 13.05.08)</p>	<p>If potable water is tested by other entities, the results of this test must be available for review during a survey.</p> <p>Results of test are forwarded to the organization’s Safety Committee for their review.</p>	<p>DOCUMENT REVIEW</p> <ul style="list-style-type: none"> Review hospital records for the annual testing and treatment of the potable water supply. Review Safety Committee minutes to ensure they are reviewing the potable water tests. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>
<p>11.06.09 Plant Equipment & Systems - Maintenance. There is an established, scheduled preventive maintenance program for plant equipment and systems, and shall be maintained and tested periodically in accordance with the manufacturers’ recommendations.</p> <p>As an alternative approach, hospitals may choose to employ alternative maintenance activities and/or schedules provided they develop, implement, and maintain a documented Alternate Equipment Management (AEM) program, to minimize risks to patients and others in the hospital associated with the use of facility equipment.</p>	<p>Plant equipment is defined as devices intended to support the physical environment of the hospital. Such equipment includes, but is not limited to, boilers, natural gas, HVAC system and related vents and filters, electrical power / equipment, and fans, plumbing and the potable water supply. Plant equipment is not limited to utilities only.</p> <p>For hospitals that elect to perform equipment maintenance in accordance with the manufacturer’s requirements, the hospital must maintain documentation of the manufacturer’s recommendations as well as the hospital’s maintenance activities.</p> <p>All equipment (electrical and non-electrical) that is used to support the physical environment shall be included in the process for preventive maintenance. There shall be written testing criteria for each type of equipment included in the preventive maintenance system.</p>	<p>DOCUMENT REVIEW</p> <ul style="list-style-type: none"> Determine if there is an established preventive maintenance program of the plant equipment and whether a routine schedule is established and operational. Review records and/or equipment for evidence of routine inspections and documentation of the hospital’s plant equipment preventive maintenance program. Are inspections conducted in a timely manner? Are past-due inspections common or rare? <p>If the hospital is utilizing an AEM program for inspection, testing and maintenance activities, then the following activities need to be reviewed:</p> <ul style="list-style-type: none"> Review the documentation for the AEM program. Determine if it addresses the requirements for equipment to have 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

PHYSICAL ENVIRONMENT

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
	<p><u>Alternate Equipment Management (AEM) Program</u> A hospital may, under certain conditions, use equipment maintenance activities and frequencies that differ from those recommended by the manufacturer, provided the activities and frequencies do not reduce the safety of the equipment. Hospitals that choose to employ alternate maintenance activities and/or schedules must develop, implement, and maintain a documented AEM program to minimize risks to patients and others in the hospital associated with the use of facility equipment. The AEM program must be based on generally accepted standards of practice for facility equipment maintenance, such as ASHE 2009, <i>Maintenance Management for Health Care Facilities</i>.</p> <p>The determination of whether it is safe to perform facility equipment maintenance without following the equipment manufacturer recommendations must be made by qualified personnel, regardless of whether they are hospital employees or contractors. In the case of facility equipment, a facilities management professional would be considered qualified.</p> <p>The hospital must maintain records of the qualifications of hospital personnel who make decisions on placing equipment in an AEM program, and must be able to demonstrate how they assure contracted personnel making such decisions are qualified.</p> <p>In determining whether or not to include equipment in an AEM program, and which maintenance strategies</p>	<p>maintenance activities and frequencies less than the manufacturer’s recommendations.</p> <ul style="list-style-type: none"> • Is the determination of the alternative maintenance activities and frequencies being performed by qualified individuals? • Verify that the hospital has documented maintenance activities and frequencies for all equipment included in the AEM program. • Verify the hospital is evaluating the safety and effectiveness of the AEM program on an annual basis. • If the hospital has identified equipment as having such a very low level of risk that it has determined it can use a broad interval range or departmental ‘sweeps’, ask the hospital for the evidence used to make this determination, and determine if it is reasonable. • Of the critical equipment that is included in the AEM program, ask the hospital to explain how the decision was made to place this critical equipment in the program. • Of the equipment that is included in the AEM program, ask the hospital to describe the methodology for applying maintenance strategies and determining alternative maintenance activities and/or frequencies. 	

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	<p>to use in developing maintenance activities and frequencies for particular equipment, the hospital must take into account the typical health and safety risks associated with the equipment’s use. Note that the risk may vary for the same type of equipment, depending on the patient care setting within the hospital where it is used.</p> <p>A hospital is expected to identify any equipment in its AEM program which is “critical equipment,” for which there is a risk of serious injury or death to a patient or staff person should the equipment fail.</p> <p>Multiple factors must be considered, since different types of equipment present different combinations of severity of potential harm and likelihood of failure. The hospital is expected to be able to demonstrate to a surveyor the factors it considered in its risk assessment for equipment placed in its AEM program.</p> <p>Some equipment may not be eligible for placement in the AEM program, for one or more of the following reasons:</p> <ul style="list-style-type: none"> • Other Federal or State laws that may require the hospital to inspect, test and maintain their equipment strictly in accordance with the manufacturer’s recommendation; • Other CMS Conditions of Participation or NFPA codes and standards which identify specific intervals, or require adherence to manufacturer’s recommendations which preclude their inclusion in the AEM program; 		

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- New equipment for which sufficient maintenance history, either based on the hospital’s own or its contractor’s records, or available publicly from nationally recognized sources, is not available to support a risk-based determination, must not be immediately included in the AEM program.

The hospital may use one or more maintenance strategies for its AEM program in order to determine the appropriate inspection, testing and maintenance activities and frequencies, based upon the nature of the equipment and the level of risk it presents to patient or staff health and safety. The risk to patient health and safety that is considered in developing alternative maintenance strategies must be explained and documented in the AEM program.

In developing AEM maintenance strategies, hospitals may rely upon information from a variety of sources, including, but not limited to:

- Manufacturer’s recommendations
- Nationally recognized expert associations
- Hospital’s own experience
- Contractor’s own experience
- Other materials

For each type of equipment subject to the AEM program, there must be documentation indicating:

- The pertinent types and level of risks to patients or staff health and safety;
- Alternative maintenance activities and the differences from the manufacturer’s

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	<p>recommendations when they are known;</p> <ul style="list-style-type: none"> • The date when AEM program maintenance activities were performed and what actions, if any, were taken; • Documentation of equipment failures and identifying if any harm resulted to an individual. <p>The AEM program must be compliant with these requirements at all times, and must have written policies and procedures that address the effectiveness of the program. The hospital must have a written annual evaluation of the AEM program that addresses the following factors:</p> <ul style="list-style-type: none"> • How equipment is evaluated to ensure there is no degradation of performance; • How incidents of equipment malfunctioning are investigated, including whether or not the malfunction could have been prevented; what steps will be taken to prevent future malfunctions; and how a determination is made whether or not the malfunction resulted from the use of an AEM strategy; • The process for the removal of equipment from service determined to be unsafe or no longer suitable for its intended application; • The use of performance data to determine if modifications in the AEM program procedures are required. 		

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<p>11.06.10 Plant Equipment Inventory. The hospital maintains a written inventory of all plant equipment available for use.</p>	<p>The inventory shall include all plant equipment used directly or indirectly for the healthcare facility.</p> <p>All equipment must be inspected, tested and maintained to ensure safety, availability and reliability. In addition, all equipment, regardless of whether it is leased or owned, and regardless of whether it is maintained in accordance to manufacturer recommendations or is in an AEM program, is listed in an inventory which includes a record of maintenance activities.</p> <p>If the hospital is using an AEM program, the equipment managed through that program must be separately identified on the equipment inventory from that equipment which is managed through the manufacturer’s recommendation program. Critical equipment, whether in an AEM program or not, must also be readily identified as such.</p> <p>To facilitate effective management, a well-designed equipment inventory contains the following information for all equipment included. However, hospitals have the flexibility to demonstrate how alternative means they use are effective in enabling them to manage their equipment.</p> <ul style="list-style-type: none"> • A unique identification number; • The equipment manufacturer; • The equipment model number; • The equipment serial number; 	<p><u>DOCUMENT REVIEW AND OBSERVATION</u></p> <ul style="list-style-type: none"> • Review inventory list. Compare with field observed equipment to ensure all plant equipment is included. • If the hospital utilizes the AEM program, does the inventory for the AEM program contain any equipment which is not eligible for the AEM? 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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- A description of the equipment;
- The location of the equipment;
- The identity of the department considered to “own” the equipment;
- Identification of the service provider;
- The acceptance date;
- Additional identification deemed useful

11.06.11 Not Applicable.
(Relocated to 13.05.10)

11.06.12 Water Temperature Control.

The hospital takes precautions to control the temperature of hot water used by patients.

Precautions shall be taken to assure that patients are protected against scalding or burning from domestic hot water.

The hospital is required to be in compliance with state and local standards regarding domestic hot water temperatures.

DOCUMENT REVIEW AND INTERVIEW

- Interview maintenance director to determine if domestic hot water is within limits set by state and local authorities.
- Does maintenance check water temperature periodically to assure that temperature is within limits?
- Review patient incident reports and talk to the hospital risk manager to determine the frequency of such incidents and what steps are or have been taken to reduce or eliminate such incidents.

1 = Compliant
 2 = Not Compliant

This standard is not met as evidenced by:

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STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<u>Design, Construction, and Monitoring of the Environment.</u>			
<p>11.07.01 Adequate Facilities and Supplies. <i>The hospital must maintain adequate facilities for its services.</i></p> <p>§482.41(d)</p> <p><i>Facilities, supplies, and equipment must be maintained to ensure an acceptable level of safety and quality.</i></p> <p>§482.41(d)(2)</p> <p><i>The extent and complexity of facilities shall be determined by the services offered.</i></p> <p>§482.41(d)(3)</p> <p>Diagnostic and therapeutic facilities must be located for the safety of patients.</p> <p>§482.41(d)(1)</p> <p>Buildings must have an outside window or outside door in every sleeping room, and for any building constructed after July 5, 2016 the sill height must not exceed 36 inches</p>	<p>The hospital shall provide facilities adequate to serve the needs of the patients served at the hospital.</p> <p>Diagnostic and therapeutic facilities must be located in rooms or areas specifically designed for the purpose intended.</p> <p>Adequate facilities means the hospital has facilities that are:</p> <ul style="list-style-type: none"> • Designed and maintained in accordance with federal, state, and local laws, regulations and guidelines; and • Designed and maintained to reflect the scope and complexity of the services it offers in accordance with accepted standards of practice. <p>Facilities must be maintained to ensure an acceptable level of safety and quality.</p> <p>Supplies are to be stored in such a manner to ensure the safety of the stored supplies (protection against theft or damage, contamination, or deterioration), as well as, that the storage practices do not violate fire codes or otherwise endanger patients (storage of flammables, blocking passageways, storage of contaminated or dangerous materials, safe storage practices for poisons, etc.). Additionally, “supplies must be maintained to ensure an acceptable level of safety” would include that the hospital identifies the</p>	<p><u>OBSERVATION, INTERVIEW, AND DOCUMENT REVIEW</u></p> <ul style="list-style-type: none"> • Observe the hospital layout and determine if the patient’s needs are met. Toilets, sinks, specialized equipment, etc. should be accessible. • Discuss with members of the medical staff and department heads the adequacy of the facilities to meet the needs of the patients being treated at the hospital. • Has the hospital identified supplies that are likely to be needed in emergency situations? • Has the hospital made adequate provisions to ensure the availability of those supplies when needed? • Verify through observation that the physical facilities are large enough and properly equipped for the scope of services provided and the number of patients served. • Are facilities appropriate to meet the needs of hospital patients? Discuss with members of the medical executive committee, members of the medical staff (team captain); nursing staff (RN surveyor), and department heads (ADM surveyor) to determine if the 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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<p><i>above the floor. Windows in atrium walls are considered outside windows for the purposes of this requirement.</i></p> <p><i>The sill height requirement does not apply to newborn nurseries and rooms intended for occupancy for less than 24 hours.</i></p> <p><i>The sill height in special nursing care areas of new occupancies must not exceed 60 inches.</i></p> <p>§482.41(b)(9) §482.41(b)(9)(i) §482.41(b)(9)(ii)</p> <p>11.07.02 Not Applicable.</p>	<p>supplies it needs to meet its patients' needs for both day-to-day operations and those supplies that are likely to be needed in likely emergency situations such as mass casualty events resulting from natural disasters, mass trauma, disease outbreaks, etc.; and that the hospital makes adequate provisions to ensure the availability of those supplies when needed.</p> <p>Physical facilities must be large enough, numerous enough, appropriately designed and equipped, and of appropriate complexity to provide the services offered in accordance with Federal and State laws, regulations and guidelines and accepted standards of practice for that location or service.</p> <p>In each area of diagnostic and/or therapeutic facilities, consideration shall be given to safety and security of equipment, persons and their personal property.</p>	<p>needs of patients are being met.</p> <ul style="list-style-type: none"> • Verify that x-ray, physical therapy, and other specialized services are provided in areas appropriate for the service provided and provide appropriate safety and security for all persons. • Discuss with members of the medical staff and department heads the adequacy of safety in service placement in the hospital. 	
<p>11.07.03 Ventilation, Light, & Temperature Controls. <i>There must be proper ventilation, light, and temperature controls in pharmaceutical, food preparation, and other appropriate areas.</i></p> <p>§482.41(d)(4)</p>	<p>Excessive humidity in the operating room is conducive to bacterial growth and compromises the integrity of wrapped sterile instruments and supplies. Humidity levels in operating rooms must comply with NFPA 99 (2012 edition) which references ASHRAE 170 for HVAC in health care facilities, which allows 20% RH or greater. RH levels must be monitored and timely corrective actions taken when necessary.</p>	<p><u>OBSERVATION, DOCUMENT REVIEW, AND INTERVIEW</u></p> <ul style="list-style-type: none"> • Verify that all food and medication preparation areas are well lighted. • Verify that the hospital is in compliance with ventilation requirements for patients with contagious airborne diseases, such as tuberculosis, patients receiving treatments 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

PHYSICAL ENVIRONMENT

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
	<p>The lower humidity levels permitted by NFPA 99 and ASHRAE 170 may not be compatible with the Instructions for Use (IFU) for some sterile supplies and electro-mechanical equipment used in operating rooms. While manufacturers of supplies and equipment will be expanding the lower level of RH range in which their products may function to 20%, the pace of this change is likely to take time. Moreover, for facilities that continue to use older equipment it could be many years before this older equipment is replaced and all of the equipment they use will function appropriately at lower RH levels. HFAP expects hospitals to follow the current IFUs for supplies and equipment used in their ORs.</p> <p>Acceptable standards such as from the Association of Operating Room Nurses (AORN) or the Facility Guidelines Institute (FGI) should be incorporated into hospital policy.</p> <p>Organization staff should obtain and be aware of current Guidelines for Design and Construction of Health Care Facilities from the Facility Guidelines Institute (FGI) and current guidelines from the Center for Disease Control (CDC).</p> <p>There must be proper ventilation and air-pressure relationships to surrounding areas in at least the following areas:</p> <ol style="list-style-type: none"> 1. Areas using ethylene oxide, nitrous oxide, glutaraldehyde, ethylene, pentamidine, or other potentially hazardous substances; 	<p>with hazardous chemical, surgical areas, and other areas where hazardous materials are stored.</p> <ul style="list-style-type: none"> • Verify that food products are stored under appropriate conditions (e.g., time, temperature, packaging, location) based on nationally-accepted sources such as the United States department of Agriculture, the Food and drug Administration, or other nationally-recognized standard. • Verify that pharmaceuticals are stored at temperatures recommended by the product manufacturer. • Verify that each operating room has temperature and humidity control mechanisms. • Review monitoring records for temperature to ensure that appropriate levels are maintained. • Review humidity maintenance records for anesthetizing locations to ensure, if monitoring determined humidity levels were not within acceptable parameters, that corrective actions were performed in a timely manner to achieve acceptable levels. • While temperature and humidity tracking logs are not mandatory, the organization 	

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STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
	<p>2. Locations where oxygen is transferred from one container to another;</p> <p>3. Isolation rooms and reverse isolation rooms (both must be in compliance with Federal and State laws, regulations, and guidelines such as OSHA, CDC, NIH, etc.);</p> <p>4. Pharmaceutical preparation areas (hoods, cabinets, etc.);</p> <p>5. Laboratory locations;</p> <p>6. Soiled utility rooms;</p> <p>7. Clean utility rooms;</p> <p>8. Sterile processing rooms;</p> <p>9. Operating rooms.</p> <p>There must be adequate lighting in all the patient care areas, and food and medication preparation areas.</p> <p>1. Temperature, humidity and airflow in the anesthetizing locations must be maintained within acceptable standards to inhibit microbial growth, reduce risk of infection, control odor, and promote patient comfort.</p> <p>2. Each operating room should have separate temperature control.</p> <p>3. The hospital must ensure that an appropriate</p>	<p>needs to have documentation that clearly indicates they are tracking the temperature and humidity settings of critical areas (such as Building Automation Systems), and taking appropriate action when a reading is out of proper range. In lieu of alternative documentation methods, review temperature and humidity tracking log(s) to ensure that appropriate temperature and humidity levels are maintained.</p> <ul style="list-style-type: none"> • Interview department heads to determine if they feel that their areas have proper and adequate ventilation, light, and temperature control. What guidelines are used in food preparation area? How often is monitoring conducted? 	

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number of refrigerators and/or heating devices are provided and ensure that food and pharmaceuticals are stored properly and in accordance with nationally accepted guidelines (food) and manufacturer’s recommendations (pharmaceuticals).

11.07.04 Not Applicable.

11.07.05 Not Applicable.

11.07.06 Assessing Risk Prior to Construction.

When the hospital plans for renovation and construction, a written assessment is made to reduce the risk to the organization.

Prior to demolition, construction and renovation activities a risk assessment is conducted on utility requirements, air quality requirements, infection control, vibrations, noise, and other hazards that could affect patients, staff and visitors.

- DOCUMENT REVIEW AND OBSERVATION**
- Review organization policies and procedures on risk assessment conducted prior to construction activities.
 - Review documented risk assessments for current renovation activities.

1 = Compliant
 2 = Not Compliant

This standard is not met as evidenced by:

11.07.07 Monitoring the Physical Environment.

A process is established by the hospital to continuously monitor the physical environment. Hazardous surveillance inspections shall be conducted semi-annually in all patient care areas, and annually in all non-patient care areas.

The appropriate committee for safety may be different depending on the issue, and patient confidentiality. When legal processes are followed, opportunities to make improvements on care, treatment and services or to prevent the same or similar incident from occurring, is not lost.

Where confidentiality is required, a summary of the incident must be share with the individual(s)

- DOCUMENT REVIEW AND OBSERVATION**
- Review organization’s documentation on hazardous surveillance inspections to ensure all areas are properly inspected.
 - Review the minutes from the appropriate committee on safety issues to determine if incidents are being investigated and reported, and if follow-up activities are being

1 = Compliant
 2 = Not Compliant

This standard is not met as evidenced by:

PHYSICAL ENVIRONMENT

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>Investigations are made and reports are submitted to the appropriate committee for safety on:</p> <ol style="list-style-type: none"> 1. Injuries to patients 2. Occupational illnesses and staff injuries 3. Incidents involving damage to the facility or property of others 4. Security incidents involving staff, patients or others within the facility 5. Spills and exposures of hazardous materials and waste 6. Deficiencies and failures of the fire safety management systems 7. Problems, failures and user errors on medical equipment; laboratory equipment; and utility equipment 	<p>designated to coordinate safety management activities.</p> <p>Reports are reviewed and appropriate action recommended by the committee(s) responsible for safety activities. The committee is responsible for follow-up activities to ensure all reported incidents are properly resolved.</p> <p>Offsite patientcare areas are inspected semi-annually.</p>	<p>tracked.</p>	

QUALITY ASSESSMENT & PERFORMANCE IMPROVEMENT (QAPI)

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**12.00.00 Condition of Participation:
Quality Assessment Performance
Improvement.**

The hospital must develop, implement, and maintain an effective, ongoing, hospital-wide, data-driven quality assessment and performance improvement program.

The hospital's governing body must ensure that the program reflects the complexity of the hospital's organization and services; involves all hospital departments and services (including those services furnished under contract or arrangement); and focuses on indicators related to improved health outcomes and the prevention and reduction of medical errors.

The hospital must maintain and demonstrate evidence of its QAPI program for review by CMS.

§482.21

The hospital must ensure that the program scope requirements are met.

DOCUMENT REVIEW

Review the hospital's Quality Assessment Performance Improvement program to determine it meets the requirement. The quality assessment performance improvement program covers each of the following elements:

1. Development
2. Implementation
3. Maintenance
4. Effectiveness
5. Ongoing
6. Data-driven
7. Hospital wide
8. Contract services
9. Improved outcomes
10. Reduction of medical errors

Surveyors:

- **If non-compliance does not rise to the Condition Level, score at standard 12.00.07.**

- 1 = Compliant
 2 = Not Compliant

COMMENTS:

QUALITY ASSESSMENT & PERFORMANCE IMPROVEMENT (QAPI)

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>12.00.01 Data Collection & Analysis: Program Scope.</p> <ul style="list-style-type: none"> • <i>The program must include, but not be limited to, an ongoing program that shows measurable improvement in indicators for which there is evidence that it will improve health outcomes and identify and reduce medical errors.</i> <p>§482.21(a)(1)</p> <ul style="list-style-type: none"> • <i>The hospital must measure, analyze, and track quality indicators, including adverse patient events, and other aspects of performance that assess processes of care, hospital service and operations.</i> <p>§482.21(a)(2)</p> <ul style="list-style-type: none"> • <i>The program must incorporate quality indicator data including patient care data, and other relevant data, for example, information submitted to, or received from, the hospital's Quality Improvement Organization (QIO).</i> <p>§482.21(b)</p>	<p>The hospital must ensure that the program data requirements are met.</p> <p>The annual QAPI Plan identifies:</p> <ol style="list-style-type: none"> 1. The goal of the quality assurance program is to identify and reduce medical errors and improve health outcomes. 2. The quality indicators, including adverse patient events, that will be measured, analyzed, and tracked on an ongoing basis. 3. The performance indicators and data collection activities for: <ol style="list-style-type: none"> a. Every department and service b. Every contracted service 4. Frequency and detail of data collection activities. 5. Methods to monitor the effectiveness and safety of services and quality of care 6. The plan to use data collected to monitor the effectiveness and safety of services. 7. Strategies to be used to identify opportunities for improvement and changes. 8. Approval of the annual Quality Plan by the governing body. <p>The facility demonstrates the ongoing review and</p>	<p style="text-align: center;"><u>DOCUMENT REVIEW & INTERVIEW</u></p> <p>Review the annual QAPI plan.</p> <p>Determine:</p> <ol style="list-style-type: none"> 1. The scope of the QAPI program is to identify and reduce medical errors and improve health outcomes. 2. The focus of the QAPI program is to identify high-risk opportunities and take action to reduce errors. 3. The hospital has an ongoing QAPI program. 4. The annual Quality Plan has been approved by the governing body. 5. The governing body has specified the frequency and detail of data collection. 6. The quality program has identified improvement indicators that will improve health outcomes and identify and reduce medical errors. 7. The hospital has a process for measuring, analyzing, and tracking quality, adverse patient events, and other aspects of performance. 8. The data collection activities are appropriate to the scope of the hospital. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>COMMENTS:</p>

QUALITY ASSESSMENT & PERFORMANCE IMPROVEMENT (QAPI)

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>§482.21(b)(1)</p> <ul style="list-style-type: none"> • <i>The hospital must use the data collected to monitor the effectiveness and safety of services and quality of care.</i> • <i>The frequency and detail of data collection must be specified by the hospital's governing body.</i> <p>§482.21(b)(2) §482.21(b)(2)(i) §482.21(b)(3)</p>	<p>analysis of the quality indicators to identify patterns and trends.</p> <p>The hospital demonstrates that it uses data to monitor the effectiveness of services and the quality of care provided.</p>	<p>9. The required processes are monitored, including:</p> <ul style="list-style-type: none"> • Quality of care provided • Effectiveness and safety of services provided • Adverse patient events <p>10. Data collection activities include:</p> <ul style="list-style-type: none"> • Every hospital department and service • Each contracted service <p>11. Data is analyzed to identify patterns and trends. Data is used to monitor the effectiveness of services provided.</p> <p>12. Is data generated from outside the organization utilized to determine program effectiveness and improve outcomes?</p>	

QUALITY ASSESSMENT & PERFORMANCE IMPROVEMENT (QAPI)

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>12.00.02 <u>Quality Improvement Program Activities.</u></p> <ul style="list-style-type: none"> • <i>The hospital must use the data collected to identify opportunities for improvement and changes that will lead to improvement.</i> <p>§482.21(b)(2)(ii)</p> <ul style="list-style-type: none"> • <i>The hospital must set priorities for its performance improvement activities that:</i> <ul style="list-style-type: none"> (i) <i>Focus on high-risk, high-volume, or problem-prone areas;</i> (ii) <i>Consider the incidence, prevalence, and severity of problems in those areas; and</i> (iii) <i>Affect health outcomes, patient safety and quality of care.</i> <p>§482.21(c) §482.21(c)(1) §482.21(c)(1)(i) §482.21(c)(1)(ii) §482.21(c)(1)(iii)</p> <ul style="list-style-type: none"> • <i>The hospital must take actions aimed at performance</i> 	<p>The facility provides evidence that it has implemented the annual QAPI Plan as approved by the governing body.</p> <ul style="list-style-type: none"> • Data is collected at the frequency established by the governing body. • The facility demonstrates the ongoing review and analysis of the quality indicators; the facility identifies patterns and trends. • The facility has a process to identify opportunities, prioritize, and select annual performance improvement activities based upon available resources. • The facility considers the incidence, prevalence, and severity of problems. • The facility takes action aimed at improving performance. The facility measures the effectiveness of the implemented actions to ensure improvement is sustained. 	<p style="text-align: center;"><u>DOCUMENT REVIEW & INTERVIEW</u></p> <p>Review tracking methodology to determine the requirement was met.</p> <p>Verify:</p> <ol style="list-style-type: none"> 1. The facility measures the quality indicators identified in the annual QAPI Plan. The collected data has been used to: <ul style="list-style-type: none"> • Identify opportunities for improvement • Implement changes that lead to improvement 2. The facility demonstrates an ongoing review and analysis of the quality indicators findings that will improve health outcomes and reduce medical errors. 3. The facility has a process to establish priorities for performance improvement activities that focus on high-risk, high volume, or problem prone areas. 4. The facility has taken action(s) to improve performance. 5. The hospital has measured the effectiveness of the implemented actions to ensure improvement is sustained. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>COMMENTS:</p>

QUALITY ASSESSMENT & PERFORMANCE IMPROVEMENT (QAPI)

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
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improvement and, after implementing those actions, the hospital must measure its success, and track performance to ensure that improvements are sustained.

§482.21(c)(3)

12.00.03 Patient Safety, Medical Errors & Adverse Events.

- *The program must include, but not be limited to, an ongoing program that shows measurable improvement in indicators for which there is evidence that it will improve health outcomes and identify and reduce medical errors.*
- *The hospital must measure, analyze, and track quality indicators, including adverse patient events, and other aspects of performance that assess processes of care, hospital service and operations.*

§482.21(a)(1)

§482.21(a)(2)

The hospital must ensure that the program activities requirements are met.

Medical errors include but are not limited to such things as medication errors and the wrong site of surgery, etc.

It is important that each error incident can be an opportunity for education and learning for the individuals and areas involved.

The facility measures, analyzes, and tracks the quality indicators consistent with the annual QAPI plan.

The facility implements a database for tracking medical errors and adverse patient events by category. Through analysis of these data, the facility determines patterns, implements strategies, and monitors the effectiveness of corrective actions implemented.

The review of errors shall involve the individual(s) directly involved as well as representatives of any

DOCUMENT REVIEW

1. Determine that the facility has demonstrated an ongoing quality program.
2. Determine that the hospital measures, analyzes, and tracks:
 - Quality indicators and other aspects of performance
 - Medical errors
 - Adverse patient events
3. Determine that the hospital has implemented improvement mechanisms, based on data analysis, to reduce medical errors and adverse patient events.
4. The governing body has clearly established expectations for safety.

- 1 = Compliant
 2 = Not Compliant

COMMENTS:

QUALITY ASSESSMENT & PERFORMANCE IMPROVEMENT (QAPI)

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p><i>Performance improvement activities must:</i></p> <ul style="list-style-type: none"> • <i>track medical errors and adverse patient events,</i> • <i>analyze their causes, and</i> • <i>implement preventive actions and mechanisms that include feedback and learning throughout the hospital.</i> <p>§482.21(c)(2)</p>	<p>involved hospital services.</p> <p>The facility provides measurable evidence of improvement in the following areas:</p> <ul style="list-style-type: none"> • Improved health outcomes • Reduction of identified medical errors <p>The annual QAPI Plan, which clearly establishes expectations for safety, is approved by the governing body.</p>		
<p><i>The hospital's governing body (organized group or individual who assumes full legal authority and responsibility for operations of the hospital), medical staff, and administrative officials are responsible and accountable for ensuring the following:</i></p> <ul style="list-style-type: none"> • <i>That clear expectations for safety are established.</i> <p>§482.21(e)(3)</p>			

QUALITY ASSESSMENT & PERFORMANCE IMPROVEMENT (QAPI)

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>12.00.04 Performance Improvement Projects. <i>As part of its quality assessment and performance improvement program, the hospital must conduct performance improvement projects.</i></p> <p>(1) <i>The number and scope of distinct improvement projects conducted annually must be proportional to the scope and complexity of the hospital's services and operations.</i></p> <p>§482.21(d) §482.21(d)(1)</p> <p>(2) <i>A hospital may, as one of its projects, develop and implement an information technology system explicitly designed to improve patient safety and quality of care. This project, in its initial stage of development, does not need to demonstrate measurable improvement in indicators related to health outcomes.</i></p> <p>§482.21(d)(2)</p> <p>(3) <i>The hospital must document:</i></p> <ul style="list-style-type: none"> • <i>what quality assessment & performance improvement</i> 	<p>Each year, the facility identifies and conducts performance improvement projects. The hospital demonstrates it uses data to identify opportunities for improvement and changes that will lead to improvement.</p> <p>The number and scope of these distinct performance improvement projects is proportional to the scope and complexity of services provided.</p> <p>The hospital has a process to documentation each performance project, including:</p> <ol style="list-style-type: none"> 1. Reason for selecting the performance improvement project 2. Initial baseline data to support the performance improvement project 3. Ongoing data that demonstrates progress with improving healthcare for each project 4. Timelines for each phase of the performance improvement project 5. Data to support sustained improvement <p>The implementation of Information Technology (IT) systems can significantly impact healthcare outcomes and improve patient safety.</p> <p>Recognizing this type of project may require capital budget expenditures and span across multiple departments and services, installation of an IT</p>	<p style="text-align: center;"><u>DOCUMENT REVIEW</u></p> <p>Review QAPI documents with hospital leadership.</p> <ol style="list-style-type: none"> 1. Does the annual Quality Plan identify the data-driven, distinct performance improvement projects to be addressed during the current year? 2. Does the hospital have evidence that it has conducted annual performance improvement projects? 3. Are the number and scope of the distinct performance improvement projects proportional to the scope and complexity of services provided? 4. Has the hospital documented the required elements for each distinct performance improvement project? 5. Has the hospital implemented strategies to effect change, improve health outcomes, or reduce medical errors? 6. Has facility achieved improvement? Has improvement been sustained? 7. Has the facility implemented an Information Technology (IT) performance improvement project? If yes, why was this determined to be a hospital priority? Has the project been 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>COMMENTS:</p>

QUALITY ASSESSMENT & PERFORMANCE IMPROVEMENT (QAPI)

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p><i>projects are being conducted,</i></p> <ul style="list-style-type: none"> <i>the reasons for conducting these projects, and</i> <i>the measurable progress achieved on these projects.</i> <p>§482.21(d)(3)</p> <p>(4) <i>A hospital is not required to participate in a QIO cooperative project but its own projects are required to be of comparable effort.</i></p> <p>§482.21(d)(4)</p>	<p>system would be an appropriate hospital-wide quality assurance performance improvement activity.</p> <p>If selected as a hospital-wide QAPI activity, documentation of the progress of installation would be expected.</p>	<p>monitored to ensure the desired outcome has been achieved?</p> <p>8. Determine if the hospital is working with the QIO or they have a similar project that meets the requirement.</p>	
<p>12.00.05 Executive Responsibilities. <i>The hospital's governing body (organized group or individual who assumes full legal authority and responsibility for operations of the hospital), medical staff, and administrative officials are responsible and accountable for ensuring the following:</i></p> <p>(1) <i>That an ongoing program for quality improvement and patient</i></p>	<p>The governing body, medical staff and administrative officials must determine priorities regarding which processes to monitor with data collection and the subsequent development of planned improvement efforts, as needed.</p> <p>The hospital's governing body must provide strong, clear, and visible attention to setting expectations for safety and for allocating adequate resources for measuring, assessing, improving, and sustaining the hospital's performance and for reducing risks to</p>	<p align="center"><u>DOCUMENT REVIEW</u></p> <p>Review the governing body mission, bylaws, annual report and meeting minutes to determine the requirement was met.</p> <p>Lack of appropriate direction from the board, or appropriate involvement and intervention by medical staff or the administrative officials will be scored here.</p> <p>Determine:</p>	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>COMMENTS:</p>

QUALITY ASSESSMENT & PERFORMANCE IMPROVEMENT (QAPI)

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p><i>safety, including the reduction of medical errors, is defined, implemented, and maintained;</i></p> <p>(2) <i>That the hospital-wide quality assessment and performance improvement efforts address priorities for improved quality of care and patient safety, and that all improvement actions are evaluated;</i></p> <p>(5) <i>That the determination of the number of distinct improvement projects is conducted annually.</i></p> <p>§482.21(e) §482.21(e)(1) §482.21(e)(2) §482.21(e)(5)</p>	<p>patients.</p> <p>The medical staff and administrative officials must be held accountable for the implementation of an effective program consistent with Governing Body direction that demonstrates a sustained improvement in patient outcomes and a reduction in medical errors.</p> <p>The hospital-wide quality assessment and performance improvement activities identify and implement strategic actions to improve the quality of care and patient safety. These strategic actions are periodically evaluated to ensure the strategies implemented have been effective.</p>	<ol style="list-style-type: none"> 1. How do the Governing Body, medical staff, and hospital leadership demonstrate responsibility and accountability for ensuring the QAPI program is ongoing, defined, implemented, and maintained? 2. Does the QAPI Program include patient safety initiatives, such as reduction of medical errors? 3. What is the evidence that the Governing Body prioritized the performance improvement projects and data collection activities? 4. What is the evidence that performance improvement actions / strategic actions have been implemented and evaluated to ensure these have been effective with improving the quality of care and patient safety? 5. What is the evidence that the Governing Body has established clear expectations for safety? 6. What is the evidence that the Governing Body has determined the number of distinct projects annually? 	

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STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>12.00.06 Adequate Resources. <i>The hospital's governing body (or organized group or individual who assumes full legal authority and responsibility for operations of the hospital), medical staff, and administrative officials are responsible and accountable for ensuring the following:</i></p> <ul style="list-style-type: none"> • <i>That adequate resources are allocated for measuring, assessing, improving, and sustaining the hospital's performance and reducing risk to patients.</i> <p>§482.21(e)(4)</p>	<p><u>ALLOCATION OF HUMAN RESOURCES</u> The hospital's governing body is responsible for allocating adequate resources for measuring, assessing, improving, and sustaining the hospital's performance and for reducing risks to patients.</p> <p>The hospital provides staff, trained in the principles of quality assurance / performance improvement, to perform QAPI activities.</p> <p><u>TRAINING</u> Hospital leadership ensures the allocation of human resources to provide education relating to the quality program and program outcomes throughout the organization.</p> <p>Hospital personnel, senior leadership, middle management, Medical Staff, and the Governing Body periodically receive training in the principles of quality assurance performance improvement.</p> <p>Personnel are knowledgeable of the quality projects, performance indicators, and findings as related to duties and areas of responsibility.</p> <p><u>ALLOCATION OF TIME</u> The hospital leadership ensures sufficient time is devoted to the quality program.</p> <p>Hospital leadership allocates staff hours to attend education sessions as well as to participate in QAPI teams and projects as needed.</p>	<p style="text-align: center;"><u>DOCUMENT REVIEW</u></p> <ol style="list-style-type: none"> 1. Review QAPI minutes and related documents to determine the requirement was met. 2. Determine the hospital has staff trained in quality principles to perform QAPI activities. 3. Determine the hospital ensures adequate time is devoted to the quality program. 4. Determine that the facility has a multi-disciplinary hospital-wide Quality Committee / function which include representatives from the Medical Staff and hospital leadership. 5. Determine that QAPI related education is periodically provided to staff, hospital leadership, Medical Staff, and the Governing Body. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>COMMENTS:</p>

QUALITY ASSESSMENT & PERFORMANCE IMPROVEMENT (QAPI)

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Quality Committee / Function

The hospital has a multi-disciplinary hospital-wide Quality Committee / quality function. The Quality Committee / quality function is responsible for the development and implementation of an ongoing program that measures performance, analyzes data, and implements strategies for the purpose of improving health outcomes and reducing risk.

Participants in the Quality Committee / quality function are representatives from hospital leadership and the Medical Staff.

The Quality Committee reviews quality reports from all departments and services, discusses opportunities for improvement, and recommends corrective actions.

Minutes of the Quality Committee / quality function memorialize the discussions of quality activities and corrective actions.

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12.00.07 STANDARD: Quality Assessment Performance Improvement.

The hospital's governing body must ensure that the program reflects the complexity of the hospital's organization and services; involves all hospital departments and services (including those services furnished under contract or arrangement); and focuses on indicators related to improved health outcomes and the prevention and reduction of medical errors.

The hospital must maintain and demonstrate evidence of its QAPI program for review by CMS.

§482.21

Self-explanatory.

DOCUMENT REVIEW

Surveyor: After reviewing all CMS requirements:

- **Identification of CMS standard-level deficiencies within the Condition of Participation should be cited here if non-compliance does not rise to the Condition level.**
- **Do NOT include HFAP standard deficiencies.**

- 1 = Compliant
- 2 = Not Compliant

COMMENTS:

QUALITY ASSESSMENT & PERFORMANCE IMPROVEMENT (QAPI)

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>12.01.01 <u>Quality Management Position.</u> There is an individual, trained in quality principles and appointed by the hospital leadership to be in charge of the Quality Assessment Performance Improvement Program.</p>	<p>Depending on the complexity of the organization, the individual in charge of the quality program may have other assigned duties; however, there shall be sufficient time spent by this individual to support all areas of this program.</p> <p>The quality manager has received formal training in principles of quality improvement to prepare the individual for the required duties.</p>	<p style="text-align: center;"><u>FILE REVIEW & INTERVIEW</u></p> <p>Review documentation of training. Interview the quality manager. Inquire of the amount of time devoted to the quality program and the nature of past quality improvement training.</p> <p>Verify:</p> <ol style="list-style-type: none"> 1. Sufficient amount of time is devoted to the quality program. 2. The individual has attended formal quality training programs and has a plan for future training. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>COMMENTS:</p>
<p>12.01.02 <u>Quality Committee / Function.</u> There is a multidisciplinary hospital wide quality assessment and performance improvement committee / function. The committee / function is responsible for the development and implementation of a program for measuring, assessing, and improving outcomes.</p> <p>Participants in the committee / function are representatives of leadership, the Medical Staff, and other hospital staff as necessary to fulfill its responsibilities.</p>	<p>The participants in the committee / function shall include individuals within the organization who have the expertise necessary to review and improve the processes that affect outcomes.</p>	<p style="text-align: center;"><u>DOCUMENT REVIEW</u></p> <p>Review the QAPI Plan and list of committee / function participants.</p> <p>Verify:</p> <ol style="list-style-type: none"> 1. There is a structured coordinated process for development and implementation of the quality program. 2. The committee / function is multidisciplinary and includes medical staff representation. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>COMMENTS:</p>

QUALITY ASSESSMENT & PERFORMANCE IMPROVEMENT (QAPI)

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>12.01.03 <u>Meetings & Documentation of Activities.</u> The Quality Assessment and Performance Improvement activity must be conducted at formal meetings.</p>	<p>Minutes must be kept in sufficient detail to track the progress of the QAPI program.</p>	<p align="center"><u>DOCUMENT REVIEW</u></p> <ol style="list-style-type: none"> 1. Review samples of minutes and track sample activities forward through time for evidence of resolution. 2. Review this activity to determine if systemic corrective action is taken. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>COMMENTS:</p>
<p>12.01.04 <u>Annual Quality Report.</u> There is an annual report based on the annual plan which details improvements made during the year as a result of quality initiatives as well as challenges that are as yet unresolved related to quality.</p> <p>The report shall be submitted to the governing body for review and approval.</p>	<p>The annual end-of-year Quality Report serves as the basis for development of the subsequent year's annual Quality Plan.</p>	<p align="center"><u>DOCUMENT REVIEW</u></p> <p>Review the last three (3) annual reports. Determine these have been reviewed and approved by the governing body.</p>	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>COMMENTS:</p>

QUALITY ASSESSMENT & PERFORMANCE IMPROVEMENT (QAPI)

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>12.01.05 Education Program. There shall be a planned, hospital wide, Quality Assessment and Performance Improvement education program.</p> <p>Training shall include general quality approaches and appropriate team and individual approaches.</p>	<p>The program design and findings are adequately disseminated. Providers are knowledgeable about their roles in the QAPI program and about findings, which impact their duties and responsibilities.</p> <p>The education program does not have to reach all individuals by the time of the survey; however there shall be an education plan which details how the hospital will accomplish its education program within one year from the date of the Quality Assessment and Performance Improvement plan.</p> <p>The education plan shall include the executive staff, the governing body, the Medical Staff, and all non-temporary staff.</p>	<p style="text-align: center;"><u>DOCUMENT REVIEW</u></p> <p>Review the education plan and documentation of staff training. Compare names of selected individuals for inclusion on the training documentation lists.</p> <p style="text-align: center;"><u>INTERVIEW</u></p> <ol style="list-style-type: none"> 1. Interview selected individuals about the quality and content of training. Are staff, medical staff and members of the governing body able to articulate quality improvement priorities in the organization? 2. Have members within the leadership of the organization attended an education session regarding principles of quality assessment performance improvement within the past year? 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>COMMENTS:</p>
<p>12.01.06 HFAP Clinical Quality Measurement Program. The hospital submits to CMS quarterly performance data of the hospital quality measures used to identify illnesses and/or clinical conditions.</p>	<p>Facilities are required to submit quarterly performance data to CMS of the hospital quality measures adopted from the consensus-derived set of measures developed by the National Quality Forum (NQF) and paralleling those required by the CMS quality initiative.</p> <p>These measures address the promotion of best practices associated with targeted clinical disorders, the prevention or reduction of further instances of these clinical disorders, and the prevention of related complications.</p>	<p style="text-align: center;"><u>INTERVIEW</u></p> <p>Verify the hospital is submitting to CMS quarterly performance data in a timely manner on hospital quality measures.</p>	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>COMMENTS:</p>

QUALITY ASSESSMENT & PERFORMANCE IMPROVEMENT (QAPI)

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>12.01.07 <u>Reporting to the Board of Trustees.</u> Periodically, hospital-wide and department-specific quality reports are prepared and submitted to the Governing Body / Board of Trustees.</p> <p>These quality reports include medical errors, hospital-acquired complications, and investigations of adverse events.</p> <p>The quality reports indicate patterns identified and corrective actions taken to improve quality of services provided.</p>	<p>The annual Quality Plan identifies the frequency / schedule for submitting quality reports from each department / service to the Governing Body / Board of Trustees.</p> <p>The minutes of the Governing Body / Board of Trustees memorializes the review and discussions of patterns identified and strategic actions to be implemented.</p>	<p align="center"><u>DOCUMENT REVIEW</u></p> <p>Review minutes of the Governing Body / Board of Trustees and related documents.</p> <ol style="list-style-type: none"> Determine each department / service has submitted quality reports to the Governing Body, consistent with the Quality Plan. Determine that the minutes of Governing Body meetings memorialize the discussion of quality reports. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>COMMENTS:</p>

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STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>12.02.01 Culture of Safety. The organization will create a healthcare culture of safety. Standardized policies and procedures are in place to:</p> <ol style="list-style-type: none"> 1. Prioritize patient safety events that should be reported. 2. Implement a non-punitive “close call” reporting system. 3. Define a process for analysis of patient safety events. 4. Implement remedial action and measure effectiveness of such action. 5. Ensure that organizational leadership is kept knowledgeable about patient safety issues present within the organization and continuously involved in processes to assure that the issues are appropriately addressed and that patient safety is improved. 6. Provide oversight and coordination of patient safety activities. 7. Provide feedback to frontline 	<p style="text-align: center;"><u>PATIENT SAFETY INITIATIVE</u></p> <p>In most settings today, the high-risk, error-prone nature of modern healthcare and the shared responsibility for risk reduction are not widely recognized. Free and open communication and non-punitive reporting of adverse events and patient safety concerns are not the norm, and organizational objectives and rewards are not clearly aligned with the goal of improving patient safety.</p> <p>To address these issues, there is a need to promote a culture of safety in all healthcare settings—that is, there is a need to promote a culture that overtly encourages and supports the reporting of any situation or circumstance that threatens or potentially threatens the safety of patients or caregivers and that views the occurrence of errors and adverse events as opportunities to make the healthcare system better.</p>	<p style="text-align: center;"><u>DOCUMENT REVIEW</u></p> <ol style="list-style-type: none"> 1. Review policies and procedures on safety to validate all required elements have been addressed. 2. Review safety reports and event analysis reports to validate process as defined in policy is actual practice. 3. Review minutes of meetings where safety is discussed. <p style="text-align: center;"><u>FILE REVIEW</u></p> <p>Review staff files to validate education on teamwork techniques have been conducted.</p> <p style="text-align: center;"><u>INTERVIEW</u></p> <p>Interview staff members regarding the organizations focus on safety.</p>	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>COMMENTS:</p>

QUALITY ASSESSMENT & PERFORMANCE IMPROVEMENT (QAPI)

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<p>healthcare providers about lessons learned.</p> <p>8. Train all staff in techniques of teamwork-based problem solving and management.</p>			
<p>12.02.02 Adverse Event Review Process. Adverse events are injuries resulting from medical care, as opposed to adverse outcomes arising from underlying disease.</p> <p>Upon discovery of an adverse event, the healthcare organization must conduct a Root Cause Analysis (RCA) and prepare and action plan.</p> <p>HFAP has adopted the following CMS’s “Hospital-Acquired Conditions” and the National Quality Forums’ “Serious Reportable Events (SRE).” This list may not be all inclusive as the “Reporting Events” may change. An annual review of Hospital-Acquired Conditions and SRE is highly recommended in order to keep current with this standard. Please check www.qualityforum.org for an updated list.</p>	<p>HFAP has adopted the following CMS “Hospital-Acquired Conditions” and the National Quality Forum’s “Serious Reportable Events” (SRE). This list is not necessarily all inclusive as the “Reporting Events” may change.</p> <p>An annual review of Hospital-Acquired Conditions and Serious Reportable Events (SRE) is highly recommended in order to keep current with this standard. Please check www.qualityforum.org for an updated list.</p> <p>Hospital-Acquired Conditions and Serious Reportable Events (SRE) include the following:</p> <ol style="list-style-type: none"> 1. Artificial insemination with the wrong donor sperm or donor egg. 2. Unintended retention of a foreign object in a patient after surgery or other procedure. 3. Patient death or serious disability associated with patient elopement (disappearance). 4. Patient death or serious disability associated with 	<p style="text-align: center;">DOCUMENT REVIEW</p> <ol style="list-style-type: none"> 1. Review the hospital’s Quality Assessment Performance Improvement program to determine it meets the requirement for Adverse Event Reporting. 2. Determine that the facility has conducted a Root Cause analysis to investigate the events contributing to the adverse event. The facility demonstrates it has used the information to implement strategic actions to improve patient care and related processes. 3. The facility retains the RCA for review during survey. 4. Survey Team will review the Root Cause Analysis (RCA) to determine that the facility is using information to improve processes. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>COMMENTS:</p>

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<p>The reporting of adverse events to HFAP is strongly encouraged. The healthcare organization should report the adverse event within 10 business days of the incident.</p>	<p>a medication error (e.g., errors involving the wrong drug, wrong dose, wrong patient, wrong time, wrong rate, wrong preparation or wrong route of administration).</p> <ol style="list-style-type: none"> 5. Patient death or serious disability associated with a hemolytic reaction due to the administration of ABO/HLA-incompatible blood or blood products. 6. Patient death or serious disability associated with an electric shock or elective cardioversion while being cared for in a healthcare facility. 7. Patient death or serious disability associated with a fall while being cared for in a healthcare facility. 8. Surgery performed on the wrong body part. 9. Surgery performed on the wrong patient. 10. Wrong surgical procedure performed on a patient. 11. Intraoperative or immediately post-operative death in an American Society Anesthesia (ASA) Class I patient. 12. Patient death or serious disability associated with the use of contaminated drugs, devices, or biologics provided by the healthcare facility. 13. Patient death or serious disability associated with the use of function of a device in patient care, in 		

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which the device is used or functions other than as intended.

- 14. Patient death or serious disability associated with intravascular air embolism that occurs while being cared for in a healthcare facility.
- 15. Infant discharged to the wrong person.
- 16. Patient suicide, or attempted suicide resulting in serious disability, while being cared for in a healthcare facility.
- 17. Maternal death or serious disability associated with labor or delivery in a low-risk pregnancy while being cared for in a health care facility.
- 18. Patient death or serious disability associated with hypoglycemia, the onset of which occurs while the patient is being cared for in a healthcare facility.
- 19. Death or serious disability (kernicterus) associated with failure to identify and treat hyperbilirubinemia in neonates.
- 20. Stage 3 or 4 pressure ulcers acquired after admission to a healthcare facility.
- 21. Patient death or serious disability due to spinal manipulative therapy.

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- 22. Any incident in which a line designated for oxygen or other gases to be delivered to a patient contains the wrong gas or is contaminated by toxic substances.
- 23. Patient death or serious disability associated with a burn incurred from any source while being cared for in a healthcare facility.
- 24. Patient death or serious disability associated with the use of restraints or bedrails which being cared for in a healthcare facility.
- 25. Abduction of a patient of any age.
- 26. Sexual assault on a patient within or on the grounds of the healthcare facility.
- 27. Death or significant injury of a patient or staff member resulting from a physical assault (i.e., battery) that occurs within or on the grounds of the healthcare facility

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<p>12.02.03 <u>Communication to the Patient of an Adverse Event.</u> The occurrence of an adverse outcome must be communicated to the patient as soon as it is recognized and the patient is ready physically and psychologically to receive the information. This should occur within 24 hours after the event is discovered.</p>	<p align="center"><u>PATIENT SAFETY INITIATIVE</u></p> <p>Initial explanations should focus on what happened and how it will affect the patient, including immediate effects and the prognosis.</p> <p>Accurate documentation of the event is important both to facilitate transparent communication with the patient and family as well as to serve as a solid foundation for patient safety improvement initiatives that follow an event.</p> <p>If not possible to communicate with the patient, the initial communications should begin with those members of the family or healthcare proxy who will be representing the patient in further discussions.</p>	<p align="center"><u>DOCUMENT REVIEW</u></p> <ol style="list-style-type: none"> Review patient record for adverse event documentation. Documentation in medical record that patient and/or family notified of adverse event. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>COMMENTS:</p>
<p>12.02.04 <u>Support of Caregivers.</u> The healthcare organization must have a program designed to provide support to their staff that are experiencing normal stress after experiencing highly abnormal event.</p>	<p align="center"><u>PATIENT SAFETY INITIATIVE</u></p> <p>Because caregivers' needs vary, the support system should incorporate a variety of offerings to meet different needs.</p> <p>The objective is to help the staff manage the stress of the adverse events so that they can better care for their patients, so healing can occur, and so the caregiver can comfortably return to the work environment with normal productivity.</p>	<p align="center"><u>DOCUMENT REVIEW</u></p> <ol style="list-style-type: none"> Review documentation of an event that has occurred. Review policies and procedures for staff debriefing following an event. Debriefing occurred by and with appropriate staff. Staff participation in Root Cause Analysis. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>COMMENTS:</p>

LIFE SAFETY

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Introduction to Chapter 13: Life Safety

The standards in this chapter are based on Conditions of Participation (CoP) requirements from the Centers for Medicare & Medicaid Services (CMS) and the 2012 edition of the NFPA 101 *Life Safety Code* and the 2012 edition of the NFPA 99 *Health Care Facilities Code*. Compliance with the Life Safety Code is based on the different occupancy chapters within the code. All hospitals must include healthcare occupancy designations; however hospitals may choose to include other occupancy designations if they comply with the respective occupancy chapter provisions.

The different occupancies may include, but are not limited to:

1. Healthcare Occupancy
2. Ambulatory Health Care Occupancy
3. Business Occupancy

Definition of Healthcare Occupancy:

An occupancy used to provide medical or other treatment or care simultaneously to four (4) or more patients on an inpatient basis, where such patients are mostly incapable of self-preservation due to age, physical or mental disability, or because of security measures not under the occupants' control.

The health care facilities regulated by this occupancy chapter are those that provide sleeping accommodations for their occupants and are occupied by persons who are mostly incapable of self-preservation because of age, because of physical or mental disability, or because of security measures not under the occupants' control.

The requirements established by this chapter do apply to all hospitals, nursing homes, and limited care facilities.

Examples of Healthcare Occupancies:

- Hospitals
- Psychiatric hospitals
- Specialty hospitals
- Inpatient hospices
- Nursing homes
- Skilled nursing facilities
- Long term care facilities
- Inpatient substance abuse facilities

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- **Emergency Departments**

CMS has determined that all emergency departments (free-standing or contiguous to a hospital) shall comply with healthcare occupancy requirements since patients routinely reside in EDs for more than 24-hours.

Definition of Ambulatory Health Care Occupancy:

An occupancy used to provide services or treatment simultaneously to four (4) or more patients that provides, on an outpatient basis, one or more of the following:

- (1) treatment for patients that renders the patients incapable of taking action for self-preservation under emergency conditions without the assistance of others;
- (2) anesthesia that renders the patients incapable of taking action for self-preservation under emergency conditions without the assistance of others;
- (3) emergency or urgent care for patients who, due to the nature of their injury or illness, are incapable of taking action for self-preservation under emergency conditions without the assistance of others.

Examples of Ambulatory Health Care Occupancies include:

- Physical rehab outpatient centers
- Ambulatory surgical centers
- Diagnostic centers

CMS has determined that all ambulatory surgical centers shall comply with ambulatory health care occupancy requirements regardless how many patients are incapable of self-preservation.

Definition of Business Occupancy:

An occupancy used for the transaction of business other than mercantile.

Examples of Business Occupancies include:

- Administrative offices
- Physician’s offices
- Support service centers (i.e. maintenance, laundry, sterile processing, boiler rooms, etc.)

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For simplification purposes, this chapter will use the term ‘hospital’ and refer to all occupancies that are included within the facility that houses the healthcare occupancy. It is expected that the hospital be compliant with the Life Safety Code at all times. However, it is recognized there may be times during construction, repairs, or emergencies that compliance with the Life Safety Code is not possible. At those times, the organization needs to either immediately resolve the deficiency or assess the non-compliant issues for Alternative Life Safety Measures, based on the organization’s policy.

Waivers

Requests for waivers are permitted but only after the Life Safety Code deficiency has been cited during an HFAP survey. As part of the organization’s Plan of Correction, a waiver request may be presented to HFAP, who will consider the request and pass it on to the respective CMS Regional Office for approval. The waiver must explain the unreasonable hardship the healthcare organization has in meeting the Life Safety Code requirement and that it does not present a safety risk to the patient or staff.

When making a waiver request, the hospital should identify the deficiency, how the hospital deviates from the code, and steps taken by the hospital to ensure the equivalent level of safety. The hospital has the option of requesting a time-limited waiver if the intent is to ‘bridge’ a period of time until a feature of safety is installed or modified, such as the installation of sprinklers. Waivers approved by CMS are only valid until the next survey cycle. §482.41(b)(2)

Equivalencies

After consideration of survey findings, the CMS may approve a Fire Safety Evaluation System (FSES) equivalency request for specific provisions of the Life Safety Code, which if rigidly applied, would result in unreasonable hardship upon the hospital, but only if the equivalency does not adversely affect the health and safety of patients.

Submission of a FSES equivalency request may be made by the hospital after the deficiency has been cited during a survey. The organization’s Plan of Correction will identify that the hospital plans to submit a FSES equivalency request as the proposed correction for that particular deficiency.

The FSES equivalency request will be submitted to HFAP after the Plan of Correction has been submitted to the HFAP central office. Once received, HFAP will review the **FSES** equivalency request and may forward it with a recommendation to the CMS Regional Office for consideration and action. Only the Regional Office of CMS may approve FSES equivalency requests for Medicare or Medicaid-participating hospitals.

When making a FSES equivalency request, the hospital should follow the provisions of NFPA 101A *Guide on Alternative Approaches to Life Safety*, **2013** edition. FSES equivalencies approved by CMS are valid until the next survey, or until major renovation or remodeling is conducted in the area where the deficiency is identified, whichever comes first.

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The main difference between a waiver request and an equivalency request is a waiver is seeking permission to not have to comply with a particular Life Safety Code requirement, without any engineering analysis to support that claim. However, an equivalency request is based on an engineering analysis that demonstrates the hospital has an acceptable level of safety based on other features of fire safety, even though the hospital has not resolved the Life Safety Code deficiency.

Instructions for Submitting a Waiver or Equivalency Request

Instructions on how to submit a waiver or equivalency request are found on the HFAP website at www.hfap.org, under the 'Resources' tab.

Definition of New Construction vs. Existing Conditions

New construction is defined as those areas whose construction documents were approved by state and local governmental agencies after July 5, 2016. Existing conditions is defined as those areas whose construction documents were approved on or before July 5, 2016.

Features of Life Safety installed under new construction requirements, must be maintained to those new construction requirements even after they later qualify as existing conditions.

Definition of Time

Please be aware that HFAP standard 13.00.06 defines the intervals between testing and inspection activities identified in this chapter. Since NFPA standards and codes are written by different technical committees, often they do not agree on the definition of what a period of time means, such as 'quarterly' or 'annually'. HFAP has reviewed all of the NFPA standards and developed a standard that everyone can follow, and still meet the intent of the respective NFPA technical committee.

For instance, where one technical committee may consider an 'annual' activity to occur anytime during a calendar year, another technical committee may want the activity to occur close to the anniversary date of the last activity. Therefore, HFAP has decided to change some of the definitions of time to no longer allow a period of time that goes beyond the intent of the NFPA technical committee. As an example, for activities that are required 'every 12 months' or 'annually', the HFAP standard now says the **completion of the** activity is performed during the 12th month of the annual period, but not beyond.

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Documentation Requirements

HFAP standard 13.00.07 has specific requirements concerning documentation of evidence of compliance for standards in this chapter. Please be fully aware of these requirements as they apply to all testing and inspection documents, whether the hospital creates their own documents or relies on those provided by contractors.

Facility Demographic Report

A Facility Demographic Report (FDR) is a document that requests basic information concerning the facility and is required to be maintained at all times, and updated annually. The FDR form is found at the end of this chapter, and it will be reviewed during a survey.

Since the FDR is a document that requests specific, detailed, engineering data about the facility, it must be completed by an individual who has a working knowledge of the applicable NFPA codes and standards, and has experience with the facility. This individual may be one who is employed by the hospital, or it may be one who is contracted by the hospital to complete the document. Failing to properly answer each question on the FDR will result in a citation.

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General Requirements.

13.00.01 Life Safety Code

Compliance.

Except as otherwise provided in this section—

The hospital must meet the applicable provisions and must proceed in accordance with the Life Safety Code (NFPA 101 and Tentative Interim Amendments TIA 12-1, TIA 12-2, TIA 12-3, and TIA 12-4.) Outpatient surgical departments must meet the provisions applicable to Ambulatory Health Care Occupancies, regardless of the number of patients served. §482.41(b)(1)(i)

Notwithstanding paragraph (b)(1)(i) of this section, corridor doors and doors to rooms containing flammable or combustible materials must be provided with positive latching hardware. Roller latches are prohibited on such doors. §482.41(b)(1)(ii)

The provisions of the Life Safety Code do not apply in a State where CMS finds that a fire and safety code imposed by State law adequately

All hospitals, regardless of size or number of beds, must comply with the NFPA 101 *Life Safety Code (2012 edition)* requirements for all locations. All buildings and spaces owned, leased or rented which is used for hospital business must comply with the Life Safety Code.

The organization is responsible for developing a systematic process for assessing the compliance with the Life Safety Code of each building under its control.

While HFAP does not specify what process to Life Safety compliance the organization should use, the results must show that the facilities are in full compliance with the Life Safety Code, and other applicable standards.

Roller latches may not be used on corridor doors, with the exception of corridor doors that are not required to latch, such as doors to toilet rooms, bathrooms, shower rooms, sink closets and similar spaces that do not contain flammable or combustible materials.

DOCUMENT REVIEW AND OBSERVATION

- Determine that buildings are in compliance with the applicable occupancy chapters of the Life Safety Code, by direct observation.

1 = Compliant
 2 = Not Compliant

Comment:

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protects patients in hospitals.
 §482.41(b)(3)

13.00.02 Alternative Life Safety Measures – Policy.

The hospital must have a written policy on Alternative Life Safety Measures (ALSM) whenever situations where a deficiency to the Life Safety Code cannot be immediately resolved, **including construction, repair and improvement operations.** All deficiencies to features of Life Safety must be assessed and documented for additional measures the same day they are discovered. The need to implement compensation measures for the life safety deficiency is based on the criteria in the hospital’s ALSM policy.

The ALSM policy must identify when a particular compensating measure is required to be implemented and to what extent that measure is implemented.

It is understood that features of life safety may be compromised or impaired during periods of construction, maintenance or emergency repairs. During these periods, the hospital must perform a documented risk assessment of the deficiency, and implement compensating measures based on the criteria of their ALSM policy.

Not all deficiencies to Life Safety may require compensation, but the ALSM policy must clearly distinguish when and to what extent such measures are implemented.

DOCUMENT REVIEW

- Review the hospital’s ALSM policy. The policy must clearly identify that it applies to all conditions when impairments to features of Life Safety exists, including during periods of construction, maintenance, and emergency repairs.
- The ALSM policy must clearly identify what compensating measures will be taken when certain deficiencies are discovered.

1 = Compliant
 2 = Not Compliant

Comment:

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<p>13.00.03 Alternative Life Safety Measures – Implementation. When a Life Safety Code deficiency cannot be corrected the same day it is discovered, the hospital conducts an assessment and implements appropriate measures to compensate for impairments to the Life Safety Code, based on their ALSM policy.</p>	<p>When conditions exist that compromises a feature of life safety, the organization must conduct an assessment to determine what ALSM, if any, to implement, based on their ALSM policy. When alternative measures are implemented, they must be continued until such time the deficiency is resolved.</p> <p>The assessment is documented.</p>	<p><u>OBSERVATION AND DOCUMENTATION</u></p> <ul style="list-style-type: none"> Examine areas in the hospital where a feature of Life Safety may be compromised, such as constructions areas and areas under maintenance for evidence of ALSM. Review ALSM assessment documentation to determine if the organization has conducted ALSM assessment for known Life Safety deficiencies. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>Comment:</p>
<p>13.00.04 Notification of Emergency Response Forces. The hospital notifies the local emergency response force (fire department) when a fire alarm system, or parts thereof, is out of service more than four (4) hours in a 24-hour period, and either evacuates the building or portions of the building affected by the outage or implements a fire watch in all affected areas.</p>	<p>The organization must take appropriate action when the fire alarm system (or parts thereof) is out of service for more than four (4) hours in a 24 hour period, and when the automatic sprinkler system (or parts thereof) is out of service for more than ten (10) hours in a 24 hour period. The phrase ‘or parts thereof’ refers to circuits or branches of the systems, not a single device.</p> <p>Refer to 13.00.09 on the proper method and procedure to conduct a fire watch.</p>	<p><u>OBSERVATION AND DOCUMENTATION</u></p> <ul style="list-style-type: none"> Ask to see the documentation of the notification of local fire departments.. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>Comment:</p>
<p>The hospital notifies the local emergency response force (fire department) when an automatic sprinkler system, or parts thereof, is out of service more than ten (10) hours in a 24-hour period, and either evacuates the building or portions of the building affected by the outage or implements a fire watch in all affected areas.</p>			

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The fire watch and the notification of the local emergency response force are documented.

§482.41(b)(8)
 §482.41(b)(8)(i)
 §482.41(b)(8)(ii)

13.00.05 Facility Demographic Report (FDR).

The hospital designates an individual to assess the facility’s compliance with the NFPA 101 Life Safety Code (2012 edition), and complete and maintain the Facilities Demographic Report (FDR) and manage all deficiencies.

Qualifications and the designation of the responsible individual are documented.

Each facility in the organization identified as a healthcare occupancy or an ambulatory healthcare occupancy has an individual FDR report completed.

These FDR reports are available for review by the surveyor.

The organization must designate an individual to be responsible for the assessment of the facility’s compliance with the Life Safety Code. This individual is responsible to complete and maintain the Facilities Demographic Report (FDR) report.

HFAP does not set qualifications for the designated individual; **however since the FDR is technical in manner, a person with technical knowledge must be designated.**

The hospital must complete the HFAP Facility Demographic Report on at least an annual basis, or more often as needed, for each facility identified as a healthcare occupancy or as an ambulatory healthcare occupancy, and maintain the accuracy of the information. **Business occupancies are not required to have a FDR completed.**

Individual healthcare occupancies or ambulatory healthcare occupancies must have individual FDRs completed for each facility.

OBSERVATION AND DOCUMENTATION

- **Review** the documentation **in the FDR** that designates the responsible individual, and **assess** the qualifications listed.
- Review the FDR to determine if it has been updated within the past 12 months, and is current and maintained.
- Review the FDR to ensure the organization completed the assessment and maintains the accuracy of the information. Determine if each question was answered accurately.

1 = Compliant
 2 = Not Compliant

Comment:

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<p>13.00.06 Testing & Inspection- Definition of Time. Unless otherwise stated, the periods of time for testing, inspection and maintenance activities specified within this chapter shall be as follows:</p> <p><u>Weekly or ‘every 7 days’:</u></p> <ul style="list-style-type: none"> • The completion of the activity is performed anytime during the calendar week. <p><u>Monthly or ‘every 30 days’:</u></p> <ul style="list-style-type: none"> • The completion of the activity is performed anytime during the calendar month. <p><u>Quarterly or ‘every 3 months’:</u></p> <ul style="list-style-type: none"> • The completion of the activity is performed quarterly, during the third month of the quarterly period. <p><u>Semi-annually or ‘every 6 months’:</u></p> <ul style="list-style-type: none"> • The completion of the activity is performed semi-annually, during the 6th month of the semi-annual period. <p><u>Annually or ‘every 12 months’:</u></p> <ul style="list-style-type: none"> • The completion of the activity is performed annually, during the 12th month of the annual period. 	<p>Testing and inspection activity cannot exceed the allowable amount of time permitted by the applicable standard or regulation.</p> <p>The completion of the weekly and monthly activities is to be performed during the designated calendar period.</p> <p>The completion of the quarterly, semi-annually, annually, 3-year, 5-year, and 6-year activities is to be performed during the last calendar month of that period.</p>	<p style="text-align: center;"><u>DOCUMENTATION</u></p> <ul style="list-style-type: none"> • When reviewing documentation, make sure testing, inspection or maintenance activity is performed within the limits of this standard. • If the testing/inspection activity was not conducted within the specified time-frame then score non-compliance with the respective standard that requires the testing/inspection activity. 	<p>Not Score Under This Standard</p>

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3-Years:

- The completion of the activity is performed once every 3 years, during the 36th month of the 3-year period.

5-Years:

- The completion of the activity is performed once every 5 years, during the 60th month of the 5-year period.

6-Years:

- The completion of the activity is performed once every 6 years, during the 72nd month of the 6-year period.

13.00.07 Testing & Inspection-Documentation.

Unless otherwise stated, testing, inspection and maintenance documentation must include, at the minimum, the following information:

1. Name of individual performing the activity
2. Affiliation of the individual performing the activity

All documentation of testing, inspection and maintenance activities must include this basic information.

If a component of safety is found to fail its test, then the component must be repaired or replaced immediately or alternative life safety measures must be implemented according to the organization's policy. (See 13.00.03)

This standard requirement on documentation does not apply to the inspection and maintenance tags located on portable fire extinguishers. The date the

DOCUMENTATION

- When reviewing documentation, make sure testing, inspection or maintenance results are documented in accordance with this standard.
- **If the testing/inspection documentation does not meet the requirements of this standard, then score a finding under the respective standard that required the test or inspection.**

Not Scored Under This Standard

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<p>3. The signature of the individual performing the activity</p> <p>4. Activity name</p> <p>5. Date(s) (month/day/year) that activity was performed</p> <p>6. The frequency that is required of the activity</p> <p>7. The NFPA code or standard which requires the activity to be performed, as applicable.</p> <p>8. The results of the activity, such as 'Pass' or 'Fail'</p>	<p>inspection or maintenance activity was performed and the initials of the person performing the activity must be recorded</p>		
<p>13.00.08 Interior Finish. The interior finish on existing walls and ceilings must be Class A or Class B, except rooms protected with sprinklers are permitted to be Class C provided the room is separated from the exit access corridor.</p> <p>The interior finish on new construction walls and ceilings must be Class A or Class B, except rooms having a capacity not exceeding four persons are permitted to be Class C; and interior finish on new</p>	<p>Class A interior wall and ceiling finishes have a flame spread rating of 0 – 25, and a smoke development rating of 0 - 450.</p> <p>Class B interior wall and ceiling finishes have a flame spread rating of 26 - 75, and a smoke development rating of 0 - 450.</p> <p>Class C interior wall and ceiling finishes have a flame spread rating of 76 - 200, and a smoke development rating of 0 - 450.</p>	<p><u>OBSERVATION & DOCUMENTATION</u></p> <ul style="list-style-type: none"> Review the flame spread rating of selected interior finishes to determine if it meets the proper classification rating Plywood used as interior finish in utility or equipment rooms would be permitted provided it met the required flame spread for that classification. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>Comment:</p>

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construction corridor walls not exceeding 4 feet in height that is restricted to the lower half of the wall is permitted to have Class A, Class B, or Class C finish.

13.00.09 Fire Watch.

A fire watch consists of dedicated, trained individual(s) with no other duties constantly circulating throughout the portion of the facility affected by the deficiency or impairment looking for a fire, fire hazards, or hazardous conditions that may affect the fire safety of the facility.

‘Constantly circulating’ the affected areas of the facility means continuous, without interruption. If breaks are desired, then a replacement individual is needed.

Only individuals with fire-response training may conduct a fire watch, and may not perform any other duty during the fire watch. They are to ensure there is no fire, and confirming that other fire protection features of the building, such as egress routes, suppression systems, and alarm systems are available and functioning. The individuals must have ready access to fire extinguishers, and the ability to promptly notify the fire department in the event of a fire.

If it requires one individual more than 30 minutes to complete one round of the affected area, then additional individuals must be assigned to fire watch duty.

Fire watches must be documented indicating the start date and time, and the end date and time. The documentation must record all individuals who conduct the fire watch, with their individual start and end times.

OBSERVATION AND DOCUMENTATION

- Ask to see the documentation of the fire watch.
- Check to see that fire watches are performed continuously, without interruption.
- Determine if the individual(s) performing the fire watch have received fire-response training.

1 = Compliant
 2 = Not Compliant

Comment:

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For guidance on Fire Watches see NFPA 25
*Inspection, Testing, and Maintenance of Water-Based
Fire Protection Systems*, 2011 edition, section
A.15.5.2 (4)(b).

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Means of Egress.

13.01.01 Doors.

Corridor doors and **doors to hazardous rooms** shall be provided with **positive latching hardware**.

Roller latches are not permitted on corridor doors that are required to latch.

Corridor doors shall be capable of resisting the passage of smoke.

Doors in the path of egress must be side-hinged or pivot-swing type.

§482.41(b)(1)(ii)

Latching devices are necessary to keep patient room doors securely closed in the event of the fire. Positive latching devices are required on all corridor doors.

The use of roller latches will not be allowed on corridor doors in hospitals where corridor doors are required to latch (see 13.00.01).

Corridor doors cannot be restrained in such a way to prevent the door from closing.

Doors in the path of egress are required to be side-hinged or pivoted-swinging type, and are required to swing in the direction of egress when serving a room or area with an occupant load of 50 or more persons.

Doors must open to a minimum of 90 degrees from its closed position, and extend no more than seven (7) inches into the corridor when opened to its fullest extent.

Horizontal sliding doors are required to be side-hinged and capable of 'breaking away', unless the door serves a room with an occupant load less than 10, and complies with all of the provisions in 19.2.2.2.10.2 of the 2012 Life Safety Code.

A level landing surface is required and shall be maintained on each side of the door threshold. The depth of the landing is to be at least equal to the width of the widest door leaf.

DOCUMENT REVIEW AND OBSERVATION

Examine corridor doors during building tour for compliance.

- **During the building tour, examine corridor doors to ensure they can close and latch. NOTE: Self-closing is not required.**
- **Examine horizontal sliding doors: Ensure they are also side-hinged and capable of 'breaking away' and swing from the side hinges unless the door serves a room with an occupant load of less than 10 persons.**
- **Ensure doors in the path of egress open to at least 90 degrees, and extend no more than seven (7) inches into the corridor when fully opened.**

1 = Compliant
 2 = Not Compliant

Comment:

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<p>13.01.02 Door Locks. Doors in the means of egress must be operable with not more than one releasing operation.</p> <p>Doors within the means of egress must not be equipped with a latch or lock that requires the use of a tool or key from the egress side, with the exception where the clinical needs of the patients require specialized security measures for their safety.</p> <p>Doors in the means of egress are permitted to be equipped with delayed egress locks provided the entire facility is protected with automatic sprinklers, or fully detected with smoke detectors.</p> <p>Doors in the means of egress are permitted to be equipped with access-control locks.</p> <p>Doors separating elevator lobbies from exit access corridors are permitted to be locked with electrical locks provided all of the provisions of 7.2.1.6.3 of the 2012 Life Safety Code are met.</p> <p>Doors in the means of egress are permitted to be equipped with locks where the patient’s special needs</p>	<p>Occupants accessing doors in the path of egress are not permitted to operate more than one device to open the door.</p> <p>A door is not permitted to have a lock separate from the latching mechanism (such as a dead-bolt lock) which would require the occupant to operate two devices to open the door. (NOTE: Pulling on a handle or pushing on the door is not considered an operation.) However, two releasing operations are permitted for existing hardware on a door leaf serving an area having an occupant load not exceeding three, provided that releasing does not require simultaneous operations.</p> <p>Normally, doors in the path of egress in a healthcare occupancy are not permitted to be locked. However, the Life Safety Code permits five (5) types of locks on doors in the path of egress.</p> <ol style="list-style-type: none"> 1. Clinical needs locks are those used in psychiatric and behavioral health units, however staff must be able to unlock the doors at all times (see 18/19.2.2.2.5.1 of the 2012 edition of the Life Safety Code). 2. Clinical needs locks are not permitted to be used for infant or pediatric security. However, door locking arrangement are permitted where patient special needs require specialized protective measures for their safety, provided that all of the provisions of 18/19.2.2.2.5.2 are met. 	<p><u>DOCUMENT REVIEW AND OBSERVATION</u></p> <ul style="list-style-type: none"> • During the building tour, observe how doors are locked and if they comply with the provisions listed. • Observe delayed egress locks to ensure that they are only installed in fully sprinklered or fully detected buildings. • Observe access-control locks to determine they have motion sensors mounted on the egress side to automatically unlock the door when someone approaches; and a ‘Push To Exit’ button mounted on the egress side within five (5) feet of the door, that unlocks the door when depressed. • Observe Clinical Needs locks and ensure they are only installed in Psychiatric, Alzheimer’s, dementia, and substance abuse units. • Observe elevator lobby locks and ensure the elevator lobby is smoke detected and the entire building is sprinklered. • Observe special arrangement locks where the needs of the patient require special protective measure locks (i.e. nurseries, mother/baby units, ICUs, ERs), to ensure the entire locked area is smoke detected and the entire building is sprinklered. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>Comment:</p>

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<p>require specialized protective measures for their safety, in accordance with section 18/19.2.2.2.5.2 of the 2012 Life Safety Code.</p>	<p>3. Delayed egress locks must comply with section 7.2.1.6.1 of the 2012 edition of the Life Safety Code and access-control locks must comply with section 7.2.1.6.2 of the same document.</p> <p>4. Elevator lobbies are permitted to be locked provided they meet all of the requirements in 7.2.1.6.3 of the 2012 Life Safety Code.</p> <p>5. Doors in the means of egress from Nurseries, Mother/Baby units, ICUs, and ERs are permitted to be locked provided they are equipped with locks in accordance with section 18/19.2.2.2.5.2 of the 2012 Life Safety Code.</p>		
<p>13.01.03 Corridor Clutter. The exit access corridor must be maintained to the full required width.</p>	<p>Minimum width of exit access corridors for new construction in an acute-care hospital is eight (8) feet.</p> <p>Minimum width of exit access corridors for new construction in a psychiatric care hospital is six (6) feet.</p> <p>Minimum width of exit access corridors for new construction in adjunct areas not intended for use by inpatients is forty-four (44) inches.</p> <p>Minimum width of exit access corridors for existing construction is four (4) feet.</p> <p>Minimum width of exit access corridors in adjunct areas not intended for use by inpatients is forty-four (44) inches.</p>	<p style="text-align: center;"><u>OBSERVATION</u></p> <ul style="list-style-type: none"> • During the building tour, observe corridors for clutter and unattended items left more than 30 minutes. Ask staff how long carts and equipment are left in corridors. • Observe if the corridor width in existing conditions has been reduced to less than what is required for new construction. • Review the organization’s plan to remove the authorized carts and equipment from the corridor during a fire emergency. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>Comment:</p>

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	<p>Alterations of the existing width of corridors cannot be reduced to less than that which is required for new construction.</p> <p>Items left unattended in the exit access corridors for more than 30 minutes are not permitted, with the exception of emergency crash carts, and patient isolation supply carts, provided the carts are mounted on wheels, and the organization has a plan to remove the carts from the corridor during a fire emergency.</p> <p>Projections into the required width of the corridor are permitted for certain wheeled equipment, such as equipment in use; medical emergency equipment not in use; and patient lift and transport equipment, provided it meets the provisions of 18/19.2.3.4(4) of the 2012 Life Safety Code.</p> <p>Projections into the required width of the corridor are permitted for fixed furniture provided it meets the provisions of 18/19.2.3.4(5) of the 2012 Life Safety Code.</p>		
<p>13.01.04 Suites. Suites containing patient sleeping rooms are limited in area to the following:</p> <ul style="list-style-type: none"> • 5,000 square feet in non-sprinklered buildings; • 7,500 square feet in smoke compartments protected with standard response sprinklers and 	<p>Sleeping room suites exceeding 1,000 square feet are required to have two exit access doors, one of which may be to an exit stairwell, direct exit, horizontal exit, or directly to an adjoining suite, provided the separation between the suites complies with the corridor requirements.</p> <p>Non-sleeping room suites exceeding 2,500 square feet are required to have two exit access doors, one of which may be to an exit stairwell, direct exit,</p>	<p style="text-align: center;"><u>OBSERVATION</u></p> <ul style="list-style-type: none"> • During the building tour, observe the size of the suites to determine if they are within the limits listed. • Check suite entrance doors to ensure they positively latch. • Check sleeping suites to ensure they are staffed continuously. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant <input type="checkbox"/> N/A</p> <p>Comment:</p>

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<p>smoke detectors, or in smoke compartments protected with quick response sprinklers;</p> <ul style="list-style-type: none"> 10,000 square feet where direct supervision of the patient sleeping rooms is arranged from a normally attended location in the suite, the suite is fully smoke detected, and the suite is fully protected with quick response sprinklers. <p>Suites containing non-sleeping room suites are limited to 10,000 square feet.</p>	<p>horizontal exit, or directly to an adjoining suite, provided the separation between the suites complies with the corridor requirements.</p> <p>Sleeping suites must be provided with constant staff supervision within the suite. Sleeping suites must be arranged to allow direct supervision of all patient sleeping rooms from a normally attended location, or the entire suite must be provided with total smoke detection coverage.</p> <p>All doors located in the boundary wall of the suite enclosure, including entrance doors, must positively latch.</p> <p>Travel distance between any point in a suite and an exit access door from the suite must not exceed 100 feet.</p>	<ul style="list-style-type: none"> Check sleeping suite to ensure they have direct supervision of patients from a normally attended location, or the entire suite must be protected with smoke detectors. 	
<p>13.01.05 Signage. Exits shall be marked by an approved sign readily visible from any direction of exit access and be illuminated. Illuminated signs must be legible in both the normal and emergency lighting mode.</p> <p>Access to exits shall be marked by approved signs in all cases where the way to reach the exit is not readily apparent to the occupants.</p>	<p>All exits must be marked with an approved 'Exit' sign, with the exception of exterior exit doors which clearly are identifiable as exits.</p> <p>This standard does not necessarily require an 'Exit' sign to be visible at every location in an exit access corridor.</p> <p>If the path of egress is apparent, then an 'Exit' sign is not required.</p> <p>Monthly inspections of 'Exit' signs are required to insure they are still illuminated.</p>	<p><u>DOCUMENT REVIEW AND OBSERVATION</u></p> <ul style="list-style-type: none"> During the building tour, observe all 'Exit' signs to insure they are properly illuminated. If the path of egress is not marked, and the way to the exit is not readily apparent, then the organization is non-compliant with this standard. During the document review session, review the monthly 'Exit' sign inspection log to insure all 'Exit' signs were inspected. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>Comment:</p>

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Exit signs shall be visually inspected monthly for operation of the illumination sources.

This inspection is documented.

Doors that do not lead to exits but could be confused as an exit must have a sign that reads “NO EXIT”, with the word “NO” two inches tall, and the word “EXIT” one inch tall.

Enclosed stairwell identification signage is required to be provided in compliance with section 7.2.2.5.4 of the 2012 Life Safety Code for new stairways serving three or more stories and existing stairways serving five or more stories.

13.01.06 Exit Discharge.

The walking surface on the exit discharge must be level, having no more than ¼ inch of abrupt change in elevation, and be free from snow and ice accumulation.

The exit discharge shall be illuminated under both the normal and emergency lighting mode, all the way to the public way.

The exit discharge is the portion of means of egress from the exit door to the public way. The walking surface must be level and free of cracks and abrupt changes in elevation exceeding ¼ inch. Note that steps are permitted.

Exit discharge must be maintained free from ice and snow.

An exit discharge across an unimproved area, such as a lawn, is not considered to be in compliance with this standard due to the uneven walking surface.

Illumination of exit discharge must be by lighting fixtures with more than one lamp, or multiple lighting fixtures to ensure path is illuminated if one lamp fails.

OBSERVATION

- During the building tour, observe all exit discharges to ensure they have level walking surfaces and illumination all the way to the public way.

1 = Compliant
 2 = Not Compliant

Comment:

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<p>13.01.07 Corridor. Items attached to the wall of the corridor cannot project more than four (4) inches into the corridor, may not exceed 36 inches in length; are separated from other wall-mounted projections by at least 48 inches; and are located at least 40 inches above the floor.</p> <p>Corridors must provide access to two (2) approved exits without passing through intervening rooms or spaces, other than other corridors or lobbies.</p> <p>Dead-end corridors are limited to 30 feet. Existing dead-end corridors are permitted to remain if determined to be impractical and unfeasible to alter them to allow two paths of egress.</p>	<p>Wall mounted items in the corridor are not permitted to project more than four (4) inches into the corridor. This includes drinking fountains, flip-down desks for wall charting stations, evacuation chairs, hand-rub dispensers, and any other item attached to the wall surface.</p> <p>This applies to new and existing conditions, regardless how long they have been installed.</p> <p>The path of egress is not permitted from a corridor into a room or suite to reach an exit.</p> <p>Dead-end corridors are created by doors that are locked in the path of egress.</p>	<p style="text-align: center;"><u>OBSERVATION</u></p> <ul style="list-style-type: none"> • During the building tour, examine wall-mounted items in the corridor to ensure they do not project more than 6 inches. • During the building tour, observe dead-end corridors, remembering locked doors in the path of egress may create an unexpected dead-end corridor. Do they exceed 30 feet in length? • If more than 30 feet, are dead-end corridors existing? If existing, would it be impractical or unfeasible to resolve? 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>Comment:</p>
<p>13.01.08 Path of Egress Obstructions. The path of egress must be free and clear of all obstructions or impediments all the way to the public way.</p>	<p>This standard applies to items and objects that would impede travel along the path of egress, including stairwells, passageways and exit discharges, all the way to the public way.</p> <p>For corridor clutter, see standard 13.01.03.</p>	<p style="text-align: center;"><u>OBSERVATION</u></p> <ul style="list-style-type: none"> • During the building tour, examine each path of egress all the way to the public way to ensure there are no objects that would impede access. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>Comment:</p>

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<p>13.01.09 <u>Travel Distance to Exits.</u> The maximum travel distance between any point in a room and the exit shall not exceed 150 feet for buildings not fully protected with automatic sprinklers.</p> <p>For buildings that are fully protected with automatic sprinklers, the maximum travel distance from any point in a room to an exit is 200 feet.</p>	<p>The travel distance to an exit is measured along the normal walking path, around objects in rooms, and no closer than 12 inches to corridor walls.</p> <p>The travel distance between any point in a healthcare sleeping room (other than suites) and the exit access door in that room must not exceed 50 feet.</p>	<p style="text-align: center;"><u>OBSERVATION</u></p> <ul style="list-style-type: none"> • During the building tour, examine selected travel distances to exits to ensure they are within the allowable amount. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>Comment:</p>
<p>13.01.10 <u>Exit Enclosures.</u> Stairwells and exit passageways must have the required fire resistive rating separation for the number of stories it serves.</p> <p>Stairwells and exit passageways must be constructed and maintained in accordance with section 7.1 of the 2012 Life Safety Code.</p>	<p>Openings in exit enclosures are limited to those necessary for access from normally occupied spaces and corridors. Existing openings to mechanical equipment spaces protected by fire rated door assemblies are permitted, provided:</p> <ul style="list-style-type: none"> • The space is used solely for non-fuel-fired mechanical equipment; • The space contains no storage of combustibles materials; • The building is protected throughout by an automatic sprinkler system. <p>Penetrations into and openings through an exit enclosure are limited to existing penetrations that are protected with fire-rated materials.</p> <p>New construction exit enclosures are prohibited from penetrations, with the exception of:</p>	<p style="text-align: center;"><u>OBSERVATION</u></p> <ul style="list-style-type: none"> • During the building tour, examine exit enclosures to ensure they do not have openings to unoccupied rooms. • If existing mechanical spaces open directly to exit enclosure, ensure the space is not used for fuel-fired equipment, the space contains no storage of combustibles, and the building is fully sprinklered. • While stairwells are not to be used as general storage areas, it is permissible to store safety-related items (i.e. evacuation chairs) in stairwells where they will not interfere with the use as an exit. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>Comment:</p>

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- Electrical conduit serving the exit enclosure;
- Required exit doors;
- Ductwork and equipment necessary for independent stair pressurization;
- Water or steam piping necessary for heating or cooling of the exit enclosure;
- Sprinkler piping;
- Standpipes;
- Penetrations for fire alarm circuits where the circuits are installed in metal conduit.

Items are not permitted to be stored in exit enclosures that have the potential to interfere with its use as an exit.

Minimum headroom in exit enclosures must be at least 7 foot 6 inches, unless existing conditions which is permitted 7 foot 0 inches.

Stairs and ramps that continue more than ½ story beyond the level of exit discharge must be provided with an interruption gate to prevent occupants from traveling past the level of exit discharge during building evacuation.

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Fire Detection Systems.

**13.02.01 Fire Alarm System-
Installation & Maintenance.**

A fire alarm system required for life safety shall be installed **and maintained** in accordance with sections 18/19.3.4 of the Life Safety Code (2012 edition), and in accordance with NFPA 72, 2010 edition.

Basic installation requirements are defined in section 18/19.3.4 in the Life Safety Code (2012 edition).

Specific installation details of the fire alarm system components are defined in NFPA 72 (2010 edition) National Fire Alarm Code.

Once installed, fire alarm systems must be maintained to the original installation requirements.

OBSERVATION

- During the building tour, observe if components of the fire alarm system are installed according to the codes and standards identified.
- **During the building tour, observe the fire alarm system to determine if it is maintained in accordance with the original installation requirements.**

1 = Compliant
 2 = Not Compliant

Comment:

**13.02.02 Fire Alarm System-
Testing.**

Fire alarm systems, and all their components, shall be tested according to NFPA 72 National Fire Alarm Code (2010 edition), Table 14.4.2.2 Test Methods, and Table 14.4.5 Testing Frequencies.

Reliability of the hospital’s fire alarm system is critical for the safety of the facilities occupants.

This standard does not require the hospital to have all of the components identified in NFPA 72 (2010 edition), Tables 14.4.2.2 and 14.4.5, but if installed, they must be maintained and tested according to the methods and frequencies identified.

The over-all fire alarm system consists of multiple connected and inter-connected components and systems that together create a detection and notification system.

Basic components include power supplies, control panels, initiating devices, notification devices and interface devices, which require specific testing procedures at specified frequencies.

DOCUMENT REVIEW

- Documentation demonstrating compliance with NFPA 72 (2010 edition) Tables 14.4.2.2 and 14.4.5 must be maintained for a minimum of three (3) years.
- Documentation must demonstrate that each and every device connected to the fire alarm system is **inventoried and** accounted for and passed (or failed) its test.
- Verify that the fire alarm test report fully complies with the frequencies identified in Table 14.4.5 of NFPA 72 (2010 edition). Each individual fire alarm device that is tested must be identified as to its location, and whether or not it passed or failed its test.

1 = Compliant
 2 = Not Compliant

Comment:

All testing results are documented.

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<p>13.02.03 Fire Alarm Systems- Transmitting Signal. The fire alarm system shall transmit an appropriate signal to an offsite monitoring station, or directly to the emergency response force.</p> <p>This signal shall be tested annually from the alarm panel in the protected premise, to the emergency response force.</p> <p>All results of the tests are documented.</p>	<p>Secondary components that are controlled by the fire alarm system such as air-handlers, smoke dampers, smoke or fire doors held open, and access-control, or delayed egress locks must be tested through their normal range of control when activated (or de-activated) by the fire alarm system.</p> <p>This standard does not require the fire alarm system to transmit all three signals, but when the fire alarm system activates an alarm signal, supervisory signal, or a trouble signal, it must be transmitted to an approved location, such as an Auxiliary Fire Alarm System, a Central Station, a Proprietary System, or a Remote Supervising Station.</p> <p>Manual reporting systems and methods are not permitted.</p> <p>Annually, the off-premises monitoring transmission equipment must be tested to ensure the local fire-responding agency received an alarm signal, even if the transmission of that signal is through a third-party entity.</p> <p>NFPA 72 (2010 edition) Table 14.4.2.2 (18) (a) through (e), and Table 14.4.5 (22) describes in detail the methods and procedures to follow for each type of system.</p>	<ul style="list-style-type: none"> • During the document review session, make sure the hospital annually tests the interface devices (relays) between the fire alarm systems and the locks used on the delayed egress and access-control locks. • Interview staff to determine if the test methods used on the fire alarm system components are consistent with Table 14.4.2.2 of NFPA 72 (2010 edition). <p>DOCUMENT REVIEW</p> <ul style="list-style-type: none"> • Review hospital records to determine whether the fire alarm system signal is transmitted annually from the fire alarm panel to the emergency response force. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>Comment:</p>

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<p>13.02.04 Fire Alarm System- Technician Qualifications. Fire alarm inspection, testing and maintenance personnel shall be qualified and experienced in the testing of fire alarm systems.</p> <p>Documentation identifying the qualification of the individual(s) performing testing, inspecting and maintenance activities on the fire alarm system must be available for review.</p>	<p>Technicians performing inspections, testing and maintenance on fire alarm systems must have proper certification, license, and/or training to do so. Examples of qualified personnel shall be permitted to include, but not limited to individuals with the following qualifications:</p> <ul style="list-style-type: none"> • Factory trained and certified • National Institute for Certification in Engineering Technologies (NICET) fire alarm certified • International Municipal Signal Association (IMSA) fire alarm certified • Certified by a state or local authority • Trained and qualified personnel employed by an organization listed by a national testing laboratory for the servicing of fire alarm system. <p>The requirement to maintain documentation on the individual providing inspection, testing or maintenance activities on the fire alarm system apply to contracted services as well hospital staff.</p>	<p style="text-align: center;">DOCUMENTATION</p> <ul style="list-style-type: none"> • Documentation for the individual(s) performing testing, inspection or maintenance of fire alarm system, and their components, must be on file for reviewed. • Review documentation that demonstrates compliance with this standard. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>Comment:</p>

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Fire Suppression Systems.

13.03.01 Water-Based Fire Protection System: Installation & Maintenance.

A water-based fire protection system must be installed **and maintained** in accordance with section 18.3.5 of the Life Safety Code (2012 edition) in all new construction, remodeled and renovated areas.

A water-based fire protection system must be installed **and maintained** in accordance with section 19.3.5 of the Life Safety Code (2012 edition) where required in existing construction, or renovated areas.

13.03.02 Water-Based Fire Protection System: Testing & Inspection.

If provided water-based fire protection systems and all their components must be tested, inspected and maintained in accordance with NFPA 25 *Standard for the Inspection, Testing and Maintenance of Water-Based Fire Protection Systems*, 2011 edition.

All results of testing, inspection and maintenance activities are documented.

This standard requires the installation of sprinklers in new construction since the adoption of the 1991 edition of the Life Safety Code.

This standard does not require the installation of sprinklers in existing construction prior to the adoption of the 1991 edition of the Life Safety Code, unless the Construction Type dictates it, or the sprinklers are a measure of equivalency.

All sprinkler systems installed must comply with NFPA 13 *Standard for the Installation of Sprinkler Systems*, (2010 edition), regardless if the sprinkler systems are required or not.

Once installed, sprinkler systems must be maintained to the original installation requirements.

Water-based sprinkler systems, including pre-action and dry-pipe systems, are included in this standard.

This standard does not require a hospital to have automatic sprinkler systems or their components installed, but if they do, the sprinkler systems must be tested, inspected and maintained according to NFPA 25 *Standard for the Inspection, Testing and Maintenance of Water-Based Fire Protection Systems* (2011 edition).

Water-based fire protection systems and components, include but are not limited to:

INTERVIEW AND OBSERVATION

- Interview facility manager to determine what areas qualify as new construction.
- Determine if Construction Type requires sprinklers in existing construction.
- During the building tour, observe if components of the sprinkler system are installed **and maintained** in accordance with NFPA 13.

- 1 = Compliant
- 2 = Not Compliant
- N/A

Comment:

DOCUMENTATION

- Documentation demonstrating compliance with NFPA 25 (2011 edition) must be maintained for a minimum of three (3) years. Documentation must demonstrate that each and every device connected to the water-based fire protection system is accounted for and passed or failed its test.
- Verify that the water-based fire protection system documentation fully complies with the frequencies identified in NFPA 25 (2011

- 1 = Compliant
- 2 = Not Compliant
- N/A

Comment:

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<p>13.03.03 Water-Based Fire Protection System: Control Valves, Piping and Hangers. If provided, control valves used in water-based fire protection systems must be electronically supervised with tamper switches and connected to the building fire alarm system. Tamper switches must be tested at intervals according to 13.02.02.</p> <p>Sprinkler piping and hangers shall be free of all material, including wire, cable, conduit, HVAC duct, or any other objects, and shall not be used to support any other item or system.</p>	<ul style="list-style-type: none"> • Sprinklers • Piping and hangers • Control valves, valve components and trim • Water-flow devices • Standpipe and hoses • Dry-pipe, deluge and pre-action valves • Service mains • Storage tanks <p>CONTROL VALVES ARE REQUIRED TO BE VISUALLY INSPECTED MONTHLY TO CONFIRM THEY ARE STILL IN THEIR DESIGNATED POSITION. THIS INSPECTION MUST BE DOCUMENTED.</p> <p>All sprinkler control valves must have tamper switches installed and connected to the building fire alarm system to send electronic supervisory signals. Chains and locks on control valves, while permitted, do not demonstrate compliance with this standard.</p> <p>Nothing is permitted to be attached to sprinkler piping and hangers, including wire and cable.</p>	<p>edition). Each individual sprinkler system device that is tested must be identified as to its location, and whether or not it passed or failed its test.</p> <ul style="list-style-type: none"> • During the document review session, ensure the sprinkler control valves are inspected monthly. <p style="text-align: center;">OBSERVATION</p> <ul style="list-style-type: none"> • During the building tour, observe sprinkler control valves to ensure they are electronically monitored. • Examine sprinkler piping and hangers to ensure nothing is suspended or attached to them. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant <input type="checkbox"/> N/A</p> <p>Comment:</p>

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<p>13.03.04 Fire Pumps: Monthly Test. If so equipped, electric-motor driven fire pumps must be tested monthly at no-flow conditions in accordance with NFPA 25 <i>Standard for the Inspection, Testing and Maintenance of Water-Based Fire Protection Systems, 2011</i> edition.</p> <p>If so equipped, engine-driven fire pumps must be tested weekly at no-flow conditions in accordance with NFPA 25, 2011 edition.</p> <p>The results of all testing activities are documented.</p>	<p>This standard does not require the installation of fire pumps in the facility.</p> <p>If so equipped, the hospital performs monthly fire pump tests at no-flow (or churn) conditions for a minimum of 10 minutes for electric-motor driven pumps and a minimum of 30 minutes for engine-driven pumps.</p> <p>No-flow test must begin by reducing water pressure at the start switch.</p> <p>Suction pressure readings and discharge pressure readings are recorded.</p>	<p style="text-align: center;"><u>DOCUMENTATION</u></p> <ul style="list-style-type: none"> During the document review session, review documentation to ensure fire pump is tested in accordance with NFPA 25. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant <input type="checkbox"/> N/A</p> <p>Comment:</p>
<p>13.03.05 Fire Pumps: Annual Test. If so equipped, fire pumps must be tested annually at specified flow conditions in accordance with NFPA 25 <i>Standard for the Inspection, Testing and Maintenance of Water-Based Fire Protection Systems, 2011</i> edition.</p> <p>The results of all testing activities are documented.</p>	<p>This standard does not require a hospital to have a fire pump installed, but if they do, the fire pump must be tested according to NFPA 25 <i>Standard for the Testing, Inspection and Maintenance of Water-Based Fire Protection Systems (2011</i> edition).</p> <p>An annual water-flow test is required for all fire pumps, which consists of:</p> <ol style="list-style-type: none"> A churn test The pump operated at design flow (100% nameplate capacity) The pump operated at peak flow (150% nameplate capacity) 	<p style="text-align: center;"><u>DOCUMENTATION</u></p> <ul style="list-style-type: none"> During the document review session, review documentation to ensure fire pump is tested annually in accordance with NFPA 25 (2011 edition) and this standard. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant <input type="checkbox"/> N/A</p> <p>Comment:</p>

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4. During peak flow, a power failure is simulated on electric-**motor** driven pumps equipped with automatic transfer switches to ensure emergency power supply is connected, and confirmation of peak flow continues
5. After peak flow has been confirmed and documented, normal power is restored to ensure circuit protection devices have not opened

Additional readings and measurements are required during this annual flow test. If peak flow is not attainable due to limitations in water supply, that shall not constitute an unsuccessful test.

13.03.06 Alternative Fire Suppression Systems: Installation & Testing.

Approved fire suppression systems that are installed, tested and maintained to their respective NFPA standard, are permitted to be an alternative to water-based fire protection systems without the facility being classified as non-sprinklered.

All such alternative fire suppression systems shall be connected to the building fire alarm system and initiate an alarm when activated.

The results of all testing activities are documented.

This standard does not require the installation of alternative fire suppression system.

If so equipped, alternative fire suppression systems must be installed, tested and maintained in accordance with their respective NFPA standard.

Examples of alternative fire suppression systems are:

- Halon systems
- FM-200 systems
- Inergen systems
- CO2 systems

INTERVIEW AND DOCUMENTATION

- Interview facility manager to determine what areas contain alternative fire suppression systems.
- Review documentation to determine if appropriate testing and inspection frequencies are achieved.

- 1 = Compliant
- 2 = Not Compliant
- N/A

Comment:

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<p>13.03.07 Water-Based Standpipes & Hoses: Inspection & Test. If so equipped, water-based automatic (wet) standpipes, must be tested once every 5-years at flow conditions equal to original acceptance requirements at the hydraulically most remote location.</p> <p>If so equipped, manual (dry) standpipes must be hydrostatic tested at not less than 200 psi pressure for 2 hours, or at 50 psi in excess of the maximum pressure, whichever is greater, at least once every 5-years.</p> <p>If so equipped, occupant-use fire hoses must be un-racked annually, inspecting for abnormal wear conditions.</p> <p>Occupant-use fire hoses must be hydraulically pressure tested in accordance with NFPA 1962, Standard for the Inspection, Care and Use of Fire Hose, Couplings, and Nozzles and the Service Testing of Fire Hose, (2008 edition) 5-years after initial installation and every 3 years thereafter.</p> <p>The results of all testing and inspection activities are documented.</p>	<p>This standard does not require the installation of standpipes or occupant-use fire hoses.</p> <p>If so equipped, the hospital must perform a 5-year flow test on a wet standpipe in the hydraulically most remote location, usually on the roof, in accordance with NFPA 25. If the hydraulically most-remote location is not attainable, then the local fire AHJ must be consulted for an acceptable alternate location.</p> <p>The water-flow for the test of the standpipe in the hydraulically most remote location must equal the original acceptance requirements. If the original acceptance requirements are not known then the water-flow must achieve 500 gallons per minute.</p> <p>Dry standpipes, including piping in the fire department connection, must be hydrostatic tested once every 5 years.</p> <p>This standard does not require the installation of occupant-use fire hoses, but if the hospital is so equipped, then they must be un-racked annually and inspected for abnormal wear, and re-racked without using the same folds.</p> <p>Occupant-use fire hoses must be pressure-tested 5 years after installation, and every 3 years thereafter.</p> <p>Organizations that remove occupant-use fire hoses must have the approval of the local or state authority on fire prevention.</p>	<p style="text-align: center;">DOCUMENTATION</p> <ul style="list-style-type: none"> Review documentation to ensure wet standpipe systems are water-flow tested at least once every 5 years in accordance with NFPA 25. Review documentation to ensure dry standpipe systems, including the piping for the fire department connections, are hydrostatic tested at least once every 5 years in accordance with NFPA 25. Review documentation of annual fire hose inspection and when it was last pressure tested or replaced. Review the documentation from the local or state authority having jurisdiction (AHJ) granting permission to remove occupant-use fire hoses from the facility. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant <input type="checkbox"/> N/A</p> <p>Comment:</p>

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STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>13.03.08 <u>Water-Based Fire Department Connections.</u> If so equipped, Fire Department Connections must be maintained in accordance with NFPA 13 (2010 edition), and inspected quarterly in accordance with NFPA 25 (2011 edition).</p> <p>The results of all inspection activities are documented.</p>	<p>The hospital must inspect the Fire Department Connections (also called Siamese connections) once per quarter. It is important to point out that this standard includes those connections where a fire department would hook-up and pump water into the buildings.</p> <p>Fire Department Connections must be properly maintained for immediate use, and not be obstructed by vehicles, vegetation or anything else preventing its view from the street.</p>	<p><u>DOCUMENTATION</u></p> <ul style="list-style-type: none"> Review documentation to ensure fire department connections are inspected at least once per quarter in accordance with NFPA 25, 2011 edition. Review documentation of quarterly fire department connections. Physically observe Fire Department Connections to determine they are not obscured and they are visible from the street. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant <input type="checkbox"/> N/A</p> <p>Comment:</p>
<p>13.03.09 <u>Portable Fire Extinguishers- Installation, Inspection and Maintenance.</u> Portable fire extinguishers must be installed, inspected and maintained in accordance with <i>NFPA 10 Standard for Portable Fire Extinguishers, 2010</i> edition.</p> <p>Fire extinguishers shall be inspected monthly and maintained annually.</p> <p>The results of all inspection and maintenance activities are documented.</p>	<p>Portable fire extinguishers are not permitted to sit on the floor, but are required to be mounted on brackets or placed in cabinets, at least four (4) inches above the floor and no higher than 60 inches above the floor.</p> <p>Access to extinguishers must not be obstructed. In large rooms and in certain locations where visual obstructions cannot be completely avoided, means must be provided to indicate the extinguisher location.</p> <p>Fire extinguishers are permitted to be electronically monitored through the building’s fire alarm system, provided it meets all of the requirements in chapter 7, of NFPA 10-2010.</p> <p>The selection of portable fire extinguishers is based on the hazard it is designated to protect.</p>	<p><u>DOCUMENTATION AND OBSERVATION</u></p> <ul style="list-style-type: none"> Review monthly inspection documentation for portable fire extinguisher during building tour. During the building tour, observe the extinguisher installation to ensure it is at least four (4) inches above the floor and the handle is no more than 60 inches above the floor. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>Comment:</p>

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The travel distance required to get to a fire extinguisher is based on the level of the hazard and the capacity and type of the extinguisher, as identified in NFPA 10.

The monthly inspection documentation must identify the date (month/day/year) and signature (or initials) of individual performing the inspection. Electronic documentation is acceptable provided it contains all required data and is retrievable at the time of survey.

13.03.10 Fire Hose Valves.
All fire hose valves must be inspected quarterly.

Class I and Class III standpipe hose valves (2½ inch hose valves) must be tested annually.

Hose valves on hose stations attached to sprinkler systems, and Class II standpipe hose valves (1½ inch hose valves) must be tested once every 3-years.

Inspections and tests are documented.

If so equipped, fire hose valves must be inspected on a quarterly basis. The inspection ensures the following:

- Hose caps are in place and not damaged.
- Hose threads are not damaged.
- Valve handles are present and not damaged.
- Gaskets are inspected for damage or deterioration.
- Hose valves are not leaking.
- Ensure there are no obstructions to hose valves.
- If required, ensure restricting devices are present.

DOCUMENTATION AND OBSERVATION

- Review quarterly inspection documentation to ensure all fire hose valves are inventoried and their location is documented and whether they passed or failed their inspection.
- Review annual test of 2½ hose valves and 3-year test of Class II and 1½ hose valves to ensure the valve was opened.
- Check test and inspection records to determine if any damaged equipment or failed test/inspection was followed up with appropriate repairs.

1 = Compliant
 2 = Not Compliant

Comment:

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<p>13.03.11 <u>Internal Inspection of Piping</u> An internal inspection of water-based fire protection system piping and branch line conditions must be conducted once every 5 years.</p>	<p>Class I and Class III (2½ inch) hose valves must be tested annually by opening and closing the valve. NOTE: Full flow of water is not required.</p> <p>Class II and 1½ inch hose valves must be tested once every 3 years by opening and closing the valve. NOTE: Full flow of water is not required.</p> <p>The internal inspection must be conducted by opening a flushing connection at the end of one main and by removing a sprinkler toward the end of one branch line for the purpose of inspecting for the presence of foreign material.</p> <p>Tubercules or slime, if found, must be tested for indications of Microbiological Influenced Corrosion (MIC).</p> <p>Non-metallic pipe is not required to be inspected internally.</p>	<p><u>DOCUMENTATION AND OBSERVATION</u></p> <ul style="list-style-type: none"> Review inspection documentation to ensure the internal inspection was conducted on the sprinkler piping. If slime was found, check the documentation for the testing of MIC. If MIC was determined to be present, check the documentation of corrective actions to eliminate MIC. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>Comment:</p>
<p>13.03.12 <u>Cooking Hood Fire Suppression.</u> The cooking hood fire suppression system must be inspected monthly, and maintained semi-annually.</p> <p>These inspections and maintenance activities are documented.</p> <p>Where cooking hoods are protected in accordance with NFPA 96, <i>Standard</i></p>	<p>Cooking hood fire suppression systems must be inspected monthly in accordance with NFPA 17A, <i>Standard for Wet Chemical Extinguishing Systems</i>, 2009 edition.</p> <p>The following items need to be verified:</p> <ul style="list-style-type: none"> The extinguishing system is in its proper location. The manual actuators are unobstructed. The tamper indicators and seals are intact. 	<p><u>DOCUMENTATION AND OBSERVATION</u></p> <ul style="list-style-type: none"> Review the documentation for the monthly inspection to verify all requirements were met. Review the documentation for the semi-annual maintenance to ensure all requirements are met. During the building tour, ensure that kitchens are separated from corridor by 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>Comment:</p>

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<p><i>for Ventilation Control and Fire Protection of Commercial Cooking Operations</i>, 2011 edition, cooking equipment will not cause the room or space housing the cooking equipment to be classified as a hazardous area.</p>	<ul style="list-style-type: none"> • The maintenance tag or certificate is in place. • No obvious physical damage or condition exists that might prevent operation. • The pressure gauge(s), if provided, shall be inspected physically or electronically to ensure it is in the operable range. • The nozzle blowoff caps, where provided, are intact and undamaged. • Neither the protected equipment nor the hazard has not been replaced, modified, or relocated. <p>At least semiannually, maintenance shall be conducted on all cooking hood fire suppression systems in accordance with the manufacturer’s listed installation and maintenance manual.</p> <p>Maintenance shall include the following:</p> <ul style="list-style-type: none"> • A check to see that the hazard has not changed • An examination of all detectors, the expellant gas container(s), the agent container(s), releasing devices, piping, hose assemblies, nozzles, signals, all auxiliary equipment, and the liquid level of all non-pressurized wet chemical containers • Verification that the agent distribution piping is not obstructed 	<p>appropriate partitions and doors.</p> <ul style="list-style-type: none"> • During the building tour, examine the kitchen storage rooms to determine compliance with hazardous area requirements. 	

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- **Kitchens that have cooking hoods that are equipped with listed, approved fire suppression systems will allow the kitchen to not be considered a hazardous area, even though the kitchen contains heat producing appliances. However, storage rooms greater than 50 square feet containing combustible supplies are still considered hazardous areas and must be protected as such.**

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Fire Safety Systems.

13.04.01 Fire Rated Barriers.

The hospital shall assure that fire rated barriers are properly rated, appropriate for their purpose, be free from unsealed penetrations, and have the appropriate fire-rated opening protectives.

Not all fire rated barriers are rated the same.

The **2012** edition of the Life Safety Code specifies which fire rated barrier receives what fire rating.

Opening protectives are fire rated door assemblies and fire dampers. Not all fire rated barriers are required to have fire dampers.

Fire rated barriers are permitted to be combined with smoke compartment barriers, provided all the requirements from each barrier are implemented.

OBSERVATION

- During the building tour, refer to the Life Safety Drawings to understand what rating each fire barrier is required to have.
- Examine fire rated barriers above and below the ceiling, looking for unsealed penetrations.
- Examine door assemblies in fire rated barriers to ensure they are properly fire rated, self-closing and positive latching.

1 = Compliant
 2 = Not Compliant

Comment:

13.04.02 Smoke Barriers.

The hospital shall assure that smoke compartments **are separated by smoke** barrier walls, **and** are properly rated; properly constructed for their purpose; be free from unsealed penetrations, and have the required opening protectives.

The **2012** edition of the Life Safety Code specifies where **barriers for** smoke compartments are required.

Opening protectives are smoke barrier door assemblies and smoke dampers. Not all smoke barriers are required to have smoke dampers. Smoke barrier doors are not required to be fire-rated or positive latching, however they must self-close.

Although smoke barrier walls are required to have a fire rating, they are not fire rated barriers. If the smoke barrier does have fire-rated doors, then the fire rated door assemblies must be maintained properly, including self-closing and positive latching.

Smoke compartment barriers are permitted to be combined with fire rated barriers, provided all the requirements from each barrier are implemented.

OBSERVATION

- During the building tour, examine smoke barriers above and below the ceiling, looking for unsealed penetrations.
- Examine door assemblies in smoke barriers to ensure they are self-closing.

1 = Compliant
 2 = Not Compliant

Comment:

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13.04.03 Fire & Smoke Dampers.

Fire and smoke dampers must be fully tested and operated one (1) year after installation and once every six (6) years thereafter in all healthcare facilities classified as hospitals.

In healthcare facilities not classified as hospitals, fire and smoke dampers must be fully tested and operated one (1) year after installation, and once every four (4) years thereafter.

The results of all inspection activities are documented.

Fire dampers are required to be **installed, maintained and** tested in accordance with NFPA 80 *Standard for Fire Doors and Other Opening Protectives (2010 edition)* and smoke dampers are required to be **installed, maintained and** tested in accordance with NFPA 105 *Standard for Smoke Door Assemblies and Other Opening Protectives (2010 edition)*.

Dampers installed in the facility must be documented identifying the following:

- **Type of damper**
- **Location of damper (i.e. Building, Floor, Unit, Room, Area, etc.)**
- **Orientation of damper (i.e. Horizontal or Vertical)**
- **Date of installation (if known)**
- **Last test date and results (Pass/Fail)**

NOTE: There are no provisions in the NFPA codes or standards that permit inaccessible dampers to remain inaccessible and untested.

DOCUMENTATION AND OBSERVATION

- Documentation demonstrating compliance with NFPA 80 (2010 edition) and NFPA 105 (2010 edition) must be maintained for a minimum of six (6) years.
- Verify that each fire and smoke damper is documented, and identified as to its location, and whether or not the damper passed or failed its test.

- 1 = Compliant
- 2 = Not Compliant

Comment:

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<p>13.04.04 Overhead Rolling / Horizontal Sliding Fire Doors. If so equipped, overhead rolling and horizontal sliding fire doors are required to be tested once per year for proper operation and closure, in accordance with NFPA 80 <i>Standard for Fire Doors and Fire Windows (2010 edition)</i>.</p> <p>The results of all testing and inspection activities are documented.</p>	<p>This standard does not require hospitals to have overhead rolling or horizontal sliding fire doors, but if they do, the doors must be installed, maintained and tested in accordance with NFPA 80 <i>Standard for Fire Doors and Fire Windows (2010 edition)</i> to ensure proper operation.</p> <p>The test of the fire door assembly must be initiated by all devices associated with the control of the door, such as smoke detector and interface, thermal link, etc.</p> <p>Overhead rolling and horizontal sliding fire doors must be tested annually.</p>	<p>DOCUMENTATION AND OBSERVATION</p> <ul style="list-style-type: none"> Documentation demonstrating compliance with NFPA 80 (2010 edition) must be maintained for a minimum of three (3) years. Verify that each overhead rolling or horizontal sliding fire door was tested at least annually, and that the test was initiated by the safety device which controls the door. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant <input type="checkbox"/> N/A</p> <p>Comment:</p>
<p>13.04.05 Construction Type. The Construction Type is identified and deemed appropriate for the number of stories in the buildings.</p> <p>The fire-proofing assembly applied to structural steel to meet the requirements of Construction Type must be installed, and maintained according to the UL listing and/or manufacturer’s recommendation.</p>	<p>Construction Type is determined by the number of stories in the building, as defined in sections 18/19.1.6, of the 2012 Life Safety Code.</p> <p>Construction type must be identified in accordance with NFPA 220, 2012 edition.</p> <p>Construction Type must be correctly identified in the HFAP Facility Demographic Report, using NFPA 220 nomenclature.</p> <p>Floor assemblies are designed and maintained in accordance with the required fire resistive rating for the facility’s Construction Type.</p>	<p>BUILDING TOUR</p> <ul style="list-style-type: none"> Examine the Facility Demographic Report to find the facility’s Construction Type. During building tour, observe number of stories and sprinkler installation to determine if the Construction Type listed is correct. During the building tour, observe the fire-proofing material applied to the structural steel to ensure it is installed and maintained correctly. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>Comment:</p>

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<p>13.04.06 Separated Occupancies. When different occupancies are claimed to be separated in the facility, 2-hour fire rated barriers separate healthcare occupancies from all other occupancies, and 1-hour fire rated barriers separate non-healthcare occupancies.</p>	<p>If the organization claims to have separated occupancies in the same building as the healthcare occupancy, then 2-hour fire rated barriers must separate the occupancies.</p> <p>Note that a 2-hour fire rated floor assembly does qualify as an appropriate barrier for occupancy separation, but does not qualify as an appropriate building (i.e. construction type) separation.</p>	<p>BUILDING TOUR</p> <ul style="list-style-type: none"> • During the building tour, refer to the Life Safety Drawings to identify barriers that separate occupancies. • Examine fire rated barriers to determine if they are free from unsealed penetrations, and have appropriately rated doors assemblies. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant <input type="checkbox"/> N/A</p> <p>Comment:</p>
<p>13.04.07 Fire Rated Door Assemblies. Fire door assemblies must meet the provisions of NFPA 80 <i>Standard for Fire Doors and Fire Windows</i>, 2010 edition.</p> <p>All fire rated doors assemblies, whether they are located in a fire rated barrier or not, must be tested and inspected on an annual basis according to NFPA 80, 2010 edition.</p> <p>The test and inspection is documented.</p>	<p>Doors in fire rated door assemblies must have a legible label that identifies its fire rating. Frames in fire rated door assemblies must have a legible label that identifies it as a fire rated frame. Note that frames are not required to be labeled with an hourly rating, unless the assembly rating is for 3 or more hours.</p> <p>Fire rated door assemblies must have self-closing devices, positive latching hardware, gaps between meeting edges of door pairs are no more than 1/8 inch, and the space between the bottom of the door and the floor is no more than 3/4 inch.</p> <p>All after-market hardware installed on fire-rated door assemblies must be listed for use on fire-rated door assemblies.</p> <p>All fire-rated door assemblies throughout the facility must be inventoried, then tested and inspected on an annual basis, including those fire rated door assemblies that are not located in a fire rated barrier.</p>	<p>BUILDING TOUR</p> <ul style="list-style-type: none"> • During the building tour, examine fire door labels to ensure the door is properly rated for the fire barrier designation. If the label is not legible, then the door is not compliant. • Measure the gap between meeting edges of door pairs and the undercut of the door to ensure they are within limits. • Examine after-market hardware installed on fire rated doors (astragals, coordinators, closers, etc.) to ensure they are listed for use on fire-rated door assemblies. • Review the documentation that demonstrates that each individual fire-rated door assembly is tested and inspected on an annual basis. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>Comment:</p>

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<p>13.04.08 Hazardous Areas. Hazardous areas, as defined in 18/19.3.2 of the 2012 edition of the Life Safety Code, must be protected with the following:</p> <ul style="list-style-type: none"> For new construction and existing areas that are remodeled or renovated, all hazardous areas must be protected with 1-hour fire rated barriers that extend from the floor to the deck, and be equipped with ¾ hour fire rated door assemblies that self-close and positively latch. The hazardous area must be protected with automatic sprinklers. For existing construction, hazardous areas must be protected with 1-hour fire rated barriers that extend from the floor to the deck and ¾ hour fire rated door assemblies that self-close and positively latch <u>if</u> the area is not protected with automatic sprinklers, OR be protected with non-rated smoke resistant barriers that extend from the floor to the ceiling (provided the ceiling also resists the passage of smoke) and equipped with doors that are smoke resistant and self-close if 	<p>Hazardous areas must be identified on the organization’s Life Safety Drawings. The type of barrier for a hazardous area is dependent on whether the area is new or existing construction, and whether or not the area is sprinklered.</p> <p>Review the list of hazardous areas found in sections 18/9.3.2 of the 2012 edition of the Life Safety Code.</p> <p>There are certain exceptions to the requirement that spaces in existing conditions that are repurposed for the storage of combustible supplies have to meet new construction requirements. Under certain conditions, the space may be able to meet hazardous area requirements for existing conditions.</p> <p>Refer to Chapter 43 in the 2012 Life Safety Code for details.</p>	<p>BUILDING TOUR</p> <ul style="list-style-type: none"> During the building tour, examine the Life Safety Drawings for hazardous areas. Once found, observe the hazardous area to determine if it meets the requirements listed. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>Comment:</p>

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the hazardous area is protected with automatic sprinklers.

13.04.09 Ceilings.

Ceilings which are required to limit the passage of smoke, such as ceilings containing smoke or heat detectors, and sprinklers, and used in conjunction with corridors and hazardous rooms that have smoke resistant barriers, are free from cracks, holes or missing tiles.

Where ceilings are expected to resist the passage of smoke, they cannot have any missing tiles, or cracks or holes. Gaps or cracks exceeding 1/8 inch constitutes non-compliance with this standard.

Suspended grid and acoustical tile type of ceiling, when properly installed and maintained, can limit the passage of smoke.

BUILDING TOUR

- During the building tour, observe ceilings for missing tiles, cracks or holes. Especially look for missing escutcheon plates around sprinklers, and communication wires penetrating the ceiling.

1 = Compliant
 2 = Not Compliant

Comment:

13.04.10 Corridor Walls.

In new construction, corridor walls are permitted to be non-rated and are required to resist the passage of smoke, and are permitted to extend from the floor to the ceiling, provided the ceiling also resists the passage of smoke.

30-minute fire rated wall is defined by NFPA as 3½ inch steel studs with one layer of 5/8 inch gypsum board on one side.

BUILDING TOUR

- During the building tour, examine above the ceilings in corridors in non-sprinklered smoke compartments to determine if corridor walls extend to the deck and are free from unsealed penetrations.

1 = Compliant
 2 = Not Compliant

Comment:

In existing construction, corridor walls are required to be 30-minute fire rated, and extend from the floor to the deck, with all penetrations properly sealed in non-sprinklered smoke compartments, and door openings are not required to be fire rated.

In existing construction, corridor walls in fully sprinklered smoke

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compartments are permitted to be non-rated and are required to resist the passage of smoke, and are permitted to extend from the floor to the ceiling, provided the ceiling also resists the passage of smoke.

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Building Services.

13.05.01 Fireplaces.

Direct-vent gas fireplaces are permitted inside smoke compartments containing patient sleeping areas, but not in patient sleeping rooms.

Direct-vent gas fireplaces are permitted inside smoke compartment containing patient sleeping areas, provided the following are met:

- All such devices are properly maintained;
- No such device is located in a patient sleeping room;
- The smoke compartment is fully protected with quick response sprinklers;
- The direct-vent fireplace is equipped with a sealed glass front with a wire mesh panel or screen;
- The controls for the direct-vent gas fireplace must be locked or located in a restricted location;
- Electrically supervised carbon monoxide detection must be provided in the room where the fireplace is located.

BUILDING TOUR AND DOCUMENT REVIEW

- During the building tour, if a fireplace is observed, determine that **is not located in a patient sleeping room.**

- 1 = Compliant
- 2 = Not Compliant
- N/A

Comment:

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<p>13.05.02 Elevator Recall. All elevators, new or existing, that have a travel distance 25 feet or more above or below the level that best serves the needs of the local emergency fire response force must be equipped with elevator recall, also known as Firefighter’s Service, Phase 1.</p> <p>Elevator recall is tested and operated monthly. All results of the test are documented.</p> <p>13.05.03 Trash & Linen Chutes. All trash and linen chute inlet and discharge door assemblies are properly fire rated, are self-closing, and positive latching. Chute door assemblies have not been modified in the field.</p> <p>Trash chutes discharge into a collection room that is not used for any other purpose.</p> <p>An approved automatic sprinkler system is installed inside the chute at the top and at the lowest service level, and on alternating floors levels.</p> <p>Trash and linen discharge rooms are separated from the corridor and other areas with 1-hour fire rated barriers.</p>	<p>Elevator recall is designed to capture the control of the car, and return it to a previously designated floor, and open its door when a smoke detector located in the elevator lobby, elevator shaft, or elevator mechanical room is in alarm.</p> <p>Elevator recall is required to be tested monthly in accordance with the Life Safety Code, regardless what the Elevator Safety Code requires.</p> <p>Trash and linen chutes must be maintained with fire rated doors at each inlet and discharge opening. Field modifications to the doors are not permitted.</p> <p>Sprinklers inside the chutes must be inspected and maintained at the same frequency as other building sprinklers.</p> <p>Existing linen chutes are permitted to discharge into the same room as trash chutes provided the room is protected with automatic sprinklers.</p>	<p>DOCUMENT REVIEW</p> <ul style="list-style-type: none"> During the document review session, review testing documents to ensure the organization is testing recall every month. <p>BUILDING TOUR</p> <ul style="list-style-type: none"> During the building tour, examine chute doors for field modification, such as welded repairs, after-market latching devices, and add-on locks. If any observed, then chute doors are not compliant with this standard. Examine sprinklers inside the chute for dust and dirt accumulation. Examine trash chute discharge room to determine if it used for any other purpose or storage. Examine trash and linen discharge room to determine if it meets the 1-hour fire separation requirement. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant <input type="checkbox"/> N/A</p> <p>Comment:</p> <p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant <input type="checkbox"/> N/A</p> <p>Comment:</p>

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<p>13.05.04 Generator Inspection. Emergency power generators and all appurtenant components must be inspected weekly.</p> <p>Generators located indoors must be separated from the rest of the facility with 2-hour fire rated barriers.</p> <p>Batteries used in connection with the generator shall be inspected weekly and maintained in full compliance with the manufacturers' recommendations, and electrolyte specific gravity levels on lead-acid batteries shall be recorded.</p> <p>Sealed lead-acid batteries must have an electrical conductive test performed.</p> <p>Results of inspection shall be documented.</p>	<p>Routine inspection must be accomplished in accordance with NFPA 110 (2010 edition).</p> <p>For all emergency power generators (regardless when they were installed) located inside the building, the generator must be installed within a separate room with a minimum of 2-hour fire rated barriers.</p> <p>If located outside the building, the generator shall be located in an enclosure capable of resisting the entrance of snow and rain.</p> <p>No other equipment except that which serves the space is permitted to be stored in these rooms.</p> <p>Where sealed lead-acid batteries are utilized, electrolyte specific gravity levels are not required to be recorded; however conductance testing will be required, with the results documented.</p> <p>A fuel quality test shall be performed at least annually using tests approved by ASTM standards.</p> <p>A remote manual stop station must be located outside the room housing the generator, or elsewhere on the premises when the generator is located outside the building.</p>	<p><u>INTERVIEW AND OBSERVATION</u></p> <ul style="list-style-type: none"> • Confirm generators located indoors are separated with 2-hour fire rated barriers, and no other items are stored in the room. • Review weekly inspection log and confirm battery electrolyte specific gravity readings or conductive readings are recorded. • Review annual fuel quality test to ensure it has been conducted. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>Comment:</p>

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13.05.05 Generator Monthly Load Test.

Emergency power generators shall be tested twelve (12) times a year with a dynamic load of at least 30% of nameplate rating, with testing intervals not less than 20 days and not more than 40 days, for a minimum of 30 minutes.

In lieu of meeting 30% nameplate rating during each monthly load test, generator may be operated to meet the manufacturers' recommended prime mover's exhaust gas temperature.

If the hospital cannot meet the 30% nameplate rating or the exhaust gas temperature for any of the monthly load tests, then a supplemental annual load test must be conducted with connected loads of 50% of nameplate rating for 30 minutes, followed by 75% of nameplate rating for 60 minutes, for a total of 90 continuous minutes. The monthly load tests must still be conducted at the appropriate intervals even if they do not meet the load requirements.

Results of tests shall be documented.

Emergency power generator sets shall be tested in accordance with NFPA 110, (2010 edition).

DOCUMENT REVIEW

- Request records to verify that testing is performed as required. Check monthly test dates to ensure no tests are accomplished sooner than 20 days and no later than 40 days from previous test.
- If applicable, examine annual load tests to ensure designated loads are met and test was for at least 90 continuous minutes.

- 1 = Compliant
- 2 = Not Compliant

Comment:

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<p>13.05.06 <u>Generator 3-Year Load Test.</u> Emergency power generators shall be tested once every 36 months for a minimum of 4 continuous hours at a connected load of at least 30% nameplate rating or operated to meet the manufacturers' recommended prime mover's exhaust gas temperature.</p> <p>Results of tests shall be documented.</p>	<p>Emergency power generator 3-year load test shall be tested in accordance with NFPA 110 (2010 edition).</p>	<p style="text-align: center;"><u>DOCUMENT REVIEW</u></p> <ul style="list-style-type: none"> Request records to verify that testing is performed as required. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>Comment:</p>
<p>13.05.07 <u>Automatic Transfer Switch Test.</u> Automatic transfer switches shall be tested twelve (12) times a year, with testing intervals not less than 20 days and not more than 40 days.</p> <p>Results of tests shall be documented.</p>	<p>All automatic transfer switches must be tested monthly, operating the transfer switch from the standard position to the alternate position and then return to the standard position. Tests shall be in accordance with NFPA 110 (2010 edition).</p>	<p style="text-align: center;"><u>DOCUMENT REVIEW</u></p> <ul style="list-style-type: none"> Request records to verify that testing is performed as required. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>Comment:</p>
<p>13.05.08 <u>Medical Gas Shutoff Valves.</u> Medical gas shutoff valves shall be labeled to reflect the rooms that are controlled by such valves.</p> <p>Medical gas shutoff valves must be accessible from a standing position in the corridor on the floor served by the</p>	<p>Medical gas shutoff valves must be accessible and properly labeled to assist in proper routine adjustment of systems and also during emergencies.</p>	<p style="text-align: center;"><u>OBSERVATION</u></p> <ul style="list-style-type: none"> Determine if medical gas shutoff valves are accessible and labeled. Determine if medical gas shutoff valves are located in the corridor on the same story as the area served. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>Comment:</p>

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<p>shut-off valves, and not located behind doors or other building appurtenances.</p> <p>Medical gas shutoff valves must be placed such that a wall intervenes between the valve and the outlets/inlets that it controls.</p> <p>The medical gas shutoff valve must not be located in a room with a station outlet/inlet that it controls.</p> <p>Access to medical gas shutoff valves must not be obstructed.</p>		<ul style="list-style-type: none"> Determine if medical gas shutoff valves are located outside of the room with outlets/inlets that it controls. 	
<p>13.05.09 Utility Systems. Utility systems are properly installed and maintained to a fire-safe condition.</p>	<p>Utility systems must be installed and maintained to a fire-safe condition.</p> <p>Access to electrical control panels must not be obstructed.</p> <p>Circuits in electrical control panels must be properly labeled as to their use.</p> <p>Electrical junction box covers must be properly installed.</p> <p>Electrical wires and cables are not permitted to be tied to conduits.</p>	<p style="text-align: center;"><u>OBSERVATION</u></p> <ul style="list-style-type: none"> Determine if electrical control panels have proper clearance, and all circuits labeled. Determine if electrical junction boxes are properly covered. Determine if electrical conduits are free of attached wires and cables. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>Comment:</p>

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<p>13.05.10 Medical Gas Systems & Equipment: Maintenance. There is a routine monitoring and maintenance system for oxygen, compressed air, and vacuum systems and equipment. Hospital medical gas systems and equipment must be installed, inspected, tested and maintained in accordance with NFPA 99 (2012 edition) chapter 5 and chapter 11.</p> <p>Storage of all medical compressed gas cylinders must comply with NFPA 99, <i>Standard for Health Care Facilities</i>, 2012 edition.</p>	<p>Storage of compressed medical gas cylinders is limited as follows:</p> <ul style="list-style-type: none"> • Up to 300 cubic feet per smoke compartment is permitted to be stored outside of a designated room provided the cylinders are properly secured. • For quantities over 300 cubic feet but less than 3,000 cubic feet per smoke compartment, cylinders must be stored outside the facility or within an interior room with limited combustible construction with a door that can be secured against unauthorized entry. • Oxidizing gases must be separated from combustibles a minimum of 20 feet in non-sprinklered areas; or five (5) feet in sprinklered areas; or in an enclosed cabinet of non-combustible construction having a minimum fire protection rating of ½ hour. • For rooms containing gas manifold systems, or storage rooms of compressed gas cylinders in total quantities of 3,000 cubic feet or greater, the room must meet the following conditions: <ul style="list-style-type: none"> ○ Walls having a minimum of 1-hour fire resistive rating; ○ Door assemblies having a minimum of 1-hour fire resistive rating; ○ Doors must be self-closing, positive latching and be secured; 	<p><u>OBSERVATION AND DOCUMENT REVIEW</u></p> <ul style="list-style-type: none"> • Observe hospital’s storage areas of compressed medical gas cylinders during building tour. • Review hospital’s policy on inspection, testing and maintenance on medical gas systems, including alarm panels. • Examine testing and inspection records for evidence of routine inspections and documentation of the hospital’s monitoring and maintenance program. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>Comment:</p>

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- All electrical devices must be protected from physical damage, or located a minimum of 60 inches above the floor;
- If heated, must be by indirect means;
- Racks and chains or other fastening devices must be present to secure all cylinders;
- A constant mechanical ventilation system with its inlet no more than 12 inches above the floor; or where natural ventilation is used in lieu of mechanical ventilation, it must consist of two louvered openings, each having a minimum free area of 72 square inches, with one located within 12 inches above the floor and the other located within 12 inches of the ceiling.
- Mechanical ventilation must be at the rate of 1 cfm/5 cubic feet of designed stored gas, but no less than 50 cfm and no more than 500 cfm.
- Flammable liquids, gases and vapors are not permitted to be stored with oxidizing gases.
- Rooms containing gas manifold systems are not permitted to be used for any other purpose.

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- The gas content of medical piping systems must be readily identifiable with appropriate labeling with the name of the gas contained. Labels must appear on piping at intervals of not more than 20 feet, and at least once in each room and each story traversed by the piping system.
- Medical gas systems, including master alarm panels and branch alarm panels must be inspected, tested and maintained according to the hospital’s policy, which is consistent with NFPA 99 (2012 edition) chapter 5. For inspection and testing frequency intervals greater than 1 year, a risk assessment must demonstrate no adverse implications based on historical evidence.

13.05.11 Cooking Hoods Cleaning.
Kitchen cooking exhaust hoods and associated equipment are inspected and cleaned on a semi-annual basis.

Kitchen cooking hoods are designed to capture air-born grease from the foods that are prepared underneath the canopies. The filters, traps, hoods, exhaust duct, and exhaust fans are required to be inspected and cleaned in accordance with NFPA 96 (2011 edition).

Fusible links must be removed and replaced with new fusible links during every semi-annual cleaning. Used fusible links must be destroyed so they cannot be used again.

OBSERVATION

- Review documentation to ensure the organization inspected and cleaned their cooking hood exhaust system(s) on a semi-annual basis.

- 1 = Compliant
- 2 = Not Compliant

Comment:

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<p>13.05.12 Health Care Facilities Code. Except as otherwise provided in this section, the hospital must meet the applicable provision and must proceed in accordance with the Health Care Facilities Code (NFPA 99-2012 edition, and Tentative Interim Amendments TIA-12-2, TIA 12-3, TIA 12-4, TIA 12-5 and TIA 12-6.</p> <p>Chapters 7, 8, 12 and 13 of the adopted Health Care Facilities Code do not apply to a hospital.</p> <p>If application of the Health Care Facilities Code required under this section would result in an unreasonable hardship for the hospital, CMS may waive specific provisions of the Health Care Facilities Code, but only if the waiver does not adversely affect the health and safety of the patients.</p>	<p>Listed hoods containing mechanical or fire-actuated dampers, internal washing components, or other mechanically operated devices shall be inspected and tested by properly trained, qualified, and certified persons every 6 months or at frequencies recommended by the manufacturer in accordance with their listings.</p> <p>NFPA 99 2012 edition, has standards that apply design and operating conditions for a variety of health care mechanical systems, such as medical gas systems, electrical systems, HVAC systems, electrical equipment, gas equipment, hyperbaric facilities, and additional information useful for the operation of a healthcare facility.</p> <p>NFPA 99 does apply to all health care facilities, with the exception of home care. Construction and equipment requirements referenced in NFPA 99 do apply to new construction and new equipment, unless otherwise stated in the individual chapters. Existing conditions must comply with either NFPA 99-2012, or the edition of NFPA 99 that was adopted by CMS at the time of the equipment or component installation.</p> <p>Only the altered, renovated, or modernized portion of an existing system or individual component shall be required to meet the installation and equipment requirements stated in NFPA 99-2012.</p> <p>An existing system that is not in strict compliance with NFPA 99 shall be permitted to be continued in</p>	<p style="text-align: center;"><u>OBSERVATION</u></p> <ul style="list-style-type: none"> • HFAP has specific standards regarding medical gas equipment, medical gas systems, utility systems, and emergency power generators that are also referenced in NFPA 99. Deficiencies with those specific systems and equipment should be scored under those explicit HFAP standards. • Other deficiencies observed pertaining to NFPA 99 issues may be scored under this standard. • Confirm the organization has conducted the necessary Risk Assessments on the building services listed, to determine the Category designation of the risk of that system to the patient and caregiver. • Confirm the organization’s Safety Committee has reviewed and approved the Category designations for the listed building services. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>Comment:</p>

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use, unless the authority having jurisdiction (i.e. CMS, or HFAP) has determined that such use constitutes a distinct hazard to life.

Certain building systems in health care facilities must be designed to meet Category 1 through Category 4 requirements as detailed in Chapter 4 of NFPA 99-2012. Each system must be evaluated for its potential impact on both the patients and the caregivers if the system should fail. Based on worst-outcome scenario of a failure’s impact, the system is assigned a category. The chapter on that particular building system then describes the requirements for the selected category. The four levels of system categories as defined by Chapter 4 of NFPA 99-2012 are based on the risks to patients and caregivers in the facility.

Therefore, a Risk Assessment is required for certain building systems that the organization has, based on a documented defined procedure. HFAP does not prescribe what format the Risk Assessment must follow, but NFPA 99-2012 recommends the following documents:

- ISO/IEC 31010 *Risk Management – Risk Assessment Techniques*
- NFPA 551 *Guide for the Evaluation of Fire Risk Assessments*
- SEMI S10-0307E *Safety Guidelines for Risk Assessment and Risk Evaluation Process*
- Other formal process

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The results of the Risk Assessment procedure must be documented and the records reviewed and approved by the organization's Safety Committee. All Risk Assessments must be available for review during a survey.

Only the following building systems are required to be evaluated for categories in a Risk Assessment:

- Gas & Vacuum Systems
- Electrical Systems
- HVAC Systems
- Electrical Equipment
- Gas Equipment

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Operating Features.

13.06.01 Decorations.

Combustible decorations are not permitted in the healthcare occupancy **unless one of the following criteria is met:**

1. They are flame-retardant or are treated with approved fire-retardant coating;
2. The decoration meets the requirements of NFPA 701, *Standard Methods of Fire Tests for Flame Propagation of Textiles and Films*, 2010 edition;
3. The decorations, such as photographs, paintings and other art, are attached directly to the walls and ceiling (but not to the doors) in accordance with the following:
 - a. The decorations do not interfere with the operation of any exit or exit access openings;
 - b. The decorations do not exceed 20 percent of the wall and ceiling area inside any room or space of a smoke

Combustible decorations consist of any material that could support flame, and if they are not flame retardant, then they are not permitted **unless they meet the provisions of this standard.**

Doors, whether they are doors to an exit access or doors to an actual exit may not be covered, obstructed, or otherwise visually obscured with coverings, furnishings, or decorations.

BUILDING TOUR

- During the building tour, observe areas for combustible decorations. If hospital claims they are fire retardant, they must have documentation to demonstrate compliance.
- For combustible decorations that are attached directly to the wall or ceiling, calculate the amount of surface covered by the decorations and compare to the total surface of the wall and ceiling in that area or room.

- 1 = Compliant
 2 = Not Compliant

Comment:

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compartment that is not protected throughout by automatic sprinklers;

c. The decorations do not exceed 30 percent of the wall and ceiling area inside any room or space of a smoke compartment that is protected throughout by automatic sprinklers;

d. Decorations do not exceed 50 percent of the wall and ceiling area inside patient sleeping rooms having a capacity not exceeding four (4) persons in a smoke compartment that is protected throughout by automatic sprinklers.

4. The decorations are photographs or paintings in such limited quantities that a hazard of fire development or spread is not present.

Exit access doors and exit doors are free from hangings, mirrors, decorations or curtains that could obscure or confuse the direction of exit.

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<p>13.06.02 <u>Trash Receptacles.</u> Trash receptacles and soiled linen hoppers exceeding 32 gallons capacity must be stored in an approved hazardous room.</p>	<p>An accumulative total capacity of trash receptacles shall not exceed 32 gallons in any 64 square foot area, outside of a hazardous room.</p> <p>Containers used solely for recycling clean waste or for patient records awaiting destruction are excluded from meeting this standard provided all of the following are met:</p> <ul style="list-style-type: none"> • Each container is limited to a maximum capacity of 96 gallons; • Containers must be labeled and listed as meeting FM Approval standard 6921 or equal. • Containers with capacities greater than 96 gallons must be located in a room protected as a hazardous area when not attended. 	<p><u>BUILDING TOUR</u></p> <ul style="list-style-type: none"> • During the building tour, observe if any trash receptacles that exceed 32 gallons are not stored in a hazardous room. • Where multiple trash receptacles that are less than 32 gallons each are accumulated, determine if they exceed 32 gallons capacity in a given 64 square foot area. • For containers containing clean waste or patient records awaiting destruction, confirm the capacity of the container does not exceed 96 gallons, and is labeled as meeting FM Approval 6921, or equal. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>Comment:</p>
<p>13.06.03 <u>Portable Heaters.</u> Portable heaters with elements that exceed 212°F are not permitted inside a healthcare occupancy.</p> <p>Portable electric heaters with elements that do not exceed 212°F are not permitted in a smoke compartments containing patient sleeping or treatment areas.</p>	<p>Self-explanatory.</p>	<p><u>BUILDING TOUR</u></p> <ul style="list-style-type: none"> • During the building tour, observe under work stations, in storage rooms, and patient rooms for portable space heaters. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>Comment:</p>

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<p>13.06.04 Life Safety Drawings. Basic drawings of the facility indicating the following features are required:</p> <ul style="list-style-type: none"> • Rated walls and barriers, including their fire rating • Exit, exit enclosure, horizontal exit, and exit discharge • Suite-of-rooms, their boundaries and total area • Hazardous rooms • Smoke barriers separating smoke compartments, the total area of each smoke compartment, and the farthest travel distance to the closest smoke barrier door • The farthest travel distance to the closest exit • Areas of the facility that are and are not protected with sprinklers • Smoke partitions 	<p>Basic Life Safety Drawings are critical to the maintenance of life safety features in the hospital.</p> <p>Life Safety Drawings must include the basic information identified in the standard and may include additional information that is pertinent to the life safety features. However, background clutter such as column lines, furniture and cabinets are not desirable.</p> <p>Hospital staff must be able to answer all questions concerning the Life Safety Drawings.</p> <p>Smoke partitions are barriers that are required to resist the passage of smoke but are not necessarily required to have a fire resistive rating.</p> <p>Examples where smoke partitions are located, are:</p> <ul style="list-style-type: none"> • Corridor walls and suite enclosure walls in fully sprinklered smoke compartments; • Hazardous room barriers in existing conditions where the hazardous room is protected with sprinklers. 	<p>BUILDING TOUR</p> <ul style="list-style-type: none"> • Examine the Life Safety drawings before starting the building tour. The hospital’s representatives must be able to interpret the drawings and be able to answer questions that may arise. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>Comment:</p>

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<p>13.06.05 Alcohol Based Hand-Rub Dispensers. Alcohol based hand-rub (ABHR) dispensers are permitted to be installed in exit access corridors of healthcare occupancies, and ambulatory health care occupancies.</p> <p>§482.41(b)(7)</p>	<p>ABHR dispensers are required to be protected in accordance with 8.7.3.1 of the 2012 Life Safety Code, unless all of the following restrictions for ABHR dispenser in healthcare occupancy corridors, are met:</p> <ul style="list-style-type: none"> • The corridor must be at least 6 feet wide • Maximum dispenser quantity is 1.2 liters in rooms, corridors and areas open to corridors • Maximum dispenser quantity is 2.0 liters in suites of rooms • ABHR dispensers must be separated by at least 4 feet • No more than 10 gallons aggregate total of ABHR solution in use per smoke compartment. NOTE: One ABHR dispenser per room or suite is not included in the aggregate total quantity per smoke compartment. • No more than five (5) gallons of ABHR solution per smoke compartment is allowed to be stored outside of a cabinet which meets NFPA 30 • ABHR dispensers shall not be installed over or within one (1) inch (side-to-side) to an ignition source • In locations with carpeted floor coverings, dispensers installed directly over carpeted surfaces shall be permitted only in sprinklered smoke compartments. 	<p>BUILDING TOUR</p> <ul style="list-style-type: none"> • During the building tour, observe ABHR dispenser locations for compliance. • Ask facility representative if they know if they have no more than 10 gallons of ABHR solution in dispensers per smoke compartment. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>Comment:</p>

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- In corridors of at least **six (6)** feet in width, maximum corridor projection is **four (4)** inches.
- **The ABHR dispensers must be installed in a manner that protects against inappropriate access.**

13.06.06 Not Applicable.

13.07.01 Not Applicable.

13.07.02 Not Applicable.

CMS Resources:

482.41(e) The standards incorporated by reference in this section are approved for incorporation by reference by the Director of the Office of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may inspect a copy at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html. If any changes in this edition of the Code are incorporated by reference, CMS will publish a document in the FEDERAL REGISTER to announce the changes.

482.41(e)(1) National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02169, www.nfpa.org, 1.617.770.3000.

- (i) NFPA 99, Standards for Health Care Facilities Code of the National Fire Protection Association 99, 2012 edition, issued August 11, 2011.
- (ii) TIA 12-2 to NFPA 99, issued August 11, 2011.
- (iii) TIA 12-3 to NFPA 99, issued August 9, 2012.
- (iv) TIA 12-4 to NFPA 99, issued March 7, 2013.
- (v) TIA 12-5 to NFPA 99, issued August 1, 2013.
- (vi) TIA 12-6 to NFPA 99, issued March 3, 2014.

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- (vii) NFPA 101, Life Safety Code, 2012 edition, issued August 11, 2011;
- (viii) TIA 12-1 to NFPA 101, issued August 11, 2011.
- (ix) TIA 12-2 to NFPA 101, issued October 30, 2012.
- (x) TIA 12-3 to NFPA 101, issued October 22, 2013.
- (xi) TIA 12-4 to NFPA 101, issued October 22, 2013.



Instructions for the Facility Demographic Report

Introduction and Overview

(Revision 2017)

Each healthcare facility is responsible for providing an environment in which to deliver healthcare services that are safe and hazard free as much as possible, for patients, staff and visitors. Management of the physical environment includes, but not limited to, having an environment that is in compliance with the National Fire Protection Association (NFPA) 101 *Life Safety Code*®, 2012 edition and NFPA 99 Health Care Facilities Code, 2012 edition.

The Healthcare Facilities Accreditation Program (HFAP) monitors the organization's management of the physical environment through the use of the Facility Demographic Report (FDR), accreditation requirements, worksheets and tools designed to provide pertinent and detailed information concerning the facility. While these worksheets and tools are mandatory, they are only designed to assist in assessing the organization's compliance with the *Life Safety Code*, and do not by themselves represent or demonstrate complete compliance. Only onsite, field review and inspection of the facility and supporting documentation can confirm compliance.

The HFAP Life Safety Assessment (LSA) form found in previous HFAP manuals is no longer a required document that organizations need to complete. While some organizations may find it useful as a tool while conducting their own evaluation, HFAP will no longer require organizations to complete it, nor will HFAP surveyors ask to review it.

Organizations must still perform their own assessment for compliance with the 2012 edition of the *Life Safety Code*, and they may use whatever tool they wish to perform this assessment. Organizations may even choose to contract with Life Safety professionals to perform this assessment. HFAP surveyors will assess the organization's level of compliance with the *Life Safety Code* based on visual inspections and review of pertinent documentation.

Following are documents that must be completed and maintained by the organization at their own facility and available for review by a surveyor. Contrary to statements made in previous editions of this manual, HFAP will no longer accept any other accreditation organization's documents to demonstrate compliance with the *Life Safety Code*, or any HFAP document.

Step 1- Facility Demographic Report

The Facility Demographic Report requests specific engineering information to be provided. It references detailed information about the facility and should be completed by individuals who have a working knowledge of the respective NFPA codes and standards and understanding of the buildings being evaluated. The Facility Demographic Report should only be completed by individuals who qualify with these requirements.

Begin by completing the Facility Demographic Report to provide basic information about the organization. Use one form per facility. Each building that is designated a healthcare occupancy or an ambulatory healthcare occupancy is required to have a Facility Demographic Report completed. Free-standing business occupancies are not required to have a Facility Demographic Report completed. If the organization has more than one location, then individual forms should be used for each location. However, do not use more than one form per facility location. Additions and wings that are contiguous to healthcare facilities should all be included on the same report even if they are separated by fire rated barriers. Each question or request for information on this report must be completed. This Facility Demographic Report must be reviewed and updated annually. Permission is granted for organizations to make as many photo copies of this report as needed to complete the required documentation.

Definitions of different occupancy classifications commonly used in healthcare facilities:

Definition of Healthcare Occupancy:

An occupancy used to provide medical or other treatment or care simultaneously to four (4) or more patients on an inpatient basis, where such patients are mostly incapable of self-preservation due to age, physical or mental disability, or because of security measures not under the occupants' control.

The health care facilities regulated by this occupancy chapter are those that provide sleeping accommodations for their occupants and are occupied by persons who are mostly incapable of self-preservation because of age, because of physical or mental disability, or because of security measures not under the occupants' control. The requirements established by this chapter do apply to all hospitals, nursing homes, and limited care facilities.

Examples of Healthcare Occupancies:

- Hospitals
- Psychiatric hospitals
- Specialty hospitals
- Inpatient hospices
- Nursing homes
- Skilled nursing facilities
- Long term care facilities
- Inpatient substance abuse facilities

Definition of Ambulatory Health Care Occupancy:

An occupancy used to provide services or treatment simultaneously to four or more patients that provides, on an outpatient basis, one or more of the following: (1) treatment for patients that renders the patients incapable of taking action for self-preservation under emergency conditions without the assistance of others; (2) anesthesia that renders the patients incapable of taking action for self-preservation under emergency conditions without the assistance of others; (3) emergency or urgent care for patients who, due to the nature of their injury or illness, are incapable of taking action for self-preservation under emergency conditions without the assistance of others.

Examples of Ambulatory Health Care Occupancies include:

- Physical rehab outpatient centers
- Ambulatory surgical centers
- Emergency departments
- Diagnostic centers

Definition of Business Occupancy:

An occupancy used for the transaction of business other than mercantile.

Examples of Business Occupancies include:

- Administrative offices
- Physician's offices
- Support service centers (i.e. maintenance, laundry, sterile processing, boiler rooms, etc.)

Step 2- Resolve the Deficiency

Once a *Life Safety Code* deficiency is identified, it needs to be resolved. If the deficiency cannot be resolved the same day it is discovered, then it needs to be documented on the organization's work order system and assessed for Alternative Life Safety Measures (ALSM). During a survey, the organization will need to be able to demonstrate that they are aware of their *Life Safety Code* deficiencies and are adequately managing their resolution.

Step 3- Equivalency

HFAP will accept Fire Safety Evaluation System (FSES) equivalency requests for those *Life Safety Code* deficiencies cited on the survey report that would be an unreasonable hardship to resolve. Only FSES equivalency requests that comply with the current approved edition of the National Fire Protection Association 101A, *Guide on Alternative Approaches to Life Safety*, will be accepted. After a successful review, HFAP will send the equivalency request to the CMS Regional Office for their approval.

Step 4- Waiver

For Life Safety Code deficiencies that cannot be resolved, or equivalized, waivers will be accepted for review at the HFAP offices. While HFAP does not have authority to approve a waiver to a *Life Safety Code* requirement, after a successful review HFAP will forward the waiver request to the Regional CMS office for approval.

Download instructions on how to submit a waiver from the www.hfap.org website.



Instructions for Completing the Facility Demographic Report

NOTE: This Facility Demographic Report must be reviewed and updated annually by the organization.

Lines 1 through 11

Enter the appropriate information in the spaces allocated, including the date the form was completed. The name of the facility may be different than the name of the organization. Many organizations have more than one facility under a corporate umbrella. This document is specific to one facility or campus only, regardless how many facilities the organization has. Each healthcare facility must have its own individual Facility Demographic Report form completed.

For the purpose of this document, the 'Contact Person' will be the individual responsible for Life Safety compliance for this facility. This may or may not be the same individual responsible for item #25.

Lines 12 and 13

Enter the current number of beds that the facility is licensed to have, not the number of actual beds. Enter the total square footage of all occupancies in this facility. Breakdown the total area and identify the amount of healthcare occupancy, the amount of ambulatory care occupancy and the amount of business/other occupancy.

Lines 14 through 16

'Construction Type' is a term used by NFPA 220 *Standard on Types of Building Construction* (2012 edition) to identify the fire resistant rating of structural members of the building. Enter the NFPA Construction Type on line 14. Construction type will be limited to one of the following designations:

Type I (442)	Type I (332)	Type II (222)	Type II (111)	Type II (000)
Type III (211)	Type III (200)	Type IV (2HH)	Type V (111)	Type V (000)

It is possible there may be more than one Construction Type used in the facility, depending on the date of original construction and subsequent additions. Identify on line 15 if there is more than one Construction Type used in this facility and the locations where they are.

The facility may be designated as being all healthcare occupancy or it may contain other occupancies, such as business or ambulatory **healthcare** occupancies. If there are different occupancies in the facility, they may be required to be separated by fire rated barriers. Identify on line 16 if there is more than healthcare occupancy, what they are, and where they are located.

Lines 17 through 19

Enter the number of stories that are designed to be normally occupied in the facility. This would include any stories that are currently vacant but were designed to be occupied, such as nursing units. However, it would exclude **any stories at the top of the facility** that are designed to be exclusively mechanical rooms and penthouses for equipment. Identify how many stories are located below the level of exit discharge. The level of exit discharge is the floor where more than 50% of the occupants are expected to exit the building in the event of an emergency.

Not all exit stairwells may actually discharge directly to the outdoors, but may discharge to a lobby or corridor that leads to the outdoors. Identify if you have any stairwells that do not discharge directly to the outdoors.

Identify the year of construction for the original building, and the year of construction for any subsequent major additions or renovations. The year of actual occupancy can be used to identify the year of construction.

Lines 20 and 21

Enter on line 20 the pertinent information concerning automatic sprinklers in the facility. Identify what areas, if any, are protected with Quick Response sprinklers. If the facility is protected with a fire pump, enter the year that the pump was installed or replaced.

Enter on line 21 the level of smoke detection in your facility. Smoke detectors are not necessarily required in all the places identified on line 21, but if they are present, indicate so.

Lines 22 and 23

Emergency power generators may be fueled by alternative fuels, other than diesel fuel. Identify the fuel your emergency power generators are powered by. Some organizations have generators that do not serve as emergency power supply systems (EPSS). Do not include any information for generators that are not considered EPSS.

Identify if your facility has any trash and/or linen chutes. Include any chutes that are present but not in operation.

Line 24

Doors in the path of egress are not permitted to be locked, unless they comply with one of exceptions permitted by the Life Safety Code. Identify the locations where doors in the path of egress are locked in your facility, and which exception is used for these locks: Clinical needs; Delayed egress; Access control; Elevator lobby locks; specialized protective measures for patient safety (i.e. infant security).

Line 25

Identify the individual who has been designated by leadership to be responsible for the completion of this Facility Demographic Report. This may or may not be the same individual identified on line 8. Line 25 asks for an explanation of the qualifications for this individual, as this report requests information that is technical and detailed. The individual completing this report must be familiar with the NFPA 101 *Life Safety Code* (2012 edition) and the details of the facility. The organization may choose one of their own staff members to complete this report or they may choose an outside source to do so. The organization needs to document what qualifications they believe the individual possess in order to be responsible for this document.

Line 26

This line requests information if the facility has received approval on any equivalencies or waivers. Such approvals must be identified as to where they apply in the facility. Hard copies of the approvals must be available for surveyor review. HFAP will not accept any equivalencies or waivers approved by any other authority, other than CMS.

Line 27

Certain building systems in health care facilities must be designed to meet Category 1 through Category 4 requirements as detailed in Chapter 4 of NFPA 99-2012. Each system must be evaluated for its potential impact on both the patients and the caregivers if the system should fail. Based on worst-outcome scenario of a failure's impact, the system is assigned a category. The chapter on that particular building system then describes the requirements for the selected category. The four levels of system categories as defined by Chapter 4 of NFPA 99-2012 are based on the risks to patients and caregivers in the facility.

Therefore, a Risk Assessment is required for certain building systems that the organization has, based on a documented defined procedure. HFAP does not prescribe what format the Risk Assessment must follow, but NFPA 99-2012 recommends the following documents:

- ISO/IEC 31010 *Risk Management – Risk Assessment Techniques*
- NFPA 551 *Guide for the Evaluation of Fire Risk Assessments*
- SEMI S10-0307E *Safety Guidelines for Risk Assessment and Risk Evaluation Process*
- Other formal process

The results of the Risk Assessment procedure must be documented and the records reviewed and approved by the organization's Safety Committee. All Risk Assessments must be available for review during a survey. Only the following building systems are required to be evaluated for categories in a Risk Assessment:

- Gas & Vacuum Systems
- Electrical Systems
- HVAC Systems
- Electrical Equipment
- Gas Equipment

Enter on Line 27, the Category designation for each of the above listed building systems based on the organization's documented Risk Assessment.

Line 28

Line 28 is the place to enter any other information that you believe is pertinent to the overall compliance with the Life Safety Code at this facility. Also, this can be used to explain answers to other questions, if needed.



Date: _____

Facility Demographic Report

- 1). Name of Organization: _____
- 2). Name of the Healthcare Facility: _____
- 3). Address: _____
- 4). City: _____ 5). State: _____ 6). Zip: _____
- 7). HFAP Facility ID Number: _____
- 8). Contact Person: _____ 9). Title: _____
- 10). Telephone Number: _____ 11). Email: _____
- 12). Number of licensed beds: _____
- 13). Total square footage of all occupancies in this facility: _____
- Healthcare Occupancy: _____
- Ambulatory Care Occupancy: _____
- Business/Other Occupancy: _____
- 14). Identify the Construction Type(s) used in this facility. Select from the list below: _____

Type I (442)	Type I (332)	Type II (222)	Type II (111)	Type II (000)
Type III (211)	Type III (200)	Type IV (2HH)	Type V (111)	Type V (000)

15). Is there more than one Construction Type in this facility? Yes No

If YES, are the different Construction Types separated by fire rated barriers? Yes No

If YES, identify the different types and their locations: _____

16). Is there more than one type of occupancy in this facility? Yes No

If YES, are the different occupancies separated by fire rated barriers? Yes No

If YES, identify the different types and the locations: _____

17). Total number of occupied stories: _____ Number of occupied stories below the level of exit discharge: _____

18). Total number of exit stairwells that do not discharge directly to the outdoors: _____

19). Date of original construction of this facility: _____ Date of subsequent additions to this facility: _____

20). Is the entire facility protected with automatic sprinklers? Yes No

If NO, what areas are not protected with automatic sprinklers? _____

List all areas, if any that are protected with Quick Response automatic sprinklers: _____

Is the facility equipped with a fire pump? Yes No If YES, what year was the fire pump installed or replaced? _____

21). What level of smoke detection does this facility have? (Check all that apply)

- | | |
|--|---|
| <input type="checkbox"/> In corridors | <input type="checkbox"/> Elevator lobbies |
| <input type="checkbox"/> In sleeping rooms | <input type="checkbox"/> Fire alarm control panels |
| <input type="checkbox"/> Near doors held open by magnets | <input type="checkbox"/> Areas open to the corridor |
| <input type="checkbox"/> None | <input type="checkbox"/> Other: _____ |

22). Emergency power generator fueled by (Must choose one):

- Diesel
- Natural gas
- Other
- None

23). Facility has linen and/or trash chutes (Must choose one):

- Yes YES, but not in operation No

24). Identify below the location(s) in the facility where doors in the path of egress are locked or None:

Clinical Needs Locks: _____

Delayed Egress Locks: _____

Access-Control Locks: _____

Elevator Lobby Locks: _____

Specialized Protective Measure Locks: _____

25). Who has been designated by leadership to be responsible for the completion of the Facility Demographic Report (FDR) form?

Name: _____

Title: _____

Organization: _____

Contact Information: Telephone: _____ Email: _____

What skills and knowledge does this person possess that qualifies them to complete the FDR? _____

26). Does the facility have any approved equivalencies or any approved waivers concerning any Life Safety Code deficiencies? Yes No

If YES, identify what the equivalency and/or waiver is for, and the location where it applies: _____

27). Based on a documented Risk Assessment conducted by the organization, please identify which NFPA 99-2012 Building System Category has been determined for the respective building services:

Gas & Vacuum Systems: Category 1 Category 2 Category 3 Category 4

Electrical Systems: Category 1 Category 2 Category 3 Category 4

HVAC Systems: Category 1 Category 2 Category 3 Category 4

Electrical Equipment: Category 1 Category 2 Category 3 Category 4

Gas Equipment: Category 1 Category 2 Category 3 Category 4

28). Please include any other information that is relevant and pertinent to the Physical Environment: _____

ORGAN PROCUREMENT

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>14.00.00 <u>Condition of Participation: Organ, Tissue and Eye Procurement.</u></p> <p>§482.45</p>	<p>The hospital must ensure the specific organ, tissue, and eye procurement requirements are met.</p>	<p style="text-align: center;"><u>DOCUMENT REVIEW, INTERVIEW, AND RECORD REVIEW</u></p> <ul style="list-style-type: none"> • Verify the facility has an effective organ procurement program in place that includes all required elements. • If facility has no Organ Procurement Organization (OPO), Tissue Bank, or Eye Bank agreement, cite as Condition-level non-compliance. 	<p style="text-align: right;"> <input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant </p> <p style="text-align: right;">This standard is not met as evidenced by:</p>
<p>14.00.01 <u>Organ/Tissue Donation & Transplantation.</u></p> <p><i>The hospital must have and implement written protocols that:</i></p> <ul style="list-style-type: none"> • <i>Incorporate an agreement with an OPO (Organ Procurement Organization), under part 486 of 42 CFR 486.322, under which it must notify, in a timely manner, the OPO or a third party designated by the OPO of individuals whose death is imminent or who have died in the hospital.</i> • <i>The OPO determines medical suitability for organ donation and, in the absence of alternative arrangements by the hospital, the OPO determines medical</i> 	<p>The hospital must have a written agreement with an Organ Procurement Organization (OPO), designated under 42 CFR Part 486.</p> <p>At a minimum, the written agreement must address the following:</p> <ol style="list-style-type: none"> 1. The criteria for referral, including the referral of all individuals whose death is imminent or who have died in the hospital; 2. Includes a definition of “imminent death”; 3. Includes a definition of “timely notification”; 4. Addresses the OPO’s responsibility to determine medical suitability for organ donation; 5. Specifies how the tissue and/or eye bank will be notified about potential donors using notification protocols developed by the OPO in consultation 	<p style="text-align: center;"><u>DOCUMENT AND RECORD REVIEW</u></p> <ol style="list-style-type: none"> 1. Review the hospital’s written agreement with the OPO to verify that it addresses all required information. 2. Verify that the hospital’s governing body has approved the hospital’s organ procurement policies. 3. Review a sample of death records to verify that the hospital has implemented its organ procurement policies. 4. Interview the staff to verify that they are aware of the hospital’s policies and procedures for organ, tissue and eye procurement. 5. Verify that the organ, tissue and eye donation program is integrated into the 	<p style="text-align: right;"> <input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant </p> <p style="text-align: right;">This standard is not met as evidenced by:</p>

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STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p><i>suitability for tissue and eye donation, using the definition of potential tissue and eye donor and the notification protocol developed in consultation with the tissue and eye banks identified by the hospital for this purpose.</i></p> <p>§482.45(a) §482.45(a)(1)</p>	<p>with the hospital-designated tissue and eye bank(s);</p> <ol style="list-style-type: none"> 6. Provides for notification of each individual death in a timely manner to the OPO (or designated third party) in accordance with the terms of the agreement; 7. Ensures that the designated requestor training program offered by the OPO has been developed in cooperation with the tissue bank and eye bank designated by the hospital; 8. Permits the OPO, tissue bank, and eye bank access to the hospital’s death record information according to a designated schedule, e.g., monthly or quarterly; 9. Includes that the hospital is not required to perform credentialing reviews for, or grant privileges to, members of organ recovery teams as long as the OPO sends only “qualified, trained individuals” to perform organ recovery; and 10. The interventions the hospital will utilize to maintain potential organ donor patients so that the patient organs remain viable. <p>Hospitals must notify the OPO of every death or imminent death in the hospital. When death is imminent, the hospital must notify the OPO both before a potential donor is removed from a ventilator and while the potential donor’s organs are still viable.</p>	<p>hospital’s QAPI program.</p>	

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Imminent Death

The hospital should have a written policy, developed in coordination with the OPO and approved by the hospital’s medical staff and governing body, to define imminent death.

The definition for imminent death should strike a balance between the needs of the OPO and the needs of the hospital’s care givers to continue treatment of a patient until brain death is declared or the patient’s family has made the decision to withdraw supportive measures. Collaboration between OPOs and hospitals will create a partnership that furthers donation, while respecting the perspective of hospital staff.

The definition for imminent death might include a patient with severe, acute brain injury who:

- Requires mechanical ventilation;
- Is in an intensive care unit (ICU) or emergency department; AND
- Exhibits clinical findings consistent with a Glasgow Coma Score that is less than or equal to a mutually-agreed-upon threshold; or
- Doctor of Medicine / Doctor of Osteopathic Medicine are evaluating a diagnosis of brain death; or
- A Doctor of Medicine / Doctor of Osteopathic Medicine has ordered that life sustaining

ORGAN PROCUREMENT

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therapies be withdrawn, pursuant to the family’s decision.

Hospitals and their OPO should develop a definition of imminent death that includes specific triggers for notifying the OPO about an imminent death. In determining the appropriate threshold for the Glasgow Coma Score (GCS), it is important to remember that if the threshold is too low, there may be too many “premature” deaths or situations where there is a loss of organ viability. Standards for appropriate GCS thresholds may be obtained from the hospital’s OPO or organizations such as The Association of Organ Procurement Organizations.

Note that a patient with “severe, acute brain injury” is not always a trauma patient. For example, post myocardial infarction resuscitation may result in a patient with a beating heart and no brain activity. The definition agreed to by the hospital and the OPO may include all of the elements listed above or just some of the elements. The definition should be tailored to fit the particular circumstances in each hospital.

Hospitals may not use “batch reporting” for deaths by providing the OPO with periodic lists of patient deaths, even if instructed to do so by the OPO. If the patient dies during a transfer from one hospital to another, it is the receiving hospital’s responsibility to notify the OPO.

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TIMELY NOTIFICATION

“Timely notification” means a hospital must contact the OPO by telephone as soon as possible after an individual has died, has been placed on a ventilator due to a severe brain injury, or who has been declared brain dead (ideally within 1 hour). That is, a hospital must notify the OPO while a brain dead or severely brain-injured, ventilator-dependent individual is still attached to the ventilator and as soon as possible after the death of any other individual, including a potential non-heart-beating donor.

Even if the hospital does not consider an individual who is not on a ventilator to be a potential donor, the hospital must call the OPO as soon as possible after the death of that individual has occurred.

Referral by a hospital to an OPO is timely if it is made:

- As soon as it is anticipated that a patient will meet the criteria for imminent death agreed to by the OPO and hospital or as soon as possible after a patient meets the criteria for imminent death agreed to by the OPO and the hospital (ideally, within one hour); AND
- Prior to the withdrawal of any life sustaining therapies (i.e., medical or pharmacological support).

Whenever possible, referral should be made early enough to allow the OPO to assess the patient’s suitability for organ donation before brain death is declared and before the option of organ donation is presented to the family of the potential donor.

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Timely assessment of the patient’s suitability for organ donation increases the likelihood that the patient’s organs will be viable for transplantation (assuming there is no disease process identified by the OPO that would cause the organs to be unsuitable), assures that the family is approached only if the patient is medically suitable for organ donation, and assures that an OPO representative is available to collaborate with the hospital staff in discussing donation with the family.

It is the OPO’s responsibility to determine medical suitability for organ donation, and, in the absence of alternative arrangements by the hospital, the OPO determines medical suitability for tissue and eye donation, using the definition of potential tissue and eye donor and the notification protocol developed in consultation with the tissue and eye banks identified by the hospital for this purpose.

14.00.02 OPO Waiver Requests.

A hospital may request and CMS may grant a waiver permitting the hospital to have an agreement with a designated OPO other than the OPO designated for the service area in which the hospital is located.

§486.316(e)

A waiver would allow the hospital to have an agreement with an “out-of-the-areas” OPO if it meets the following criteria in the statute (Section 1138(a) (2) (a) (i) (ii)).

To qualify for a waiver, the hospital must submit data to CMS establishing that:

1. The waiver is expected to increase organ donations; and
2. The waiver will ensure equitable treatment of

DOCUMENT REVIEW

- Review the waiver agreement from the Secretary of HHS to determine when, and why, it was issued and the time period for which it was granted.

- 1 = Compliant
- 2 = Not Compliant

This standard is not met as evidenced by:

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patients referred for transplants within the service area served by the hospital's designated OPO and within the service area served by the OPO with which the hospital seeks to enter into an agreement.

14.00.03 Tissue & Eye Bank Agreements.

The hospital must have and implement written protocols that:

- Incorporates an agreement with at least one tissue bank and at least one eye bank to cooperate in the retrieval, processing, preservation, storage, and distribution of tissues and eyes, as may be appropriate to assure that all usable tissues and eyes are obtained from potential donors, insofar as such agreement does not interfere with organ procurement.*

§482.45(a)(2)

The hospital must have an agreement with at least one tissue bank and at least one eye bank.

The OPO may serve as a “gatekeeper” receiving notification about every hospital death and should notify the tissue bank or eye bank chosen by the hospital about potential tissue and eye donors.

It is not necessary for a hospital to have a separate agreement with a tissue bank if it has an agreement with its OPO to provide tissue procurement services; nor is it necessary for a hospital to have a separate agreement with an eye bank if its OPO provides eye procurement services.

The hospital is not required to use the OPO for tissue or eye procurement but is free to have an agreement with the tissue bank or eye bank of its choice. The tissue banks and eye banks define “usable tissues” and “usable eyes.”

The requirements of this regulation may be satisfied through a single agreement with an OPO that provides services for organ, tissue and eye, or by a separate agreement with another tissue and/or eye bank outside the OPO, chosen by the hospital. The hospital

DOCUMENT REVIEW

1. Verify that the hospital has an agreement with at least one tissue bank and one eye bank that specifies criteria for referral of all potential tissue and eye donors, or an agreement with an OPO that specifies the tissue bank and eye bank to which referrals will be made.
2. The agreement should also acknowledge that it is the OPO’s responsibility to determine medical suitability for tissue and eye donation, unless the hospital has an alternative agreement with a different tissue and/or eye bank.

- 1 = Compliant
- 2 = Not Compliant

This standard is not met as evidenced by:

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	<p>may continue current successful direct arrangements with tissue and eye banks as long as the direct arrangement does not interfere with organ procurement.</p>		
<p>14.00.04 <u>Informed Consent Requirements.</u> <i>The hospital must have and implement written protocols that:</i></p> <ul style="list-style-type: none"> • <i>Ensure, in collaboration with the designated OPO, that the family of each potential donor is informed of its option to donate organs, tissues, or eyes, or to decline to donate.</i> <p>§482.45(a)(3)</p>	<p>It is the responsibility of the OPO to screen for medical suitability in order to select potential donors. Once the OPO has selected a potential donor, that person’s family must be informed of the family’s donation options.</p> <p>Ideally, the OPO and the hospital will decide together how and by whom the family will be approached.</p>	<p style="text-align: center;"><u>DOCUMENT REVIEW</u></p> <ol style="list-style-type: none"> 1. Verify that the hospital ensures that the family of each potential donor is informed of its options to donate organs, tissues, or eyes, including the option to decline to donate. 2. Does the hospital have QAPI mechanisms in place to ensure that the families of all potential donors are informed of their options to donate organs, tissues, or eyes, or to decline to donate? 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>
<p>14.00.05 <u>Designated Requestors.</u> <i>The individual designated by the hospital to initiate the request to the family must be an organ procurement representative or a designated requestor.</i></p> <p><i>A designated requestor is an individual who has completed a course offered or approved by the OPO and designed in</i></p>	<p>The individual designated by the hospital to initiate the request to a family must be an organ procurement representative, an organizational representative of a tissue or eye bank, or a designated requestor. Any individuals involved in a request for organ, tissue, and eye donation must be formally trained in the donation request process.</p> <p>The individual designated by the hospital to initiate the request to the family must be an OPO, tissue</p>	<p style="text-align: center;"><u>DOCUMENT REVIEW, FILE REVIEW</u></p> <ol style="list-style-type: none"> 1. Review hospital records to determine if hospital staff request organ donation. If so, is hospital staff trained as designated requestors? 2. Review training schedules and personnel files to verify that all designated requestors have completed the required training. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

ORGAN PROCUREMENT

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<p><i>conjunction with the tissue and eye bank community in the methodology for approaching potential donor families and requesting organ or tissue donation.</i></p> <p>§482.45(a)(3)</p>	<p>bank, or eye bank representative or a designated requestor. A “designated requestor” is defined as a hospital-designated individual who has completed a course offered or approved by the OPO and designed in conjunction with the tissue and eye bank community.</p> <p>Ideally, the OPO and the hospital will decide together how and by whom the family will be approached. If possible, the OPO representative and a designated requestor should approach the family together. The hospital must ensure that any designated requestor for organs, tissues or eyes has completed a training course either offered or approved by the OPO, which addresses methodology for approaching potential donor families.</p> <p>Research has shown that the highest consent rates occur when the OPO and hospital staff approaches the family together. In the event that collaboration is not possible, the hospital decides who approaches the family to provide information, discuss the family’s options, and request donation. The hospital may have chosen to have an organ procurement coordinator from the OPO approach the family or may choose to have a “designated requestor” approach the family.</p>	<p>3. Review employee records to determine if individuals involved in organ / tissue / eye donation have received formal training in the consent process for donation.</p> <p style="text-align: center;"><u>INTERVIEW</u></p> <p>1. How does the hospital ensure that only OPO, tissue bank, or eye bank staff or designated requestors are approaching families to ask them to donate?</p> <p>2. Does hospital staff know if there has been an improvement in donations?</p>	

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STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>14.00.06 Sensitivity Training. <i>The hospital must have and implement written protocols that:</i></p> <ul style="list-style-type: none"> • <i>Encourages discretion and sensitivity with respect to the circumstances, views, and beliefs of the families of potential donors.</i> <p>§482.45(a)(4)</p>	<p>Using discretion does not mean a judgment can be made that certain families should not be approached about donation.</p> <p>Hospitals should approach the family with the belief that a donation is possible and should take steps to ensure the family is treated with respect and care. The hospital staff's perception that a family's grief, race, ethnicity, religion or socioeconomic background would prevent donation should never be used as a reason not to approach a family.</p> <p>All potential donor families must be approached and informed of their donation rights.</p>	<p style="text-align: center;"><u>DOCUMENT REVIEW</u></p> <ol style="list-style-type: none"> 1. Review training plans and ensure they encourage discretion. 2. Review the designated requestor training program to verify that it addresses the use of discretion. 3. Review the hospital's complaint file for any relevant complaints. <p style="text-align: center;"><u>INTERVIEW</u></p> <ol style="list-style-type: none"> 1. Verify through staff interviews that there has been sensitivity training regarding the process. 2. Interview a hospital-designated requestor regarding approaches to donation requests. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>
<p>14.00.07 OPO Responsibilities. <i>The hospital must have and implement written protocols that:</i></p> <ul style="list-style-type: none"> • <i>Ensures that the hospital works cooperatively with the designated OPO, tissue bank and eye bank in:</i> <ol style="list-style-type: none"> (1) <i>Educating staff on donation issues;</i> (2) <i>Reviewing death records to improve identification of potential donors; and</i> 	<p>Appropriate hospital staff, including all patient care staff, must be trained on donation issues. The training program must be developed in cooperation with the OPO, tissue bank and eye bank, and should include, at a minimum:</p> <ol style="list-style-type: none"> 1. Consent process; 2. Importance of using discretion and sensitivity when approaching families; 3. Role of the designated requestor; 4. Transplantation and donation, including pediatrics, if appropriate; 	<p style="text-align: center;"><u>INTERVIEW & DOCUMENT REVIEW</u></p> <p>Review staff training schedules and attendance sheets.</p> <ol style="list-style-type: none"> 1. Request protocols related to death record review. (Who reviews the records and how often are reviews done?) 2. Request recorded examples of maintaining potential donors. <ul style="list-style-type: none"> • How does the hospital ensure that all appropriate staff has attended an educational program regarding donation issues and how to work 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

ORGAN PROCUREMENT

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<p>(3) <i>Maintaining potential donors while necessary testing and placement of potential donated organs, tissues, and eyes take place.</i></p> <p>§482.45(a)(5)</p>	<p>5. Quality improvement activities; and</p> <p>6. Role of the organ procurement organization.</p> <p>Training should be conducted with new employees annually, whenever there are policy / procedure changes, or when problems are determined through the hospital’s QAPI program. Those hospital staff who may have to contact or work with the OPO, tissue bank and eye bank staff must have appropriate training on donation issues including their duties and roles.</p> <p>Hospitals must cooperate with the OPOs, tissue banks and eye banks in regularly or periodically reviewing death records. This means that the hospital must develop policies and procedures which permit the OPO, tissue bank, and eye bank access to death record information that will allow the OPO, tissue bank and eye bank to assess the hospital’s donor potential, assure that all deaths or imminent deaths are being referred to the OPO in a timely manner, and identify areas where the hospital, OPO, tissue bank and eye bank staff performance might be improved. The policies must address how patient confidentiality will be maintained during the review process.</p> <p>The hospital must have policies and procedures, developed in cooperation with the OPO, that ensure that potential donors are maintained in a manner that maintains the viability of their organs.</p>	<p>with the OPO, tissue bank, and eye bank?</p> <p>3. Verify by review of policies and records that the hospital works with the OPO, tissue bank, and eye bank in reviewing death records.</p> <p>4. Verify that the effectiveness of any protocols and policies is monitored as part of the hospital’s quality improvement program.</p> <p>5. Validate how often the reviews are to occur. Review the protocols that are in place to guide record reviews and analysis.</p> <p>6. Determine how confidentiality is ensured.</p> <p>7. Determine by review, what policies and procedures are in place to ensure that potential donors are identified and declared dead by an appropriate practitioner within an acceptable timeframe.</p> <p>8. Verify that there are policies and procedures in place to ensure the coordination between facility staff and OPO staff in maintaining the potential donor.</p>	

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The hospital must have policies in place to ensure that potential donors are identified and declared dead within an acceptable time frame by an appropriate practitioner.

14.00.08 Organ Transplant Facilities.

A hospital in which organ transplants are performed must be a member of the Organ Procurement and Transplantation Network (OPTN) established and operated in accordance with section 372 of the Public Health Service (PHS) Act (42 U.S.C. 274) and abide by its rules.

*The term “Rules of the OPTN” means those rules provided for in regulations issued by the Secretary in accordance with section 372 of the PHS Act which are enforceable under 42 CFR 121.10. No hospital is considered to be out of compliance with section 1138(a)(1)(B) of the Act (**Social Security Act**), or with the requirements of this paragraph, unless the Secretary has given the OPTN formal notice that he or she approves the decision to exclude the hospital from the OPTN and has notified the hospital in writing.*

§482.45(b)
§482.45(b)(1)

If you have questions concerning the facility membership in the Organ Procurement and Transplantation Network; you may verify the membership by contacting the CMS regional office or by calling the United Network for Organ sharing (UNOS) at 1-804-330-8500.

DOCUMENT REVIEW

1. Determine that the hospital is an active Organ Procurement Organization member of a regional affiliate of an OPTN by reviewing documentation.
2. Determine that there are current copies of all communications from the OPTN regarding standards and regulations impacting procurement and transplant activities.
3. Verify by review, one year of reports submitted by the facility to the OPTN, the Scientific Registry, the OPOs, and any data submitted to the Department per request of the Secretary.

- 1 = Compliant
- 2 = Not Compliant
- N/A = Not Applicable

This standard is not met as evidenced by:

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For the purpose of these standards, the term “organ” means a human kidney, liver, heart, lung, or pancreas.

§482.45(b)(2)

14.00.09 Data Collection & Reporting.

If a hospital performs any type of transplants, it must provide organ-transplant-related data, as requested by the OPTN, the Scientific Registry, and the OPOs.

The hospital must also provide data directly to the Department of Health and Human Services when requested by the Secretary.

§482.45(b)(3)

If you have questions concerning the facility membership in the Organ Procurement and Transplantation Network; you may verify the membership by contacting the CMS regional office or by calling the United Network for Organ sharing (UNOS) at 1-804-330-8500.

DOCUMENT REVIEW

Verify by review one year of reports submitted by the facility to the OPTN, the Scientific Registry, the OPOs, and any data submitted to the Department per request of the Secretary.

Verify:

1. The facility submits reports to the OPTN, the Scientific Registry, and the OPOs.
2. The facility submits data, as requested, to CMS.

- 1 = Compliant
- 2 = Not Compliant
- N/A = Not Applicable

This standard is not met as evidenced by:

14.00.10 Confidentiality of Patient Records.

Hospitals and OPOs must have procedures for ensuring the confidentiality of patient records.

§482.24(b)(3)
§486.306(o)

Processes are in place to insure the patient records and information exchanged among the hospitals and OPOs shall remain confidential and is not accessed by unauthorized individuals.

Unauthorized individuals are those individuals not directly involved as employees of the hospital or OPO in facilitating organ donation or transplantation.

DOCUMENT REVIEW

Review hospital procedures.

Verify:

- A process is in place for ensuring confidentiality of patient records exchanged with the OPO.

- 1 = Compliant
- 2 = Not Compliant

This standard is not met as evidenced by:

INTERVIEW

- Interview staff for how information is shared and protected. Check for complaints about any lack of confidentiality.

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**15.00.00 Condition of Participation:
Patient's Rights.**

A hospital must protect and promote each patient's rights.

§482.13

The facility must protect and promote each patient's rights. Protection of patient's rights is demonstrated through a variety of modalities which includes privacy, safety, confidentiality of records, the grievance process, advance directives, participation in the plan of care, and use of restraints or seclusion.

These requirements apply to all Medicare or Medicaid participating hospitals including short-term, acute care, surgical, specialty, psychiatric, rehabilitation, long-term, children's and cancer, whether or not they are accredited. This rule does not apply to critical access hospitals. (See Social Security Act (the Act) §1861(e))

These requirements, as well as the other Conditions of Participation in 42 CFR §482, apply to all parts and locations (outpatient services, provider-based entities, inpatient services) of the Medicare participating hospital.

DOCUMENT REVIEW & OBSERVATION

Determine that the facility protects and promotes each patient's rights throughout the facility.

This full Condition of Participation applies to all §482.13 standards listed within this chapter.

Survey of the Patients' Rights Condition of Participation (CoP) should be coordinated by one surveyor. However, each surveyor, as he/she conducts his/her survey assignments, should assess the hospital's compliance with the Patients' Rights CoP.

- 1 = Compliant
- 2 = Not Compliant

This standard is not met as evidenced by:

15.01.00 Not Applicable.

15.01.01 Not Applicable.

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<p>15.01.02 Notice of Patient Rights. <i>A hospital must inform each patient, or when appropriate, the patient’s representative (as allowed under State law), of the patient’s rights in advance of furnishing or discontinuing patient care whenever possible.</i></p> <p>§482.13(a) §482.13(a)(1)</p>	<p>The hospital must ensure the notice of rights requirements is met.</p> <p>The hospital must inform each patient, or when appropriate, the patient’s representative as allowed by State law, of the patient’s rights.</p> <ul style="list-style-type: none"> • Whenever possible, this notice must be provided before providing or stopping care. • All patients, inpatient or outpatient, must be informed of their rights as hospital patients. • The patient’s rights include all of those discussed in this condition, as well as any other rights for which notice is required under State or Federal law or regulations for hospital patients. (See 42 CFR §482.11.) • The patient’s rights should be provided and explained in a language or manner that the patient (or the patient’s representative) can understand. This is consistent with the guidance related to Title VI of the Civil Rights Act of 1964 issued by the Department of Health and Human Services- Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons (August 8, 2003, 68 FR 47311). In accordance with §482.11, hospitals are expected to comply with Title VI and may use this guidance to assist it in ensuring patient’s rights information is provided in a language and manner 	<p style="text-align: center;"><u>DOCUMENT REVIEW, INTERVIEW, & OBSERVATION</u></p> <ol style="list-style-type: none"> 1. Determine the hospital’s policy for notifying all patients of their rights, both inpatient and outpatient. 2. Determine that the hospital’s policy provides for determining when a patient has a representative and who that representative is, consistent with this guidance and State law. 3. Determine that the information provided to the patients by the hospital complies with Federal and State law. 4. Review records and interview staff to examine how the hospital communicates information about their rights to diverse patients, including individuals who need assistive devices or translation services. Does the hospital have alternative means, such as written materials, signs, or interpreters (when necessary), to communicate patients’ rights? 5. Review records and interview staff and patients or patients’ representatives (as appropriate) to examine how the hospital determines whether the patient has a representative, who that representative is, and whether notice of patients’ rights is 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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	<p>that the patient understands. Surveyors do not assess compliance with these requirements on limited English proficiency, but may refer concerns about possible noncompliance to the Office for Civil Rights in the applicable Department of Health and Human Services Regional Office.</p> <p>Hospitals are expected to take reasonable steps to determine the patient’s wishes concerning designation of a representative. Unless prohibited by applicable State law:</p> <ul style="list-style-type: none"> • When a patient who is not incapacitated has designated, either orally to hospital staff or in writing, another individual to be his/her representative, the hospital must provide the designated individual with the required notice of patients’ rights in addition to the patient. The explicit designation of a representative takes precedence over any non-designated relationship and continues throughout the patient’s inpatient stay or outpatient visit, unless expressly withdrawn, either orally or in writing, by the patient. • In the case of a patient who is incapacitated, when an individual presents the hospital with an advance directive, medical power of attorney or similar document executed by the patient and designating an individual to make medical decisions for the patient when incapacitated, then the hospital must, when presented with the 	<p>provided as required to patients’ representatives.</p> <ol style="list-style-type: none"> 6. Ask patients to tell you what the hospital has told them about their rights. 7. Does staff know what steps to take to inform a patient about their patients’ rights, including those patients’ with special communication needs? 8. Review a sample of inpatient medical records for Medicare beneficiaries, to determine whether the records contain a signed and dated IM provided within 2 days of the admission of the patient. 9. For patients whose discharge occurred more than 2 days after the initial IM notice was issued, determine whether the hospital provided another copy of the IM to the patient prior to discharge in a timely manner. 	

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document, provide the required notice of its policies to the designated representative. The explicit designation of a representative takes precedence over any non-designated relationship and continues throughout the patient's inpatient stay or outpatient visit, unless the patient ceases to be incapacitated and expressly withdraws the designation, either orally or in writing.

- When a patient is incapacitated or otherwise unable to communicate his or her wishes, there is no written advance directive on file or presented, and an individual asserts that he or she is the patient's spouse, domestic partner (whether or not formally established and including a same-sex domestic partner), parent (including someone who has stood in loco parentis for the patient who is a minor child), or other family member and thus is the patient's representative, the hospital is expected to accept this assertion, without demanding supporting documentation, and provide the required notice to the individual, unless:
 - More than one individual claims to be the patient's representative. In such cases, it would be appropriate for the hospital to ask each individual for documentation supporting his/her claim to be the patient's representative. The hospital should make its determination of who is the patient's representative based upon the hospital's determination of who the patient would most

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	<p>want to make decisions on his/her behalf. Examples of documentation a hospital might consider could include, but are not limited to, the following: proof of a legally recognized marriage, domestic partnership, or civil union; proof of a joint household; proof of shared or co-mingled finances; and any other documentation the hospital considers evidence of a special relationship that indicates familiarity with the patient's preferences concerning medical treatment;</p> <ul style="list-style-type: none"> ○ Treating the individual as the patient's representative without requesting supporting documentation would result in the hospital violating State law. State laws, including State regulations, may specify a procedure for determining who may be considered to be the incapacitated patient's representative, and may specify when documentation is or is not required; or ○ The hospital has reasonable cause to believe that the individual is falsely claiming to be the patient's spouse, domestic partner, parent or other family member. <p>Hospitals are expected to adopt policies and procedures that facilitate expeditious and non-discriminatory resolution of disputes about whether an individual is the patient's representative, given the critical role of the representative in exercising the</p>		

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patient's rights.

A refusal by the hospital of an individual's request to be treated as the patient's representative, based on one of the above-specified familial relationships, must be documented in the patient's medical record, along with the specific basis for the refusal.

In addition, according to the regulation at 42 CFR §489.27(a), (which cross references the regulation at 42 CFR 405.1205), each Medicare beneficiary who is an inpatient (or his/her representative) must be provided the standardized notice, "An Important Message from Medicare (IM)", within 2 days of admission.

- Medicare beneficiaries who have not been admitted (e.g., patients in observation status or receiving other care on an outpatient basis) are not required to receive the IM. The IM is a standardized, OMB-approved form and cannot be altered from its original format. The IM is to be signed and dated by the patient to acknowledge receipt. See Exhibit 16 for a copy of the IM.

Furthermore, 42 CFR §405.1205(c) requires that hospitals present a copy of the signed IM in advance of the patient's discharge, but not more than two calendar days before the patient's discharge.

In the case of short inpatient stays, however, where initial delivery of the IM is within 2 calendar days of the discharge, the second delivery of the IM is not required.

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<p>15.01.03 Patient Grievances. <i>The hospital must establish a process for prompt resolution of patient grievances and must inform each patient whom to contact to file a grievance.</i> §482.13(a)(2)</p>	<p>The hospital must establish and implement policies and procedures that effectively ensure that patients and/or their representatives have the information necessary to exercise their rights.</p> <p>Patient’s Rights are posted in clear sight for patients and visitors to view throughout the hospital and all outpatient settings.</p> <p>The patient should have reasonable expectations of care and services and the facility should address those expectations in a timely, reasonable, and consistent manner. Although <u>§482.13(a)(2)(ii) and (iii)</u> address documentation of facility time frames for a response to a grievance, the expectation is that the facility will have a process to comply with a relatively minor request in a more timely manner than a written response.</p> <ul style="list-style-type: none"> For example, a change in bedding, housekeeping of a room, and serving preferred food and beverage may be made relatively quickly and would not usually be considered a "grievance" and therefore would not require a written response. <p>The hospital must inform the patient and/or the patient's representative of the internal grievance process, including whom to contact to file a grievance (complaint).</p>	<p><u>DOCUMENT REVIEW, OBSERVATION, AND INTERVIEW</u></p> <ol style="list-style-type: none"> Review the hospital’s policies and procedures to assure that its grievance process encourages all personnel to alert appropriate staff concerning any patient grievance. <ul style="list-style-type: none"> Does the hospital adhere to its policy / procedure established for grievances? Interview patients or the patient’s legal representative to determine if they know how to file a complaint (grievance) and who to contact if they have a complaint (grievance). Is the hospital following its grievance policies and procedures? Does the hospital’s process assure that grievances involving situations or practices that place the patient in immediate danger 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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	<ul style="list-style-type: none"> • As part of its notification of patient rights, the hospital must provide the patient or the patient's representative a phone number and address for lodging a grievance with the State agency. • The hospital must inform the patient that he/she may lodge a grievance with the State agency (the State agency that has licensure survey responsibility for the hospital) directly, regardless of whether he/she has first used the hospital's grievance process. <p>A “patient grievance” is a formal or informal written or verbal complaint that is made to the hospital by a patient, or the patient’s representative, regarding the patient's care (when the complaint is not resolved at the time of the complaint by staff present), abuse or neglect, issues related to the hospital's compliance with the CMS Hospital Conditions of Participation (CoPs), or a Medicare beneficiary billing complaint related to rights and limitations provided by <u>42 CFR §489</u>.</p> <ul style="list-style-type: none"> • “Staff present” includes any hospital staff present at the time of the complaint or who can quickly be at the patient's location (i.e., nursing, administration, nursing supervisors, patient advocates, etc.) to resolve the patient's complaint. • If a patient care complaint cannot be resolved at the time of the complaint by staff present, is postponed for later resolution, is referred to other staff for later resolution, requires investigation, 	<p>are resolved in a timely manner?</p> <ol style="list-style-type: none"> 5. Does the patient or the patient’s representative know that he/she has the right to file a complaint with the State agency as well as or instead of utilizing the hospital’s grievance process? 6. Has the hospital provided the telephone number for the State agency to all patients/patient representatives? 7. Are beneficiaries aware of their right to seek review by the QIO for quality of care issues, coverage decisions, and to appeal a premature discharge? 	

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and/or requires further actions for resolution, then the complaint is a grievance for the purposes of these requirements. A complaint is considered resolved when the patient is satisfied with the actions taken on their behalf.

- Billing issues are not usually considered grievances for the purposes of these requirements. However, a Medicare beneficiary billing complaint related to rights and limitations provided by 42 CFR §489 is considered a grievance.
- A written complaint is always considered a grievance. This includes written complaints from an inpatient, an outpatient, a released/discharged patient, or a patient's representative regarding the patient care provided, abuse or neglect, or the hospital's compliance with CoPs. For the purposes of this requirement, an email or fax is considered "written."
- Information obtained from patient satisfaction surveys usually does not meet the definition of a grievance. If an identified patient writes or attaches a written complaint on the survey and requests resolution, then the complaint meets the definition of a grievance. If an identified patient writes or attaches a complaint to the survey but has not requested resolution, the hospital must treat this as a grievance if the hospital would usually treat such a complaint as a grievance.

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	<ul style="list-style-type: none"> • Patient complaints that are considered grievances also include situations where a patient or a patient's representative telephones the hospital with a complaint regarding the patient's care or with an allegation of abuse or neglect, or failure of the hospital to comply with one or more CoPs, or other CMS requirements. Those post-hospital verbal communications regarding patient care that would routinely have been handled by staff present if the communication had occurred during the stay / visit are not required to be defined as a grievance. • All verbal or written complaints regarding abuse, neglect, patient harm, or hospital compliance with CMS requirements are considered grievances for the purposes of these requirements. • Whenever the patient or the patient's representative requests that his or her complaint be handled as a formal complaint or grievance or when the patient requests a response from the hospital, the complaint is considered a grievance and all the requirements apply. • Data collected regarding patient grievances, as well as other complaints that are not defined as grievances (as determined by the hospital), must be incorporated in the hospital's Quality Assessment and Performance Improvement (QAPI) Program. 		

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<p>15.01.04 Governing Body Responsibility for the Grievance Process. <i>[The hospital must establish a process for prompt resolution of patient grievances and must inform each patient whom to contact to file a grievance.]</i></p> <ul style="list-style-type: none"> • <i>The hospital's governing body must approve and be responsible for the effective operation of the grievance process and must review and resolve grievances, unless it delegates the responsibility in writing to a grievance committee.</i> <p>§482.13(a)(2)</p>	<p>The hospital's grievance process must be approved by the governing body.</p> <p>The hospital's governing body is responsible for the effective operation of the grievance process. This includes the hospital's compliance with all of the CMS grievance process requirements.</p> <p>The hospital's governing body must review and resolve grievances, unless it delegates this responsibility in writing to a grievance committee.</p> <p>A committee is more than one person. The committee membership should have adequate numbers of qualified members to review and resolve the grievances the hospital receives (this includes providing written responses) in a manner that complies with the CMS grievance process requirements.</p>	<p style="text-align: center;"><u>DOCUMENT REVIEW</u></p> <ol style="list-style-type: none"> 1. Review the hospital's protocol to determine that it meets the requirement. 2. Determine if the hospital's governing body approved the grievance process. 3. Is the governing body responsible for the operation of the grievance process, or has the governing body delegated the responsibility in writing to a grievance committee? 4. Determine how effectively the grievance process works. <ul style="list-style-type: none"> • Are patient's or the patient representative's concerns addressed in a timely manner? • Are patients informed of any resolution to their grievances? • Does the hospital apply what it learns from the grievance as part of its continuous quality improvement activities? 5. Is the grievance process reviewed and analyzed through the hospital's QAPI process or some other mechanisms that provides oversight of the grievance process? 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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<p>15.01.05 Timely Referrals. <i>[The hospital must establish a process for prompt resolution of patient grievances and must inform each patient whom to contact to file a grievance.]</i></p> <ul style="list-style-type: none"> • <i>The grievance process must include a mechanism for timely referral of patient concerns regarding quality of care or premature discharge to the appropriate Utilization and Quality Control, Quality Improvement Organization (QIO).</i> <p>§482.13(a)(2)</p>	<p>Quality Improvement Organizations (QIOs) are CMS contractors charged with reviewing the appropriateness and quality of care rendered to Medicare beneficiaries in the hospital setting. The QIOs are also tasked with reviewing utilization decisions. Part of this duty includes reviewing discontinuation of stay determinations based upon a beneficiary's request.</p> <p>The regulations state the functions of the QIOs in order to make Medicare beneficiaries aware of the fact that if they have a <u>complaint regarding quality of care</u>, disagree with a <u>coverage decision</u>, or they wish to appeal a premature discharge, they may contact the QIO to lodge a complaint.</p> <p>The hospital is required to have procedures for referring Medicare beneficiary concerns to the QIOs; additionally, CMS expects coordination between the grievance process and existing grievance referral procedures so that beneficiary complaints are handled timely and referred to the QIO at the beneficiary's request.</p> <p>This regulation requires coordination between the hospital's existing mechanisms for utilization review notice and referral to QIOs for Medicare beneficiary concerns (See <u>42 CFR Part §489.27</u>).</p> <p>This requirement does not mandate that the hospital automatically refer each Medicare beneficiary's grievance to the QIO; however, the hospital must</p>	<p style="text-align: center;"><u>DOCUMENT REVIEW AND INTERVIEW</u></p> <ol style="list-style-type: none"> 1. Review patient discharge materials. Is the hospital in compliance with 42 CFR §489.27? 2. Does the hospital grievance process include a mechanism for timely referral of Medicare patient concerns to the QIO? <ul style="list-style-type: none"> • What time frames are established? 3. Interview Medicare patients. Are they aware of their right to appeal premature discharge? 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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inform all beneficiaries of this right, and comply with his or her request if the beneficiary asks for QIO review.

Medicare patients have the right to appeal a premature discharge (see Interpretive Guidelines for [42 CFR §482.13\(a\)](#)). Pursuant to [42 CFR §412.42\(c\)\(3\)](#), a hospital must provide a hospital-issued notice of non-coverage (HINN) to any fee-for-service beneficiary that expresses dissatisfaction with an impending hospital discharge. Medicare Advantage (MA) organizations are required to provide enrollees with a notice of non-coverage, known as the Notice of Discharge and Medicare Appeal Rights (NODMAR), only when a beneficiary disagrees with the discharge decision or when the MA organization (or hospital, if the MA organization has delegated to it the authority to make the discharge decision) is not discharging the enrollee, but no longer intends to cover the inpatient stay.

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<p>15.01.06 <u>Grievance Process.</u> <i>At a minimum:</i></p> <ul style="list-style-type: none"> • <i>The hospital must establish a clearly explained procedure for the submission of a patient's written or verbal grievance to the hospital.</i> <p>§482.13(a)(2)(i)</p>	<p>The hospital's procedure for a patient or the patient's representative to submit written or verbal grievances must be clearly explained. The patient or patient's representative should be able to clearly understand the procedure.</p>	<p style="text-align: center;"><u>DOCUMENT REVIEW AND INTERVIEW</u></p> <p>Review the hospital's procedure.</p> <ol style="list-style-type: none"> 1. Review the information provided to patients that explains the hospital's grievance procedures. Does it clearly explain how the patient is to submit either a verbal or written grievance? 2. Interview patients or patient representatives. Does the patient, or (if he/she is incapacitated) his/her representative, know about the grievance process and how to submit a grievance? 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>
<p>15.01.07 <u>Grievance Process Response Time Frames.</u> <i>At a minimum:</i></p> <ul style="list-style-type: none"> • <i>The grievance process must specify time frames for review of the grievance and the provision of a response.</i> <p>§482.13(a)(2)(ii)</p>	<p>The hospital must review, investigate, and resolve each patient's grievance within a reasonable time frame. For example, grievances about situations that endanger the patient, such as neglect or abuse, should be reviewed immediately, given the seriousness of the allegations and the potential for harm to the patient. However, regardless of the nature of the grievance, the hospital should make sure that it is responding to the substance of each grievance while identifying, investigating, and resolving any deeper, systemic problems indicated by the grievance.</p> <p>Document when a grievance is so complicated that it may require an extensive investigation. We recognize that staff scheduling as well as fluctuations in the numbers and complexity of grievances can affect the</p>	<p style="text-align: center;"><u>DOCUMENT REVIEW</u></p> <p>Review hospital procedures. Determine:</p> <ol style="list-style-type: none"> 1. The procedure specifies time frames for responding to grievances. 2. The hospital responds to grievances within those timeframes. 3. What time frames are established to review and respond to patient grievances? Are these time frames clearly explained in the information provided to the patient that explains the hospital's grievance process? 4. On average, does the hospital provide a written response to most of its grievances 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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	<p>timeframes for the resolution of a grievance and the provision of a written response. On average, a time frame of 7 days for the provision of the response would be considered appropriate. We do not require that every grievance be resolved during the specified timeframe although most should be resolved. <u>42 CFR §482.13(a)(2)(iii)</u> specifies information the hospital must include in their response.</p> <p>If the grievance will not be resolved, or if the investigation is not or will not be completed within 7 days, the hospital should inform the patient or the patient's representative that the hospital is still working to resolve the grievance and that the hospital will follow-up with a written response within a stated number of days in accordance with the hospital's grievance policy. The hospital must attempt to resolve all grievances as soon as possible.</p>	<p>within the timeframe specified in its policy?</p>	
<p>15.01.08 <u>Patient Notification of the Grievance Process.</u> <i>At a minimum:</i></p> <ul style="list-style-type: none"> <i>In its resolution of the grievance, the hospital must provide the patient with a written notice of its decision that contains the name of the hospital contact person, the steps taken on behalf of the patient to investigate the grievance, the results of the</i> 	<p>In all cases, the hospital must provide a written response to the patient grievance. The written notice of the hospital's determination regarding the grievance must be communicated to the patient or the patient's representative in a language and manner the patient or the patient's legal representative understands.</p> <p>The hospital may use additional tools to resolve a grievance, such as meeting with the patient and his family. The regulatory requirements for the grievance process are minimum standards, and do not inhibit</p>	<p style="text-align: center;"><u>DOCUMENT REVIEW</u></p> <ol style="list-style-type: none"> Review the protocol for resolution of the patient's grievance to assure that it meets the requirement. Review a sampling of grievance response letters to determine whether they include all required components. Review the hospital's copies of written notices (responses) to patients. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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<p><i>grievance process, and the date of completion.</i></p> <p>§482.13(a)(2)(iii)</p>	<p>the use of additional effective approaches in handling patient grievances.</p> <p>However, in all cases the hospital must provide a written notice (response) to each patient’s grievance(s). The written response must contain the elements listed in this requirement.</p> <ol style="list-style-type: none"> 1. The hospital’s decision. 2. The name of the hospital contact person. 3. The steps taken on behalf of the patient to investigate the grievance. 4. The date of grievance investigation completion. <p>When a patient communicates a grievance to the hospital via email the hospital may provide its response via email pursuant to hospital policy. (Some hospitals have policies against communicating to patients over email.) If the patient requests a response via email, the hospital may respond via email. When the email response contains the information stated in this requirement, the email meets the requirement for a written response.</p> <ul style="list-style-type: none"> • The hospital must maintain evidence of its compliance with these requirements. <p>A grievance is considered resolved when the patient is satisfied with the actions taken on their behalf. There may be situations where the hospital has taken appropriate and reasonable actions on the patient's behalf in order to resolve the patient's grievance and the patient or the patient's representative remains</p>	<ul style="list-style-type: none"> • Are all patients provided a written notice? • Do the notices comply with the requirements? 	

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<p>15.01.09 Exercise of Patient Rights. The Patient's Rights document includes, at a minimum, that the patient has:</p> <p>A. <i>The right to participate in the development and implementation of his or her plan of care;</i></p> <p style="padding-left: 20px;">§482.13(b)(1)</p> <p>B. <i>Or his or her representative (as allowed under state law) has the right to make informed decisions regarding his or her care. The patient's rights include being</i></p>	<p>unsatisfied with the hospital's actions. In these situations, the hospital may consider the grievance closed for the purposes of these requirements. The hospital must maintain documentation of its efforts and demonstrate compliance with CMS requirements. In its written response, the hospital is not required to include statements that could be used in a legal action against the hospital, but the hospital must provide adequate information to address each item stated in this requirement.</p> <p>The hospital is not required to provide an exhaustive explanation of every action the hospital has taken to investigate the grievance, resolve the grievance, or other actions taken by the hospital.</p> <p>The hospital must ensure that the exercise of patient's rights requirements are met.</p> <p>The posted and promulgated Patient's Rights documents may include additional statements of rights. Any rights, which are mandated by state or local jurisdictions, not listed, are included.</p> <p>Other statements may derive from organizational philosophy or be influenced by hospital ownership or affiliation. Some facilities may wish to include "freedom to unhampered exercise of religious or spiritual practices, within constraint of law" or other similar statements.</p>	<p style="text-align: center;"><u>OBSERVATION</u></p> <ol style="list-style-type: none"> 1. Review the posted and promulgated statements of Patient's Rights to determine that they are congruent with these and any other known requirements. 2. Score any noncompliance with patient notification of their rights in this standard. Facility compliance with the rights listed will be scored individually in the standards following. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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	<p><i>informed of his or her health status, being involved in care planning and treatment, and being able to request or refuse treatment. This right must not be construed as a mechanism to demand the provision of treatment or services deemed medically unnecessary or inappropriate;</i></p> <p>§482.13(b)(2)</p>		
C.	<p><i>The right to formulate advance directives and to have hospital staff and practitioners who provide care in the hospital comply with these directives, in accordance with §489.100 of 42 CFR 489.100, §489.102 of 42 CFR 489.102, and §489.104 of 42 CFR 489.104;</i></p> <p>§482.13(b)(3)</p>		
D.	<p><i>The right to have a family member or representative of his or her choice and his or her own physician notified promptly of his or her admission to the hospital;</i></p> <p>§482.13(b)(4)</p>		
E.	<p><i>The right to personal privacy;</i></p>		

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§482.13(c)(1)			
F.	<i>The right to receive care in a safe setting;</i>		
	§482.13(c)(2)		
G.	<i>The right to be free from all forms of abuse or harassment;</i>		
	§482.13(c)(3)		
H.	<i>The right to the confidentiality of his or her clinical records;</i>		
	§482.13(d)(1)		
I.	<i>The right to access information contained in his or her clinical records within a reasonable time frame. The hospital must not frustrate the legitimate efforts of individuals to gain access to their own medical records and must actively seek to meet these requests as quickly as its record keeping system permits.</i>		
	§482.13(d)(2)		
J.	<i>The right to be free from restraints of any form that are not medically necessary or are used as a means of coercion, discipline, convenience, or retaliation by staff;</i>		

PATIENT RIGHTS & DISCHARGE PLANNING

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
§482.13(e)(1)			
K.	The right to be fully informed of and to consent or refuse to participate in any unusual, experimental or research project without compromising his/her access to services;		
L.	The right to know the professional status of any person providing his/her care / services;		
M.	The right to know the reasons for any proposed change in the Professional Staff responsible for his/her care;		
N.	The right to know the reasons for his/her transfer either within or outside the hospital;		
O.	The relationship(s) of the hospital to other persons or organizations participating in the provision of his/her care;		
P.	The right of access to the cost, itemized when possible, of services rendered within a reasonable period of time;		

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STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>Q. The right to be informed of the source of the hospital's reimbursement for his/her services, and of any limitations which may be placed upon his/her care;</p> <p>R. Informed of the right to have pain treated as effectively as possible.</p> <p>S. A hospital must have written policies and procedures regarding the visitation rights of patients, including those setting forth any clinically necessary or reasonable restriction or limitation that the hospital may need to place on such rights and the reason for the clinical restriction or limitation. A hospital must meet the following requirements:</p> <ul style="list-style-type: none"> • <i>Inform each patient (or support person, where appropriate) of his or her visitation rights, including any clinical restriction or limitation on such rights, when he or she is informed of his or her other rights under this section.</i> <p>§482.13(h)(1)</p>			

PATIENT RIGHTS & DISCHARGE PLANNING

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<ul style="list-style-type: none"> • <i>Inform each patient (or support person, where appropriate) of the right, subject to his or her consent, to receive the visitors whom he or she designates, including, but not limited to, a spouse, a domestic partner (including a same sex domestic partner), another family member, or a friend, and his or her right to withdraw or deny such consent at any time.</i> <p>§482.13(h)(2)</p>	<ul style="list-style-type: none"> • <i>Not restrict, limit or otherwise deny visitation privileges on the basis of race, color, national origin, religion, sex, gender identity, sexual orientation, or disability.</i> <p>§482.13(h)(3)</p>	<ul style="list-style-type: none"> • <i>Ensure that all visitors enjoy full and equal visitation privileges consistent with patient preferences.</i> <p>§482.13(h)(4)</p>	

PATIENT RIGHTS & DISCHARGE PLANNING

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
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T. The patient's family has the right of informed consent for donation of organs and tissues.

15.01.10 Participation in the Plan of Care.
The patient has the right to participate in the development and implementation of his or her plan of care.
 §482.13(b)(1)

This regulation requires the hospital to actively include the patient in the development, implementation and revision of his/her plan of care. It requires the hospital to plan the patient’s care, with patient participation, to meet the patient’s psychological and medical needs.

The patient’s (or patient’s representatives, as allowed by State law) right to participate in the development and implementation of his or her plan of care includes at a minimum, the right to:

- participate in the development and implementation of his/her inpatient treatment / care plan,
- outpatient treatment / care plan,
- participate in the development and implementation of his/her discharge plan, and participate in the development and
- implementation of his/her pain management plan.

Hospitals are expected to take reasonable steps to determine the patient’s wishes concerning designation of a representative to exercise the patient’s right to

OBSERVATION, DOCUMENT, CHART REVIEW, & INTERVIEW

1. Does the hospital have policies and procedures to involve the patient or the patient’s representative (as appropriate) in the development and implementation of his/her inpatient treatment / care plan, outpatient treatment / care plan, discharge plan, and pain management plan?
2. Review records and interview staff and patients, or patients’ representatives (as appropriate), to determine how the hospital involves the patient or the patient’s representative (as appropriate) in the development and implementation of his/her plan of care?
3. Does the hospital’s policy provide for determining when a patient has a representative who may exercise the patient’s right to participate in developing and implementing his/her plan of care, and who that representative is, consistent with this guidance and State law?

- 1 = Compliant
- 2 = Not Compliant

This standard is not met as evidenced by:

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STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
	<p>participate in the development and implementation of the patient’s plan of care. Unless prohibited by applicable State law:</p> <ul style="list-style-type: none"> • When a patient who is not incapacitated has designated, either orally to hospital staff or in writing, another individual to be his/her representative, the hospital must involve the designated representative in the development and implementation of the patient’s plan of care. The explicit designation of a representative by the patient takes precedence over any non-designated relationship and continues throughout the patient’s inpatient stay or outpatient visit, unless expressly withdrawn, either orally or in writing, by the patient. • In the case of a patient who is incapacitated, when an individual presents the hospital with an advance directive, medical power of attorney or similar document executed by the patient and designating an individual to make medical decisions for the patient when incapacitated, the hospital, when presented with the document, must involve the designated representative in the development and implementation of the patient’s plan of care. The explicit designation of a representative takes precedence over any non-designated relationship and continues throughout the patient’s inpatient stay or outpatient visit, unless the patient ceases to be incapacitated and expressly withdraws the designation, either orally or in writing. 	<ol style="list-style-type: none"> 4. Is there evidence that the patient or the patient’s representative was included or proactively involved in the development and implementation of the patient’s plan of care? 5. Were revisions in the plan of care explained to the patient and/or the patient’s representative (when appropriate)? 	

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STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
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- When a patient is incapacitated or otherwise unable to communicate his or her wishes, there is no written advance directive on file or presented, and an individual asserts that he or she is the patient’s spouse, domestic partner (whether or not formally established and including a same-sex domestic partner), parent (including someone who has stood in loco parentis for the patient who is a minor child) or other family member and thus is the patient’s representative, the hospital is expected to accept this assertion, without demanding supporting documentation, and must involve the individual as the patient’s representative in the development and implementation of the patient’s plan of care, unless:

- More than one individual claims to be the patient’s representative. In such cases, it would be appropriate for the hospital to ask each individual for documentation supporting his/her claim to be the patient’s representative. The hospital should make its determination of who is the patient’s representative based upon the hospital’s determination of who the patient would most want to make decisions on his/her behalf.

Examples of documentation a hospital might consider could include, but are not limited to, the following:

- proof of a legally recognized marriage, domestic partnership, or

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	<p>civil union;</p> <ul style="list-style-type: none"> • proof of a joint household; • proof of shared or co-mingled finances; and any other documentation the hospital considers evidence of a special relationship that indicates familiarity with the patient’s preferences concerning medical treatment; <ul style="list-style-type: none"> • Treating the individual as the patient’s representative without requesting supporting documentation would result in the hospital violating State law. State laws, including State regulations, may specify a procedure for determining who may be considered to be the incapacitated patient’s representative, and may specify when documentation is or is not required; or • The hospital has reasonable cause to believe that the individual is falsely claiming to be the patient’s spouse, domestic partner, parent or other family member. <p>Hospitals are expected to adopt policies and procedures that facilitate expeditious and non-discriminatory resolution of disputes about whether an individual is the patient’s representative, given the critical role of the representative in exercising the patient’s rights.</p>		

PATIENT RIGHTS & DISCHARGE PLANNING

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>15.01.11 Participation in Decision Making. <i>The patient or his or her representative (as allowed under State law) has the right to make informed decisions regarding his or her care.</i></p> <p><i>The patient's rights include being informed of his or her health status, being involved in care planning and treatment, and being able to request or refuse treatment.</i></p> <p><i>This right must not be construed as a mechanism to demand the provision of treatment or services deemed medically unnecessary or inappropriate. §482.13(b)(2)</i></p>	<p>A refusal by the hospital of an individual's request to be treated as the patient's representative, based on one of the above-specified familial relationships, must be documented in the patient's medical record, along with the specific basis for the refusal.</p> <p>The right to make informed decisions means that the patient or patient's representative is given the information needed in order to make "informed" decisions regarding his/her care.</p> <p><u>Patient's Representative</u> A patient may wish to delegate his/her right to make informed decisions to another person (as allowed under State law).</p> <p>Hospitals are expected to take reasonable steps to determine the patient's wishes concerning designation of a representative. Unless prohibited by applicable State law:</p> <ul style="list-style-type: none"> • When a patient who is not incapacitated has designated, either orally to hospital staff or in writing, another individual to be his/her representative, the hospital must provide the designated individual with the information required to make an informed decision about the patient's care. • The hospital must also seek the written consent of the patient's representative when informed consent is required for a care decision. The 	<p><u>DOCUMENT, CHART REVIEW, INTERVIEW, & OBSERVATION</u></p> <p>1. Is there a hospital policy addressing the patient's or the patient's representative (as appropriate) right to make informed decisions? Does it articulate how the hospital assures patients' ability to exercise this right?</p> <ul style="list-style-type: none"> • Does the hospital's policy provide for determining when a patient has a representative who may exercise the patient's right to make informed decisions, and who that representative is, consistent with this guidance and State law? • Is there a hospital policy addressing the patient's right to have information on his/her medical status, diagnosis, and prognosis? Does it articulate the hospital's process for assuring that patients have this information? • Is there a hospital policy addressing how the patient will be involved in his/her 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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	<p>explicit designation of a representative by the patient takes precedence over any non-designated relationship and continues throughout the patient's inpatient stay or outpatient visit, unless expressly withdrawn, either orally or in writing, by the patient.</p> <ul style="list-style-type: none"> • In the case of a patient who is incapacitated, when an individual presents the hospital with an advance directive, medical power of attorney or similar document executed by the patient and designating an individual to make medical decisions for the patient when incapacitated, the hospital must, when presented with the document, provide the designated individual the information required to make informed decisions about the patient's care. <p>The hospital must also seek the consent of the designated individual when informed consent is required for a care decision. The explicit designation of a representative takes precedence over any non-designated relationship and continues throughout the patient's inpatient stay or outpatient visit, unless the patient ceases to be incapacitated and expressly withdraws the designation, either orally or in writing.</p> <ul style="list-style-type: none"> • When a patient is incapacitated or otherwise unable to communicate his or her wishes, there is no written advance directive on file or presented, and an individual asserts that he or she is the 	<p>care planning and treatment?</p> <ol style="list-style-type: none"> 2. Is there evidence that the hospital routinely complies with its policies? <ul style="list-style-type: none"> • Evidence would be obtained through review of medical records, interviewing current patients and/or interviewing hospital personnel to determine their understanding of the hospital's informed decision-making policies and how they are implemented. • Review of evidence would be designed to determine whether patients / patient representatives are provided adequate information about the patient's medical status, diagnosis, and prognosis, and then allowed to make informed decisions about their care planning and treatment. 3. Review records and interview staff and patients or patients' representatives (as appropriate) to determine how the hospital assures the patient or the patient's representative (as appropriate) ability to exercise the right to make informed decisions. <p>ASSESSING REQUIRED DISCLOSURES Physician Ownership:</p> <ol style="list-style-type: none"> 1. If the hospital indicates that it is physician- 	

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	<p>patient’s spouse, domestic partner (whether or not formally established and including a same-sex domestic partner), parent (including someone who has stood in loco parentis for the patient who is a minor child), or other family member and thus is the patient’s representative, the hospital is expected to accept this assertion, without demanding supporting documentation, and provide the individual the information required to make informed decisions about the patient’s care.</p> <p>The hospital must also seek the consent of the individual when informed consent is required for a care decision. Hospitals are expected to treat the individual as the patient’s representative unless:</p> <ul style="list-style-type: none"> • More than one individual claims to be the patient’s representative. In such cases, it would be appropriate for the hospital to ask each individual for documentation supporting his/her claim to be the patient’s representative. The hospital should make its determination of who is the patient’s representative based upon the hospital’s determination of who the patient would most want to make decisions on his/her behalf. Examples of documentation a hospital might consider could include, but are not limited to, the following: proof of a legally recognized marriage, domestic partnership, or civil union; proof of a joint household; proof of shared or co-mingled finances; and any other documentation the hospital considers 	<p>owned but is exempt under §489.20(v) from the disclosure requirement of §489.20(u)(2), ask to see the signed attestation that it does not have any referring physicians with an ownership/investment interest or whose immediate family member has an ownership/investment interest in the hospital. (As with any other on-the-spot correction of a deficiency during a survey, creation of an attestation at the time of a survey does not mean that there was no deficiency and that the hospital would not be cited.)</p> <p>2. If the hospital is physician-owned but not exempt from the physician ownership disclosure requirements:</p> <ul style="list-style-type: none"> • Verify that appropriate policies and procedures are in place to assure that necessary written notices are provided to all patients at the beginning of an inpatient or outpatient stay. • Review the notice the hospital issues to each patient to verify that it discloses, in a manner reasonably designed to be understood by all patients, that the hospital meets the Federal definition of “physician-owned,” that a list of owners and investors who are physicians or immediate family members of physicians is available upon request, and that such a 	

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	<p>evidence of a special relationship that indicates familiarity with the patient’s preferences concerning medical treatment;</p> <ul style="list-style-type: none"> • Treating the individual as the patient’s representative without requesting supporting documentation would result in the hospital violating State law. State laws, including State regulations, may specify a procedure for determining who may be considered to be the incapacitated patient’s representative, and may specify when documentation is or is not required; or • The hospital has reasonable cause to believe that the individual is falsely claiming to be the patient’s spouse, domestic partner, parent or other family member. <p>Hospitals are expected to adopt policies and procedures that facilitate expeditious and non-discriminatory resolution of disputes about whether an individual is the patient’s representative, given the critical role of the representative in exercising the patient’s rights.</p> <p>A refusal by the hospital of an individual’s request to be treated as the patient’s representative, based on one of the above-specified familial relationships, must be documented in the patient’s medical record, along with the specific basis for the refusal.</p>	<p>list is provided to the patient at the time the request is made by or on behalf of the patient.</p> <ul style="list-style-type: none"> • Determine through staff interviews, observation, and a review of policies and procedures whether the hospital furnishes its list of physician owners and investors at the time a patient or patient’s representative requests it. • Determine through staff interviews and review of policies, procedures, and staff records whether a physician-owned hospital’s medical staff membership and admitting privileging requirements include a requirement that, as a condition of continued membership or admitting privileges, physician owners who refer patients to the hospital agree to provide written disclosure of their own or any immediate family member’s ownership or investment interest to all patients at the time of the referral to the hospital. <p><u>MD/DO 24/7 On-Site Presence</u></p> <ol style="list-style-type: none"> 1. Determine through interviews, observation, and medical record review whether an MD/DO is present in the hospital, at each campus or satellite location providing 	

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	<p><u>Informed Decisions</u> The right to make informed decisions regarding care presumes that the patient has been provided information about his/her health status, diagnosis, and prognosis.</p> <p>Furthermore, it includes the patient's participation in the development of their plan of care, including providing consent to, or refusal of, medical or surgical interventions, and in planning for care after discharge from the hospital. The patient or the patient's representative should receive adequate information, provided in a manner that the patient or the patient's representative can understand, to assure that the patient can effectively exercise the right to make informed decisions.</p> <p>Hospitals must establish processes to assure that each patient or the patient's representative is given information on the patient's health status, diagnosis, and prognosis.</p> <p>Giving informed consent to a treatment or a surgical procedure is one type of informed decision that a patient or patient's representative may need to make regarding the patient's plan of care. Hospitals must utilize an informed consent process that assures patients or their representatives are given the information and disclosures needed to make an informed decision about whether to consent to a procedure, intervention, or type of care that requires consent. See the guidelines for 42 CFR §482.51(b)(2)</p>	<p>inpatient services 24 hours/day, seven days/week.</p> <p>2. For each required location where an MD/DO is not present:</p> <ul style="list-style-type: none"> • Verify that the appropriate policies and procedures are in place to assure written notices that an MD/DO is not present at all times are provided at the beginning of an inpatient stay or outpatient stay to all inpatients and to all outpatients receiving observation services, surgery or another procedure requiring anesthesia. • Verify that there is signed acknowledgment by patients of such disclosure, obtained by the hospital prior to the patient's admission or before applicable outpatient services were provided. • Ask a sample of inpatients and affected outpatients whether they were provided notice about an MD/DO not being present at all times in the hospital. • Verify that the hospital's emergency department has signage with the appropriate disclosure information. • Review the notice the hospital issues to verify that it indicates how the hospital 	

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	<p>pertaining to surgical services informed consent and the guidelines for 42 CFR §482.24(c)(2)(v) pertaining to medical records for further detail.</p> <p>Informed decisions related to care planning also extend to discharge planning for the patient's post-acute care. See the guidelines at 42 CFR §482.43(c) pertaining to discharge planning for discussion of pertinent requirements.</p> <p>Hospitals must also establish policies and procedures that assure a patient's right to request or refuse treatment. Such policies should indicate how the patient's request will be addressed. However, hospitals are under no obligation to fulfill a patient's request for a treatment or service that the responsible practitioner has deemed medically unnecessary or even inappropriate.</p> <p>REQUIRED HOSPITAL DISCLOSURES TO PATIENTS: <u>Physician Ownership</u> In addition, there are certain provisions of the Medicare provider agreement rules concerning disclosures that certain hospitals are required to make which are enforced under 42 CFR §482.13(b)(2):</p> <ul style="list-style-type: none"> • 42 CFR §489.3 defines a “physician-owned hospital” as any participating hospital in which a physician or physicians have an ownership or investment interest, except for those satisfying exception criteria found at 42 CFR §411.356(a) or (b). Surveyors are not required to make an independent determination regarding whether a 	<p>will meet the medical needs of any patient who develops an emergency medical condition at a time when no physician is present at that hospital, including any remote location or satellite.</p>	

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	<p>hospital meets the Medicare definition of “physician-owned,” but they must ask whether the hospital is physician-owned.</p> <ul style="list-style-type: none"> • <u>42 CFR §489.20(u)(1)</u> requires that all physician-owned hospitals provide written notice to their patients at the beginning of each patient’s hospital inpatient stay or outpatient visit stating that the hospital is physician-owned, in order to assist the patient in making an informed decision about his/her care, in accordance with requirements of <u>§42 CFR §482.13(b)(2)</u>. • A planned inpatient stay or outpatient visit which is subject to the notice requirement begins with the provision of a package of information regarding scheduled preadmission testing and registration for a planned hospital admission for inpatient care or for an outpatient service subject to notice. An unplanned inpatient stay or outpatient visit subject to the notice requirement begins at the earliest point at which the patient presents to the hospital. • The notice must disclose, in a manner reasonably designed to be understood by all patients, that the hospital is physician-owned and that the list of physician owners or investors is available upon request. If the patient (or someone on behalf of the patient) requests this list, the hospital must provide it at the time of the request. 		

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- However, the notice requirement does not apply to any physician-owned hospital that does not have at least one referring physician (as defined at §411.351) who has an ownership or investment interest in the hospital or who has an immediate family member who has an ownership or investment interest in the hospital. In such cases, the hospital must sign an attestation statement that it has no referring physician with an ownership or investment interest or whose immediate family member has an ownership or investment interest in the hospital. The hospital must maintain this attestation in its records.
- 42 CFR 489.20(u)2) provides that physician-owned hospitals must require each physician owner who is a member of the hospital’s medical staff to agree, as a condition of obtaining/retaining medical staff membership or admitting privileges, to disclose in writing to all patients they refer to the hospital their ownership or investment interest in that hospital or that of any immediate family member. The hospital must require that this disclosure be made at the time of the referral and the requirement should be reflected in the hospital’s policies and procedures governing privileges for physician owners.
- The hospital may exempt from this disclosure requirement any physician owner who does not refer any patients to the hospital.

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	<ul style="list-style-type: none"> • 42 CFR 489.12 permits CMS to refuse to enter into a provider agreement with a physician-owned hospital applicant that does not have procedures in place to notify patients of physician ownership in the hospital as required under §489.20(u). • 42 CFR 489.53(c) permits CMS to terminate a provider agreement with a physician-owned hospital if the hospital fails to comply with the requirements at §489.20(u). <p><u>MD/DO 24/7 On-Site Presence</u></p> <p>42 CFR 489.20(w) mandates that if there is no doctor of medicine or osteopathy present in the hospital 24 hours per day, seven days per week, the hospital must provide written notice of this to all inpatients at the beginning of a planned or unplanned inpatient stay, and to outpatients for certain types of planned or unplanned outpatient visits. The purpose of this requirement is to assist the patient in making an informed decision about his/her care, in accordance with 42 CFR 482.13(b)(2).</p> <p>Hospitals that have an MD/DO on-site 24/7 (including residents who are MDs or DOs) do not need to issue any disclosure notice about emergency services capability.</p> <ul style="list-style-type: none"> • The notice must be provided to all inpatients and to those outpatients who are under observation or who are having surgery or any other procedure using anesthesia. 		

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	<ul style="list-style-type: none"> • The notice must be provided at the beginning of the planned or unplanned inpatient stay, or outpatient visit subject to notice. • A planned inpatient stay or outpatient visit which is subject to the notice requirement begins with the provision of a package of information regarding scheduled preadmission testing and registration for a planned hospital admission for inpatient care or for an outpatient service subject to notice. • An unplanned inpatient stay or outpatient visit which is subject to the notice requirement begins at the earliest point at which the patient presents to the hospital. • Individual notices are not required in the hospital's dedicated emergency department (DED) (as that term is defined in 42 CFR 489.24(b)), but the DED must post a notice conspicuously, in a place or places likely to be noticed by all individuals entering the DED. • The posted notice must state that the hospital does not have a doctor of medicine or a doctor of osteopathy present in the hospital 24 hours per day, 7 days per week, and must indicate how the hospital will meet the medical needs of any patient with an emergency medical condition, as defined in 42 CFR 489.24(b) [the EMTALA definition], at a time when there is no doctor of 		

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	<p>medicine or doctor of osteopathy present in the hospital.</p> <ul style="list-style-type: none"> • If an emergency department patient is determined to require admission, then the individual notice requirements of 42 CFR 489.20(w) would apply to that patient. • Before admitting an inpatient or providing outpatient services requiring notice, the hospital must obtain a signed acknowledgement from the patient stating that he/she understands that a doctor of medicine or doctor of osteopathy may not be present at all times services are furnished to him/her. • In the event of an unplanned surgery or inpatient admission to treat an emergency medical condition, it may in some cases be necessary in the interest of the patient's safety to proceed with treatment before the required notice can be given and acknowledgement can be obtained. In such circumstances, the hospital must provide notice and obtain acknowledgement as soon as possible after the patient's stay or visit begins. • For a hospital that participates in Medicare with multiple campuses providing inpatient services (e.g., a main provider campus and separate satellite, remote, and/or provider-based locations) under one CMS Certification Number, a separate determination is made for each campus 		

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<p>15.01.12 Advance Directives. <i>The patient has the right to formulate advance directives and to have hospital staff and practitioners who provide care in the hospital comply with these directives, in accordance with:</i></p> <ul style="list-style-type: none"> • §489.100 of 42 CFR 489.100 	<p>or satellite location with inpatient services as to whether the disclosure notice is required. For example, if a hospital has a main campus and a satellite location and a physician is present 24/7 on the main campus but not at the satellite location, the hospital is required to provide the disclosure notice only at the satellite location. No notice is required for patients presenting to the main provider campus in this case.</p> <ul style="list-style-type: none"> • In this same example, if the hospital also has a provider-based, off-campus ambulatory (i.e., same-day) surgery department, no notice is required at that off-campus surgery site, since the hospital’s main campus does have an MD/DO present 24/7. <p>42 CFR 489.53(c) permits CMS to terminate a provider agreement with a hospital if the hospital fails to comply with the requirements at §489.20(w) when it does not have an MD or DO on-site 24/ 7.</p> <p>An advance directive is defined at §489.100 as “a written instruction, such as a living will or durable power of attorney for health care, recognized under State law (whether statutory or as recognized by the courts of the State), relating to the provision of health care when the individual is incapacitated.”</p>	<p style="text-align: center;"><u>DOCUMENT REVIEW</u></p> <ol style="list-style-type: none"> 1. Review the hospital’s advance directive notice. <ul style="list-style-type: none"> • Does it advise inpatients or applicable outpatients, or their representatives, of the patient’s right to formulate an advance directive and to have hospital 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

PATIENT RIGHTS & DISCHARGE PLANNING

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<p>(“Definition”),</p> <ul style="list-style-type: none"> • §489.102 of 42 CFR 489.102 (“Requirements for providers”) and • §489.104 of 42 CFR 489.104. (“Effective dates”). <p>§482.13(b)(3)</p>	<p>The patient (inpatient or outpatient) has the right to formulate advance directives, and to have hospital staff implement and comply with their advance directive. The regulation at 42 CFR §489.102 specifies the rights of a patient (as permitted by State law) to make medical care decisions, including the right to accept or refuse medical or surgical treatment and the right to formulate, at the individual’s option, advance directives.</p> <p>In the advance directive, the patient may provide guidance as to his/her wishes concerning provision of care in certain situations; alternatively the patient may delegate decision-making authority to another individual, as permitted by State law. (In addition, the patient may use the advance directive to designate a support person, as that term is used in §482.13(h), for purposes of exercising the patient’s visitation rights.)</p> <p>When a patient who is incapacitated has executed an advance directive designating a particular individual to make medical decisions for him/her when incapacitated, the hospital must, when presented with the document, provide the designated individual the information required to make informed decisions about the patient’s care. (See also the requirements at §482.13(b) (2).)</p> <p>The hospital must also seek the consent of the patient’s representative when informed consent is required for a care decision. The explicit designation of a representative in the patient’s advance directive</p>	<p>staff comply with the advance directive (in accordance with State law)?</p> <ul style="list-style-type: none"> • Does it include a clear, precise and valid statement of limitation if the hospital cannot implement an advance directive on the basis of conscience? <p>2. What mechanism does the hospital have in place to allow patients to formulate an advance directive or to update their current advance directive? Is there evidence that the hospital is promoting and protecting each patient’s right to formulate an advance directive?</p> <p>3. Determine to what extent the hospital educates its staff regarding advance directives.</p> <p>4. Determine to what extent the hospital provides education for the patient population (inpatient and outpatient) regarding one’s rights under State law to formulate advance directives.</p> <p style="text-align: center;"><u>CHART REVIEW</u></p> <p>Review the records of a sample of patients for evidence of hospital compliance with advance directive notice requirements.</p> <p>1. Does every inpatient or applicable outpatient record contain documentation that notice of the hospital’s advance directives policy was</p>	

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	<p>takes precedence over any non-designated relationship and continues throughout the patient’s inpatient stay or, as applicable, outpatient visit, unless the patient ceases to be incapacitated and expressly withdraws the designation, either orally or in writing. §489.102 also requires the hospital to:</p> <ul style="list-style-type: none"> • Provide written notice of its policies regarding the implementation of patients’ rights to make decisions concerning medical care, such as the right to formulate advance directives. If an individual is incapacitated or otherwise unable to communicate, the hospital may provide the advance directive information required under §489.102 to the individual’s “family or surrogate in the same manner that it issues other materials about policies and procedures to the family of the incapacitated individual or to a surrogate or other concerned persons in accordance with State law. (§489.102(e)) The guidance concerning the regulation at §482.13(a)(1) governing notice to the patient or the patient’s representative of the patient’s rights applies to the required provision of notice concerning the hospital’s advance directive policies. <p>Although both inpatients and outpatients have the same rights under §482.13(a)(1), §489.102(b)(1) requires that notice of the hospital’s advance directive policy be provided at the time an individual is admitted as an inpatient. However, in view of the broader notice requirements at §482.13(a)(1), the hospital</p>	<p>provided at the time of admission or registration?</p> <ol style="list-style-type: none"> 2. Is there documentation of whether or not each patient has an advance directive? 3. For those patients who have reported an advance directive, has a copy of the patient’s advance directive been placed in the medical record? 4. Determine to what extent the hospital complies, as permitted under State law, with patient advance directives that delegate decisions about the patient’s care to a designated individual. <p style="text-align: center;"><u>INTERVIEW</u></p> <p>Interview staff to determine their knowledge of the advance directives of the patients in their care.</p>	

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	<p>should also provide the advance directive notice to outpatients (or their representatives) who are in the emergency department, who are in an observation status, or who are undergoing same-day surgery. The notice should be presented at the time of registration. Notice is not required for other outpatients, given that they are unlikely to become incapacitated.</p> <ul style="list-style-type: none"> • The notice must include a clear and precise statement of limitation if the hospital cannot implement an advance directive on the basis of conscience. At a minimum, a statement of limitation should: <ul style="list-style-type: none"> ○ Clarify any differences between institution-wide conscience objections and those that may be raised by individual physicians or other practitioners; ○ Identify the State legal authority permitting such an objection; and ○ Describe the range of medical conditions or procedures affected by the conscience objection. <p>It should be noted that this provision allowing for certain conscience objections to implementing an advance directive is narrowly focused on the directive's content related to medical conditions or procedures.</p>		

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	<p>This provision would not allow a hospital or individual physician or practitioner to refuse to honor those portions of an advance directive that designate an individual as the patient’s representative and/or support person, given that such designation does not concern a medical condition or procedure. Issuance of the written notice of the hospital’s advance directive policies to the patient or the patient’s representative must be documented in the patient’s medical record.</p> <ul style="list-style-type: none"> • Document in a prominent part of the patient’s medical record whether or not the patient has executed an advance directive; • Not condition the provision of care or otherwise discriminate against an individual based on whether or not the individual has executed an advance directive; • Ensure compliance with requirements of State law concerning advance directives and inform individuals that complaints concerning the advance directive requirements may be filed with the State survey and certification agency; • Provide for the education of staff concerning its policies and procedures on advance directives. The right to formulate advance directives includes 		

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the right to formulate a psychiatric advance directive (as allowed by State law); and

- Provide community education regarding advance directives and the hospital must document its efforts.

PSYCHIATRIC ADVANCE DIRECTIVE

A psychiatric advance directive is akin to a traditional advance directive for health care. This type of advance directive might be prepared by an individual who is concerned that at some time he or she may be subject to involuntary psychiatric commitment or treatment. The psychiatric advance directive may cover a range of subjects, and may name another person who is authorized to make decisions for the individual if he or she is determined to be legally incompetent to make his/her own choices. It may also provide the patient's instructions about hospitalization, alternatives to hospitalization, the use of medications, types of therapies, and the patient's wishes concerning restraint or seclusion. The patient may designate who should be notified upon his/her admission to the hospital, as well as who should not be permitted to visit him or her. State laws regarding the use of psychiatric advance directives vary.

In accordance with State law, a psychiatric advance directive should be accorded the same respect and consideration that a traditional advance directive for health care is given. Hospitals should carefully

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coordinate how the choices of a patient balance with the rights of other patients, staff, and individuals in the event that a dangerous situation arises.

However, even if State law has not explicitly spoken to the use of psychiatric advance directives, consideration should be given to them inasmuch as this regulation also supports the patient’s right to participate in the development and implementation of his or her plan of care.

When the patient is, for whatever reason, unable to communicate his/her wishes, the preferences expressed in the psychiatric advance directive can give critical insight to the Doctor of Medicine / Doctor of Osteopathic Medicine, nurses, and other staff as they develop a plan of care and treatment for the patient.

15.01.13 Not Applicable.

15.01.14 Admission Notification.

The patient has the right to have a family member or representative of his or her choice and his or her own physician notified promptly of his or her admission to the hospital.
§482.13(b)(4)

Identifying Who Is to Be Notified

For every inpatient admission, the hospital must ask the patient whether the hospital should notify a family member or representative about the admission.

If the patient requests such notice and identifies the family member or representative to be notified, the hospital must provide such notice promptly to the designated individual. The explicit designation of a family member or representative by the patient takes

CHART REVIEW, DOCUMENT REVIEW, AND INTERVIEW

1. Determine if the hospital has policies that address notification of a patient’s family or representative and physician when the patient is admitted as an inpatient.
2. Ask the hospital who is responsible for providing the required notice.
 - Interview person(s) responsible for

- 1 = Compliant
- 2 = Not Compliant

This standard is not met as evidenced by:

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	<p>precedence over any non-designated relationship.</p> <p>The hospital must also ask the patient whether the hospital should notify his/her own physician. In the case of scheduled admissions, the patient's own physician likely is already aware of the admission. However, if the patient requests notice to and identifies the physician, the hospital must provide such notice promptly to the designated physician, regardless of whether the admission was scheduled in advance or emergent.</p> <p>When a patient is incapacitated or otherwise unable to communicate and to identify a family member or representative to be notified, the hospital must make reasonable efforts to identify and promptly notify a family member or patient's representative. If an individual who has accompanied the patient to the hospital, or who comes to or contacts the hospital after the patient has been admitted, asserts that he or she is the patient's spouse, domestic partner (whether or not formally established and including a same-sex domestic partner), parent (including someone who has stood in loco parentis for the patient who is a minor child), or other family member, the hospital is expected to accept this assertion, without demanding supporting documentation, and provide this individual information about the patient's admission, unless:</p> <ul style="list-style-type: none"> • More than one individual claims to be the patient's family member or representative. In such cases it would not be inappropriate for the hospital to ask each individual for documentation 	<p>providing the notice to determine how they identify the persons to be notified and the means of notification.</p> <ul style="list-style-type: none"> • What do they do in the case of an incapacitated person to identify a family member / representative and the patient's physician? <p>3. Review a sample of inpatient medical records.</p> <ul style="list-style-type: none"> • Do the medical records provide evidence that the patient was asked about notifying a family member / representative and his/her physician? • Is there a record of when and how notice was provided? Was notice provided promptly? • Is there a record of the patient declining to have notice provided to a family member / representative and his/her physician? • Is there documentation of whether the patient was incapacitated at the time of admission, and if so, what steps were taken to identify a family member / representative and the patient's physician? 	

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	<p>supporting his/her claim to be the patient’s family member or representative. The hospital should make its determination of who is the patient’s representative based upon the hospital’s determination of who the patient would most want to make decisions on his/her behalf.</p> <p>Examples of documentation a hospital might consider could include, but are not limited to, the following: proof of a legally recognized marriage, domestic partnership, or civil union; proof of a joint household; proof of shared or co-mingled finances; and any other documentation the hospital considers evidence of a special relationship that indicates familiarity with the patient’s preferences concerning medical treatment;</p> <ul style="list-style-type: none"> • Treating the individual as the patient’s family member or representative without requesting supporting documentation would result in the hospital violating State law. State laws, including State regulations, may specify a procedure for determining who may be considered to be the incapacitated patient’s family member or representative, and may specify when documentation is or is not required; or • The hospital has reasonable cause to believe that the individual is falsely claiming to be the patient’s spouse, domestic partner, parent or other family member. 		

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Hospitals are expected to adopt policies and procedures that facilitate expeditious and non-discriminatory resolution of disputes about whether an individual should be notified as the patient’s family member or representative, given the critical role of the representative in exercising the patient’s rights. Hospitals may also choose to provide notice to more than one family member.

When a patient is incapacitated and the hospital is able through reasonable efforts to identify the patient’s own physician – e.g., through information obtained from a family member, or from review of prior admissions or outpatient encounters, or through access to the patient’s records in a regional system of electronic patient medical records in which the hospital participates – the hospital must promptly notify the patient’s physician of the admission.

Prompt Notice

The hospital must provide the required notice promptly. “**Promptly**” means as soon as possible after the physician’s or other qualified practitioner’s order to admit the patient has been given.

Notice may be given orally in person, by telephone, by e-mail or other electronic means, or by other methods that achieve prompt notification.

It is not acceptable for the hospital to send a letter by regular mail.

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Medical Record Documentation

The hospital must document that the patient, unless incapacitated, was asked no later than the time of admission whether he or she wanted a family member / representative notified, the date, time and method of notification when the patient requested such, or whether the patient declined to have notice provided.

If the patient was incapacitated at the time of admission, the medical record must indicate what steps were taken to identify and provide notice to a family member / representative and to the patient’s physician.

15.01.15 Not Applicable.

15.01.16 Privacy & Safety: Personal Privacy.

The patient has the right to personal privacy.

§482.13(c)
§482.13(c)(1)

The underlying principle of this requirement is the patient’s basic right to respect, dignity, and comfort while in the hospital.

Physical Privacy

“The right to personal privacy” includes at a minimum, that patients have physical privacy to the extent consistent with their care needs during personal hygiene activities (e.g., toileting, bathing, dressing), during medical / nursing treatments, and when requested as appropriate.

People not involved in the care of the patient should

OBSERVATION, DOCUMENT REVIEW, AND INTERVIEW

1. Conduct observations/interview patients or their representatives to determine if patients are provided reasonable privacy during examinations or treatments, personal hygiene activities and discussions about their health status/care and other appropriate situations?
2. Review hospital policy and interview staff concerning their understanding of the use of patient information in the facility directory. Does the policy address the opportunity for

- 1 = Compliant
 2 = Not Compliant

This standard is not met as evidenced by:

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	<p>not be present without his/her consent while he/she is being examined or treated, nor should video or other electronic monitoring / recording methods be used while he/she is being examined without his/her consent. If an individual requires assistance during toileting, bathing, and other personal hygiene activities, staff should assist, giving utmost attention to the individual's need for privacy.</p> <p>Privacy should be afforded when the Doctor of Medicine / Doctor of Osteopathic Medicine or other staff visits the patient to discuss clinical care issues or conduct any examination or treatment.</p> <p>However, audio / video monitoring (does not include recording) of patients in medical-surgical or intensive-care type units would not be considered violating the patient's privacy, as long as there exists a clinical need, the patient/patient's representative is aware of the monitoring and the monitors or speakers are located so that the monitor screens are not readily visible or where speakers are not readily audible to visitors or the public.</p> <ul style="list-style-type: none"> • Video recording of patients undergoing medical treatment requires the consent of the patient or his/her representative. <p>A patient's right to privacy may also be limited in situations where a person must be continuously observed to ensure his or her safety, such as when a patient is simultaneously restrained and in seclusion to manage violent or self-destructive behavior or</p>	<p>the patient or patient's representative to restrict or prohibit use of patient information in emergent and non-emergent situations?</p> <ol style="list-style-type: none"> 3. Review hospital policy and conduct observations/interview staff to determine if reasonable safeguards are used to reduce incidental disclosures of patient information. 4. If audio and/or visual monitoring is utilized in the medical/surgical or ICU setting, conduct observations to determine that monitor screens and/or speakers are not readily visible or audible to visitors or the public. 5. Is the hospital promoting and protecting each patient's right to privacy? <ul style="list-style-type: none"> • Are patient names posted in public view? • Is patient information posted in public view? 	

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when the patient is under suicide precautions. In most situations, security cameras in non-patient care areas such as stairwells, public waiting areas, outdoor areas, entrances, etc., are not generally affected by this requirements.

Protecting Patient Personal Information

The right to personal privacy also includes limiting the release or disclosure of patient information.

Patient information includes, but is not limited to, the patient’s presence or location in the hospital; demographic information the hospital has collected on the patient, such as name, age, address, income; or information on the patient’s medical condition. Such patient information may not be disclosed without informing the patient or the patient’s representative in advance of the disclosure and providing the patient or the patient’s representative an opportunity to agree, prohibit, or restrict the disclosure. Below is a summary of privacy issues that surveyors might encounter in hospital settings, and the related privacy requirements.

Permitted Disclosures

A hospital is permitted to use and disclose patient information, without the patient’s authorization, in order to provide patient care and perform related administrative functions, such as payment and other hospital operations.

- Payment operations include hospital activities to obtain payment or be reimbursed for the

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	<p>provision of health care to an individual.</p> <ul style="list-style-type: none"> • Hospital operations are administrative, financial, legal, and quality improvement activities of a hospital that are necessary to conduct business and to support the core functions of treatment and payment. These activities include, but are not limited to: <ol style="list-style-type: none"> (1) quality assessment and improvement activities, (2) case management and care coordination; (3) competency assurance activities, conducting or arranging for medical reviews, audits, or legal services, including fraud and abuse detection and compliance programs; (4) business planning, development, management, and administration and certain hospital-specific fundraising activities. <p>Hospitals must develop and implement policies and procedures that restrict access to and use of patient information based on the specific roles of the members of their workforce.</p> <ul style="list-style-type: none"> • These policies and procedures must identify the persons, or classes of persons, in the workforce who need access to protected health information to carry out their duties and the categories of protected health information to which access is needed. 		

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- One example of a permitted disclosure is a Facility Directory. It is common practice in many hospitals to maintain a directory of patient contact information.

- The hospital must inform the patient, or the patient’s representative, of the individual information that may be included in a directory and the persons to whom such information may be disclosed. The patient, or the patient’s representative, must be given the opportunity to restrict or prohibit any or all uses and disclosures. The hospital may rely on a patient’s/representative’s individual’s informal permission to list in its facility directory the patient’s name, general condition, religious affiliation, and location in the provider’s facility. The provider may then disclose the patient’s condition and location in the facility to anyone asking for the patient by name, and also may disclose religious affiliation to clergy. If the opportunity to prohibit or restrict uses and disclosures cannot be provided due to the patient’s incapacity or emergency treatment circumstance, and there is no patient representative available, the hospital may disclose patient information for the facility’s directory if such disclosure is in the patient’s best interest.

The hospital must provide the patient or the

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	<p>patient’s representative an opportunity to prohibit or restrict disclosure as soon as it becomes practicable to do so. The hospital may use patient information to notify, or assist in the notification of, a family member, a personal representative of the patient, or another person responsible for the care of the patient of their location, general condition, or death.</p> <ul style="list-style-type: none"> • The hospital must have procedures in place, in accordance with State law, to provide appropriate information to patient families or others in those situations where the patient is unable to make their wishes known. <p><u>Incidental Uses and Disclosures May be Acceptable</u> An incidental use or disclosure is a secondary use or disclosure of patient information that cannot reasonably be prevented, is limited in nature, and that occurs as a result of another use or disclosure that is permitted. Many customary health care communications and practices play an important role in ensuring the prompt delivery of effective care. Due to the nature of these communications and practices, as well as of the hospital environment, the potential exists for a patient’s information to be disclosed incidentally.</p> <p>For example, a hospital visitor may overhear a health care professional’s confidential conversation with another health care professional or the patient, or</p>		

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	<p>may glimpse a patient’s information on a sign-in sheet or nursing station whiteboard. The regulation protecting patient privacy does not impede these customary and essential communications and practices and, thus, a hospital is not required to eliminate all risk of incidental use or disclosure secondary to a permitted use or disclosure, so long as the hospital takes reasonable safeguards and discloses only the minimum amount of personally identifiable information necessary.</p> <p>For example, hospitals may:</p> <ul style="list-style-type: none"> • Use patient care signs (e.g. “falls risk” or “diabetic diet”) displayed at the bedside or outside a patient room; • Display patient names on the outside of patient charts; or • Use “whiteboards” that list the patients present on a unit, in an operating room suite, etc. <p>Hospitals are expected to review their practices and determine what steps are reasonable to safeguard patient information while not impeding the delivery of safe patient care or incurring undue administrative or financial burden as a result of implementing privacy safeguards.</p> <p>Examples of reasonable safeguards could include, but are not limited to:</p> <ul style="list-style-type: none"> • Requesting that waiting customers stand a few feet back from a counter used for patient 		

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registration;

- Use of dividers or curtains in areas where patient and physician or other hospital staff communications routinely occur;
- Health care staff speaking quietly when discussing a patient’s condition or treatment in a semi-private room;
- Utilizing passwords and other security measures on computers maintaining personally identifiable health information; or
- Limiting access to areas where white boards or x-ray light boards are in use, or posting the board on a wall not readily visible to the public, or limiting the information placed on the board.

15.01.17 Privacy & Safety: Safe Setting.

The patient has the right to receive care in a safe setting.

§482.13(c)(2)

The intention of this requirement is to specify that each patient receives care in an environment that a reasonable person would consider to be safe. For example, hospital staff should follow current standards of practice for patient environmental safety, infection control, and security.

The hospital must protect vulnerable patients, including newborns and children.

DOCUMENT REVIEW

1. Review and analyze patient and staff incident and accident reports to identify any incidents or patterns of incidents concerning a safe environment. Expand your review if you suspect a problem with safe environment in the hospitals.
2. Review QAPI, safety, infection control and security (or the committee that deals with

- 1 = Compliant
- 2 = Not Compliant

This standard is not met as evidenced by:

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	<p>Additionally, this standard is intended to provide protection for the patient’s emotional health and safety as well as his/her physical safety. Respect, dignity and comfort would be components of an emotionally safe environment.</p>	<p>security issues) committee minutes and reports to determine if the hospital is identifying problems, evaluating those problems and taking steps to ensure a safe patient environment.</p> <p>3. Review policy and procedures on what the facility does to curtail unwanted visitors or contaminated materials.</p> <p style="text-align: center;"><u>OBSERVATION</u></p> <p>Observe the environment where care and treatment are provided.</p> <p>1. Observe and interview staff at units where infants and children are inpatients. Are appropriate security protections (such as alarms, arm banding systems, etc.) in place? Are they functioning?</p> <p>2. Access the hospital’s security efforts to protect vulnerable patients including newborns and children. Is the hospital providing appropriate security to protect patients? Are appropriate security mechanisms in place and being followed to protect patients?</p>	

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<p>15.01.18 <u>Privacy & Safety: Free From Abuse.</u> <i>The patient has the right to be free from all forms of abuse or harassment.</i></p> <p>§482.13(c)(3)</p>	<p>The intent of this requirement is to prohibit all forms of abuse, neglect (as a form of abuse) and harassment whether from staff, other patients or visitors.</p> <p>The hospital must ensure that patients are free from all forms of abuse, neglect, or harassment. The hospital must have mechanisms / methods in place that ensure patients are free of all forms of abuse, neglect, or harassment.</p> <p>Abuse is defined as the willful infliction of injury, unreasonable confinement, intimidation, or punishment, with resulting physical harm, pain, or mental anguish. This includes staff neglect or indifference to infliction of injury or intimidation of one patient by another.</p> <p>Neglect, for the purpose of this requirement, is considered a form of abuse and is defined as the failure to provide goods and services necessary to avoid physical harm, mental anguish, or mental illness.</p> <p>The following components are suggested as necessary for effective abuse protection:</p> <ul style="list-style-type: none"> • Prevent. A critical part of this system is that there are adequate staff on duty, especially during the evening, nighttime, weekends and holiday shifts, to take care of the individual needs of all patients. (See information regarding meaning of adequate at those requirements that require the hospital to have adequate staff. Adequate staff would include that the hospital ensures that there are the 	<p style="text-align: center;"><u>DOCUMENT REVIEW, INTERVIEW, AND FILE REVIEW</u></p> <p>Examine the extent to which the hospital has a system in place to protect patients from abuse, neglect and harassment of all forms, whether from staff, other patients, visitors or other persons. In particular, determine the extent to which the hospital addresses the following issues.</p> <ol style="list-style-type: none"> 1. Are staffing levels across all shifts sufficient to care for individual patient’s needs? 2. Does the hospital have a written procedure for investigating allegations of abuse and neglect including methods to protect patients from abuse during investigations of allegations? 3. How does the hospital substantiate allegations of abuse and neglect? 4. Do incidents of substantiated abuse and neglect result in appropriate action? 5. Has the hospital implemented an abuse protection program? Does it comply with Federal, State and local laws and regulations? Is it effective? 6. Are appropriate agencies notified in accordance with State and Federal laws regarding incidents of substantiated abuse and neglect? 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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	<p>number and types of qualified, trained, and experienced staff at the hospital and available to meet the care needs of every patient.)</p> <ul style="list-style-type: none"> • Screen. Persons with a record of abuse or neglect should not be hired or retained as employees. • Identify. The hospital creates and maintains a proactive approach to identify events and occurrences that may constitute or contribute to abuse and neglect. • Train. The hospital, during its orientation program, and through an ongoing training program, provides all employees with information regarding abuse and neglect, and related reporting requirements, including prevention, intervention, and detection. • Protect. The hospital must protect patients from abuse during investigation of any allegations of abuse or neglect or harassment. • Investigate. The hospital ensures, in a timely and thorough manner, objective investigation of all allegations of abuse, neglect or mistreatment. • Report / Respond. The hospital must assure that any incidents of abuse, neglect or harassment are reported and analyzed, and the appropriate corrective, remedial or disciplinary action occurs, in accordance with applicable local, State, or 	<p>7. Can staff identify various forms of abuse or neglect?</p> <p>8. Do staff members know what to do if they witness abuse and neglect?</p> <p>9. What evidence is there that allegations of abuse and neglect are thoroughly investigated?</p> <p>10. Does the hospital conduct criminal background checks as allowed by State law for all potential new hires?</p> <p>11. Is there evidence the hospital employs people with a history of abuse, neglect or harassment?</p> <p>12. Request a copy of the State rules relative to the identification and reporting of abuse (including sexual assault) and neglect.</p> <p>13. Review education documents. Verify:</p> <ul style="list-style-type: none"> • Staff education is provided on the prevention, identification, and reporting of suspected abuse (including sexual assault) or neglect. <p>14. Review personnel files of clinical personnel. Verify:</p> <ul style="list-style-type: none"> • Staff has received training on the 	

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	<p>Federal law.</p> <p>As a result of the implementation of this system, changes to the hospital's policies and procedures should be made accordingly.</p>	<p>prevention, identification, and reporting of suspected abuse (including sexual assault) and neglect within the past 24 months.</p>	
15.01.19 <u>Not Applicable.</u>			
15.01.20 <u>Not Applicable.</u>			
<p>15.01.21 <u>Confidentiality of Patient Records.</u> <i>The patient has the right to the confidentiality of his or her clinical records.</i></p> <p>§482.13(d) §482.13(d)(1)</p>	<p>The hospital must ensure the confidentiality of patient records requirements are met.</p> <p>The right to confidentiality of the patient's medical record means the hospital must safeguard the contents of the medical record, whether it is in paper or electronic format, or a combination of the two, from unauthorized disclosure.</p> <p>Confidentiality applies wherever the record or portions thereof are stored, including but not limited to central records, patient care locations, radiology, laboratories, record storage areas, data systems, etc.</p> <p>A hospital is permitted to disclose patient information, without a patient's authorization, in order to provide patient care and perform related administrative</p>	<p style="text-align: center;"><u>OBSERVATION</u></p> <ol style="list-style-type: none"> 1. Verify that the hospital has policies and procedures addressing the protecting of information in patients' medical record from unauthorized disclosures. 2. Observe locations where medical records are stored to determine whether appropriate safeguards are in place to protect medical record information. 3. Interview staff to determine their understanding of and compliance with the hospital's policies and procedures for protecting medical record information. 4. Observe care units. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
	<p>functions, such as payment and other hospital operations.</p> <ul style="list-style-type: none"> • Payment operations include hospital activities to obtain payment or be reimbursed for the provision of health care to an individual. • Hospital operations are administrative, financial, legal, and quality improvement activities of a hospital that are necessary to conduct business and to support the core functions of treatment and payment. These activities include, but are not limited to: quality assessment and improvement activities, case management and care coordination; competency assurance activities, conducting or arranging for medical reviews, audits, or legal services, including fraud and abuse detection and compliance programs; business planning, development, management, and administration and certain hospital-specific fundraising activities. <p>The hospital must develop policies and procedures that reasonably limit disclosures of information contained in the patient’s medical record to the minimum necessary, even when the disclosure is for treatment or payment purposes, or as otherwise required by State or Federal law. When the minimum necessary standard is applied, a hospital may not disclose the entire medical record for a particular purpose, unless it can specifically justify that the whole record is the amount reasonably needed for the purpose.</p>	<ul style="list-style-type: none"> • Is patient information posted where it can be viewed by visitors or other non-hospital staff? • Are medical records accessible to people not involved with the patient’s care? • Is it likely that unauthorized persons could read or remove the clinical record? • Are patient clinical information / records available and accessible at the bedside or in the patient’s room where people not involved in the patient’s care could likely read the information? 	

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<p>15.01.22 Access to Medical Records. <i>The patient has the right to access information contained in his or her clinical records within a reasonable time frame.</i></p> <p><i>The hospital must not frustrate the legitimate efforts of individuals to gain access to their own medical records and must actively seek to meet these requests as quickly as its record keeping system permits.</i></p> <p>§482.13(d)(2)</p>	<p>A hospital may make an authorized disclosure of information from the medical record electronically, and may also share an electronic medical record system with other health care facilities, physicians and practitioners, so long as the system is designed and operated with safeguards that ensure that only authorized disclosures are made.</p> <p>The hospital must obtain the patient’s, or the patient’s representative’s, written authorization for any disclosure of information in the medical record when the disclosure is not for treatment, payment or health care operations.</p> <p>The requirements of the Department of Health and Human Services with regard to the confidentiality rights of individuals are set forth in the Privacy Rule at <u>42 CFR §164.500</u> et seq., pursuant to §264 of the Health Insurance Portability and Accountability Act of 1996.” The regulation at <u>42 CFR §164.524</u> specifies that patients should be allowed to inspect and obtain a copy of health information about them that is held by providers; and that providers may not withhold information except under limited circumstances.</p> <p>These circumstances include:</p> <ul style="list-style-type: none"> • Psychotherapy notes; • A correctional institution or a health care provider acting at the direction of a correctional institution may deny an inmate’s request for access, if 	<p style="text-align: center;"><u>DOCUMENT REVIEW</u></p> <ol style="list-style-type: none"> 1. Does the hospital promote and protect the patient’s right to access information contained in his/her clinical record? 2. Does the hospital have a procedure for providing records to patients within a reasonable time frame? 3. Does the hospital’s system frustrate the legitimate efforts of individuals to gain access to their own medical record? 4. Does the procedure include the method to identify what documents were not provided and the reason? 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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	<p>providing such access would jeopardize the health or security of the individual, other inmates, or officers or employees of the correctional institution;</p> <ul style="list-style-type: none"> • The information is about another person (other than a health care provider) and the hospital determines that the patient inspection is reasonably likely to cause sufficient harm to that person to warrant withholding; • A licensed health care professional has determined that the access requested is reasonably likely to endanger the life or physical safety of the individual or another person; • The information contains data obtained under a promise of confidentiality (from someone other than a health care provider), and inspection could reasonably reveal the source; • The information is collected in the course of research that includes treatment and the research is in progress, provided that the individual has agreed to the denial of access and the provider informs the individual that his or her right of access will be reinstated when the research is completed; • The protected health information is subject to the Clinical Laboratory Improvements Amendments of 1988, <u>42 CFR §263a</u>, to the extent that providing 		

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the requested access would be prohibited by law;

- The protected health information is exempt from the Clinical Laboratory Improvements Amendments of 1988, pursuant to 42 CFR §493.3(a)(2);
- The information is compiled in reasonable anticipation of, or for use in, a civil, criminal or administrative action or proceeding; and
- The request is made by an individual’s personal representative (as allowed under state law) and a licensed health care professional has determined that access is reasonably likely to cause substantial harm to the individual or another person.

In general, each patient should be able to see and obtain a copy of his/her records. Record holders may not deny access except to a portion of the record that meets criteria specified above. In these cases, the record holder may decide to withhold portions of the record; however, to the extent possible, the patient should be given as much information as possible. If the patient is incompetent, the patient record should be made available to his or her representative (as allowed under State law). Upon the patient’s request, other designated individuals may access the patient’s records.

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	<p>The patient has the right to easily access his/her medical records.</p> <ul style="list-style-type: none"> • Reasonable cost-based fees may be imposed only to cover the cost of copying, postage, and/or preparing an explanation or summary of patient health information, as outlined in <u>42 CFR §164.524(c)</u>. • The cost of duplicating a patient’s record must not create a barrier to the individual’s receiving his or her medical record. 		
15.01.23 <u>Not Applicable.</u>			
15.01.24 <u>Not Applicable.</u>			
<p>15.01.25 <u>Visitation Rights.</u> <i>A hospital must have written policies and procedures regarding the visitation rights of patients, including those setting forth any clinically necessary or reasonable restriction or limitation that the hospital may need to place on such rights and the reasons for the clinical restriction or limitation.</i></p> <p>§482.13(h)</p>	<p>Visitation plays an important role in the care of hospital patients.</p> <ul style="list-style-type: none"> • An article published in 2004 in the Journal of the American Medical Association (Berwick, D.M., and Kotagal, M.: Restricted visiting hours in ICUs: time to change. JAMA. 2004; Vol. 292, pp. 736-737) discusses the health and safety benefits of open visitation for patients, families, and intensive care unit (ICU) staff and debunks some of the myths surrounding the issue (physiologic stress for the patient; barriers to provision of care; exhaustion of family and friends). The article ultimately concluded that available evidence indicates that hazards and problems regarding open visitation 	<p style="text-align: center;"><u>DOCUMENT REVIEW AND INTERVIEW</u></p> <ol style="list-style-type: none"> 1. Verify that the hospital has written policies and procedures that address the right of patients to have visitors. 2. Review the policy to determine if there are limitations or restrictions on visitation. If there are, does the policy explain the clinical rationale for the restrictions or limitations? Is the rationale clear and reasonably related to clinical concerns? 3. Is there documentation of how the hospital identifies and trains staff who play a role in 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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	<p>are generally overstated and manageable, and that such visitation policies do not harm patients but rather may help them by providing a support system and shaping a more familiar environment as they engender trust in families, creating a better working relationship between hospital staff and family members.</p> <p>Hospitals that unnecessarily restrict patient visitation often miss an opportunity to gain valuable patient information from those who may know the patient best with respect to the patient’s medical history, conditions, medications, and allergies, particularly if the patient has difficulties with recall or articulation, or is totally unable to recall or articulate this vital personal information. Many times visitors who may know the patient best act as an intermediary for the patient, helping to communicate the patient’s needs to hospital staff.</p> <p>Although visitation policies are generally considered to relate to visitors of inpatients, visitors also play a role for outpatients who wish to have a support person present during their outpatient visit. For example, a same-day surgery patient may wish to have a support person present during the pre-operative patient preparation or post-operative recovery. Or an outpatient clinic patient may wish to have a support person present during his or her examination by a physician.</p>	<p>facilitating or controlling access of visitors to patients?</p> <p>4. Are hospital staff aware of the visitation policies and procedures? Can staff on a given unit correctly describe the hospital’s visitation policies for that unit?</p>	

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	<p>Accordingly, hospital visitation policies must address both the inpatient and outpatient settings.</p> <p>Hospitals are required to develop and implement written policies and procedures that address the patient’s right to have visitors. If the hospital’s policy establishes restrictions or limitations on visitation, such restrictions / limitations must be clinically necessary or reasonable.</p> <ul style="list-style-type: none"> • Furthermore, the hospital’s policy must include the reasons for any restrictions / limitations. The right of a patient to have visitors may be limited or restricted when visitation would interfere with the care of the patient and/or the care of other patients. • The regulation permits hospitals some flexibility, so that health care professionals may exercise their best clinical judgment when determining when visitation is, and is not, appropriate. Best clinical judgment takes into account all aspects of patient health and safety, including the benefits of visitation on a patient’s care as well as potential negative impacts that visitors may have on other patients in the hospital. <p>Broad examples of circumstances reasonably related to the care of the patient and/or the care of other patients that could provide a basis for a hospital to impose restrictions or limitations on visitors might include (but are not limited to) when:</p> <ul style="list-style-type: none"> • there may be infection control issues; 		

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- visitation may interfere with the care of other patients;
- the hospital is aware that there is an existing court order restricting contact;
- visitors engage in disruptive, threatening, or violent behavior of any kind;
- the patient or patient’s roommate(s) need rest or privacy; and
- in the case of an inpatient substance abuse treatment program, there are protocols limiting visitation; and
- the patient is undergoing care interventions. However, while there may be valid reasons for limiting visitation during a care intervention, we encourage hospitals to try to accommodate the needs of any patient who requests that at least one visitor be allowed to remain in the room to provide support and comfort at such times.

It may also be reasonable to limit the number of visitors for any one patient during a specific period of time, as well as to establish minimum age requirements for child visitors. However, when a hospital adopts policies that limit or restrict patients’ visitation rights, the burden of proof is upon the hospital to demonstrate that the visitation restriction is reasonably necessary to provide safe care.

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Hospitals are expected to provide a clear explanation in their written policy of the clinical rationale for any visitation restrictions or limitations reflected in that policy.

Hospitals are not required, however, to delineate each specific clinical reason for policies limiting or restricting visitation, given that it is not possible to anticipate every instance that may give rise to a clinically appropriate rationale for a restriction or limitation.

If visitation policies differ by type of unit, e.g., separate policies for intensive care units, or for newborn nurseries, the hospital policy must address the clinical rationale for this differentiation explicitly.

The hospital's policies and procedures are expected to address how hospital staff who play a role in facilitating or controlling visitor access to patients will be trained to assure appropriate implementation of the visitation policies and procedures and avoidance of unnecessary restrictions or limitations on patients' visitation rights.

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<p>15.01.26 Patient Visitation Rights. <i>A hospital must have written policies and procedures regarding the visitation rights of patients, including those setting forth any clinically necessary or reasonable restriction or limitation that the hospital may need to place on such rights and the reason for the clinical restriction or limitation.</i></p> <p><i>A hospital must meet the following requirements:</i></p> <p>(1) <i>Inform each patient (or support person, where appropriate) of his or her visitation rights, including any clinical restriction or limitation on such rights, when he or she is informed of his or her other rights under this section.</i></p> <p>(2) <i>Inform each patient (or support person, where appropriate) of the right, subject to his or her consent, to receive the visitors whom he or she designates, including, but not limited to, a spouse, a domestic partner (including a same sex domestic partner), another family member, or a friend, and his or her right to withdraw or deny such consent at any time.</i></p> <p>§482.13(h)(1) §482.13(h)(2)</p>	<p>Hospitals are required to inform each patient (or the patient’s support person, where appropriate) of his/her visitation rights.</p> <p>A patient’s “support person” does not necessarily have to be the same person as the patient’s representative who is legally responsible for making medical decisions on the patient’s behalf.</p> <p>A support person could be a family member, friend, or other individual who supports the patient during the course of the hospital stay. Not only may the support person visit the patient, but he or she may also exercise a patient’s visitation rights on behalf of the patient with respect to other visitors when the patient is unable to do so.</p> <p>Hospitals must accept a patient’s designation, orally or in writing, of an individual as the patient’s support person.</p> <p>When a patient is incapacitated or otherwise unable to communicate his or her wishes and an individual provides an advance directive designating an individual as the patient’s support person (it is not necessary for the document to use this exact term), the hospital must accept this designation, provide the required notice of the patient’s visitation rights, and allow the individual to exercise the patient’s visitation rights on the patient’s behalf.</p> <p>When a patient is incapacitated or otherwise unable</p>	<p><u>INTERVIEW, CHART REVIEW & DOCUMENT REVIEW</u></p> <ol style="list-style-type: none"> 1. Determine whether the hospital’s visitation policies and procedures require providing notice of the patient’s visitation rights to each patient or, if appropriate, to a patient’s support person and/or, as applicable, the patient’s representative. 2. Review the hospital’s standard notice of visitation rights. Does it clearly explain the: <ul style="list-style-type: none"> • hospital’s visitation policy, including any limitations or restrictions, such as visiting hours, numbers of visitors, unit-specific restrictions, etc., and the clinical rationale for such limitations or restrictions? • right of the patient to have designated visitors, including but not limited to, a spouse, a domestic partner (including a same-sex domestic partner), another family member, or a friend, and the right to withdraw or deny consent to visitation? 3. Review a sample of medical records to determine if there is documentation that the required notice was provided. 4. Ask the hospital to identify how the required notice is provided. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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	<p>to communicate his or her wishes, there is no advance directive designating a representative on file, and no one has presented an advance directive designating himself or herself as the patient’s representative, but an individual asserts that he or she, as the patient’s spouse, domestic partner (including a same-sex domestic partner), parent or other family member, friend, or otherwise, is the patient’s support person, the hospital is expected to accept this assertion, without demanding supporting documentation, provide the required notice of the patient’s visitation rights, and allow the individual to exercise the patient’s visitation rights on the patient’s behalf.</p> <p>However, if more than one individual claims to be the patient’s support person, it would not be inappropriate for the hospital to ask each individual for documentation supporting his/her claim to be the patient’s support person.</p> <ul style="list-style-type: none"> • Hospitals are expected to adopt policies and procedures that facilitate expeditious and non-discriminatory resolution of disputes about whether an individual is the patient’s support person, given the critical role of the support person in exercising the patient’s visitation rights. • A refusal by the hospital of an individual’s request to be treated as the patient’s support person with respect to visitation rights must be documented in the patient’s medical record, along with the specific basis for the refusal. 	<ul style="list-style-type: none"> • Ask staff responsible for providing the notice how they accomplish this. • Ask the staff if they are familiar with the concept of a patient’s support person and what it means. <p>5. Ask a sample of current hospital patients or patients’ support persons (where appropriate) whether they were provided notice of their right to have visitors.</p> <ul style="list-style-type: none"> • Ask if they were able to have visitors when they wanted to. If not, verify whether the restriction/limitation on visitors was addressed in the hospital’s visitation policies and notice, and does not violate the regulations at §482.13(h)(3)&(4). (See interpretive guidelines for the latter provisions.) <p>6. Ask a sample of current hospital patients or patients’ support persons (where appropriate) whether the hospital did not limit some or all visitors, contrary to the patient’s wishes.</p>	

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	<p>Consistent with the patients’ rights notice requirements under the regulation at §482.13(a)(1), the required notice of the patient’s visitation rights must be provided, whenever possible, before the hospital provides or stops care.</p> <p>The notice to the patient, or to the patient’s support person, where appropriate, must be in writing.</p> <p>If the patient also has a representative who is different from the support person, the representative must also be provided information on the patient’s visitation rights, in addition to the support person, if applicable.</p> <p>In the event that a patient has both a representative and a support person who are not the same individual, and they disagree on who should be allowed to visit the patient, the hospital must defer to the decisions of the patient’s representative. As the individual responsible for making decisions on the patient’s behalf, the patient’s representative has the authority to exercise a patient’s right to designate and deny visitors just as the patient would if he or she were capable of doing so.</p> <p>The designation of, and exercise of authority by, the patient’s representative is governed by State law, including statutory and case law. Many State courts have addressed the concept of substituted judgment, whereby the patient’s representative is expected to make medical decisions based on the patient’s values and interests, rather than the representative’s own</p>		

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	<p>values and interests. State courts have also developed a body of closely related law around the matter of a representative acting in the patient’s best interest. Such case law regarding substituted judgment and best interest may be a resource for hospitals on how to address such conflict situations as they establish visitation policies and procedures. Hospitals may also choose to utilize their own social work and pastoral counseling resources to resolve such conflicts to assure the patient’s well-being.</p> <p>The required visitation rights notice must address any clinically necessary or reasonable limitations or restrictions imposed by hospital policy on visitation rights, providing the clinical reasons for such limitations/restrictions, including how they are aimed at protecting the health and safety of all patients. The information must be sufficiently detailed to allow a patient (or the patient’s support person) to determine what the visitation hours are and what restrictions, if any, apply to that patient’s visitation rights.</p> <p>The notice must also inform the patient (or the patient’s support person, where appropriate) of the patient’s right to:</p> <ul style="list-style-type: none"> • Consent to receive visitors he or she has designated, either orally or in writing, including but not limited to, a spouse, a domestic partner (including a same-sex domestic partner), another family member, or a friend; • Receive the visitors he or she has designated, 		

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including but not limited to, a spouse, a domestic partner (including a same-sex domestic partner), another family member, or a friend; and

- Withdraw or deny his/her consent to receive specific visitors, either orally or in writing.

The medical record must contain documentation that the required notice was provided to the patient or, if appropriate, the patient's support person.

15.01.27 Not Applicable.

15.01.28 Visitation Rights – Discrimination.

A hospital must have written policies and procedures regarding the visitation rights of patients, including those setting forth any clinically necessary or reasonable restriction or limitation that the hospital may need to place on such rights and the reason for the clinical restriction or limitation.

A hospital must meet the following requirements:

- (3) *Not restrict, limit or otherwise deny visitation privileges on the basis of race, color, national origin,*

The hospital's visitation policies and procedures may not use the race, color, national origin, religion, sex, gender identity, sexual orientation, or disability of either the patient (or the patient's support person or representative, where appropriate) or the patient's visitors (including individuals seeking to visit the patient) as a basis for limiting, restricting, or otherwise denying visitation privileges.

The hospital's policies and procedures must ensure that all visitors (including individuals seeking to visit the patient) enjoy full and equal visitation privileges, consistent with the preferences the patient (or, where appropriate, the patient's support person) has expressed concerning visitors. In other words, it is permissible for the patient (or the patient's support

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1. Review the hospital's visitation policies and procedures to determine whether they restrict, limit, or otherwise deny visitation to individuals on a prohibited basis.
2. Interview patients to determine if rights regarding visitation have been explained and enforced.
3. Ask the hospital how it educates staff to assure that visitation policies are implemented in a non-discriminatory manner.
4. Ask hospital staff who plays a role in

- 1 = Compliant
 2 = Not Compliant

This standard is not met as evidenced by:

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<p><i>religion, sex, gender identity, sexual orientation, or disability.</i></p> <p>(4) <i>Ensure that all visitors enjoy full and equal visitation privileges consistent with patient preferences.</i></p> <p>§482.13(h)(3) §482.13(h)(4)</p>	<p>person, where appropriate) to limit the visiting privileges of his/her visitors, including providing for more limited visiting privileges for some visitors than those for others.</p> <p>But it is not permissible for the hospital, on its own, to differentiate among visitors without any clinically necessary or reasonable basis. This includes visitors designated by the patient who have characteristics not addressed specifically in §482.13(h)(3), when those characteristics do not reasonably relate to a clinically reasonable basis for limiting or denying visitation. For example, it would not be appropriate to prohibit a designated visitor based on that individual’s style of dress, unless there was a clinically reasonable basis for doing so.</p> <p>The hospital is responsible for ensuring that hospital staff treat all individuals seeking to visit patients equally, consistent with the preferences of the patient (or, where appropriate, the patient’s support person) and do not use the race, color, national origin, religion, sex, gender identity, sexual orientation, or disability of either the patient (or the patient’s support person or representative, where appropriate) or the patient’s visitors (including individuals seeking to visit the patient) as a basis for limiting, restricting, or otherwise denying visitation privileges.</p> <p>Hospitals are expected to educate all staff who play a role in facilitating or controlling visitors on the hospital’s visitation policies and procedures, and are</p>	<p>facilitating or controlling visitors to discuss their understanding of the circumstances under which visitors may be subject to restrictions/limitations.</p> <ul style="list-style-type: none"> • Are the restrictions/limitations appropriately based on the hospital’s clinically-based policies? <p>5. Ask hospital patients (or patients’ support persons, where appropriate) whether the hospital has restricted or limited visitors against their wishes.</p> <ul style="list-style-type: none"> • If yes, verify whether the restriction/limitation on visitors was addressed in the hospital’s visitation policies and in the patient notice, and whether it was appropriately based on a clinical rationale rather than impermissible discrimination. 	

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	responsible for ensuring that staff implement the hospital's policies correctly. Hospitals are urged to develop culturally competent training programs designed to address the range of patients served by the hospital.		
15.01.29 <u>Not Applicable.</u>			
<p>15.02.00 Restraint or Seclusion. <i>All patients have the right to be free from physical or mental abuse, and corporal punishment.</i></p> <p><i>All patients have the right to be free from restraint or seclusion, of any form, imposed as a means of coercion, discipline, convenience, or retaliation by staff.</i></p> <p><i>Restraint or seclusion may only be imposed to ensure the immediate physical safety of the patient, a staff member, or others and must be discontinued at the earliest possible time.</i></p> <p>§482.13(e)</p>	<p>The intent of this standard is to identify patients' basic rights, ensure patient safety, and eliminate the inappropriate use of restraint or seclusion.</p> <p>Each patient has the right to receive care in a safe setting. The safety of the patient, staff, or others is the basis for initiating and discontinuing the use of restraint or seclusion.</p> <p>Each patient has the right to be free from all forms of abuse and corporal punishment. Each patient has the right to be free from restraint or seclusion, of any form, imposed as a means of coercion, discipline, convenience, or retaliation by staff.</p> <p>Restraint or seclusion may not be used unless the use of restraint or seclusion is necessary to ensure the immediate physical safety of the patient, a staff member, or others.</p>	<p style="text-align: center;"><u>DOCUMENT REVIEW, CHART REVIEW, INTERVIEW, & OBSERVATION</u></p> <ol style="list-style-type: none"> 1. Review hospital restraint and seclusion policies and procedures to determine if they address, at a minimum: <ul style="list-style-type: none"> • Who has the authority to discontinue the use of restraint or seclusion (based on State law and hospital policies); and • Circumstances under which restraint or seclusion should be discontinued. (Also see <u>§482.13(e)(3)</u>). 2. Review a sample of medical records of patients for whom restraints were used to manage non-violent, non-self-destructive behavior, as well as a sample of medical records of patients for whom restraint or seclusion was used to manage violent or self- 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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	<p>The use of restraint or seclusion must be discontinued as soon as possible based on an individualized patient assessment and re-evaluation.</p> <p>A violation of any of these patients' rights constitutes an inappropriate use of restraint or seclusion and would be subject to a condition level deficiency.</p> <p>The patient protections contained in this standard apply to <u>all hospital patients</u> when the use of restraint or seclusion becomes necessary, regardless of patient location. The requirements contained in this standard are not specific to any treatment setting within the hospital. They are not targeted only to patients on psychiatric units or those with behavioral/mental health care needs. Instead, the requirements are specific to the patient behavior that the restraint or seclusion intervention is being used to address. In summary, these restraint and seclusion regulations apply to:</p> <ul style="list-style-type: none"> • All hospitals (acute care, long-term care, psychiatric, children's, and cancer); • All locations within the hospital (including medical / surgical units, critical care units, forensic units, emergency department, psychiatric units, etc.); and • All hospital patients, regardless of age, who are restrained or secluded (including both inpatients and outpatients). 	<p>destructive behavior;</p> <ol style="list-style-type: none"> 3. Include in the review patients who are currently in restraint or seclusion, as well as those who have been in restraint or seclusion during their hospital stay (include both violent or self-destructive patients as well as non-violent, non-self-destructive patients). 4. What evidence is there that hospital staff identified the reason for the restraint or seclusion, and determined that other less restrictive measures would not be effective before applying the restraint? 5. Interview staff who work directly with patients to determine their understanding of the restraint and seclusion policies. If any patients are currently in restraint or seclusion, ascertain the rationale for use and when the patient was last monitored and assessed. 6. Is the actual use of restraints or seclusion consistent with hospital restraint and seclusion policies and procedures, as well as CMS requirements? 7. Review incident and accident reports to determine whether patient injuries occurred proximal to or during a restraint or seclusion intervention. Are incidents and accidents 	

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	<p>The decision to use a restraint or seclusion is not driven by diagnosis, but by a comprehensive individual patient assessment. For a given patient at a particular point in time, this comprehensive individualized patient assessment is used to determine whether the use of less restrictive measures poses a greater risk than the risk of using a restraint or seclusion.</p> <p>The comprehensive assessment should include a physical assessment to identify medical problems that may be causing behavior changes in the patient. For example, temperature elevations, hypoxia, hypoglycemia, electrolyte imbalances, drug interactions, and drug side effects may cause confusion, agitation, and combative behaviors. Addressing these medical issues may eliminate or minimize the need for the use of restraints or seclusion.</p> <p>Staff must assess and monitor a patient's condition on an ongoing basis to ensure that the patient is released from restraint or seclusion at the earliest possible time. Restraint or seclusion may only be employed while the unsafe situation continues. Once the unsafe situation ends, the use of restraint or seclusion should be discontinued. However, the decision to discontinue the intervention should be based on the determination that the need for restraint or seclusion is no longer present, or that the patient's needs can be addressed using less restrictive methods.</p> <p>Hospital leadership is responsible for creating a</p>	<p>occurring more frequently with restrained or secluded patients?</p> <p>8. If record review indicates that restrained or secluded patients sustained injuries, determine what the hospital did to prevent additional injury. Determine if the hospital investigated possible changes to its restraint or seclusion policies.</p> <p>9. Obtain data on the use of restraint and seclusion for a specified time period (e.g., 3 months) to determine any patterns in their use for specific units, shifts, days of the week, etc.</p> <p>10. Does the number of patients who are restrained or secluded increase on weekends, on holidays, at night, on certain shifts; where contract nurses are used; in one unit more than other units? Such patterns of restraint or seclusion use may suggest that the intervention is not based on the patient's need, but on issues such as convenience, inadequate staffing or lack of staff training. Obtain nursing staffing schedules during time periods in question to determine if staffing levels impact the use of restraint or seclusion.</p> <p>11. Interview a random sample of patients who were restrained to manage non-violent, non-self-destructive behavior. Were the reasons</p>	

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	<p>culture that supports a patient’s right to be free from restraint or seclusion. Leadership must ensure that systems and processes are developed, implemented, and evaluated that support the patients’ rights addressed in this standard, and that eliminate the inappropriate use of restraint or seclusion.</p> <p>Through their QAPI program, hospital leadership should:</p> <ul style="list-style-type: none"> • Assess and monitor the use of restraint or seclusion in their facility; • Implement actions to ensure that restraint or seclusion is used only to ensure the physical safety of the patient, staff and others; and • Ensure that the hospital complies with the requirements set forth in this standard as well as those set forth by State law and hospital policy when the use of restraint or seclusion is necessary. <p>Patients have a right to receive safe care in a safe environment. However, the use of restraint is inherently risky. When the use of restraint is necessary, the least restrictive method must be used to ensure a patient’s safety. The use of restraint for the management of patient behavior should not be considered a routine part of care.</p> <p>The use of restraints for the prevention of falls should not be considered a routine part of a falls prevention</p>	<p>for the use of a restraint to manage non-violent, non-self-destructive behavior explained to the patient in understandable terms? Could the patient articulate his/her understanding?</p>	

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program. Although restraints have been traditionally used as a falls prevention approach, they have major, serious drawbacks and can contribute to serious injuries. There is no evidence that the use of physical restraint, (including, but not limited to, raised side rails) will prevent or reduce falls. Additionally, falls that occur while a person is physically restrained often result in more severe injuries.¹

FOOTNOTES

1- *American Geriatrics Society, British Geriatrics Society, and American Academy of Orthopaedic Surgeons Panel on Falls Prevention. Guideline for the prevention of falls in older persons. Journal of the American Geriatrics Society. 49(5):664-72, 2001 May.*

- *Neufeld RR, Libow LS, Foley WJ, Dunbar JM, Cohen C, Breuer B. Restraint reduction reduces serious injuries among nursing home residents. J Am Geriatr Soc 1999; 47:1202-1207.*
- *Si M, Neufeld RR, Dunbar J. Removal of bedrails on a short-term nursing home rehabilitation unit. Gerontologist 1999; 39:611-614.*
- *Hanger HC, Ball MC, Wood LA. An analysis of falls in the hospital: can we do without bedrails? J Am Geriatr Soc 1999; 47:529-531.*
- *Tinetti ME, Liu YB, Ginter S. Mechanical restraint use and fall related injuries among residents of skilled nursing facilities. Ann Intern Med 1992; 116:369-374.*
- *Capezuti E, Evans L, Strumpf N, Maislin G. Physical restraint use and falls in nursing home residents. J Am Geriatr Soc 1996; 44:627-633.*

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- *Capezuti E, Strumpf NE, Evans LK, Grisso JA, Maislin G. The relationship between physical restraint removal and falls and injuries among nursing home residents. J Gerontol A Biol Sci Med Sci 1998; 53:M47-M52.*

In fact in some instances reducing the use of physical restraints may actually decrease the risk of falling.²

² *University of California at San Francisco (UCSF)-Stanford University Evidence-based Practice Center Subchapter 26.2. Interventions that Decrease the Use of Physical Restraints” of the Evidence Report/Technology Assessment, No. 43.*

Consider, for example, a patient who is displaying symptoms of Sundowner’s Syndrome, a syndrome in which a patient’s dementia becomes more apparent at the end of the day than at the beginning of the day. The patient is not acting out or behaving in a violent or self-destructive manner. However, the patient has an unsteady gait and continues to get out of bed even after staff has tried alternatives to keep the patient from getting out of bed. There is nothing inherently dangerous about a patient being able to walk or wander, even at night. Under the provisions of this regulation, the rationale that the patient should be restrained because he “might” fall does not constitute an adequate basis for using a restraint for the purposes of this regulation.

When assessing a patient’s risk for falls and planning care for the patient, staff should consider whether the

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	<p>patient has a medical condition or symptom that indicates a current need for a protective intervention to prevent the patient from walking or getting out of bed.</p> <p>A history of falling without a current clinical basis for a restraint intervention is inadequate to demonstrate the need for restraint. It is important to note that the regulation specifically states that convenience is not an acceptable reason to restrain a patient. In addition, a restraint must not serve as a substitute for the adequate staffing needed to monitor patients.</p> <p>An individualized patient assessment is critical. In this example, an assessment should minimally address the following questions:</p> <ul style="list-style-type: none"> • Are there safety interventions or precautions (other than restraint) that can be taken to reduce the risk of the patient slipping, tripping, or falling if the patient gets out of bed? • Is there a way to enable the patient to safely ambulate? • Is there some assistive device that will improve the patient's ability to self ambulate? • Is a medication or a reversible condition causing the unsteady gait? • Would the patient be content to walk with a staff person? 		

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- Could the patient be brought closer to the nurse’s station where he or she could be supervised?

If an assessment reveals a medical condition or symptom that indicates the need for an intervention to protect the patient from harm, the regulation requires the hospital to use the least restrictive intervention that will effectively protect the patient from harm. Upon making this determination, the hospital may consider the use of a restraint; however, that consideration should weigh the risks of using a restraint (which are widely documented in research) against the risks presented by the patient’s behavior.

If the hospital chooses to use the restraint, it must meet the requirements contained in this standard. In addition, a request from a patient or family member for the application of a restraint, which they would consider to be beneficial, is not a sufficient basis for the use of a restraint intervention.

- A patient or family member request for a restraint intervention, such as a vest restraint or raising all four side rails, to keep the patient from getting out of bed or falling should prompt a patient and situational assessment to determine whether such a restraint intervention is needed. If a need for restraint is confirmed, the practitioner must then determine the type of restraint intervention that will meet the patient’s needs with the least risk and most benefit to the patient. If restraint (as defined by the regulation) is used, then the

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requirements of the regulation must be met.

Patient care staff must demonstrate through their documentation in the patient’s medical record that the restraint intervention used is the least restrictive intervention that protects the patient’s safety, and that the use of restraint is based on individual assessments of the patient. The assessments and documentation of those assessments must be ongoing in order to demonstrate a continued need for restraint.

Documentation by the physician or other staff once a day may not be adequate to support that the restraint intervention needs to continue and may not comply with the requirement to end the restraint as soon as possible. A patient’s clinical needs often change over time.

CMS does not consider the use of weapons in the application of restraint or seclusion as a safe, appropriate health care intervention.

- For the purposes of this regulation, the term “weapon” includes, but is not limited to, pepper spray, mace, nightsticks, tazers, cattle prods, stun guns, and pistols.
- Security staff may carry weapons as allowed by hospital policy, and State and Federal law. However, the use of weapons by security staff is considered a law enforcement action, not a health care intervention. CMS does not support the use

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of weapons by any hospital staff as a means of subduing a patient in order to place that patient in restraint or seclusion. If a weapon is used by security or law enforcement personnel on a person in a hospital (patient, staff, or visitor) to protect people or hospital property from harm, we would expect the situation to be handled as a criminal activity and the perpetrator be placed in the custody of local law enforcement.

- The use of handcuffs, manacles, shackles, other chain-type restraint devices, or other restrictive devices applied by non-hospital employed or contracted law enforcement officials for custody, detention, and public safety reasons are not governed by this rule. The use of such devices are considered law enforcement restraint devices and would not be considered safe, appropriate health care restraint interventions for use by hospital staff to restrain patients. The law enforcement officers who maintain custody and direct supervision of their prisoner (the hospital's patient) are responsible for the use, application, and monitoring of these restrictive devices in accordance with Federal and State law. However, the hospital is still responsible for an appropriate patient assessment and the provision of safe, appropriate care to its patient (the law enforcement officer's prisoner).

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<p>15.02.01 <u>Restraint Definitions.</u> <i>A restraint is—</i></p> <ul style="list-style-type: none"> • <i>Any manual method, physical or mechanical device, material, or equipment that immobilizes or reduces the ability of a patient to move his or her arms, legs, body, or head freely;</i> <p>§482.13(e)(1)(i)(A)</p>	<p>This restraint definition applies to all uses of restraint in all hospital care settings.</p> <p>Under this definition, commonly used hospital devices and other practices could meet the definition of a restraint, such as:</p> <ul style="list-style-type: none"> • Tucking a patient’s sheets in so tightly that the patient cannot move; • Use of a “net bed” or an “enclosed bed” that prevents the patient from freely exiting the bed; EXCEPTION: Placement of a toddler in an "enclosed" or "domed" crib; • Use of "Freedom" splints that immobilize a patient's limb; • Using side rails to prevent a patient from voluntarily getting out of bed; or • Geri chairs or recliners, only if the patient cannot easily remove the restraint appliance and get out of the chair on his or her own. <p>NOTE: Generally, if a patient can easily remove a device, the device would not be considered a restraint. In this context, “easily remove” means that the manual method, device, material, or equipment can be removed intentionally by the patient in the same manner as it was applied by the staff (e.g., side rails are put down, not climbed over; buckles are intentionally unbuckled; ties or knots are intentionally</p>	<p><u>DOCUMENT REVIEW, OBSERVATION, AND INTERVIEW</u></p> <ol style="list-style-type: none"> 1. Determine whether the hospital’s policy and procedures employ a definition or description of what constitutes a restraint that is consistent with the regulation. 2. While touring hospital units look for restraints in use. Where a restraint is in use, check the medical record for appropriate documentation. 3. Interview hospital staff to determine whether they know the definition of a restraint. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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<p>15.02.02 Medication as a Restraint. <i>A restraint is –</i></p> <ul style="list-style-type: none"> • <i>A drug or medication when it is used as a restriction to manage the patient's behavior or restrict the patient's freedom of movement and is not a standard treatment or dosage for the patient's condition.</i> <p>§482.13(e)(1)(i)(B)</p>	<p>untied; etc.) considering the patient's physical condition and ability to accomplish objective (e.g., transfer to a chair, get to the bathroom in time).</p> <p>Drugs or medications that are used as part of a patient's standard medical or psychiatric treatment, and are administered within the standard dosage for the patient's condition, would not be subject to the requirements of standard (e).</p> <p>These regulations are not intended to interfere with the clinical treatment of patients who are suffering from serious mental illness and who need therapeutic doses of medication to improve their level of functioning so that they can more actively participate in their treatment. Similarly, these regulations are not intended to interfere with appropriate doses of sleeping medication prescribed for patients with insomnia, anti-anxiety medication prescribed to calm a patient who is anxious, or analgesics prescribed for pain management. The regulatory language is intended to provide flexibility and recognize the variations in patient conditions.</p> <p>Whether or not an order for a drug or medication is PRN (Latin abbreviation for pro re nata - as needed; as circumstances require) or a standing-order does not determine whether or not the use of that drug or medication is considered a restraint. The use of PRN or standing-order drugs or medications is only prohibited if the drug or medication meets the definition of a</p>	<p style="text-align: center;">DOCUMENT REVIEW AND INTERVIEW</p> <ol style="list-style-type: none"> 1. Determine whether the hospital's policies and procedures employ a definition or description of what constitutes the use of drugs or medications as a restraint that is consistent with the regulation. 2. Interview hospital staff to determine whether they can identify when the use of a drug or medication is considered a chemical restraint. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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	<p>drug or medication used as a restraint.</p> <p>Criteria used to determine whether the use of a drug or medication, or combination of drugs or medications is a standard treatment or dosage for the patient's condition includes all of the following:</p> <ul style="list-style-type: none"> • The drug or medication is used within the pharmaceutical parameters approved by the Food and Drug Administration (FDA) and the manufacturer for the indications that it is manufactured and labeled to address, including listed dosage parameters; • The use of the drug or medication follows national practice standards established or recognized by the medical community, or professional medical associations or organizations; and, • The use of the drug or medication to treat a specific patient's clinical condition is based on that patient's symptoms, overall clinical situation, and on the physician's or other licensed independent practitioner's (LIP) knowledge of that patient's expected and actual response to the medication. <p>Another component of "standard treatment or dosage" for a drug or medication is the expectation that the standard use of a drug or medication to treat the patient's condition enables the patient to more effectively or appropriately function in the world around them than would be possible without the use</p>		

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of the drug or medication. If the overall effect of a drug or medication, or combination of drugs or medications, is to reduce the patient's ability to effectively or appropriately interact with the world around the patient, then the drug or medication is not being used as a standard treatment or dosage for the patient's condition.

As with any use of restraint or seclusion, staff must conduct a comprehensive patient assessment to determine the need for other types of interventions before using a drug or medication as a restraint. For example, a patient may be agitated due to pain, an adverse reaction to an existing drug or medication, or other unmet care need or concern.

There are situations where the use of a drug or medication is clearly outside the standard for a patient or a situation, or a medication is not medically necessary but is used for patient discipline or staff convenience (neither of which is permitted by the regulation).

EXAMPLE 1: A patient has Sundowner's Syndrome, a syndrome in which a patient's dementia becomes more apparent at the end of the day rather than at the beginning of the day. The patient may become agitated, angry, or anxious at sundown. This may lead to wandering, pacing the floors, or other nervous behaviors. The staff finds the patient's behavior bothersome, and asks the physician to order a high dose of a sedative to "knock out" the patient and keep him

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	<p>in bed. The patient has no medical symptoms or condition that indicates the need for a sedative. In this case, for this patient, the sedative is being used inappropriately as a restraint for staff convenience. Such use is not permitted by the regulation.</p> <p>A drug or medication that is not being used as a standard treatment for the patient’s medical or psychiatric condition, and that results in restricting the patient’s freedom of movement would be a drug used as a restraint.</p> <p>In addition, the regulation does not permit a drug or medication to be used to restrain the patient for staff convenience, to coerce or discipline the patient, or as a method of retaliation. While drugs or medications can be a beneficial part of a carefully constructed, individualized treatment plan for the patient, drug and medication use should be based on the assessed needs of the individual patient, and the effects of drugs and medications on the patient should be carefully monitored.</p> <p>EXAMPLE 2: A patient is in a detoxification program. The patient becomes violent and aggressive. Staff administers a PRN medication ordered by the patient’s physician or other LIP to address these types of outbursts. The use of the medication enables the patient to better interact with others or function more effectively. In this case, the medication used for this patient is not</p>		

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considered a “drug used as a restraint.” The availability of a PRN medication to manage outbursts of specific behaviors, such as aggressive, violent behavior is standard for this patient’s medical condition (i.e., drug or alcohol withdrawal). Therefore, this patient’s medication does not meet the definition of “drug used as a restraint” since it is a standard treatment or dosage for the patient’s medical or psychiatric condition. The use of this medication for this patient is not affected by standard (e). If a drug or medication is used as a standard treatment (as previously defined) to address the assessed symptoms and needs of a patient with a particular medical or psychiatric condition, its use is **not** subject to the requirements of this regulation. However, the patient would still need to receive assessments, monitoring, interventions, and care that are appropriate for that patient’s needs.

The regulation supports existing State laws that provide more vigorous promotion of the patient’s choice and rights. Therefore, when a State’s law prohibits the administration of drugs against the wishes of the patient without a court order, the State law applies.

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<p>15.02.03 Non-Restraints. <i>A restraint does not include –</i></p> <p><i>Devices, such as orthopedically prescribed devices, surgical dressings or bandages, protective helmets, or other methods that involve the physical holding of a patient for the purpose of conducting routine physical examinations or tests, or to protect the patient from falling out of bed, or to permit the patient to participate in activities without the risk of physical harm (this does not include a physical escort).</i></p> <p>§482.13(e)(1)(i)(C)</p>	<p>The devices and methods listed here would not be considered restraints, and, therefore, not subject to these requirements.</p> <p>These devices and methods are typically used in medical-surgical care.</p> <ul style="list-style-type: none"> • Use of an IV arm board to stabilize an IV line is generally not considered a restraint. However, if the arm board is tied down (or otherwise attached to the bed), or the entire limb is immobilized such that the patient cannot access his or her body, the use of the arm board would be considered a restraint. • A mechanical support used to achieve proper body position, balance, or alignment so as to allow greater freedom of mobility than would be possible without the use of such a mechanical support is not considered a restraint. For example, some patients lack the ability to walk without the use of leg braces, or to sit upright without neck, head, or back braces. • A medically necessary positioning or securing device used to maintain the position, limit mobility, or temporarily immobilize the patient during medical, dental, diagnostic, or surgical procedures is not considered a restraint. <p>Recovery from anesthesia that occurs when the patient is in a critical care or postanesthesia care unit is considered part of the surgical procedure; therefore,</p>	<p><u>DOCUMENT REVIEW, OBSERVATION, AND INTERVIEW</u></p> <ol style="list-style-type: none"> 1. Determine whether the hospital’s policies and procedures employ a definition or description of what constitutes a restraint that is consistent with the regulation. 2. While touring hospital units look for bed side rail use to determine whether it is consistent with the definition of a restraint. <ul style="list-style-type: none"> • Where bed side rails are being used as a restraint, check the medical record for appropriate documentation. 3. Interview hospital staff to determine whether they know the definition of a restraint, particularly with respect to use of bed side rails. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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	<p>medically necessary restraint use in this setting would not need to meet the requirements of the regulation.</p> <ul style="list-style-type: none"> • However, if the intervention is maintained when the patient is transferred to another unit, or recovers from the effects of the anesthesia (whichever occurs first), a restraint order would be necessary and the requirements of standard (e) would apply. <p>Many types of hand mitts would not be considered restraint.</p> <ul style="list-style-type: none"> • However, pinning or otherwise attaching those same mitts to bedding or using a wrist restraint in conjunction with the hand mitts would meet the definition of restraint and the requirements would apply. • In addition, if the mitts are applied so tightly that the patient's hand or fingers are immobilized, this would be considered restraint and the requirements would apply. • Likewise, if the mitts are so bulky that the patient's ability to use their hands is significantly reduced, this would be considered restraint and the requirements would apply. <p>NOTE: Because this definition of physical restraint does not name each device and situation that can be used to immobilize or reduce the ability of the patient to move his or her arms, legs, body or head</p>		

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freely, it promotes looking at each patient situation on a case-by-case basis.

In addition, if a patient can easily remove a device, the device would not be considered a restraint. In this context, “**easily remove**” means that the manual method, device, material, or equipment can be removed intentionally by the patient in the same manner as it was applied by the staff (e.g., side rails are put down, not climbed over; buckles are intentionally unbuckled; ties or knots are intentionally untied; etc.) considering the patient’s physical condition and ability to accomplish the objective (e.g., transfer to a chair, get to the bathroom in time).

Age or developmentally appropriate protective safety interventions

Age or developmentally appropriate protective safety interventions (such as stroller safety belts, swing safety belts, high chair lap belts, raised crib rails, and crib covers) that a safety-conscious child care provider outside a health care setting would utilize to protect an infant, toddler, or preschool-aged child would not be considered restraint or seclusion for the purposes of this regulation.

- The use of these safety interventions needs to be addressed in the hospital’s policies or procedures.

Physical Escort

A physical escort would include a “light” grasp to escort the patient to a desired location.

- If the patient can easily remove or escape the

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	<p>grasp, this would not be considered physical restraint.</p> <ul style="list-style-type: none"> • However, if the patient cannot easily remove or escape the grasp, this would be considered physical restraint and all the requirements would apply. <p>Physical Holding</p> <p>The regulation permits the physical holding of a patient for the purpose of conducting routine physical examinations or tests.</p> <ul style="list-style-type: none"> • However, patients do have the right to refuse treatment. See <u>§482.13(b)(2)</u>. This includes the right to refuse physical examinations or tests. • Holding a patient in a manner that restricts the patient's movement against the patient's will is considered restraint. This includes holds that some member of the medical community may term "therapeutic holds." Many deaths have occurred while employing these practices. • Physically holding a patient can be just as restrictive, and just as dangerous, as restraining methods that involve devices. Physically holding a patient during a forced psychotropic medication procedure is <u>considered a restraint</u> and is not included in this exception. • For the purposes of this regulation, a staff member picking up, redirecting, or holding an infant, toddler, or preschool-aged child to comfort 		

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the patient is not considered restraint.

Physical Holding for Forced Medications

The application of force to physically hold a patient, in order to administer a medication against the patient’s wishes, is considered restraint.

- The patient has a right to be free of restraint and, in accordance with §482.13(b)(2), also has a right to refuse medications, unless a court has ordered medication treatment.

- A **court order** for medication treatment only removes the patient’s right to refuse the medication.

- Additionally, in accordance with State law, some patients may be medicated against their will in certain emergency circumstances. However, in both of these circumstances, health care staff is expected to use the least restrictive method of administering the medication to avoid or reduce the use of force, when possible.
 - The use of force in order to medicate a patient, as with other restraint, must have a physician’s order prior to the application of the restraint (use of force).

 - If physical holding for forced medication is necessary with a violent patient, the 1-hour face-to-face evaluation requirement would also apply.

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In certain circumstances, a patient may consent to an injection or procedure, but may not be able to hold still for an injection, or cooperate with a procedure.

- In such circumstances, and at the patient’s request, staff may “hold” the patient in order to safely administer an injection (or obtain a blood sample, or insert an intravenous line, if applicable) or to conduct a procedure. This is not considered restraint.

Side Rails

A restraint does not include methods that protect the patient from falling out of bed.

- Examples include raising the side rails when a patient is: on a stretcher, recovering from anesthesia, sedated, experiencing involuntary movement, or on certain types of therapeutic beds to prevent the patient from falling out of the bed. The use of side rails in these situations protects the patient from falling out of bed and, therefore, would not be subject to the requirements of standard (e).
- However, side rails are frequently not used as a method to prevent the patient from falling out of bed, but instead, used to restrict the patient’s freedom to exit the bed.
- The use of side rails to prevent the patient from exiting the bed would be considered a restraint and would be subject to the requirements of standard (e).

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	<p>The use of side rails is inherently risky, particularly if the patient is elderly or disoriented. Frail elderly patients may be at risk for entrapment between the mattress or bed frame and the side rail.</p> <p>Disoriented patients may view a raised side rail as a barrier to climb over, may slide between raised, segmented side rails, or may scoot to the end of the bed to get around a raised side rail and exit the bed. When attempting to leave the bed by any of these routes, the patient is at risk for entrapment, entanglement, or falling from a greater height posed by the raised side rail, with a possibility for sustaining greater injury or death than if the patient had fallen from the height of a lowered bed without raised side rails. In short, the patient may have an increased risk for a fall or other injury by attempting to exit the bed with the side rails raised. The risk presented by side rail use should be weighed against the risk presented by the patient's behavior as ascertained through individualized assessment.</p> <p>When the clinician raises all four side rails in order to restrain a patient, defined in this regulation as immobilizing or reducing the ability of a patient to move his or her arms, legs, body, or head freely to ensure the immediate physical safety of the patient, then the requirements of this rule apply.</p> <ul style="list-style-type: none"> • Raising fewer than four side rails when the bed has segmented side rails would not necessarily immobilize or reduce the ability of a patient to move freely as defined in the 		

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regulation.

- For example, if the side rails are segmented and all but one segment are raised to allow the patient to freely exit the bed, the side rail is not acting as a restraint and the requirements of this rule would not apply.
- Conversely, if a patient is not physically able to get out of bed regardless of whether the side rails are raised or not, raising all four side rails for this patient would not be considered restraint because the side rails have no impact on the patient's freedom of movement. In this example, the use of all four side rails would not be considered restraint. Therefore, the requirements of this rule would not apply.

Not A Restraint

- When a patient is on a bed that constantly moves to improve circulation or prevents skin breakdown, raised side rails are a safety intervention to prevent the patient from falling out of bed and are not viewed as restraint.
- When a patient is placed on **seizure precautions** and all side rails are raised, the use of side rails would not be considered restraint. The use of padded side rails in this situation should protect the patient from harm; including falling out of bed should the patient have a seizure.

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<p>15.02.04 <u>Definition of Seclusion.</u> <i>Seclusion is the involuntary confinement of a patient alone in a room or area from which the patient is physically prevented from leaving.</i></p> <p><i>Seclusion may only be used for the management of violent or self-destructive behavior.</i> §482.13(e)(1)(ii)</p>	<ul style="list-style-type: none"> • Placement in a crib with raised rails is an age-appropriate standard safety practice for every infant or toddler. Therefore, placement of an infant or toddler in the crib with raised rails would not be considered restraint. • If the patient is on a stretcher (a narrow, elevated, and highly mobile cart used to transport patients and to evaluate or treat patients), there is an increased risk of falling from a stretcher without raised side rails due to its narrow width, and mobility. In addition, because stretchers are elevated platforms, the risk of patient injury due to a fall is significant. Therefore, the use of raised side rails on stretchers is not considered restraint but a prudent safety intervention. • Likewise, the use of a seat belt when transporting a patient in a wheelchair is not considered restraint. <p>Seclusion may only be used for the management of violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others.</p> <p>Seclusion is not just confining a patient to an area, but involuntarily confining the patient alone in a room or area where the patient is physically prevented from leaving.</p>	<p><u>DOCUMENT REVIEW, OBSERVATION, AND INTERVIEW</u></p> <ol style="list-style-type: none"> 1. Determine whether the hospital’s policy and procedures employ a definition or description of what constitutes seclusion that is consistent with the regulation. 2. While touring hospital units look for cases where a patient is in seclusion. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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<p>15.02.05 <u>Least Restrictive Interventions.</u> <i>Restraint or seclusion may only be used when less restrictive interventions have been determined to be ineffective to protect the patient, a staff member, or others from harm.</i></p> <p>§482.13(e)(2)</p>	<p>If a patient is restricted to a room alone and staff are physically intervening to prevent the patient from leaving the room or giving the perception that threatens the patient with physical intervention if the patient attempts to leave the room, the room is considered locked, whether the door is actually locked or not. In this situation, the patient is being secluded. A patient physically restrained alone in an unlocked room does not constitute seclusion.</p> <p>Confinement on a locked unit or ward where the patient is with others does not constitute seclusion. Timeout is not considered seclusion. Timeout is an intervention in which the patient consents to being alone in a designated area for an agreed upon timeframe from which the patient is not physically prevented from leaving. Therefore, the patient can leave the designated area when the patient chooses.</p> <p>A comprehensive assessment of the patient must determine that the risks associated with the use of the restraint or seclusion is outweighed by the risk of not using the restraint or seclusion.</p> <p>Less restrictive interventions do not always need to be tried, but less restrictive interventions must be determined by staff to be ineffective to protect the patient or others from harm prior to the introduction of more restrictive measures.</p>	<p>3. Interview hospital staff to determine whether they know the definition of seclusion.</p> <p>CHART REVIEW</p> <ol style="list-style-type: none"> 1. Do physician’s or other LIP’s orders specify the reason for restraint or seclusion, the type of restraint, and the duration of restraint or seclusion? 2. Does the severity of the behavior justify seclusion or restraint usage by identifying an immediate and serious danger to the physical safety of the patient or others? 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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	<p>Alternatives attempted or the rationale for not using alternatives must be documented.</p> <p>The underpinning of this regulation is the concept that safe patient care hinges on looking at the patient as an individual and assessing the patient’s condition, needs, strengths, weaknesses, and preferences. Such an approach relies on caregivers who are skilled in individualized assessment and in tailoring interventions to the individual patient’s needs after weighing factors such as the patient’s condition, behaviors, history, and environmental factors.</p> <p>Resources Resources are available to assist clinicians in identifying less restrictive interventions. For example, the American Psychiatric Association (APA), American Psychiatric Nurses Association (APNA), and the National Association of Psychiatric Health Systems (NAPHS), with support from the American Hospital Association (AHA), have sponsored the publication of a document entitled, “Learning from Each Other— Success Stories and Ideas for Reducing Restraint / Seclusion in Behavioral Health.” This document, published in 2003, was developed through dialogue with clinicians in the field and included extensive input from behavioral healthcare providers throughout the country who have been working to reduce the use of restraint and seclusion and to improve care within their facilities. To access this document and other useful resources, visit the web sites of the sponsoring organizations: http://www.naphs.org;</p>	<ol style="list-style-type: none"> 3. Is there evidence that the hospital considers factors other than the individual patient in determining causes for the need for restraints or seclusion (i.e., environmental factors)? 4. Does the medical record include documentation of an individual patient assessment and a revision of the plan of care? 5. Does the medical record reflect changes in behavior and staff concerns regarding safety risks to the patient, staff, or others prompting use of seclusion or restraints? 6. Did the patient’s behavior place the patient or others at risk for harm? Was the patient’s behavior violent or self-destructive? 7. Were other, less restrictive interventions tried and documented, or is there evidence that alternatives were considered and determined to be insufficient? <p style="text-align: center;"><u>INTERVIEW</u></p> <p>Interview staff that have been a position to restraint patients.</p> <ul style="list-style-type: none"> • How did the staff assess the patient and determine the least restrictive interventions that would be ineffective to protect the patient, staff, or others from harm? 	

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<http://www.psych.org>; <http://www.apna.org>;
<http://www.aha.org>.

15.02.06 Not Applicable.

15.02.07 Effective Restraints.

The type or technique of restraint or seclusion used must be the least restrictive intervention that will be effective to protect the patient, a staff member, or others from harm.

§482.13(e)(3)

Resources are available to assist clinicians in identifying less restrictive restraint or seclusion interventions.

For example, the American Psychiatric Association (APA), American Psychiatric Nurses Association (APNA), and the National Association of Psychiatric Health Systems (NAPHS), with support from the American Hospital Association (AHA), have sponsored the publication of a document entitled, “Learning from Each Other—Success Stories and Ideas for Reducing Restraint / Seclusion in Behavioral Health.”

This document, published in 2003, was developed through dialogue with the field and extensive input from behavioral healthcare providers throughout the country who have been working to reduce the use of restraint and seclusion and to improve care within their facilities.

To access this document and other useful resources, visit the web sites of the sponsoring organizations:
<http://www.naphs.org>; <http://www.psych.org>;
<http://www.apna.org>; <http://www.aha.org>

CHART REVIEW

1. Is there clear documentation in the patient’s medical record describing the steps or interventions used prior to the use of the needed restraint or seclusion? That is, what documentation is in the medical record to explain the rationale for the use of restraint or seclusion?
2. Is there documentation that less restrictive measures were tried or considered?
 - Is the restraint or seclusion intervention the least restrictive intervention that meets the patient’s clinical needs and protects the safety of the patient, staff, or others?
 - Did the staff determine that less restrictive alternatives would not meet the patient’s clinical needs, or protect the patient’s safety or the safety of others?
 - Do ongoing documented assessments demonstrate that the

- 1 = Compliant
 2 = Not Compliant

This standard is not met as evidenced by:

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<p>15.02.08 Modification of the Plan of Care – Restraint or Seclusion. <i>The use of restraint or seclusion must be –</i></p> <ul style="list-style-type: none"> <i>in accordance with a written modification to the patient’s plan of care.</i> <p>§482.13(e)(4) §482.13(e)(4)(i)</p>	<p>An order for restraint <u>must</u> result in a modification of the individualized plan of care.</p> <p>Plan of Care The individualized plan of care describes the rationale for restraint or seclusion use.</p> <ul style="list-style-type: none"> The plan lists the interventions selected, patient monitoring, and re-assessments. The plan addresses the frequency and content of the patient re-assessments including vital signs, safety, comfort, mental status, skin integrity / circulation checks, hydration, toileting, and readiness for release from restraint or seclusion, 	<p>restraint or seclusion intervention is needed at this time (or at a time in the past) and that the restraint or seclusion intervention remains the least restrictive way to protect the patient’s safety?</p> <ul style="list-style-type: none"> If the time of restraint or seclusion use is lengthy, look for evidence that the symptoms necessitating the use of restraint or seclusion have persisted. Is there evidence to indicate that the staff have evaluated whether or not the restraint or seclusion can be safely discontinued? <p>CHART REVIEW Review at least five medical records of patients who required restraint or seclusion.</p> <ol style="list-style-type: none"> Has the plan of care been modified to reflect the use of restraint or seclusion based on the patient assessment? Has the plan of care been reviewed and updated in writing, according to hospital policy? Are patient safety assessments and monitoring documented in the progress notes linked to the patient care plan, per hospital 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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	<p>as outlined by hospital policy.</p> <p>The use of restraint or seclusion (including drugs or medications used as restraint as well as physical restraint) must be documented in the patient’s plan of care or treatment plan.</p> <ul style="list-style-type: none"> • The use of restraint or seclusion constitutes a change in a patient’s plan of care. <p>The regulation does not require that a modification to the patient’s plan of care be made before initiating or obtaining an order for the use of restraint or seclusion. The use of a restraint or seclusion intervention should be reflected in the patient’s plan of care or treatment plan based on an assessment and evaluation of the patient.</p> <p>The plan of care or treatment plan should be reviewed and updated in writing within a timeframe specified by hospital policy.</p>	<p>policy, e.g., vital signs, circulation and skin integrity checks, readiness for release of restraint?</p> <p>4. Does the plan of care or treatment reflect a process of assessment, intervention, and evaluation when restraint or seclusion is used?</p> <p>5. Is there evidence of assessment of the identified problem or of an individual patient assessment?</p> <p>6. Does the patient’s plan of care reflect that assessment?</p> <p>7. What was the goal of the intervention?</p> <p>8. What was the described intervention?</p> <p>9. Who is responsible for implementation?</p> <p>10. Did the physician or other LIP write orders that included a time limit? Were these orders incorporated into the plan of care?</p> <p>11. Was the patient informed of the changes in his or her treatment plan or plan of care?</p> <p>12. After the discontinuation of the restraint or seclusion intervention, was this information documented in an update of the plan of care</p>	

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15.02.09 Safe Application.

The use of restraint or seclusion must be –

- *implemented in accordance with safe and appropriate restraint and seclusion techniques as determined by hospital policy in accordance with State law.*

§482.13(e)(4)(ii)

Restraint or seclusion must be implemented appropriately and safely, and reflect hospital policy in accordance with State law.

The use of restraint or seclusion must never act as a barrier to the provision of other interventions to meet the patient’s needs.

or treatment plan?

DOCUMENT REVIEW AND CHART REVIEW

1. Review the hospital’s policies and procedures to determine if they reflect current standards of practice regarding safe and appropriate restraint and seclusion techniques.
 - Are there any references to State law statutes or any indication State laws were reviewed and incorporated?
2. Review a sample of patient medical records that include patients who required the use of restraint or seclusion for the management of both violent, self-destructive behaviors, and non-violent, non-self-destructive behaviors.
3. After restraints were applied, was an assessment immediately made to ensure that restraints were properly and safely applied?
4. Were the hospital policies and procedures followed?
5. Was the use of restraint or seclusion effective in achieving the purpose for which it was ordered? If not, were timely changes made?
6. Was there any evidence of injury to the patient?

- 1 = Compliant
- 2 = Not Compliant

This standard is not met as evidenced by:

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<p>15.02.10 Orders for Restraint or Seclusion. <i>The use of restraint or seclusion must be –</i></p> <ul style="list-style-type: none"> • <i>in accordance with the order of a physician or other licensed independent practitioner who is responsible for the care of the patient as specified under §482.12 (c) and authorized to order restraint or seclusion by hospital policy in accordance with State law.</i> <p>§482.13(e)(5)</p>	<p>The use of a restraint or seclusion must be in accordance with the order of a physician or other licensed independent practitioner (LIP) permitted by the State and hospital to order a restraint.</p> <p>Hospitals must have policies and procedures for the initiation of restraint or seclusion that identify the categories of LIPs that are permitted to order restraint or seclusion in that hospital, consistent with State law.</p> <p>The regulation requires that a physician or other LIP responsible for the care of the patient to order restraint or seclusion prior to the application of restraint or seclusion.</p> <ul style="list-style-type: none"> • In some situations, however, the need for a restraint or seclusion intervention may occur so quickly that an order cannot be obtained prior to the application of restraint or seclusion. <p>In these emergency application situations, the order must be obtained either during the emergency application of the restraint or seclusion, or immediately (within a few minutes) after the restraint or seclusion has been applied.</p> <ul style="list-style-type: none"> • The failure to immediately obtain an order is viewed as the application of restraint or seclusion without an order. • The hospital should address this process in its restraint and seclusion policies and procedures. The policies and procedures should specify who can initiate the emergency application of restraint or seclusion prior to obtaining an order from a physician or other LIP. 	<p style="text-align: center;"><u>CHART REVIEW</u></p> <p>Review at least five medical records of patients who required restraint or seclusion. Verify:</p> <ol style="list-style-type: none"> 1. Each use of restraint or seclusion has been ordered by a physician or LIP authorized by the State and hospital policy. 2. There are no restraint orders written on a PRN basis or as standing orders. 3. Do the medical records reviewed identify the physician or LIP who ordered each use of restraint or seclusion? 4. During the medical record review, verify that a physician or LIP order was obtained prior to the initiation of restraint or seclusion. <ul style="list-style-type: none"> • When emergency application of restraint or seclusion was necessary, verify that a physician or LIP order was obtained immediately (within a few minutes) after application of the restraint or seclusion. <p style="text-align: center;"><u>DOCUMENT REVIEW</u></p> <ol style="list-style-type: none"> 1. Review hospital policies and medical staff bylaws to ascertain clinical practice guidelines that describe the responsibilities of medical staff and clinicians who are privileged to order restraint and seclusion. 2. Do the hospital’s written policies identify what categories of practitioners the State 	<div style="text-align: right;"> <input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant </div> <p style="text-align: center;">This standard is not met as evidenced by:</p>

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	<p><u>Licensed Independent Practitioner (LIP)</u> For the purpose of ordering restraint or seclusion, an LIP is any practitioner permitted by State law and hospital policy as having the authority to independently order restraints or seclusion for patients.</p> <ul style="list-style-type: none"> • A resident who is authorized by State law and the hospital's residency program to practice as a physician can carry out functions reserved for a physician or LIP by the regulation. • A medical school student holds no license, and his/her work is reviewed and must be countersigned by the attending physician; therefore, he or she is not licensed or independent. A medical school student is not an LIP. <p><u>Protocols</u> A protocol cannot serve as a substitute for obtaining a physician's or other LIP's order prior to initiating each episode of restraint or seclusion use.</p> <ul style="list-style-type: none"> • If a hospital uses protocols that include the use of restraint or seclusion, a specific physician or LIP order is still required for each episode of restraint or seclusion use. The philosophy that serves as a foundation for the regulation is that restraint or seclusion use is an exceptional event, not a routine response to a certain patient condition or behavior. • Each patient must be assessed, and interventions 	<p>recognizes as an LIP or as having the authority to order restraint and seclusion?</p> <p>3. Does the hospital have written policies indicating which practitioners are permitted to order restraint or seclusion in the facility?</p> <ul style="list-style-type: none"> • Do the hospital's written policies conform to State law? • Does the hospital have established policies for who can initiate restraint or seclusion? • Does the hospital utilize protocols for the use of restraint or seclusion? If so, is the use of protocols consistent with the requirements of the regulation? 	

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<p>15.02.11 <u>Use of Standing or PRN Orders.</u> <i>Orders for the use of restraint or seclusion must never be written as a standing order or on an as needed basis (PRN).</i></p> <p>§482.13(e)(6)</p>	<p>should be tailored to meet the individual patient’s needs. The creation of a protocol can run counter to this philosophy if it sets up the expectation that restraint or seclusion will be used as a routine part of care.</p> <p>The use of restraint or seclusion is a last resort when less restrictive measures have been determined ineffective to ensure the safety of the patient, staff or others, should not be a standard response to a behavior or patient need.</p> <p>This regulation prohibits the use of standing or PRN (Latin abbreviation for pro re nata - as needed; as circumstances require) orders for the use of restraint or seclusion.</p> <p>The ongoing authorization of restraint or seclusion is not permitted.</p> <ul style="list-style-type: none"> • Each episode of restraint or seclusion must be initiated in accordance with the order of a physician or other LIP. • If a patient was recently released from restraint or seclusion, and exhibits behavior that can only be handled through the reapplication of restraint or seclusion, <u>a new order</u> would be required. Staff cannot discontinue a restraint or seclusion intervention, and then re-start it under the same order. This would constitute a PRN order. 	<p style="text-align: center;"><u>CHART REVIEW</u></p> <p>Review a random sample of medical records for patients that have been restrained or secluded.</p> <p>Review orders, progress notes, flow sheets, and nursing notes to:</p> <ol style="list-style-type: none"> 1. Verify that there is a physician or other LIP order for each episode of restraint or seclusion. 2. Evaluate patterns of use and verify that orders were obtained when necessary. 3. Verify that the documentation specifically addresses the patients’ behaviors or symptoms. 4. Determine if restraint or seclusion is being improperly implemented on a PRN basis. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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	<ul style="list-style-type: none"> • A “trial release” constitutes a PRN use of restraint or seclusion, and, therefore, is not permitted by this regulation. <p>When a staff member ends an ordered restraint or seclusion intervention, the staff member has no authority to reinstitute the intervention without a new order. For example, a patient is released from restraint or seclusion based on the staff’s assessment of the patient’s condition. If this patient later exhibits behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others that can only be handled through the use of restraint or seclusion, a new order would be required.</p> <p>NOTE: A temporary, directly-supervised release, however, that occurs for the purpose of caring for a patient’s needs (e.g., toileting, feeding, or range of motion exercises) is not considered a discontinuation of the restraint or seclusion intervention. As long as the patient remains under direct staff supervision, the restraint is not considered to be discontinued because the staff member is present and is serving the same purpose as the restraint or seclusion.</p> <p>The use of PRN orders for drugs or medications is only prohibited when a drug or medication is being used as a restraint.</p> <ul style="list-style-type: none"> • A drug or medication is deemed to be a restraint only if it is not a standard treatment or dosage for the patient’s condition, and the drug or medication is a restriction to manage the patient’s 		

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behavior or restricts the patient's freedom of movement.

- Using a drug to restrain the patient for staff convenience is expressly prohibited.

EXCEPTIONS

- **Geri chair.** If a patient requires the use of a Geri chair with the tray locked in place in order for the patient to safely be out of bed, a standing or PRN order is permitted. Given that a patient may be out of bed in a Geri chair several times a day, it is not necessary to obtain a new order each time.
- **Raised side rails.** If a patient's status requires that all bedrails be raised (restraint) while the patient is in bed, a standing or PRN order is permitted. It is not necessary to obtain a new order each time the patient is returned to bed after being out of bed.
- **Repetitive self-mutilating behavior.** If a patient is diagnosed with a chronic medical or psychiatric condition, such as Lesch-Nyham Syndrome, and the patient engages in repetitive self-mutilating behavior, a standing or PRN order for restraint to be applied in accordance with specific parameters established in the treatment plan would be permitted. Since the use of restraints to prevent self-injury is needed for these types of rare, severe, medical and psychiatric conditions, the specific requirements (1-hour face-to-face

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evaluation, time-limited orders, and evaluation every 24 hours before renewal of the order) for the management of violent or self-destructive behavior do not apply.

15.02.12 Physician Notification of Restraint Use.

The attending physician must be consulted as soon as possible if the attending physician did not order the restraint or seclusion.

§482.13(e)(7)

- Hospital policy provides practice expectations:
1. If the attending physician did not order the restraint or seclusion, the attending physician must be consulted as soon as possible. This requirement may be achieved through a telephone call. The attending physician is notified to ensure continuity of care, to ensure patient safety, and to obtain other relevant information about the care of the patient.
 2. When the attending physician is not available and has delegated patient responsibility to another physician, the covering physician is considered the attending physician.

The attending physician is the Doctor of Medicine / Doctor of Osteopathic Medicine who is responsible for the management and care of the patient.

Hospital medical staff policies determine who is considered the attending physician.

CHART REVIEW, DOCUMENT REVIEW, AND INTERVIEW

1. Review the patient’s medical record for documentation that the attending physician was notified immediately if the attending physician did not order the restraint or seclusion.
 - Was the attending physician notified “as soon as possible?”
2. Review the hospital’s policies and procedures regarding consultation with the attending physician if the attending physician did not order the restraint or seclusion.
3. Interview staff to determine if actual practice is consistent with written hospital policies and procedures.

- 1 = Compliant
- 2 = Not Compliant

This standard is not met as evidenced by:

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	<p>The intent of this requirement is to ensure that the physician who has overall responsibility and authority for the management and care of the patient is aware of the patient’s condition and is aware of the restraint or seclusion intervention. It is important to consult with the attending physician to promote continuity of care, to ensure patient safety, and to elicit information that might be relevant in choosing the most appropriate intervention for the patient. The attending physician may have information regarding the patient’s history that may have a significant impact on the selection of a restraint or seclusion intervention or an alternative intervention, and the subsequent course of treatment. Therefore, consultation should occur as soon as possible.</p> <p>Hospital policies and procedures should address the definition of “as soon as possible” based on the needs of their particular patient population(s). However, any established time frames must be consistent with “as soon as possible.”</p> <p>The hospital CoPs do permit the patient to be under the care of a treating LIP other than a physician.</p> <ul style="list-style-type: none"> • Section §482.12(c)(1) requires every Medicare patient to be under the care of a doctor of medicine or osteopathic medicine; or, within the scope of their respective licenses, a doctor of dental surgery or dental medicine, a doctor of podiatry, chiropractor, or clinical psychologist. 		

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<p>15.02.13 Restraint Orders for Management of Violent Behavior. <i>Unless superseded by State law that is more restrictive --</i></p> <p>(i) <i>Each order for restraint or seclusion used for the management of violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others may only be renewed in accordance with the following limits for up to a total of 24 hours:</i></p> <p>(A) <i>4 hours for adults 18 years of</i></p>	<ul style="list-style-type: none"> • The individual overseeing the patient’s care may be the attending physician or a health professional practicing with the delegated authority or supervision of a doctor of medicine or osteopathic medicine as permitted by State law and hospital policy. <p>When the attending physician of record is unavailable, responsibility for the patient must be delegated to another physician, who would then be considered the attending physician.</p> <p>This provision does not specify that consultation with the attending physician be face-to-face. The consultation can occur via telephone.</p> <p>Patients of all ages are vulnerable and at risk when restrained or secluded to manage violent or self-destructive behavior. Therefore, time limits have been established for each order for restraint or seclusion used to manage violent or self-destructive behavior. State law may require more restrictive time limits.</p> <ul style="list-style-type: none"> • These time limits do not apply to orders for restraint used to manage non-violent or non-self-destructive behavior. However, the requirement that restraint use be ended at the earliest possible time applies to all uses of restraint. <p>In the final rule on the use of restraint or seclusion, CMS did not include specific criteria for differentiating</p>	<p style="text-align: center;"><u>CHART REVIEW</u></p> <ol style="list-style-type: none"> 1. When restraint or seclusion is used to manage violent or self-destructive behavior, do orders contain the appropriate time frames based on the patient’s age? <ul style="list-style-type: none"> • Does the total number of hours covered by an order or its renewal exceed 24 hours? • If more restrictive State laws apply, are they being followed? 2. Is the renewal order for restraint or seclusion based on a comprehensive individual patient assessment? 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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<p><i>age or older;</i> (B) <i>2 hours for children and adolescents 9 to 17 years of age; or</i> (C) <i>1 hour for children under 9 years of age.</i></p> <p>§482.13(e)(8)(i) §482.13(e)(8)(i)(A) §482.13(e)(8)(i)(B) §482.13(e)(8)(i)(C)</p>	<p>between emergency situations where the patient’s behavior is violent or self-destructive and jeopardizes the immediate physical safety of the patient, a staff member, or others, and non-emergency use of restraint.</p> <p>Clinicians are adept at identifying various behaviors and symptoms, and can readily recognize violent and self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others. Asking clinicians to act based on an evaluation of the patient’s behavior is no different than relying on the clinical judgment that they use daily in assessing the needs of each patient and taking actions to meet those individual needs.</p> <p>The regulation identifies maximum time limits on the length of each order for restraint or seclusion based on age.</p> <ul style="list-style-type: none"> • The physician or other LIP has the discretion to write the order for a shorter length of time. • The length-of-order requirement identifies critical points at which there is mandatory contact with a physician or other LIP responsible for the care of the patient. In addition, the time limits do not dictate how long a patient should remain in restraint or seclusion. • Staff is expected to continually assess and 	<p>3. Is there evidence in the patient’s medical record that the symptoms necessitating the continued use of restraint or seclusion have persisted?</p>	

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	<p>monitor the patient to ensure that the patient is released from restraint or seclusion at the earliest possible time. Restraint or seclusion may only be employed while the unsafe situation continues.</p> <ul style="list-style-type: none"> • Once the unsafe situation ends, the use of restraint or seclusion should be discontinued. <p>The regulation explicitly states that the intervention must be discontinued at the earliest possible time, regardless of the length of time identified in the order.</p> <ul style="list-style-type: none"> • For example, if a patient’s behavior is no longer violent or self-destructive 20 minutes after the intervention is initiated, then the restraint or seclusion should be discontinued, even if the order was given for up to 4 hours. • If restraint or seclusion is discontinued prior to the expiration of the original order, a new order must be obtained prior to reinitiating the use of restraint or seclusion. <p>At the end of the time frame, if the continued use of restraint or seclusion to manage violent or self-destructive behavior is deemed necessary based on an individualized patient assessment, another order is required.</p> <ul style="list-style-type: none"> • When the original order is about to expire, an RN must contact the physician or other LIP, report the results of his or her most recent assessment and request that the original 		

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order be renewed (not to exceed the time limits established in the regulation).

- Whether or not an onsite assessment is necessary prior to renewing the order is left to the discretion of the physician or other LIP in conjunction with a discussion with the RN who is over-seeing the care of the patient. Another 1-hour face-to-face patient evaluation (see §482.13(e)(12) and the related interpretive guidance) is not required when the original order is renewed.

Renewal of Original Order for Violent Behavior

The original restraint or seclusion order may only be renewed within the required time limits for up to a total of 24 hours. After the original order expires, a physician or other LIP must see and assess the patient before issuing a new order.

EXCEPTION: Repetitive self-mutilating behaviors – see interpretive guidance for §482.13(e)(6).

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<p>15.02.14 Physician Assessment. <i>Unless superseded by State law that is more restrictive --</i></p> <ul style="list-style-type: none"> • <i>After 24 hours, before writing a new order for the use of restraint or seclusion for the management of violent or self-destructive behavior, a physician or other licensed independent practitioner who is responsible for the care of the patient as specified under §482.12(c) of 42 CFR 482.12 and authorized to order restraint or seclusion by hospital policy in accordance with State law must see and assess the patient.</i> <p>§482.13(e)(8)(ii)</p>	<p><u>VIOLENT OR SELF-DESTRUCTIVE BEHAVIOR</u></p> <p>At a minimum, if a patient remains in restraint or seclusion for the management of violent or self-destructive behavior 24 hours after the original order, the physician or other LIP must see the patient and conduct a face-to-face re-evaluation before writing a new order for the continued use of restraint or seclusion.</p> <p>Twenty-four hours of restraint or seclusion for the management of violent or self-destructive behavior is an extreme measure with the potential for serious harm to the patient.</p> <p>State laws may be more restrictive and require the physician or other LIP to conduct a face-to-face re-evaluation within a shorter timeframe.</p> <p>When the physician or other LIP renews an order or writes a new order authorizing the continued use of restraint or seclusion, there must be documentation in the patient's medical record that describes the findings of the physician's or other LIP's re-evaluation supporting the continued use of restraint or seclusion.</p> <p>EXCEPTION: Repetitive self-mutilating behaviors – see interpretive guidance for §482.13(e)(6).</p>	<p style="text-align: center;"><u>CHART REVIEW</u></p> <ol style="list-style-type: none"> 1. If restraint or seclusion is used to manage violent or self-destructive behavior for longer than 24 hours, is there documentation of a new written order, patient assessments, and a re-evaluation by a physician or other LIP in the medical record? <ul style="list-style-type: none"> • Does the documentation provide sufficient evidence to support the need to continue the use of restraint or seclusion? • Is there evidence in the medical record that the symptoms necessitating the continued use of restraint or seclusion have persisted? 2. Does the patient's plan of care or treatment plan address the use of restraint or seclusion? 3. What is the patient's documented clinical response to the continued need for restraint or seclusion? 	<p> <input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant </p> <p>This standard is not met as evidenced by:</p>

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<p>15.02.15 <u>Renewal of Restraint Orders.</u> <i>Unless superseded by State law that is more restrictive --</i></p> <ul style="list-style-type: none"> • <i>Each order for restraint used to ensure the physical safety of the non-violent or non-self-destructive patient may be renewed as authorized by hospital policy.</i> <p>§482.13(e)(8)(iii)</p>	<p>Hospitals have the flexibility to determine time frames for the renewal of orders for restraint of the non-violent, non-self-destructive patient.</p> <p>These time frames should be addressed in hospital policies and procedures.</p>	<p><u>DOCUMENT REVIEW, INTERVIEW AND CHART REVIEW</u></p> <ol style="list-style-type: none"> 1. Review the hospital policy on renewal of restraint orders for the management of non-violent, non-self-destructive patient behavior. 2. Interview staff and review the medical record documentation to ensure that practice is consistent with the hospital policy. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>
<p>15.02.16 <u>Discontinuation of Restraints.</u> <i>Restraint or seclusion must be discontinued at the earliest possible time, regardless of the length of time identified in the order.</i></p> <p>§482.13(e)(9)</p>	<p>Restraint or seclusion may only be employed while the unsafe situation continues. Once the unsafe situation ends, the use of restraint or seclusion must be discontinued.</p> <p>Staff members are expected to assess and monitor the patient’s condition on an ongoing basis to determine whether restraint or seclusion can safely be discontinued.</p> <ul style="list-style-type: none"> • The regulation requires that these interventions be ended as quickly as possible. • However, the decision to discontinue the intervention should be based on the determination that the patient’s behavior is no longer a threat to self, staff members, or others. <p>When the physician or LIP renews an order or writes a new order authorizing the continued use of restraint</p>	<p><u>DOCUMENT REVIEW, CHART REVIEW, AND INTERVIEW</u></p> <ol style="list-style-type: none"> 1. Does the hospital have policies and procedures for ending restraint or seclusion? 2. Do the policies include a requirement to end the restraint or seclusion as soon as is safely possible? 3. Does the medical record contain evidence that the decision to continue or discontinue the use of restraint or seclusion was based on an assessment and re-evaluation of the patient’s condition? 4. Interview staff to determine whether they are aware that use of a restraint or seclusion must be discontinued as soon as is safely possible. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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<p>15.02.17 Monitoring of the Patient. <i>The condition of the patient who is restrained or secluded must be monitored by a physician, other licensed independent practitioner or trained staff that have completed the training criteria specified in paragraph (f) of 42 CFR 482.13 at an interval determined by hospital policy.</i></p> <p>§482.13(e)(10)</p>	<p>or seclusion, there must be documentation in the medical record that describes the patient’s clinical needs and supports the continued use of restraint or seclusion.</p> <p>The hospital policies and procedures should address, at a minimum:</p> <ul style="list-style-type: none"> • Categories of staff that the hospital authorizes to discontinue restraint or seclusion in accordance with State law; and • The circumstance under which restraint or seclusion is to be discontinued. <p>Ongoing assessment and monitoring of the patient's condition by a physician, other LIP or trained staff is crucial for prevention of patient injury or death, as well as ensuring that the use of restraint or seclusion is discontinued at the earliest possible time.</p> <p>Hospital policies are expected to guide staff in determining appropriate intervals for assessment and monitoring based on the individual needs of the patient, the patient's condition, and the type of restraint or seclusion used.</p> <p>The selection of an intervention and determination of the necessary frequency of assessment and monitoring should be individualized, taking into consideration variables such as the patient’s condition, cognitive status, risks associated with the use of the</p>	<p style="text-align: center;"><u>DOCUMENT REVIEW</u></p> <p>Review hospital policies regarding assessment and monitoring of a patient in restraint or seclusion.</p> <ol style="list-style-type: none"> 1. What evidence do you find that the hospital’s monitoring policies are put into practice for all restrained or secluded patients? 2. Do hospital policies identify which categories of staff are responsible for assessing and monitoring the patient? 3. Do hospital policies include time frames for offering fluids and nourishment, toileting / elimination, range of motion, exercise of limbs and systematic release of restrained limbs? Is this documented in the patient’s medical record? 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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	<p>chosen intervention, and other relevant factors.</p> <ul style="list-style-type: none"> • In some cases, checks every 15 minutes or vital signs taken every 2 hours may not be sufficient to ensure the patient’s safety. • In others, it may be excessive or disruptive to patient care (e.g., it may be unnecessary to mandate that a patient with wrist restraints, and who is asleep, be checked every 15 minutes and awakened every 2 hours to take the patient’s vital signs). • Similarly, depending on the patient’s needs and situational factors, the use of restraint or seclusion may require either periodic (e.g., every 15 minutes, every 30 minutes, etc.) or continual (i.e., moment to moment) monitoring and assessment. <p><u>Policies</u> Hospital policies should address:</p> <ol style="list-style-type: none"> 1. Frequencies of monitoring and assessment; 2. Assessment content (e.g., vital signs, circulation, hydration needs, elimination needs, level of distress and agitation, mental status, cognitive functioning, skin integrity, etc.); 3. Providing for nutritional needs, range of motion exercises, and elimination needs; and 4. Mental status and neurological evaluations. 	<p style="text-align: center;"><u>CHART REVIEW</u></p> <p>Review patient medical records:</p> <ol style="list-style-type: none"> 1. Was there a valid rationale for the decision regarding the frequency of patient assessment and monitoring documented in the medical record? 2. Was documentation consistent, relevant, and reflective of the patient’s condition? 3. Are time frames described for how often a patient is monitored for vital signs, respiratory and cardiac status, and skin integrity checks? 4. Is there documentation of ongoing patient monitoring and assessment (e.g., skin integrity, circulation, respiration, intake and output, hygiene, injury, etc.)? 5. Is the patient’s mental status assessed? Is this documented in the medical record? 6. Is the patient assessed regarding continued need for the use of seclusion or restraint? 7. Is there adequate justification for continued use and is this documented? 8. Is the level of supervision appropriate to meet the safety needs of the patient who is 	

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	<p>With the exception of the simultaneous use of restraint and seclusion, one-to-one observation with a staff member in constant attendance is not required by this regulation unless deemed necessary based on a practitioner's clinical judgment.</p> <ul style="list-style-type: none"> • For example, placing staff at the bedside of a patient with wrist restraints may be unnecessary. • However, for a more restrictive or risky intervention and/or a patient who is suicidal, self-injurious, or combative, staff may determine that continual face-to-face monitoring is needed. • The hospital is responsible for providing the level of monitoring and frequency of reassessment that will protect the patient's safety. <p>Hospitals have flexibility in determining which staff performs the patient assessment and monitoring.</p> <ul style="list-style-type: none"> • This determination must be in accordance with the practitioner's scope of clinical practice and State law. • For example, assessment and monitoring are activities within a registered nurse's scope of practice. • However, some trained, unlicensed staff may perform components of monitoring (e.g., checking the patient's vital signs, hydration and circulation; the patient's level of distress and agitation; or skin 	<p>at a higher risk for injury (e.g., self-injurious, suicidal)?</p> <p>9. Is the patient's mental status assessed? Is this documented in the medical record?</p> <p>10. Is the patient assessed regarding continued need for the use of seclusion or restraint?</p> <p>11. Is there adequate justification for continued use and is this documented?</p> <p>12. Is the level of supervision appropriate to meet the safety needs for the patient who is at a higher risk for injury (e.g., self-injurious, suicidal)?</p>	

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<p>15.02.18 Physician Training. <i>Physician and other licensed independent practitioner training requirements must be specified in hospital policy.</i></p> <p><i>At a minimum, physicians and other licensed independent practitioners authorized to order restraint or seclusion by hospital policy in accordance with State law must have a working knowledge of hospital policy regarding the use of restraint or seclusion.</i></p> <p>§482.13(e)(11)</p>	<p>integrity), and may also provide for general care needs (e.g., eating, hydration, toileting, and range of motion exercises).</p> <ul style="list-style-type: none"> Section §482.13(f) requires that before applying restraints, implementing seclusion, or performing associated monitoring and care tasks, staff must be trained and able to demonstrate competency in the performance of these actions. <p>At a minimum, physicians and other LIPs authorized to order restraint and seclusion must have a working knowledge of hospital policy regarding the use of restraint and seclusion.</p> <p>Hospitals have the flexibility to identify training requirements above this minimum requirement based on the competency level of their physicians and other LIPs, and the needs of the patient population(s) that they serve.</p> <p>Physicians receive training in the assessment, monitoring, and evaluation of a patient’s condition as part of their medical school education. However, physicians generally do not receive training regarding application of restraint or implementation of seclusion as part of their basic education.</p> <ul style="list-style-type: none"> Depending on the level and frequency of involvement that a physician or other LIP has in the performance of these activities, additional 	<p style="text-align: center;"><u>DOCUMENT REVIEW</u></p> <p>Review the hospital policy regarding restraint and seclusion training requirements for physicians and other LIPs.</p> <ul style="list-style-type: none"> Are the minimum training requirements addressed? <p style="text-align: center;"><u>FILE REVIEW</u></p> <p>Review medical staff credentialing and privileging files to determine if physicians or other LIPs involved in restraint and seclusion activities have completed the required training.</p>	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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<p style="text-align: center;">training may or may not be necessary to ensure the competency of these individuals in this area.</p> <p style="text-align: center;">The hospital is in the best position to determine if additional physician or other LIP training is necessary based on the model of care, level of physician competency, and the needs of the patient population(s) that the hospital serves.</p> <p>15.02.19 One Hour Face-to-Face. <i>When restraint or seclusion is used for the management of violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others, the patient must be seen face-to-face within 1 hour after the initiation of the intervention –</i></p> <p>(i) <i>By a –</i></p> <p>(A) <i>Physician or other licensed independent practitioner; or</i></p> <p>(B) <i>Registered nurse or physician assistant who has been trained in accordance with the requirements specified in paragraph (f) of 42 CFR 482.13.</i></p>	<p style="text-align: center;"><u>VIOLENT OR SELF-DESTRUCTIVE BEHAVIOR</u></p> <p>When restraint or seclusion is used to manage violent or self-destructive behavior, a physician or other LIP, or a registered nurse (RN) or physician assistant (PA) trained in accordance with the requirements specified under §482.13(f), must see the patient face-to-face within 1-hour after the initiation of the intervention.</p> <ul style="list-style-type: none"> • This requirement also applies when a drug or medication is used as a restraint to manage violent or self-destructive behavior. <p>The 1-hour face-to-face patient evaluation must be conducted in person by a physician or other LIP, or trained RN or PA.</p> <ul style="list-style-type: none"> • A telephone call or telemedicine methodology is not permitted. <p>If a patient’s violent or self-destructive behavior resolves and the restraint or seclusion intervention is discontinued before the practitioner arrives to</p>	<p style="text-align: center;"><u>DOCUMENT REVIEW AND INTERVIEW</u></p> <ol style="list-style-type: none"> 1. Review the hospital policy regarding the 1-hour face-to-face evaluation. <ul style="list-style-type: none"> • What categories of practitioners does the hospital policy authorize to conduct the 1-hour face-to-face evaluation? 2. Interview staff to determine if practice is consistent with hospital policy. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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<p>§482.13(e)(12) §482.13(e)(12)(i) §482.13(e)(12)(i)(A) §482.13(e)(12)(i)(B)</p>	<p>perform the 1-hour face-to-face evaluation, the practitioner is still required to see the patient face-to-face and conduct the evaluation within 1 hour after the initiation of this intervention.</p> <p>The fact that the patient’s behavior warranted the use of a restraint or seclusion indicates a serious medical or psychological need for prompt evaluation of the patient behavior that led to the intervention. The evaluation would also determine whether there is a continued need for the intervention, factors that may have contributed to the violent or self-destructive behavior, and whether the intervention was appropriate to address the violent or self-destructive behavior.</p> <p>EXCEPTION: Repetitive self-mutilating behaviors: See Explanation for §482.13(e)(6).</p>	<p>CHART REVIEW, DOCUMENT REVIEW, AND FILE REVIEW</p> <ol style="list-style-type: none"> 1. Was the 1-hour face-to-face evaluation conducted by a practitioner authorized by hospital policy in accordance with State law to conduct this evaluation? 2. Does documentation of the 1-hour face-to-face evaluation in the patient’s medical record include all the listed elements of this requirement? 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>
<p>15.02.20 Physician Assessment Requirements. <i>When restraint or seclusion is used for the management of violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others, the patient must be seen face-to-face within 1 hour after the initiation of the intervention to evaluate –</i></p>	<p>The 1-hour face-to-face evaluation includes both a physical and behavioral assessment of the patient that must be conducted by a qualified practitioner within the scope of their practice.</p> <p>An evaluation of the patient’s medical condition would include a complete review of systems assessment, behavioral assessment, as well as review and assessment of the patient’s history, drugs and medications, most recent lab results, etc. The purpose is to complete a comprehensive review of the</p>	<p>CHART REVIEW, DOCUMENT REVIEW, AND FILE REVIEW</p> <ol style="list-style-type: none"> 1. Was the 1-hour face-to-face evaluation conducted by a practitioner authorized by hospital policy in accordance with State law to conduct this evaluation? 2. Does documentation of the 1-hour face-to-face evaluation in the patient’s medical record include all the listed elements of this requirement? 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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<p>(A) <i>The patient's immediate situation;</i></p> <p>(B) <i>The patient's reaction to the intervention;</i></p> <p>(C) <i>The patient's medical and behavioral condition; and</i></p> <p>(D) <i>The need to continue or terminate the restraint or seclusion.</i></p> <p>§482.13(e)(12)(ii) §482.13(e)(12)(ii)(A) §482.13(e)(12)(ii)(B) §482.13(e)(12)(ii)(C) §482.13(e)(12)(ii)(D)</p>	<p>patient's condition to determine if other factors, such as drug or medication interactions, electrolyte imbalances, hypoxia, sepsis, etc., are contributing to the patient's violent or self-destructive behavior.</p> <p>Training for an RN or PA to conduct the 1-hour face-to-face evaluation would include all of the training requirements at §482.13(f) as well as</p> <ul style="list-style-type: none"> • content to evaluate the patient's immediate situation, • the patient's reaction to the intervention, • the patient's medical and behavioral condition (documented training in conducting physical and behavioral assessment); and • the need to continue or terminate the restraint or seclusion. 	<p>3. Did the evaluation indicate whether changes in the patient's care were required, and, if so, were the changes made?</p> <p>4. If the 1-hour face-to-face evaluations are conducted by RNs who are not advanced practice nurses (APN), verify:</p> <ul style="list-style-type: none"> • that those RNs have documented training that demonstrates they are qualified to conduct a physical and behavioral assessment of the patient that addresses the patient's immediate situation, the patient's reaction to the intervention, the patient's medical and behavioral condition, and the need to continue or terminate the restraint or seclusion. <p>5. Is practice consistent with hospital policy and State law?</p>	

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<p>15.02.21 State Requirements. <i>States are free to have requirements by statute or regulation that are more restrictive than those contained in paragraph (e)(12)(i) of 42 CFR 482.13.</i></p> <p>§482.13(e)(13)</p>	<p>States are free to have requirements that are more restrictive regarding the types of practitioners who may conduct the 1-hour face-to-face evaluation.</p> <p>Generally, States may have more restrictive requirements as long as they do not conflict with Federal requirements.</p>	<p style="text-align: center;"><u>DOCUMENT REVIEW</u></p> <ol style="list-style-type: none"> 1. When preparing for the hospital survey, determine whether there are State provisions governing the use of restraint or seclusion that are more restrictive than those found in this section. 2. When State requirements are more restrictive, apply those requirements instead of those found in this section. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>
<p>15.02.22 Physician Notification. <i>If the face-to-face evaluation specified in paragraph (e)(12) of 42 CFR 482.13 is conducted by a trained registered nurse or physician assistant, the trained registered nurse or physician assistant must consult the attending physician or other licensed independent practitioner who is responsible for the care of the patient as specified under §482.12(c) as soon as possible after the completion of the 1 hour face-to-face evaluation.</i></p> <p>§482.13(e)(14)</p>	<p>When a trained RN or PA conducts the required face-to-face evaluation, he or she must consult the attending physician or other LIP responsible for the patient’s care as soon as possible after the completion of the evaluation.</p> <p>Hospital policy should address the expected time frame for and the components of the consultation with the attending physician or other LIP consistent with “as soon as possible.”</p> <p>This consultation should include, at a minimum,</p> <ul style="list-style-type: none"> • a discussion of the findings of the 1-hour face-to-face evaluation, • the need for other interventions or treatments, and • the need to continue or discontinue the use of restraint or seclusion. 	<p style="text-align: center;"><u>DOCUMENT REVIEW AND CHART REVIEW</u></p> <ol style="list-style-type: none"> 1. Review the relevant hospital restraint and seclusion policy. 2. Does the hospital policy clarify expectations regarding the requirement, “as soon as possible”? 3. Does documentation in the patient’s medical record indicate consultation with the attending physician or other LIP when the 1-hour face-to-face evaluation was conducted by a trained RN or PA? 4. Is practice consistent with hospital policy? 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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<p>15.02.23 Simultaneous Use of Restraint and Seclusion. <i>All requirements specified under this paragraph are applicable to the simultaneous use of restraint and seclusion.</i></p> <p><i>Simultaneous restraint and seclusion use is only permitted if the patient is continually monitored:</i></p> <p>(i) <i>Face-to-face by an assigned, trained staff member; or</i></p> <p>(ii) <i>By trained staff using both video and audio equipment. This monitoring must be in close proximity to the patient.</i></p> <p>§482.13(e)(15)</p>	<p>A consultation that is not conducted prior to a renewal of the order would not be consistent with the requirement, “as soon as possible.”</p> <p>When the simultaneous use of restraint and seclusion is employed, there must be adequate documentation that justifies the decision for simultaneous use as well as vigilance in continuously monitoring the patient so that the patient’s care needs are met.</p> <p>All requirements specified under standard (e) apply to the simultaneous use of restraint and seclusion. The simultaneous use of restraint and seclusion is not permitted unless the patient is continually monitored by trained staff, either through face-to-face observation or through the use of both video and audio equipment.</p> <p><u>Video and Audio Equipment</u> Monitoring with video and audio equipment further requires that staff perform the monitoring in close proximity to the patient. For the purposes of this requirement, “continually” means ongoing without interruption. The use of video and audio equipment does not eliminate the need for frequent monitoring and assessment of the patient.</p> <p>An individual who is physically restrained alone in his or her room is not necessarily being simultaneously secluded.</p>	<p><u>DOCUMENT REVIEW, OBSERVATION, AND INTERVIEW</u></p> <ol style="list-style-type: none"> 1. Review the hospital’s policy regarding simultaneous use of restraint and seclusion to determine whether it provides for continual monitoring and otherwise complies with all requirements of <u>§482.13</u>. 2. Conduct document review and staff interviews to determine if practice is consistent with the hospital policy and required uninterrupted audio and visual monitoring is provided as required. 3. Is the staff member monitoring the patient with video and audio equipment trained and in close proximity to ensure prompt emergency intervention if a problem arises? 4. Does the video equipment cover all areas of the room or location where the patient is restrained or secluded? 5. Is the audio and video equipment located in an area that assures patient privacy? 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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	<p>The individual's privacy and dignity should be protected to the extent possible during any intervention.</p> <ul style="list-style-type: none"> • In fact, the purpose of restraining a patient alone in his or her room may be to promote privacy and dignity versus simultaneously using seclusion and restraint. While this distinction may be difficult to make, it is helpful to consider whether the patient would, in the absence of the physical restraint, be able to voluntarily leave the room. If so, then the patient is not also being secluded. • However, if the physical restraint was removed and the patient was still unable to leave the room because the door was locked or staff were otherwise physically preventing the patient from doing so, then the patient is also being secluded. <p>Staff must take extra care to protect the safety of the patient when interventions that are more restrictive are used. Monitoring must be appropriate to the intervention chosen, so that the patient is protected from possible abuse, assault, or self-injury during the intervention.</p>	<p>6. Is the equipment appropriately maintained and in working condition?</p>	

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<p>15.02.24 Requirements for Documentation. <i>When restraint or seclusion is used, there must be documentation in the patient's medical record of the following:</i></p> <p>(i) <i>The 1-hour face-to-face medical and behavioral evaluation if restraint or seclusion is used to manage violent or self-destructive behavior;</i></p> <p>§482.13 (e)(16)(i)</p>	<p>When restraint or seclusion is used to manage violent or self-destructive behavior, the 1 hour face-to-face medical and behavioral evaluation must be documented in the patient's medical record.</p>	<p style="text-align: center;"><u>CHART REVIEW</u></p> <p>Review clinical records of patients who recently required restraint or seclusion.</p> <ul style="list-style-type: none"> • Does the patient's medical record include documentation of the 1 hour face-to-face medical and behavioral evaluation when restraint or seclusion is used to manage violent or self-destructive behavior? 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>
<p>15.02.25 Requirements for Documentation. <i>When restraint or seclusion is used, there must be documentation in the patient's medical record of the following:</i></p> <p>(ii) <i>A description of the patient's behavior and the intervention used;</i></p> <p>§482.13(e)(16)(ii)</p>	<p>Documentation that must be included in the patient's medical record when the patient is restrained or secluded includes a description of the patient's behavior and the intervention used. The patient's behavior should be documented in descriptive terms to evaluate the appropriateness of the interventions used.</p> <p>The documentation should include a detailed description of the patient's physical and mental status assessments, and of any environmental factors (e.g., physical, milieu, activities, etc.) that may have contributed to the situation at the time of the intervention.</p>	<p style="text-align: center;"><u>CHART REVIEW</u></p> <ol style="list-style-type: none"> 1. Does the patient's medical record include a clear description of the patient's behavior that warranted the use of restraint or seclusion? 2. Was the intervention employed appropriate for the identified behavior? 3. What was the patient's clinical response to the intervention(s)? 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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<p>15.02.26 Requirements for Documentation. <i>When restraint or seclusion is used, there must be documentation in the patient's medical record of the following:</i></p> <p>(iii) <i>Alternatives or other less restrictive interventions attempted (as applicable);</i></p> <p>§482.13 (e)(16)(iii)</p>	<p>The use of restraint or seclusion must be selected only when less restrictive measures have been judged to be ineffective to protect the patient or others from harm.</p> <p>It is not always appropriate for less restrictive alternatives to be attempted prior to the use of restraint or seclusion.</p> <p>When a patient's behavior presents an immediate and serious danger to his- or herself, or others, immediate action is needed.</p> <ul style="list-style-type: none"> • For example, when a patient physically attacks someone, immediate action is needed. • While staff should be mindful of using the least intrusive intervention, it is critical that the intervention selected be effective in protecting the patient or others from harm. 	<p style="text-align: center;"><u>CHART REVIEW</u></p> <ol style="list-style-type: none"> 1. Does the patient's medical record document any alternatives or less restrictive interventions attempted by staff, if appropriate? 2. What was the effect of less restrictive interventions, if attempted by staff? 3. Were the interventions selected appropriate to the targeted patient behaviors? 4. When an immediate and serious danger to the patient or others occurred, was the more restrictive intervention(s) effective? <ul style="list-style-type: none"> • Could a less restrictive intervention have been used to ensure the safety of the patient, staff or others? 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>
<p>15.02.27 Requirements for Documentation. <i>When restraint or seclusion is used, there must be documentation in the patient's medical record of the following:</i></p> <p>(iv) <i>The patient's condition or symptom(s) that warranted the use of the restraint or seclusion; and</i></p> <p>§482.13(e)(16)(iv)</p>	<p>A comprehensive, individualized patient assessment is necessary to identify the most appropriate intervention to effectively manage a patient's condition or symptom(s).</p> <p>When using a restraint or seclusion intervention, the patient's condition or symptom(s) must be identified and documented in the patient's medical record.</p>	<p style="text-align: center;"><u>CHART REVIEW</u></p> <ul style="list-style-type: none"> • Does the patient's medical record include descriptions of the patient's condition or symptom(s) that warranted the use of restraint or seclusion? 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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<p>15.02.28 <u>Requirements for Documentation.</u> <i>When restraint or seclusion is used, there must be documentation in the patient's medical record of the following:</i></p> <p>(v) <i>The patient's response to the interventions(s) used, including the rationale for continued use of the intervention.</i></p> <p>§482.13 (e)(16)(v)</p>	<p>When using a restraint or seclusion intervention, the patient's response to the intervention must be documented in the patient's medical record.</p>	<p style="text-align: center;"><u>CHART REVIEW</u></p> <ol style="list-style-type: none"> 1. Does the patient's medical record include descriptions of the impact of the intervention on the patient behavior that resulted in the use of restraint or seclusion? 2. Does the patient's medical record include a detailed assessment of the patient's response to the intervention and a well-reasoned plan for the continued use of restraint or seclusion? 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>
<p>15.02.29 <u>Staff Training Requirements – Use of Restraints or Seclusion.</u> <i>The patient has the right to safe implementation of restraint or seclusion by trained staff.</i></p> <p>§482.13(f)</p>	<p>Without adequate staff training and competency, the direct care staff, patients, and others are placed at risk.</p> <p>Patients have a right to the safe application of restraint or seclusion by trained and competent staff. Staff training and education play a critical role in the reduction of restraint and seclusion use in a hospital.</p>	<p style="text-align: center;"><u>DOCUMENT REVIEW AND OBSERVATION</u></p> <ol style="list-style-type: none"> 1. Determine whether the hospital has staff training and education program that protects the patient's right to safe implementation of restraint or seclusion. 2. Observe patients in restraint or seclusion to verify safe application of the restraint or seclusion. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>15.02.30 <u>Training Intervals.</u> <i>Training Intervals –</i></p> <p><i>Staff must be trained and able to demonstrate competency in the application of restraints, implementation of seclusion, monitoring, assessment, and providing care for a patient in restraint or seclusion –</i></p> <p><i>(i) Before performing any of the actions specified in this paragraph;</i></p> <p><i>(ii) As part of orientation; and</i></p> <p><i>(iii) Subsequently on a periodic basis consistent with hospital policy.</i></p> <p>§482.13(f)(1)(i) §482.13(f)(1)(ii) §482.13(f)(1)(iii)</p>	<p>All staff designated by the hospital as having direct patient care responsibilities, including contract or agency personnel, must demonstrate the competencies specified in standard (f) prior to participating in the application of restraints, implementation of seclusion, monitoring, assessment, or care of a patient in restraint or seclusion.</p> <ul style="list-style-type: none"> • These competencies must be demonstrated initially as part of orientation and subsequently on a periodic basis consistent with hospital policy. Hospitals have the flexibility to identify a time frame for ongoing training based on the level of staff competency, and the needs of the patient population(s) served. <p>Training for an RN or PA to conduct the 1-hour face-to-face evaluation would include all of the training requirements at <u>§482.13(f)</u> as well as content to:</p> <ul style="list-style-type: none"> • evaluate the patient's immediate situation, • the patient's reaction to the intervention, • the patient's medical and behavioral condition, and • the need to continue or terminate the restraint or seclusion. <p>An evaluation of the patient's medical condition would include a:</p>	<p style="text-align: center;"><u>DOCUMENT REVIEW</u></p> <ol style="list-style-type: none"> 1. Does the hospital have a documented training program for the use of restraint and seclusion interventions employed by the hospital? 2. Does the hospital have documented evidence that all levels of staff, including agency or contract staff, that have direct patient care responsibilities and any other individuals who may be involved in the application of restraints (e.g., security guards) have been trained and are able to demonstrate competency in the safe use of seclusion and the safe application and use of restraints? 3. Review and verify restraint and seclusion education staff training documentation for all new employees and contract staff. <ul style="list-style-type: none"> • Does the training include demonstration of required competencies? • What areas were included in this training program? 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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	<ul style="list-style-type: none"> • complete review of systems assessment, • behavioral assessment, as well as • review and assessment of the patient’s history, medications, most recent lab results, etc. <p>The purpose of the 1-hour face-to-face evaluation is to complete a comprehensive review of the patient’s condition and determine if other factors, such as drug or medication interactions, electrolyte imbalances, hypoxia, sepsis, etc., are contributing to the patient’s violent or self-destructive behavior.</p> <p>Once initial training takes place, training must be provided frequently enough to ensure that staff possesses the requisite knowledge and skills to safely care for restrained or secluded patients in accordance with the regulations.</p> <ul style="list-style-type: none"> • The results of skills and knowledge assessments, new equipment, or QAPI data may indicate a need for targeted training or more frequent or revised training. <p>Hospitals are required to have appropriately trained staff for the proper and safe use of seclusion and restraint interventions.</p> <ul style="list-style-type: none"> • It would not be appropriate for a hospital to routinely call upon a law enforcement agency or agencies as a means of applying restraint or initiating seclusion. 		

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<p>15.02.31 Training Content. <i>Training Content –</i></p> <p><i>The hospital must require appropriate staff to have education, training, and demonstrated knowledge based on the specific needs of the patient population in at least the following:</i></p> <ul style="list-style-type: none"> • <i>Techniques to identify staff and patient behaviors, events, and environmental factors that may trigger circumstances that require the use of a restraint or seclusion.</i> <p>§482.13(f)(2)(i)</p>	<ul style="list-style-type: none"> • If hospital security guards, or other non-healthcare staff, as part of hospital policy, may assist direct care staff, when requested, in the application of restraint or seclusion, the security guards, or other non-healthcare staff, are also expected to be trained and able to demonstrate competency in the safe application of restraint and seclusion (in accordance with <u>§482.13(f)</u>). <p>The term “appropriate staff” includes all staff that apply restraint or seclusion, monitor, assess, or otherwise provide care for patients in restraint or seclusion.</p> <ul style="list-style-type: none"> • All staff, including contract or agency personnel, designated by the hospital as having direct patient care responsibilities are required to receive training in the areas of clinical techniques used to identify patient and staff behaviors, events and environmental factors that may trigger circumstances that require the use of restraint or seclusion. <p>This training should be targeted to the specific needs of the patient populations being served, and to the competency level of staff.</p> <p>Staff needs to be able to employ a broad range of clinical interventions to maintain the safety of the patient and others.</p>	<p style="text-align: center;"><u>DOCUMENT REVIEW AND INTERVIEW</u></p> <ol style="list-style-type: none"> 1. Does the hospital educational program include techniques related to the specific patient populations being served? 2. Does the hospital educational program include techniques to identify staff and patient behaviors, events, and environmental factors that may trigger circumstances that require the use of restraint or seclusion? 3. Does the hospital educational program provide more in-depth training in the areas included in the regulation for staff members who routinely provide care to patients who exhibit violent or self-destructive behavior (e.g., staff who work in the emergency department or psychiatric unit)? 4. Interview staff to assess their knowledge of 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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	<p>The hospital is expected to provide education and training at the appropriate level to the appropriate staff based upon the specific needs of the patient population being served.</p> <ul style="list-style-type: none"> • For example, staff routinely providing care for patients who exhibit violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others (such as in an emergency department or on a psychiatric unit) generally require more in-depth training in the areas included in the regulation than staff routinely providing medical / surgical care. • Hospitals may develop and implement their own training programs or use an outside training program. • However, standard (f) specifies that individuals providing staff training must be qualified as evidenced by education, training, and experience. <p>Hospitals have the flexibility to develop their own training program to meet the staff training requirements at <u>§482.13(f)</u> or purchase a training program from the outside.</p> <ul style="list-style-type: none"> • CMS does not specify that any particular outside vendor must be used to provide the required training. 	<p>the restraint and seclusion techniques addressed in this requirement.</p>	

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- Each hospital must assess the learning needs and competency of their staff to determine how extensive periodic training and staff competency demonstration must be subsequent to initial training. The training program must be provided to all appropriate staff.

- Any person monitoring or providing care to a restrained patient must demonstrate the knowledge and abilities required by the regulations.

At a minimum, physicians and other LIPs authorized to order restraint or seclusion by hospital policy in accordance with State law must have a working knowledge of hospital policy regarding the use of restraint and seclusion.

- Hospitals have the flexibility to identify training requirements above this minimum based on the competency level of their physicians and other LIPs and the needs of the patient population that they serve.

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<p>15.02.32 <u>Training Requirements:</u> <u>Nonphysical Intervention.</u> <i>Training Content –</i></p> <p><i>The hospital must require appropriate staff to have education, training, and demonstrated knowledge based on the specific needs of the patient population in at least the following:</i></p> <ul style="list-style-type: none"> • <i>The use of nonphysical intervention skills.</i> <p>§482.13(f)(2)(ii)</p>	<p>Although we recognize that there may be circumstances in which the use of restraint or seclusion may be necessary to prevent a patient situation from escalating, staff often skillfully intervene with alternative techniques to redirect a patient, engage the patient in constructive discussion or activity, or otherwise help the patient maintain self-control and avert escalation.</p> <p>The use of nonphysical intervention skills does not mean attempting a complex series of interventions or a lengthy checklist of steps to initiate before restraining or secluding a patient. Rather, a whole toolbox of possible interventions can be implemented during the course of a patient’s treatment based upon the assessment of an individual patient’s responses.</p>	<p style="text-align: center;"><u>DOCUMENT REVIEW AND INTERVIEW</u></p> <ol style="list-style-type: none"> 1. Does the hospital educational program address the use of nonphysical intervention skills? 2. Does the hospital’s training program comply with the regulatory requirements? 3. Interview staff to assess their non-physical intervention skills. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>
<p>15.02.33 <u>Training Requirements:</u> <u>Least Restrictive Intervention.</u> <i>Training Content –</i></p> <p><i>The hospital must require appropriate staff to have education, training, and demonstrated knowledge based on the specific needs of the patient population in at least the following:</i></p> <ul style="list-style-type: none"> • <i>Choosing the least restrictive intervention based on an individualized assessment of the</i> 	<p>The underpinning of this regulation is the concept that safe patient care hinges on looking at the patient as an individual and assessing the patient’s condition, needs, strengths, weaknesses, and preferences. Such an approach relies on caregivers who are skilled in individualized assessment and in tailoring interventions to individual patient’s needs after weighing factors such as the patient’s condition, behaviors, history, and environmental factors.</p> <p>Resources Resources are available to assist clinicians in identifying less restrictive interventions. For example,</p>	<p style="text-align: center;"><u>DOCUMENT REVIEW AND INTERVIEW</u></p> <ol style="list-style-type: none"> 1. Does the hospital educational program address choosing the least restrictive intervention based on an individualized assessment of the patient’s medical or behavioral status or condition? 2. Does the hospital educational program address how to conduct an assessment of a patient’s medical and behavioral conditions? 3. Does the hospital educational program address types of interventions appropriate to 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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<p><i>patient’s medical, or behavioral status or condition.</i></p> <p>§482.13(f)(2)(iii)</p>	<p>the American Psychiatric Association (APA), American Psychiatric Nurses Association (APNA), and the National Association of Psychiatric Health Systems (NAPHS), with support from the American Hospital Association (AHA), have sponsored the publication of a document entitled, “Learning from Each Other— Success Stories and Ideas for Reducing Restraint / Seclusion in Behavioral Health.” This document, published in 2003, was developed through dialogue with the field and extensive input from behavioral healthcare providers throughout the country who have been working to reduce the use of restraint and seclusion, and to improve care within their facilities.</p> <p>To access this document and other useful resources, visit the web sites of the sponsoring organizations: http://www.naphs.org; http://www.psych.org; http://www.apna.org; http://www.aha.org</p>	<p>the specific needs of the patient population(s) served and ranging from less to more restrictive?</p> <p>4. Interview staff to determine if they are able to demonstrate the abilities addressed in this requirement.</p>	
<p>15.02.34 Training Requirements: Safe Application. <i>Training Content –</i></p> <p><i>The hospital must require appropriate staff to have education, training, and demonstrated knowledge based on the specific needs of the patient population in at least the following:</i></p> <ul style="list-style-type: none"> • <i>The safe application and use of all types of restraint or seclusion</i> 	<p>Patients have a right to the safe application of restraint or seclusion by trained and competent staff.</p>	<p><u>FILE REVIEW, DOCUMENT REVIEW, AND INTERVIEW</u></p> <ol style="list-style-type: none"> 1. Is all staff, including contract or agency personnel, identified by the hospital as direct caregivers trained and able to demonstrate competency in the safe use of all types of restraints or seclusion used in the hospital? 2. Does the hospital educational program address recognition and response to patient signs of physical and psychological distress? 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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<p><i>used in the hospital, including training in how to recognize and respond to signs of physical and psychological distress (for example, positional asphyxia).</i></p> <p>§482.13(f)(2)(iv)</p>		<p>3. Review hospital data (i.e., incident reports, patient injury or death reports, etc.) to identify any patterns of patient injuries or death that may indicate that staff are not adequately trained to recognize and respond to patient signs of physical and psychological distress.</p> <p>4. Is staff able to identify signs of physical and psychological distress in a timely manner?</p> <p>5. Is staff able to respond to and appropriately treat signs of physical and psychological distress?</p>	
<p>15.02.35 Training Requirements: Restraint Removal. <i>Training Content –</i></p> <p><i>The hospital must require appropriate staff to have education, training, and demonstrated knowledge based on the specific needs of the patient population in at least the following:</i></p> <ul style="list-style-type: none"> • <i>Clinical identification of specific behavioral changes that indicate that restraint or seclusion is no longer necessary.</i> <p>§482.13(f)(2)(v)</p>	<p>The use of restraint or seclusion must be ended at the earliest possible time regardless of the length of time identified in the order.</p> <p>Staff must be trained and demonstrate competency in their ability to identify specific patient behavioral changes that may indicate that restraint or seclusion is no longer necessary and can be safely discontinued.</p>	<p style="text-align: center;"><u>DOCUMENT REVIEW AND INTERVIEW</u></p> <p>1. Does the hospital educational program address identification of specific behavioral changes that may indicate that restraint or seclusion is no longer necessary?</p> <p>2. Interview staff to determine if they are able to demonstrate the abilities addressed in this requirement.</p>	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>15.02.36 <u>Training Requirements:</u> <u>Patient Monitoring.</u> <i>Training Content –</i></p> <p><i>The hospital must require appropriate staff to have education, training, and demonstrated knowledge based on the specific needs of the patient population in at least the following:</i></p> <ul style="list-style-type: none"> • <i>Monitoring the physical and psychological well-being of the patient who is restrained or secluded, including but not limited to, respiratory and circulatory status, skin integrity, vital signs, and any special requirements specified by hospital policy associated with the 1-hour face-to-face evaluation.</i> <p>§482.13(f)(2)(vi)</p>	<p>Staff must be trained and demonstrate competency in monitoring the physical and psychological well-being of a patient who is restrained or secluded, including but not limited to, respiratory and circulatory status, skin integrity, vital signs, and as well as any special requirements specified by hospital policy associated with the 1-hour face-to-face evaluation.</p>	<p style="text-align: center;"><u>DOCUMENT REVIEW AND INTERVIEW</u></p> <ol style="list-style-type: none"> 1. Does the hospital educational program address monitoring the physical and psychological needs of patients who are restrained or secluded, including but not limited to, respiratory and circulatory status, skin integrity, vital signs, and any special requirements specified by hospital policy associated with the 1-hour face-to-face evaluation? 2. Does the hospital educational program address the specific requirements for the training of RNs and PAs that the hospital authorizes to conduct the 1-hour face-to-face evaluation? 3. Interview staff to determine if they are able to demonstrate the competencies addressed in this regulation. 	<p style="text-align: center;"> <input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant </p> <p style="text-align: center;">This standard is not met as evidenced by:</p>

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<p>15.02.37 <u>Training Requirements:</u> <u>CPR Training.</u> <i>Training Content –</i></p> <p><i>The hospital must require appropriate staff to have education, training, and demonstrated knowledge based on the specific needs of the patient population in at least the following:</i></p> <ul style="list-style-type: none"> • <i>The use of first aid techniques and certification in the use of cardiopulmonary resuscitation, including required periodic recertification.</i> <p>§482.13(f)(2)(vii)</p>	<p>Hospitals are required to provide a safe environment for the patients in their care. When restraint or seclusion techniques are used, patients are placed at a higher risk for injuries or even death.</p> <p>Hospitals must require appropriate staff (all staff who apply restraint or seclusion, monitor, access or provide care for a patient in restraint or seclusion) to receive education and training in the use of first aid techniques as well as training and certification in the use of cardiopulmonary resuscitation.</p> <ul style="list-style-type: none"> • Hospitals are not required to use any particular recognized first aid course. • Additionally, such courses may not adequately address the immediate interventions, the “first aid,” that needs to be rendered to a restrained or secluded patient who is in distress or injured. The goal is for staff to be able to render the appropriate “first aid” required if a restrained or secluded patient is in distress or injured. For example, a patient is found hanging in a vest restraint, a restrained patient is choking on food, a secluded suicidal patient is found hanging, a secluded suicidal patient has cut himself, etc. <p>Hospital staff need to assess their patient population and identify likely scenarios, develop a first aid training that addresses those scenarios, and provide that “first aid” training to all staff that care for restrained or secluded patients.</p>	<p style="text-align: center;"><u>DOCUMENT REVIEW AND FILE REVIEW</u></p> <ol style="list-style-type: none"> 1. Does the hospital educational program address first aid techniques? 2. Does the hospital educational program include, or provide for, staff training and certification in cardiopulmonary resuscitation (including provisions for recertification)? 3. Is appropriate staff certified in cardiopulmonary resuscitation? 	<p style="text-align: center;"> <input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant </p> <p style="text-align: center;">This standard is not met as evidenced by:</p>

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<p>15.02.38 <u>Trainer Requirements.</u> <i>Trainer Requirements.</i></p> <ul style="list-style-type: none"> • <i>Individuals providing staff training must be qualified as evidenced by education, training, and experience in techniques used to address patients' behaviors.</i> <p>§482.13(f)(3)</p>	<p>There is no requirement that training be obtained from Federally-specified programs.</p> <ul style="list-style-type: none"> • Hospitals may develop and implement their own training programs or use an outside training program. • However, individuals providing the training must be qualified as evidenced by education, training and experience in techniques used to address patients' behaviors for the patient populations being served. <p>Trainers should demonstrate a high level of knowledge regarding all the requirements of these regulations as well as the hospital's policies and procedures that address these requirements.</p>	<p style="text-align: center;"><u>FILE REVIEW, DOCUMENT REVIEW AND INTERVIEW</u></p> <ol style="list-style-type: none"> 1. Review personnel files of individuals responsible for providing staff education and training. 2. Do the individuals providing the education and training possess education, training, and experience to qualify them to teach the staff? 3. Are they qualified to identify and meet the needs of the patient population(s) being served? 4. Does the hospital have a system for documenting and ensuring that the individuals providing education and training have the appropriate qualifications required by this regulation? 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>
<p>15.02.39 <u>Training Documentation.</u> <i>Training Documentation.</i></p> <ul style="list-style-type: none"> • <i>The hospital must document in the staff personnel records that the training and demonstration of competency were successfully completed.</i> <p>§482.13(f)(4)</p>	<p>Staff personnel records must contain documentation that the training and demonstration of competency were successfully completed initially during orientation and on a periodic basis consistent with hospital policy.</p>	<p style="text-align: center;"><u>FILE REVIEW</u></p> <ul style="list-style-type: none"> • Review a sample of staff personnel records, including contract or agency staff, to determine if the training and demonstration of competency have been completed during orientation and on a periodic basis consistent with hospital policy. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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<p>15.02.40 <u>Not Applicable.</u></p>			
<p>15.02.41 <u>Death Related to Restraint or Seclusion – Reporting Requirements.</u> <i>Hospitals must report deaths associated with the use of seclusion or restraint.</i></p> <p>(1) <i>With the exception of deaths described under paragraph (g)(2) of 42 CFR 482.13, the hospital must report the following information to CMS by telephone, facsimile, or electronically, as determined by CMS, no later than the close of business on the next business day following knowledge of the patient’s death:</i></p> <p>(i) <i>Each death that occurs while a patient is in restraint or seclusion.</i></p> <p>(ii) <i>Each death that occurs within 24 hours after the patient has been removed from restraint or seclusion.</i></p> <p>(iii) <i>Each death known to the hospital that occurs within 1 week after restraint or seclusion where it is reasonable to assume that</i></p>	<p>The hospital must report to its CMS Regional Office each death that occurs:</p> <ol style="list-style-type: none"> 1. While a patient is in restraint or in seclusion, except when no seclusion has been used and the only restraint used was a soft, cloth-like two-point wrist restraints; 2. Within 24 hours after the patient has been removed from restraint or seclusion except when no seclusion has been used and the only restraint used was a soft, two-point wrist restraint; or, 3. Within 1 week after use of restraint or seclusion where the death is known to the hospital and it is reasonable to assume that the use of restraint or seclusion contributed directly or indirectly to the patient’s death, regardless of the type(s) of restraint used on the patient during this time. <ul style="list-style-type: none"> • “Reasonable to assume” applies only to those deaths that occur on days 2-7 after restraint or seclusion has been discontinued. • This criterion applies regardless of the type of restraint that was used on the patient. In other words, it applies to all uses of restraint or seclusion where the patient has died on days 2-7 after the restraint or seclusion was discontinued, and it is reasonable to assume 	<p style="text-align: center;"><u>DOCUMENT REVIEW</u></p> <p>Review hospital policies.</p> <ol style="list-style-type: none"> 1. Does the hospital have restraint/seclusion death reporting policies and procedures that addresses responsibilities and systems for identifying restraint/seclusion-associated deaths reportable to CMS and for implementing the reporting and recordkeeping requirements? 2. Can the hospital provide examples of restraint/seclusion-associated deaths that were reported to CMS? <u>If Yes:</u> Review the report and medical records to determine whether: <ul style="list-style-type: none"> • The reports met the criteria for reporting to CMS; • Were submitted timely to CMS; • Were complete; and • The date and time the death reported to CMS was entered into the patient’s medical record. <u>If No:</u> <ul style="list-style-type: none"> • Ask the hospital how it ensures that there were no reportable restraint/seclusion-associated deaths. • If the hospital’s system relies upon staff 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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<p><i>use of restraint or placement in seclusion contributed directly or indirectly to a patient's death, regardless of the type(s) of restraint used on the patient during this time. "Reasonable to assume" in this context includes, but is not limited to, deaths related to restrictions of movement for prolonged periods of time, or death related to chest compression, restriction of breathing or asphyxiation.</i></p> <p>§482.13(g)(1) §482.13(g)(1)(i) §482.13(g)(1)(ii) §482.13(g)(1)(iii)</p> <p>(2) <i>When no seclusion has been used and when the only restraints used on the patient are those applied exclusively to the patient's wrist(s), and which are composed solely of soft, non-rigid, cloth-like materials, the hospital staff must record in an internal log or other system, the following information:</i></p> <p>(i) <i>Any death that occurs while a patient is in such</i></p>	<p>the use of the restraint or seclusion contributed to the patient's death. In a case where only two-point soft wrist restraints were used and there was no seclusion, it may reasonably be presumed that the patient's death was not caused by the use of restraints.</p> <ul style="list-style-type: none"> • In cases involving death within one week after the use of restraint or seclusion where the intervention may have contributed to the patient's death, it is possible that the patient's death might occur outside the hospital and that the hospital might not learn of the patient's death, or that there might be a delay in the hospital's learning of the patient's death. <p>See the guidance for §482.13(g)(2) for handling of deaths while a patient was in, or within 24 hours after removal of a soft, two-point wrist restraint, when no other restraint or seclusion was used.</p> <ol style="list-style-type: none"> 1. The reports required under §482.13(g)(1) must be submitted to the CMS Regional Office by telephone, facsimile, or electronically, as determined by the Regional Office no later than close of the next business day following the day in which the hospital knows of the patient's death. 2. The report must include basic identifying information related to the hospital, the patient's name, date of birth, date of death, 	<p>identification of reportable deaths, interview several applicable staff members to determine whether they are aware of the hospital's policy and know when and where to report internally a restraint / seclusion-associated death.</p> <ul style="list-style-type: none"> • Ask if there have been any patient deaths that meet the reporting requirements. <ol style="list-style-type: none"> 3. Interview staff in various types of inpatient units, including a psychiatric unit if applicable, to determine whether they are aware of any patients who died while in restraints or seclusion or within one day of restraint or seclusion discontinuation, excluding cases involving only the use of two-point soft wrist restraints and no seclusion. <ul style="list-style-type: none"> • If yes, check whether the hospital has any evidence that these cases were reported to CMS. <p>Death Report Log:</p> <ol style="list-style-type: none"> 1. Does the hospital have restraint/seclusion death reporting policies and procedures that address responsibilities and systems for identifying restraint / seclusion-associated deaths that must be recorded in an internal hospital log/tracking system, and for implementing the reporting and recordkeeping requirements? 2. Ask the hospital how it ensures that each 	

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<p><i>restraints.</i></p> <p>(ii) <i>Any death that occurs within 24 hours after a patient has been removed from such restraints.</i></p> <p>§482.13(g)(2) §482.13(g)(2)(i)(ii)</p>	<p>name of attending physician/ practitioner, primary diagnosis(es), cause of death (preliminary, in case a final, official cause of death is not yet available), and type(s) of restraint or seclusion used. CMS makes a standard form available for hospitals to use in submitting the required reports.</p>	<p>death that must be captured in the log/tracking system is identified and entered.</p>	
<p>(3) <i>The staff must document in the patient’s medical record the date and time the death was:</i></p> <p>(i) <i>Reported to CMS for deaths described in paragraph (g)(1) of 42 CFR 482.13, or</i></p> <p>(ii) <i>Recorded in the internal log or other system for deaths described in paragraph (g)(2) of 42 CFR 482.13.</i></p> <p>§482.13(g)(3) §482.13(g)(3)(i)(ii)</p>	<p>Hospitals must document in the patient’s medical record the date and time each reportable death associated with the use of restraint or seclusion was reported to the CMS Regional Office.</p> <p><u>CMS Regional Office</u> After reviewing the submitted information, the Regional Office will determine whether an on-site investigation of the circumstances surrounding the patient’s death is warranted and will direct the State Survey Agency to conduct a survey if applicable.</p> <p><u>Hospital Restraint Death Log</u> Hospitals must maintain an internal log or other type of tracking system for recording information on each death that occurs:</p> <ul style="list-style-type: none"> • While a patient is in only 2-point soft, cloth-like non-rigid wrist restraints and there is no use of seclusion; and • Within 24 hours of the patient being removed from 2-point soft, cloth-like non-rigid wrist restraints where there was no use of any other type of restraint or seclusion. 	<p>3. Interview inpatient unit staff to determine whether they have had patients who die while 2-point soft wrist restraints are being used without seclusion or within 24 hours of their discontinuance.</p> <ul style="list-style-type: none"> • If yes, ask the hospital to demonstrate that it has recorded such deaths. <p>4. If the hospital’s log or tracking system relies upon staff identification of reportable deaths, interview several applicable staff members to determine whether they are aware of the hospital’s policy and know when and where to report internally a restraint/seclusion-associated death.</p> <p>5. Review the log/tracking system for patient deaths associated with use of only 2-point soft wrist restraints to determine if:</p> <ul style="list-style-type: none"> • Each entry was made within 7 days of the patient’s death; and • Each entry contains all the information required under the regulation. 	
<p>(4) <i>For deaths described in paragraph (g)(2) of 42 CFR 482.13, entries into the log or other system must be documented as follows:</i></p> <p>(i) <i>Each entry must be made not later than seven days after the date of death of the patient.</i></p> <p>(ii) <i>Each entry must document the patient’s name, date of birth,</i></p>		<p>6. Is the hospital able to make the log or tracking system available immediately on request?</p>	

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<p><i>date of death, name of attending physician or other licensed independent practitioner who is responsible for the care of the patient as specified under §482.12(c), medical record number and primary diagnosis(es).</i></p> <p><i>(iii) The information must be made available in either written or electronic form to CMS immediately upon request.</i></p> <p>§482.13(g)(4) §482.13(g)(4)(i)(ii)(iii)</p>	<p>Use of the log or tracking system is limited only to patient deaths meeting one of these two criteria. Examples of patient deaths associated with restraints that must still be reported to CMS include:</p> <ul style="list-style-type: none"> • Deaths occurring during or within 24 hours of discontinuation of 2-point soft, cloth-like non-rigid wrist restraints used in combination with any other restraint device or with seclusion; or • Deaths associated with the use of other types of wrist restraints, such as 2-point rigid or leather wrist restraints. <p>These cases would not be included in this internal log or tracking system and would require reporting the death to CMS using telephone, fax, or electronically.</p> <p>The two-point soft wrist restraint death report must be entered into the internal log or tracking system within 7 days of the patient's death. The death report log or tracking system entry must include:</p> <ol style="list-style-type: none"> 1. The patient's name; 2. Patient's date of birth; 3. Patient's date of death; 4. Name of the attending physician or other licensed independent practitioner who is responsible for the care or the patient; 	<ol style="list-style-type: none"> 7. Review a sample of medical records of patients whose deaths were entered in the log or tracking system. <ul style="list-style-type: none"> • Does the medical record indicate that only soft, 2-point wrist restraints were used? 8. Is there documentation in the medical record of the entry into the log or tracking system? 	

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	<p>5. Patient’s medical record number; and</p> <p>6. Primary diagnosis(es).</p> <p>Depending on the size and nature of the patient population the hospital serves and the types of services it provides, there will likely be variations in the frequency of restraint use as well as in the incidence of patient deaths.</p> <ul style="list-style-type: none"> • Surveyors should adjust their expectations for the volume of log or tracking system entries accordingly. • For example, hospitals with intensive care units might be more likely to use both soft, 2-point wrist restraints and to have seriously ill patients who die as a result of their disease while such restraints are being used or within 24 hours after their discontinuance. • On the other hand, a rehabilitation hospital would be expected to use such restraints less frequently, and to have patients who die less frequently while hospitalized. <p>The log or tracking system must be available in written, i.e., hard copy, or electronic form immediately upon CMS’s request.</p> <ul style="list-style-type: none"> • CMS will specify the form in which the information is to be provided. • Generally CMS would request access to the log or 		

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tracking system during an on-site survey by CMS staff or State surveyors acting on CMS's behalf when assessing compliance with restraint/seclusion requirements.

- However, CMS may also request that a copy of portions or the entire log or tracking system be provided, even though no survey is in progress. Accreditation organizations conducting hospital inspections in accordance with a CMS-approved Medicare hospital accreditation program are also entitled to immediate access to the log or tracking system.

The hospital is not required to make the contents of the log or tracking system available to any other outside parties, unless required to do so under other Federal or State law.

The hospital must document in the patient's medical record the date and time the death report entry was made into the log or tracking system.

Refer to CMS Form 353 "**HOSPITAL RESTRAINT /SECLUSION DEATH REPORT WORKSHEET**"

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<p>15.03.00 Condition of Participation: Discharge Planning. <i>The hospital must have an effective discharge planning process that applies to all patients.</i></p> <p><i>The hospital's policies and procedures must be specified in writing.</i></p> <p>§482.43</p>	<p>This CoP applies to all types of hospitals and requires all hospitals to conduct appropriate discharge planning activities for all inpatients. It applies to patients who are admitted to the hospital as inpatients. This CoP does not apply to patients who appear in a hospital emergency department but are not admitted as hospital inpatients.</p> <div style="border: 1px solid black; padding: 5px; margin: 10px 0;"> <p>Note: Hospitals should ensure their discharge practices comply with applicable Federal civil rights laws, which are not addressed in these standards.</p> </div> <p>Hospital discharge planning is a process that involves determining the appropriate post-hospital discharge destination for a patient; identifying what the patient requires for a smooth and safe transition from the hospital to his/her discharge destination; and beginning the process of meeting the patient's identified post-discharge needs.</p> <p>Newer terminology, such as "transition planning" or "community care transitions" is preferred by some, since it moves away from a focus primarily on a patient's hospital stay to consideration of transitions among the multiple types of patient care settings that may be involved at various points in the treatment of a given patient. This approach recognizes the shared responsibility of health care professionals and facilities as well as patients and their support persons throughout the continuum of care, and the need to foster better communication among the various groups.</p>	<p style="text-align: center;">DOCUMENT REVIEW</p> <ol style="list-style-type: none"> 1. Determine whether the hospital has written policies and procedures for discharge planning. 2. Evaluate compliance with each standard within the discharge planning CoP in accordance with the guidance below. Following standard practice, depending on the manner and degree of deficiencies identified related to specific discharge planning standards, determine whether deficiencies in one or more of these areas rises to the level of substantial, i.e., condition-level, noncompliance with this CoP. 	<p> <input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant </p> <p>This standard is not met as evidenced by:</p>

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	<p>Much of the interpretive guidance for this CoP has been informed by newer research on care transitions, understood broadly. At the same time, the term “discharge planning” is used both in Section 1861(ee) of the Social Security Act as well as in §482.43. In this guidance, therefore, we continue to use the term “discharge planning.”</p> <p>When the discharge planning process is well executed, and absent unavoidable complications or unrelated illness or injury, the patient continues to progress towards the goals of his/her plan of care after discharge. However, it is not uncommon in the current health care environment for patients to be discharged from inpatient hospital settings only to be readmitted within a short timeframe for a related condition. Some readmissions may not be avoidable. Some may be avoidable, but are due to factors beyond the control of the hospital that discharged the patient. On the other hand, a poor discharge planning process may slow or complicate the patient’s recovery, may lead to readmission to a hospital, or may even result in the patient’s death.</p> <p>Jencks¹ et al. analyzed Medicare claims data for a two-year period in an attempt to more accurately identify readmission (called “rehospitalization”) rates and associated costs. They found approximately 19.6% of Medicare fee-for-service beneficiaries were rehospIALIZED within 30 days of discharge and 34.0% within 60 days of discharge. 70.5% of those surgical</p>		

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	<p>patients subsequently readmitted within 30 days had a medical cause for the readmission. Only approximately 10% of rehospitalizations were estimated to have been planned.</p> <p>Reducing the number of preventable hospital readmissions is a major priority for patient safety, and holding hospitals accountable for complying with the discharge planning CoP is one key element of an overall strategy for reducing readmissions. With respect to the causes of the high rate of preventable readmissions, “Multiple factors contribute to the high level of hospital readmissions in the U.S.... They may result from poor quality care or from poor transitions between different providers and care settings. Such readmissions may occur if patients are discharged from hospitals or other health care settings prematurely; if they are discharged to inappropriate settings; or if they do not receive adequate information or resources to ensure a continued progression of services. System factors, such as poorly coordinated care and incomplete communication and information exchange between inpatient and community-based providers, may also lead to unplanned readmissions.”²</p> <p>The discharge planning CoP requirements address all of these factors. While hospitals are not solely responsible for the success of their patients’ post-hospital care transitions, under the discharge planning CoP hospitals are expected to employ a discharge planning process that improves the quality of care for</p>		

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	<p>patients and reduces the chances of readmission. The plain language of the regulation requires hospitals to have a discharge planning process in effect for “all” patients. However, the preamble to the adoption of this regulation on December 13, 1994 makes it clear that this “all patients” language was meant to distinguish the final rule from the proposed rule, which would have applied only to hospital inpatients who were Medicare beneficiaries. It was not intended to apply the discharge planning process to outpatients as well as inpatients. Specifically, the preamble stated, “Discharge planning presupposes hospital admission and section 9305(c) of OBRA ‘86 specifically indicates that discharge planning follows hospitalization.” (59 FR at 64141, December 13, 1994).</p> <p>Accordingly, under the regulation,</p> <ul style="list-style-type: none"> • hospitals are required to have a discharge planning process that applies to all inpatients; • discharge planning is not required for outpatients. <p>The discharge planning CoP (and Section 1861(ee) of the Act on which the CoP is based) provides for a four-stage discharge planning process:</p> <ol style="list-style-type: none"> 1. Screening all inpatients to determine which ones are at risk of adverse health consequences post-discharge if they lack discharge planning; 2. Evaluation of the post-discharge needs of inpatients identified in the first stage, or of 		

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	<p style="text-align: center;">inpatients who request an evaluation, or whose physician requests one;</p> <p>3. Development of a discharge plan if indicated by the evaluation or at the request of the patient’s physician; and</p> <p>4. Initiation of the implementation of the discharge plan prior to the discharge of an inpatient.</p> <p>The hospital is required to specify in writing its discharge planning policies and procedures. The policies and procedures must address all of the requirements of 42 CFR 482.43(a) – 482.43(e). The hospital must take steps to assure that its discharge planning policies and procedures are implemented consistently.</p> <p>The discharge planning CoP specifically addresses the role of the patient, or the patient’s representative, by requiring the hospital to develop a discharge planning evaluation at the patient’s request, and to discuss the evaluation and plan with the patient. This is consistent with the regulations at 42 CFR 482.13(b)(1) & (2), that provide the patient has the right to participate in the development and implementation of his/her plan of care, and to make informed decisions regarding his/her care.</p> <p>Accordingly, hospitals must actively involve patients or their representatives throughout the discharge</p>		

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planning process.

Further, the specific discharge planning evaluation requirement to assess a patient’s capability for post-discharge self-care requires the hospital, as needed, to actively solicit information not only from the patient or the patient’s representative, but also from family/friends/support persons.

1. Jencks, F. J., Williams, M. V., Coleman, E. A. Rehospitalizations among Patients in the Medicare Fee-for-Service program. *The New England Journal of Medicine* 2009; 360;14: 1418-1428.
2. Modifications to the Maryland Hospital Preventable Readmissions (MHPR) Draft Recommendations, Staff Report, Maryland Health Services Cost Review Commission, December 1, 2010, accessed via the agenda for the December 8, 2010 Commission meeting.

Note: While not a requirement, due to the increasing complexity of services offered in the outpatient setting, hospitals may wish to consider an abbreviated post-hospital planning process for certain categories of outpatients, such as patients discharge from observation services, same day surgery, and certain emergency department discharges.

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<p>15.03.01 Discharge Planning – Identification of Patients in Need. <i>The hospital must identify at an early stage of hospitalization all patients who are likely to suffer adverse health consequences upon discharge if there is no adequate discharge planning.</i></p> <p>§482.43(a)</p>	<p>If a hospital does not voluntarily adopt a policy of developing a discharge plan for every inpatient, then the hospital must evaluate all inpatients to identify those patients for whom the lack of an adequate discharge plan is likely to result in an adverse impact on the patient’s health.</p> <div style="border: 1px solid black; padding: 10px; margin: 10px 0;"> <p style="text-align: center;">For Information – Not Required/Not to be Cited</p> <p>Given the high level of readmissions that hospitals experience, a hospital would be well advised to assume that every inpatient requires a discharge plan to reduce the risk of adverse health consequences post-discharge. Providing a discharge plan for every inpatient means the hospital avoids the problems that result if it utilizes a screening process that fails to predict adequately which patients need a discharge plan to avoid adverse consequences.</p> <p>This does not mean that every discharge plan will be equally detailed or complex; some may be comparatively simple, for example, focusing on clear instructions for self-care for patients whose post-care needs may be readily met in their home environment. On the other hand, other patients may have complex needs for care after discharge. It is common for many patients to be discharged with a need for numerous on-going services/therapies, such as intravenous (IV) medications, intensive physical and occupational</p> </div>	<p><u>DOCUMENT REVIEW AND CHART REVIEW</u></p> <ol style="list-style-type: none"> 1. Determine whether hospital policy addresses: <ul style="list-style-type: none"> • Hospital must identify at an early stage of hospitalization all patients who are likely to suffer adverse health consequences upon discharge or readmission if there is inadequate discharge planning. 2. In every inpatient unit surveyed is there evidence of timely screening to determine if a discharge planning evaluation is needed? (Not applicable in hospitals that require a discharge planning evaluation for all inpatients.) 3. Conduct discharge tracers for several open and closed inpatient records to determine: <ol style="list-style-type: none"> (a) When was the screening done to identify inpatients needing a discharge planning evaluation? <ul style="list-style-type: none"> • If the hospital conducts an evaluation for all inpatients, or if it documents in the medical record screening of an inpatient before or at time of admission, or at least 48 hours prior to discharge, it is in compliance. • For patients whose stay was less than 48 hours is there any evidence of a screening to determine if discharge planning was needed? 	<div style="display: flex; align-items: center;"> <input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant </div> <p>This standard is not met as evidenced by:</p>

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	therapy, remote monitoring, wound care, etc. The key is that the discharge plan must reflect a thorough evaluation of the patient’s post hospital care needs and must address the needs identified.	(b) Can hospital staff demonstrate that the hospital’s criteria and screening process for a discharge planning evaluation are correctly applied?	
	<p>While there is no one nationally accepted tool or criteria for identifying those patients who require discharge planning, the following factors have been identified as important:</p> <ul style="list-style-type: none"> • the patient’s functional status and cognitive ability; • the type of post-hospital care the patient requires, and whether such care requires the services of health care professionals or facilities; • the availability of the required post-hospital health care services to the patient; and • the availability and capability of family and/or friends to provide follow-up care in the home. <p><u>POLICIES AND PROCEDURES</u></p> <p>For hospitals that do not develop a discharge plan for every inpatient, the hospital’s discharge planning policies and procedures must document the criteria and screening process it uses to identify patients likely to need discharge planning, including the evidence or basis for the criteria and process. They must also identify which staff are responsible for carrying out the evaluation to identify patients likely to need discharge planning.</p>	<p>4. For patients not initially identified as in need of a discharge plan, is there a process for updating this determination based on changes in the patient’s condition or circumstances?</p> <p>(a) Does the discharge planning policy address changes in patient condition that would call for a discharge planning evaluation of patients not previously identified as in need of one?</p> <p>(b) Are inpatient unit staff aware of how, when, and whom to notify of changes in the patient’s clinical condition that might warrant a change in the discharge planning process?</p>	

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The regulation requires that the identification of patients must be made at an early stage of the patient’s hospitalization. This is necessary in order to allow sufficient time to complete discharge planning evaluations and develop appropriate discharge plans, for those patients who need them. (See §482.43((b)(5))

- Ideally the identification process will be completed when the patient is admitted as an inpatient, or shortly thereafter. However, no citations will be made if the identification of patients likely to need discharge planning is completed at least 48 hours in advance of the patient’s discharge and there is no evidence that the patient’s discharge was delayed due to the hospital’s failure to complete an appropriate discharge planning evaluation on a timely basis or that the patient was placed unnecessarily in a setting other than where he/she was admitted from primarily due to a delay in discharge planning.

- For example, a delay in identification of a patient in need of discharge planning might result in discharging the patient to a nursing facility, because such placements can be arranged comparatively quickly, when the patient preferred to return home, and could have been supported in the home environment with arrangement of appropriate community services.

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LESS THAN 48 HOURS STAY

If the patient’s stay is for less than 48 hours, hospitals must nevertheless ensure that they are screened so that, if needed, the discharge planning process is completed before the patient’s discharge.

Changes in the patient’s condition may warrant development of a discharge plan for a patient not identified during the initial screening process. The hospital’s discharge planning policies and procedures must address how the staff responsible for discharge planning will be made aware of changes in a patient’s condition that require a discharge planning evaluation. In the event that a patient is transferred to another hospital, any pertinent information concerning the identification of the patient’s post-hospital needs should be in the patient’s medical record that is transferred with the patient.

The receiving hospital then becomes responsible for the discharge planning process for the patient.

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<p>15.03.02 Discharge Planning Evaluation.</p> <p>(1) <i>The hospital must provide a discharge planning evaluation to the patients identified in paragraph (a) of 42 CFR 482.43, and to other patients upon the patient’s request, the request of a person acting on the patient’s behalf, or the request of the physician.</i></p> <p>3. <i>The discharge planning evaluation must include an evaluation of the likelihood of a patient needing post-hospital services and of the availability of the services.</i></p> <p>(4) <i>The discharge planning evaluation must include an evaluation of the likelihood of a patient’s capacity for self-care or of the possibility of the patient being cared for in the environment from which he or she entered the hospital.</i></p> <p>§482.43(b) §482.43(b)(1) §482.43(b)(3) §482.43(b)(4)</p>	<p>For every inpatient identified under the process required at §482.43(a) as at potential risk of adverse health consequences without a discharge plan, a discharge planning evaluation must be completed by the hospital.</p> <p>In addition, an evaluation must also be completed if the patient, or the patient’s representative, or the patient’s attending physician requests one.</p> <p>Unless the hospital has adopted a voluntary policy of developing an evaluation for every inpatient, the hospital must also have a process for making patients, including the patient’s representative, and attending physicians aware that they may request a discharge planning evaluation, and that the hospital will perform an evaluation upon request.</p> <p>Hospitals must perform the evaluation upon request, regardless of whether the patient meets the hospital’s screening criteria for an evaluation. In contrast to the screening process, the evaluation entails a more detailed review of the individual patient’s post-discharge needs, in order to identify the specific areas that must be addressed in the discharge plan.</p> <p>§482.43(b)(3) requires the evaluation to consider the patient’s likelihood of needing post-hospital services and the availability of such services.</p> <p>If neither the patient nor the patient’s family or</p>	<p style="text-align: center;">INTERVIEW</p> <p>1. Determine whether hospital policy addresses:</p> <ul style="list-style-type: none"> • Processes to provide discharge planning evaluation to patients identified by admission screening, upon patient/family request, and upon request of the physician. <p>2. In every unit with inpatient beds surveyed, is there evidence of discharge planning evaluation activities?</p> <p>3. Are staff members who are responsible for discharge planning evaluation correctly following the hospital’s policies and procedures?</p> <p>4. If the hospital does not require a discharge planning evaluation for all inpatients:</p> <ul style="list-style-type: none"> • Does the hospital have a standard process for notifying patients, their representative, and physicians that they may request a discharge planning evaluation and that the hospital will conduct an evaluation upon request? • Can discharge planning and unit nursing staff describe the process for a patient or the patient’s representative to request a discharge planning evaluation? • Interview patients and their 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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	<p>informal caregiver(s) are able to address all of the required care needs, then the evaluation must determine whether there are community-based services that are available to meet the patient’s needs while allowing the patient to continue living at home. Such health care services include, but are not limited to:</p> <ul style="list-style-type: none"> • Home health, attendant care, and other community-based services; • Hospice or palliative care; • Respiratory therapy; • Rehabilitation services (PT, OT, Speech, etc.); • End Stage Renal Dialysis services; • Pharmaceuticals and related supplies; • Nutritional consultation/supplemental diets; and/or • Medical equipment and related supplies. <p>However, services may also include those that are not traditional health care services, but which may be essential to a patient’s ongoing ability to live in the community, including, but not limited to:</p> <ul style="list-style-type: none"> • Home and physical environment modifications; • Transportation services; • Meal services; and/or • Household services, such as housekeeping, shopping, etc. <p>Some of the information related to needed services will emerge from the required evaluation of the patient’s ability to receive care in the home, either as</p>	<p>representatives. If they say they were not aware they could request a discharge planning evaluation, can the hospital provide evidence they received notice of their right?</p> <ul style="list-style-type: none"> • Interview attending physicians to see if they are aware they can request a discharge planning evaluation. If they are not aware, can the hospital provide evidence of how they inform the medical staff about this? <p>5. Review a sample of cases to determine if the discharge planning evaluation documents the patient’s (or the patient’s representatives) goals and preferences for post-discharge placement and care.</p> <p>6. Review a sample of cases to determine if the discharge planning evaluation includes an assessment of:</p> <ul style="list-style-type: none"> • The patient’s post-discharge care needs being met in the environment from which he/she entered the hospital? What the patient’s care needs will be immediately upon discharge, and whether those needs are expected to remain constant or lessen over time? • The patient’s insurance coverage (if applicable) and how that coverage might 	

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	<p>self-care or provided by someone else. All patients, even those with a high capability for self-care, are likely to require some follow-up ambulatory health care services, e.g., a post-discharge appointment with their surgeon, specialist or primary care physician, or a series of appointments for physical or occupational therapy. Some patients might have more complex care needs which nevertheless may still be met in the home setting, depending on the specific clinical needs and the services available in the patient’s community.</p> <ul style="list-style-type: none"> • For example, some patients require wound care that exceeds the capabilities of their family or others who act as informal caregivers. But they may be able to receive sufficient care in the home setting through a home health service, if such services are available. Some patients with chronic conditions may prefer to remain in their home and would be able to do so using available community-based services, but also require financial supports, such as Medicaid-financed home and community-based waiver services. If such supports are not immediately available at the time of discharge while an application for waiver services is pending, the evaluation should consider the availability of other short term supports that would allow the patient to be discharged home. <p>If the result of the evaluation is that the patient cannot receive required care if he/she returns to</p>	<p>or might not provide for necessary services post-hospitalization?</p> <p>7. For patients admitted from home --</p> <ul style="list-style-type: none"> • Whether the patient can perform activities of daily living (personal hygiene and grooming, dressing and undressing, feeding, voluntary control over bowel and bladder, ambulation, etc.)? • The patient’s or family/other support person’s ability to provide self-care/care? • Whether the patient will require specialized medical equipment or home modification? <p>If yes, did the evaluation include an assessment of whether the equipment is available or if the modifications can be made to safely discharge the patient to that setting?</p> <ul style="list-style-type: none"> • If the patient or family/support person is unable to meet care needs or there are additional care needs above their capabilities, did the evaluation include an assessment of available community-based services to meet post-hospital needs? <p>8. For patients admitted from a nursing facility,</p>	

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	<p>home, then an assessment must be made of options for transfer to another inpatient or residential health care facility that can address the patient’s needs, including other types of hospitals, such as rehabilitation hospitals; skilled nursing facilities; assisted living facilities; nursing homes; or inpatient hospice facilities.</p> <p>If prior to the hospital admission the patient was a resident in a facility that he or she wishes to return to, such as an assisted living or nursing facility or skilled nursing facility, the evaluation must address whether that facility has the capability to provide the post-hospital care required by the patient. The post-discharge care requirements may be different than the care that was previously provided. This requires dialogue and cooperation between hospitals and post-hospital care facilities in the area served by the hospital, as well as with the physicians who provide care to patients in either or both of these settings.</p> <p>Long term care facilities often express concern that hospitals discharge patients to their facilities with care needs that exceed their care capabilities, necessitating sending the patient to the emergency department for care and possible readmission. On the other hand, hospitals often express concern that long term care facilities send patients to the emergency department with ambulatory care-sensitive conditions, i.e., conditions that either do not require an acute level of care, or which could have been prevented from escalating to an acute level had appropriate primary</p>	<p>skilled nursing facility or assisted living facility did the evaluation assess whether the prior facility has the capability to provide necessary post-hospital services to the patient (i.e. is the same, higher, or lower level of care required and can those needs be met?)</p> <ul style="list-style-type: none"> • If yes, is there any documentation that the patient’s care needs fall within the capabilities of the facility? <p>9. Are the results of the discharge planning evaluation documented in the medical record?</p>	

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care been provided in a timely manner.

While hospitals cannot address these concerns in isolation, they are expected to be knowledgeable about the care capabilities of area long term care facilities and to factor this knowledge into the discharge planning evaluation.

CAPABILITIES OF COMMUNITY SERVICES

Hospitals are expected to have knowledge of the capabilities and capacities of not only of long term care facilities, but also of the various types of service providers in the area where most of the patients it serves receive post-hospital care, in order to develop a discharge plan that not only meets the patient’s needs in theory, but also can be implemented.

- This includes knowledge of community services, as well as familiarity with available Medicaid home and community-based services (HCBS), since the State’s Medicaid program plays a major role in supporting post-hospital care for many patients.

If the hospital is one with specialized services that attract a significant number of patients who will receive their post-hospital care in distant communities, the hospital is expected to take reasonable steps to identify the services that will be available to the patient.

Once the determination has been made that services will be necessary post-discharge, the team must then

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determine availability of those services or identify comparable substitutions. Included in the evaluation is coordination with insurers and other payors, including the State Medicaid agency, as necessary to ensure resources prescribed are approved and available.

**For Information–
Not Required/Not to be Cited**

Although not required under the regulations, hospitals would be well advised to develop collaborative partnerships with post-hospital care providers to improve care transitions of care that might support better patient outcomes. This includes not only skilled nursing facilities and nursing facilities, but also providers of community-based services. For example, Centers for Independent Living (CIL) and Aging and Disability Resource Centers (ADRC) are resources for community-based services and housing available to persons with disabilities and older adults.

Hospitals can find local CIL's at <http://www.ilru.org/html/publications/directory/index.html> and ADRC's and other resources at <http://www.adrc-tae.org/tiki-index.php?page=HomePage>.

- The ability to pay out of pocket for services must also be discussed with the family or other support persons.
- Although hospitals are not expected to have

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	<p>definitive knowledge of the terms of any given patient’s insurance coverage or eligibility for community-based services, or for Medicaid coverage, they are expected to have a general awareness of these matters and their impact on the patient’s post-discharge needs and prospects for recovery. For example, if the patient is a Medicare beneficiary, the hospital is expected to be aware of Medicare coverage requirements for home health care or admission to a rehabilitation hospital, a skilled nursing facility, or a long term care hospital, etc. and to make the beneficiary aware that they may have to pay out of pocket for services not meeting the coverage requirements.</p> <ul style="list-style-type: none"> • Similarly, for Medicaid, they should know coverage options for home health, attendant care, and long term care services or have contacts at the State Medicaid agency that can assist with these issues. As noted above, hospitals are also expected to have knowledge of community resources to assist in arranging services. Some examples include Aging and Disability Resource Centers and Centers for Independent Living (see box above). <p>The hospital CoP governing patients’ rights at §482.13(b) provides that “The patient has the right to participate in the development and implementation of his or her plan of care.” (CMS views discharge planning as part of the patient’s plan of care). “The patient or his/her representative (as allowed under State law)</p>		

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	<p>has the right to make informed decisions regarding his/her care” and “The patient’s rights include...being involved in care planning and treatment.”</p> <ul style="list-style-type: none"> • Accordingly, hospitals are expected to engage the patient, or the patient’s representative, actively in the development of the discharge evaluation, not only as a source of information required for the assessment of self-care capabilities, but also to incorporate the patient’s goals and preferences as much as possible into the evaluation. • A patient’s goals and preferences may be, in the hospital’s view, unrealistic. Identifying divergent hospital and patient assessments of what is realistic enables a discussion of these differences and may result in an assessment and subsequent development of a discharge plan that has a better chance of successful implementation. <p>§482.43(b)(4) requires that the evaluation include assessment of the patient’s capacity for self-care or, alternatively, to be cared for by others in the environment, i.e., the setting, from which the patient was admitted to the hospital. In general, the goal upon discharge is for a patient to be able to return to the setting in which they were living prior to admission. This may be the patient’s home in the community or residence in a nursing home. In the case of transfer from another hospital, generally the preferred goal is to return the patient to the setting from which he/she presented to the transferring hospital.</p>		

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The evaluation must consider what the patient’s care needs will be immediately upon discharge, and whether those needs are expected to remain constant or lessen over time.

- If the patient was admitted from his/her private residence, the evaluation must include an assessment of whether the patient is capable of addressing his/her care needs through self-care.

- The evaluation must include assessment of whether the patient will require specialized medical equipment or permanent physical modifications to the home, and the feasibility of acquiring the equipment or the modifications being made. If the patient is not able to provide some or all of the required self-care, the evaluation must also address whether the patient has family or friends available who are willing and able to provide the required care at the times it will be needed, or who could, if willing, be trained by the hospital sufficiently to provide the required care.

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<p>15.03.03 Discharge Planning – Staff Qualifications. <i>A registered nurse, social worker, or other appropriately qualified personnel must develop or supervise the development of, the evaluation.</i></p> <p>§482.43(b)(2)</p>	<p>The patient’s discharge planning evaluation must be developed by a registered nurse, social worker, or other appropriate qualified personnel, or by a person who is supervised by such personnel.</p> <p>State law governs the qualifications required to be considered a registered nurse or a social worker. The hospital’s written discharge planning policies and procedures must specify the qualifications for personnel other than registered nurses or social workers who develop or supervise the development of the evaluation.</p> <p>The qualifications must include such factors as previous experience in discharge planning, knowledge of clinical and social factors that affect the patient’s functional status at discharge, knowledge of community resources to meet post-discharge clinical and social needs, and assessment skills.</p> <p>All personnel performing or supervising discharge planning evaluations, including registered nurses and social workers, must have knowledge of clinical, social, insurance/financial and physical factors that must be considered when evaluating how a patient’s expected post-discharge care needs can be met.</p> <p>It is acceptable for a hospital to include new staff who may not have had previous discharge planning experience, but who are being trained to perform discharge planning duties and whose work is reviewed by qualified personnel.</p>	<p><u>DOCUMENT REVIEW AND INTERVIEW</u></p> <ol style="list-style-type: none"> 1. Review a sample of cases to determine if the discharge planning evaluation was developed by an RN, Social Worker, or other qualified personnel, as defined in the hospital discharge planning policies and procedures, or someone they supervise? In order to assess this: <ul style="list-style-type: none"> • Review the hospital’s written policy and procedure governing who is responsible for developing or supervising the development of the discharge planning evaluation. • Does the policy permit someone other than a RN or social worker to be responsible for developing or supervising such evaluations? If yes, does the policy specify the qualifications of the personnel other than a RN or social worker to perform this function? 2. Determine which individual(s) is (are) responsible for developing or supervising discharge planning evaluations. <ul style="list-style-type: none"> • Review their personnel folders to determine if they are a RN, social worker, or meet the hospital’s criteria for developing/supervising the discharge planning evaluation. • If they are not, are they supervised 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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by an individual who is an RN, social worker or is qualified according to the hospital's policies?

- Are their discharge planning evaluations reviewed by their supervisor before being finalized?

3. Ask personnel who supervise or develop discharge planning evaluations to give examples illustrating how they apply their knowledge of clinical, social, insurance/financial and physical factors when performing an evaluation.

15.03.04 Not Applicable.

15.03.05 Not Applicable.

15.03.06 Timeliness of Assessment.
The hospital personnel must complete the evaluation on a timely basis so that appropriate arrangements for post-hospital care are made before discharge, and to avoid unnecessary delays in discharge.

§482.43(b)(5)

After a patient has been identified as needing an evaluation, or after a request for an evaluation has been made by the physician, patient and/or patient's representative, the evaluation must be completed timely.

This means there must be sufficient time after completion to allow arrangements for post-hospital care to be made, without having to delay the patient's discharge in order to do so, or requiring the patient to transfer to a different setting from where he/she was

DOCUMENT REVIEW AND CHART REVIEW

Determine whether hospital policy addresses:

1. Timely completion of the discharge planning evaluation so arrangements for post-hospital care can be made before discharge and to avoid unnecessary delays in discharge.
2. Review a sample of cases to determine if the discharge planning evaluation was completed on a timely basis to allow for appropriate arrangements to be made for post-hospital

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	<p>admitted from primarily due to the delay in making appropriate arrangements.</p> <ul style="list-style-type: none"> • The comparatively short average length of stay of a short term acute care hospital inpatient necessitates prompt attention to patients' discharge planning needs in that type of hospital. • Failure to complete the evaluation in a timely manner could make it more difficult to implement the patient's final discharge plan, and/or may cause an unnecessary delay in the patient's discharge from the hospital. While other types of hospitals with a longer average length of stay may be able to complete the evaluation at a later point after admission, they too must complete it on a timely basis to avoid delays in discharge. <p>Where a team approach is utilized by the hospital in developing the discharge planning evaluation, there must be a process to promote efficient collaboration among team members to complete the evaluation in a timely manner.</p> <p>Changes in patient condition throughout the hospitalization warrant adjustments to the discharge plan.</p>	<p>care and to avoid delays in discharge. In order to assess this:</p> <ul style="list-style-type: none"> • Determine when the discharge planning evaluation was initiated. If the evaluation was not begun within 24 hours of the request or identification of the need for an evaluation, ask why. • Is there a pattern of delayed start or completion of the evaluation? If so, is the delay due to circumstances beyond the hospital's control (e.g., inability to reach the beneficiary's support person(s), continuing changes in the patient's condition) and/or is the delay due to the hospital's failure to develop timely discharge planning evaluations? 	

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<p>15.03.07 <u>Patient Involvement & Documentation Requirements.</u> <i>The hospital must:</i></p> <ul style="list-style-type: none"> • <i>Include the discharge planning evaluation in the patient’s medical record for use in establishing an appropriate discharge plan and</i> • <i>Must discuss the results of the evaluation with the patient or individual acting on his/her behalf.</i> <p>§482.43(b)(6)</p>	<p>The hospital must include the discharge planning evaluation in the patient’s medical record in order for it to guide the development of the patient’s discharge plan.</p> <p>Timely placement of the evaluation in the medical record facilitates communication among members of the patient’s healthcare team who should participate in a multidisciplinary process to develop and implement the discharge plan. The evaluation and subsequent planning process may be a continuous one and hospitals may choose not to divide the process into distinct documents.</p> <ul style="list-style-type: none"> • The key requirement is that the evaluation results are included in the patient’s medical record and are used in the development of the features of the discharge plan. <p>The results of the discharge planning evaluation must be discussed with the patient or the patient’s representative.</p> <ul style="list-style-type: none"> • Documentation of this communication must be included in the medical record, including if the patient rejects the results of the evaluation. • It is not necessary for the hospital to obtain a signature from the patient (or the patient’s representative, as applicable) documenting the discussion. 	<p style="text-align: center;"><u>CHART REVIEW</u></p> <ol style="list-style-type: none"> 1. Review a sample of cases to determine if the discharge planning evaluation results are included in the medical record. 2. Review a sample of cases to determine if the discharge planning evaluation results were discussed with the patient or the patient’s representative. 	<p> <input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant </p> <p>This standard is not met as evidenced by:</p>

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The patient or the patient’s representative must be actively engaged in the development of the plan, so that the discussion of the evaluation results represents a continuation of this active engagement. It would not be appropriate for a hospital to conduct an evaluation without the participation of the patient or the patient’s representative, and then present the results of the evaluation to the patient as a finished product, since this would place the patient in a passive position that is not consistent with the requirements of the patients’ rights CoP at §482.13(b).

15.03.08 Not Applicable.

15.03.09 Discharge Planning: Required Supervision.

A registered nurse, social worker, or other appropriately qualified personnel must develop, or supervise the development of, a discharge plan if the discharge planning evaluation indicates a need for a discharge plan.

§482.43(c)
§482.43(c)(1)

The discharge plan that is based on the findings of the discharge planning evaluation must be developed by a registered nurse, social worker, or other appropriate qualified personnel, or by a person who is supervised by such personnel. State law governs the qualifications required to be considered a registered nurse or a social worker.

The hospital’s written discharge planning policies and procedures must specify the qualifications for personnel other than registered nurses or social workers who develop or supervise the development of the plan.

CHART REVIEW, DOCUMENT REVIEW, AND INTERVIEW

Review a sample of cases to determine if the discharge plan was developed by an RN, Social Worker, or other qualified personnel, as defined in the hospital discharge planning policies and procedures, or someone they supervise? In order to assess this:

1. Review the hospital’s written policy and procedure governing who is responsible for developing or supervising the development of the discharge plan.
 - Does the policy permit someone other than a RN or social worker to be

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	<p>The qualifications should include such factors as:</p> <ul style="list-style-type: none"> • previous experience in discharge planning, • knowledge of clinical and social factors that affect the patient’s functional status at discharge, • knowledge of community resources to meet post-discharge clinical and social needs, and • assessment skills. <p>All personnel performing or supervising development of discharge plans, including registered nurses and social workers, must have knowledge of clinical, social, insurance/financial and physical factors that must be considered when evaluating how a patient’s expected post-discharge care needs can be met.</p> <p>The hospital CoP governing patients’ rights at §482.13(b) provides that “The patient has the right to participate in the development and implementation of his or her plan of care.” (CMS views discharge planning as part of the patient’s plan of care). “The patient or his/her representative (as allowed under State law) has the right to make informed decisions regarding his/her care” and “The patient’s rights include...being involved in care planning and treatment.”</p> <p>Accordingly, hospitals are expected to engage the patient, or the patient’s representative, actively in the development of the discharge plan, not only to provide them the necessary education and training to provide self-care/care, but also to incorporate the patient’s goals and preferences as much as possible</p>	<p>responsible for developing or supervising development of such plans?</p> <ul style="list-style-type: none"> • If yes, does the policy specify the qualifications of the personnel other than a RN or social worker to perform this function? <p>2. Determine which individual(s) are responsible for developing or supervising the development of discharge plans.</p> <ul style="list-style-type: none"> • Review their personnel folders to determine if they are a RN, social worker, or meet the hospital’s criteria for developing/supervising the discharge plan. • If they are not, are they supervised by an individual who is an RN, social worker or qualified according to the hospital’s policies? <ul style="list-style-type: none"> ○ Are their discharge plans reviewed by their supervisor before being finalized? <p>3. Ask personnel who supervise or develop discharge plans to give examples illustrating their knowledge of healthcare and other resources available in the community that could be utilized to meet patients’ expected post-discharge care needs.</p> <p>4. Ask the discharge planner how the patient or</p>	

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	<p>into the plan. A patient will be more likely to cooperate in the implementation of a discharge plan that reflects his/her preferences, increasing the likelihood of a successful care transition and better health outcomes.</p> <p>A patient's goals and preferences may be, in the hospital's view, unrealistic. A hospital is not obligated to develop a discharge plan that cannot be implemented. However, the fact that a plan incorporating the patient's goals and preferences might be more time-consuming for the hospital to develop and implement than another alternative does not make the patient's preferred plan unrealistic.</p>	<p>patient's representative is engaged to participate in the development of the discharge plan. Does the discharge plan identify the patient's or patient's representative discharge preferences?</p> <p>5. Does the discharge plan match the identified needs as determined by the discharge planning evaluation?</p>	
<p>15.03.10 Discharge Plan – Physician Request. <i>In the absence of a finding by the hospital that a patient needs a discharge plan, the patient's physician may request a discharge plan.</i></p> <p><i>In such case, the hospital must develop a discharge plan for the patient.</i></p> <p>§482.43(c)(2)</p>	<p>If a patient is not identified through the hospital's discharge planning evaluation process as requiring a discharge plan, the patient's physician may nevertheless request a discharge plan. The hospital must develop a discharge plan when requested to do so by the patient's physician.</p> <p>If the hospital's policies and procedures call for a discharge plan for every hospital inpatient, then it is not necessary to include a separate provision in those policies requiring development of a plan upon physician request, since such a provision would be superfluous.</p>	<p style="text-align: center;"><u>DOCUMENT REVIEW AND INTERVIEW</u></p> <p>1. Review the hospital's discharge planning policies and procedures to determine whether it requires the development of a discharge plan for all inpatients, or only for those identified as needing a plan through a risk-based identification and evaluation process.</p> <p>2. If the hospital does not require a discharge planning evaluation for all inpatients:</p> <ul style="list-style-type: none"> • Does the hospital have a standard process for notifying physicians that they may request a discharge plan evaluation and that the hospital will develop a plan 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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<p>15.03.11 Implementation of the Discharge Plan. <i>The hospital must arrange for the initial implementation of the patient’s discharge plan.</i></p> <p><i>As needed, the patient and family members or interested persons must be counseled to prepare them for post-hospital care.</i></p> <p>§482.43(c)(3) §482.43(c)(5)</p>	<p>The hospital is required to arrange for the initial implementation of the discharge plan.</p> <p>This includes providing in-hospital education/training to the patient for self-care or to the patient’s family or other support person(s) who will be providing care in the patient’s home. It also includes arranging:</p> <ul style="list-style-type: none"> • Transfers to rehabilitation hospitals, long term care hospitals, or long term care facilities; • Referrals to home health or hospice agencies; • Referral for follow-up with physicians/ practitioners, occupational or physical therapists, etc.; • Referral to medical equipment suppliers; and • Referrals to pertinent community resources that may be able to assist with financial, transportation, meal preparation, or other post- 	<p style="text-align: center;"><u>DOCUMENT REVIEW</u></p> <p>Determine whether hospital policy addresses:</p> <ul style="list-style-type: none"> • The initial implementation of the patient’s discharge plan. <p style="text-align: center;"><u>CHART REVIEW</u></p> <p>Review cases of discharged patients to determine if the hospital arranges initial implementation of the discharge plan by providing:</p> <p>For patients discharged to home:</p> <ol style="list-style-type: none"> 1. In-house training to patient and family/support persons, using recognized methods; 2. Written discharge instructions that are legible and use non-technical language; 3. A legible, complete, reconciled medication list that highlights changes from the post hospital regimen; 	<p style="text-align: center;">upon request?</p>

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	<p>discharge needs.</p> <p>(See §482.43(d) for more discussion about the hospital’s transfer or referral obligations and the initial implementation of the plan relating to transfer/referral.)</p> <p>The discharge planning process is a collaborative one that must include the participation of the patient and the patient’s informal caregiver or representative, when applicable. In addition, other family or support persons who will be providing care to the patient after discharge need to be engaged in the process. Keeping the patient, and, when applicable, the patient’s representative and other support persons informed throughout the development of the plan is essential for its success. Providing them with information on post-discharge options, what to expect after discharge and, as applicable, instruction and training in how to provide care is essential.</p> <p>The patient needs clear instructions regarding what to do when concerns, issues, or problems arise, including who to call and when they should seek emergency assistance. Although it may be an important component of the discharge instructions, it is not acceptable to only advise a patient to “return to the ED” whenever problems arise.</p> <p>There are a variety of tools and techniques that have focused on improving the support provided to patients who are discharged back to their homes. A</p>	<ol style="list-style-type: none"> 4. Referrals as applicable to specialized ambulatory services, e.g. physical therapy, occupational therapy, home health, hospice, mental health, etc.; 5. Referrals as applicable to community-based resources other than health services, e.g. Departments of Aging, elder services, transportation services, Centers for Independent Living, Aging and Disability Resource Centers, etc.; 6. Arranging essential durable medical equipment, e.g. oxygen, wheel chair, hospital bed, commode, etc.; 7. Sending necessary medical information to providers that the patient was referred to prior to the first post-discharge appointment or within 7 days of discharge, whichever comes first.; and 8. For patients transferred to another inpatient facility, was necessary medical information ready at time of transfer and sent to the receiving facility with the patient? 9. Were there portions of the plan the hospital failed to begin implementing, resulting in delays in discharge? 	

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	<p>comprehensive approach employing combinations of these techniques has been found to improve patient outcomes and reduce hospital readmission rates, including, but not limited to:</p> <ul style="list-style-type: none"> • Improved education to patients and support persons regarding disease processes, medications, treatments, diet and nutrition, expected symptoms, and when and how to seek additional help. Teaching methods must be based on recognized methodologies. CMS does not prescribe any specific methodologies, but examples include the teach-back, repeat-back approach and simulation laboratories; • Written discharge instructions, in the form of checklists when possible, that are legible, in plain language, culturally sensitive and age appropriate; • Providing supplies, such as materials for changing dressings on wounds, needed immediately post-discharge; and • A list of all medications the patient should be taking after discharge, with clear indication of changes from the patient’s pre-admission medications. <p>The education and training provided to the patient or the patient’s caregiver(s) by the hospital must be tailored to the patient’s identified needs related to medications, treatment modalities, physical and occupational therapies, psychosocial needs,</p>		

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appointments, and other follow-up activities, etc.

Repeated review of instructions with return demonstrations and/or repeat-backs by the patient, and their support persons will improve their ability to deliver care properly. This includes providing instructions in writing as well as verbally reinforcing the education and training.

TRANSFERS TO REHAB OR LONG TERM FACILITIES

It is also necessary to provide information to patients and their support persons when the patient is being transferred to a rehabilitation or a long term care hospital, or to a long term care setting, such as a skilled nursing facility or nursing facility. The information should address questions such as: the goal of treatment in the next setting and prospects for the patient’s eventual discharge home.

The hospital must document in the patient’s medical record the arrangements made for initial implementation of the discharge plan, including training and materials provided to the patient or patient’s informal caregiver or representative, as applicable.

<p>For Information – Not Required/Not to be Cited</p> <p>Additional actions hospitals might consider taking to improve the patient’s post-discharge care transition:</p> <ul style="list-style-type: none"> • Scheduling follow-up appointments with the
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	<p>patient's primary care physician/practitioner and in-home providers of service as applicable;</p> <ul style="list-style-type: none"> • Filling prescriptions prior to discharge; • If applicable, arranging remote monitoring technologies, e.g., pulse oximetry and daily weights for congestive heart failure (CHF) patients; pulse and blood pressure monitoring for cardiac patients; and blood glucose levels for diabetic patients; and • Follow-up phone calls within 24 -72 hours by the hospital to the patient after discharge. <p>The communication with the patient to ensure implementation of the discharge plan does not stop at discharge. An initiative showing significant success in reducing preventable readmissions involves the hospital contacting the patient by phone in the first 24 to 72 hours after discharge.</p> <p>The phone contact provides an opportunity for the patient to pose questions and for the hospital to address any confusion related to medications, diet, activity, etc., and to reinforce the education/instruction that took place in the hospital prior to discharge. This also helps to reduce patient and family member anxieties as they manage post-hospital care needs.</p>		

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Hospital staff placing the calls should be familiar with the patient’s discharge plan and qualified to address typical questions that might be expected. They should also be knowledgeable about when to instruct the patient to seek a more immediate evaluation, including where to go for such evaluation. Although this follow-up phone call can serve as a customer service initiative for the hospital, the primary intent would be to provide an opportunity for questions and to reduce or eliminate any confusion or concerns regarding post-hospital care.

15.03.12 Plan Reassessment.

The hospital must reassess the patient’s discharge plan if there are factors that may affect continuing care needs or the appropriateness of the discharge plan.

§482.43(c)(4)

Changes in a patient’s condition may warrant adjustments to the discharge plan.

Hospitals must have in place either a routine reassessment of all plans or a process for triggering a reassessment of the patient’s post-discharge needs, capabilities and discharge plan when significant changes in the patient’s condition or available supports occur.

DOCUMENT REVIEW, CHART REVIEW, AND INTERVIEW

1. Determine whether hospital policy addresses the reassessment of the discharge plan as indicated for changes in the patient’s condition.
2. Review a sample of cases to determine if any significant changes in the patient’s condition were noted in the medical record that changed post-discharge needs, and if the discharge plan was updated accordingly.
 - In making this determination, ask staff responsible for discharge planning when and how they reassess a patient’s discharge plan. If none of the records being used for the tracers suggest a need to revise

- 1 = Compliant
 2 = Not Compliant

This standard is not met as evidenced by:

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the discharge plan, ask staff to present one or more clinical records that document reassessment.

15.03.13 Not Applicable.

15.03.14 Selection of Discharge Care Providers.

The hospital must include in the discharge plan a list of home health agencies (HHA) or skilled nursing facilities (SNF) that are available to the patient, that are participating in the Medicare program, and that serve the geographic area (as defined by the HHA) in which the patient resides, or in the case of the SNF, in the geographic area requested by the patient. HHAs must request to be listed by the hospital as available.

(i) This list must only be presented to patients for whom home health care or post hospital extended care services are indicated and appropriate as determined by the discharge planning evaluation.

(ii) For patients enrolled in managed care organizations, the hospital

The hospital must include a list of Medicare-participating home health agencies (HHAs) and skilled nursing facilities (SNFs) in the discharge plan for those patients for whom the plan indicates home health or post-hospital extended care services are required.

- “**Extended care services**” are defined at sections 1861(h) and (i) of the Social Security Act as items or services furnished in a skilled nursing facility (SNF). SNFs included on the list must be located in a geographic area that the patient or patient’s representative indicated he/she prefers.
- For Home Health Agencies (HHAs) the list must consist of Medicare-participating HHAs that have requested the hospital to be listed and which serve the geographic area where the patient lives. Hospitals may expect the HHA to define its geographic service area when it submits its request to be listed.

During the discharge planning process the hospital must inform the patient of his/her freedom to choose among Medicare-participating post-hospital providers and must not direct the patient to specific provider(s)

CHART REVIEW AND DOCUMENT REVIEW

1. Review a sample of cases of patients discharged to HHAs or SNFs to determine if, when applicable, the hospital provided the patient with lists of Medicare-participating HHAs or SNFs. In making this determination:
 - Is there documentation of a list of multiple HHAs or SNFs being provided (including electronically) to the patient?
 - If not, is there documentation for an acceptable rationale for providing only one option, e.g., the patient’s home is included in the service area of only one Medicare-participating HHA that requested to be included on hospital lists, or there is only one Medicare-participating SNF in the area preferred by the patient?
2. Ask to see examples of lists of HHAs and SNFs provided to patients prior to discharge.

- 1 = Compliant
 2 = Not Compliant

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<p><i>must indicate the availability of home health and post hospital extended care services through individuals and entities that have a contract with the managed care organizations.</i></p> <p>(iii) <i>The hospital must document in the patient's medical record that the list was presented to the patient or to the individual acting on the patient's behalf.</i></p> <p>§482.43(c)(6) §482.43(c)(6)(i) §482.43(c)(6)(ii) §482.43(c)(6)(iii)</p> <p><i>The hospital, as part of the discharge planning process, must inform the patient or the patient's family of their freedom to choose among participating Medicare providers of post-hospital care services and must, when possible, respect patient and family preferences when they are expressed. The hospital must not specify or otherwise limit the qualified providers that are available to the patient.</i></p> <p>§482.43(c)(7)</p>	<p>or otherwise limit which qualified providers the patient may choose among.</p> <p>Hospitals have the flexibility either to develop their own lists or to print a list of skilled nursing facilities and home health agencies in the applicable geographic areas from the CMS websites, Nursing Home Compare (www.medicare.gov/NHcompare) and Home Health Compare (www.medicare.gov/homehealthcompare).</p> <ul style="list-style-type: none"> • If hospitals develop their own lists, they are expected to update them at least annually. (69 FR 49226, August 11, 2004). <div style="border: 1px solid black; padding: 5px; margin-top: 10px;"> <p style="text-align: center;">For Information – Not Required/Not to be Cited</p> <p>Hospitals may also refer patients and their families to the Nursing Home Compare and Home Health Compare websites for additional information regarding Medicare-certified skilled nursing facilities and home health agencies, as well as Medicaid-participating nursing facilities. The data on the Nursing Home Compare website include an overall performance rating, nursing home characteristics, performance on quality measures, inspection results, and nursing staff information.</p> <p>Home Health Compare provides details about every Medicare-certified home health agency in the country. Included on the website are quality indicators such as managing daily activities,</p> </div>	<ol style="list-style-type: none"> 3. Ask the hospital if it has any disclosable financial interests in any HHA or SNF on its lists, or if an HHA or SNF has a disclosable financial interest in the hospital. <ul style="list-style-type: none"> • If yes, is this stated clearly on the lists? 4. Interview staff members involved with the discharge planning process. <ul style="list-style-type: none"> • Ask them to describe how patient preferences are taken into account in the selection of post-hospital HHA or SNF services. 5. Ask the hospital to identify current patients for whom HHA or SNF services are planned. Interview the patient or the patient's family to ask them: <ul style="list-style-type: none"> • Were they presented with a list of HHAs or SNFs, as applicable, to choose from? • Did the hospital emphasize their freedom of choice? • Did the hospital arrange for their referral/transfer to an HHA or SNF reflecting their preferences? If not, did the hospital explain why their choice was not feasible? • If applicable, were they made aware of disclosable financial interest? 	

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<p><i>The discharge plan must identify any HHA or SNF to which the patient is referred in which the hospital has a disclosable financial interest, as specified by the Secretary, and any HHA or SNF that has a disclosable financial interest in a hospital under Medicare. Financial interests that are disclosable under Medicare are determined in accordance with the provisions of Part 420, Subpart C, of 42 CFR 420.</i></p> <p>§482.43(c)(8)</p>	<p>managing pain and treating symptoms, treating wounds and preventing pressure sores, preventing harm, and preventing unplanned hospital care.</p> <p>The hospital might also refer the patient and their representatives to individual State agency websites, Long-Term Care Ombudsmen Program, Protection and Advocacy Organizations, Citizen Advocacy Groups, Area Agencies on Aging, Centers for Independent Living, and Aging and Disability Resource Centers for additional information on long term care facilities and other types of providers of post-hospital care. Having access to the information found at these sources may assist in the decision making process regarding post-hospital care options.</p> <p>If the patient is enrolled in a managed care insurance program that utilizes a network of exclusive or preferred providers, the hospital must make reasonable attempts, based on information from the insurer, to limit the list to HHAs and SNFs that participate in the insurer’s network of providers. If the hospital has a disclosable financial interest in a HHA or SNF on a patient’s list, or an HHA or SNF on the list has a disclosable financial interest in the hospital, these facts must also be stated on the list provided to the patient. Surveyors are not expected to know the requirements for a disclosable financial interest under Part 420, Subpart C, but hospitals are expected to know and comply with these requirements, and to</p>		

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identify for the surveyor whether there are such disclosable financial interests between the hospital and any specific HHAs or SNFs to which they refer/transfer patients.

When the patient or the patient’s family has expressed a preference, the hospital must attempt to arrange post-hospital care with an HHA or SNF, as applicable, which meets these preferences. If the hospital is unable to make the preferred arrangement, e.g., if there is no bed available in the preferred SNF, it must document the reason the patient’s preference could not be fulfilled and must explain that reason to the patient.

15.03.15 Not Applicable.

15.03.16 Not Applicable.

15.03.17 Not Applicable.

15.03.18 Not Applicable.

15.03.19 Not Applicable.

15.03.20 Not Applicable.

15.03.21 Not Applicable.

15.03.22 Not Applicable.

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<p>15.03.23 <u>Transfer or Referral.</u> <i>The hospital must transfer or refer patients, along with necessary medical information, to appropriate facilities, agencies, or outpatient services, as needed, for follow-up or ancillary care.</i></p> <p>§482.43(d)</p>	<p>The hospital must take steps to ensure that patients receive appropriate post-hospital care by arranging, as applicable, transfer to appropriate facilities or referrals to follow-up ambulatory care services.</p> <p>“Appropriate facilities, agencies, or outpatient services” refers to entities such as:</p> <ul style="list-style-type: none"> • skilled nursing facilities, • nursing facilities, • home health agencies, • hospice agencies, • mental health agencies, • dialysis centers, • suppliers of durable medical equipment, • suppliers of physical and occupational therapy, physician offices, etc. which offer post-acute care services that address the patient’s post-hospital needs identified in the patient’s discharge planning evaluation. <p>The term does not refer to non-healthcare entities, but hospitals also are encouraged to make appropriate referrals to community-based resources that offer transportation, meal preparation, and other services that can play an essential role in the patient’s successful recovery.</p> <p>“Appropriate facilities” may also include other hospitals to which a patient is transferred for follow-up care, such as:</p> <ul style="list-style-type: none"> • rehabilitation hospitals, • long term care hospitals, or 	<p style="text-align: center;"><u>CHART REVIEW</u></p> <ol style="list-style-type: none"> 1. Determine whether hospital policy addresses: <ul style="list-style-type: none"> • The hospital will transfer or refer patients along with necessary medical information to appropriate facilities, agencies, or outpatient services, as needed. 2. Review a sample of records for discharged patients who had a discharge plan to determine if: <ol style="list-style-type: none"> a. For patients discharged home: <ul style="list-style-type: none"> • Necessary medical information was sent to a practitioner with which the patient has an established relationship prior to the first post-discharge appointment or within 7 days of discharge, whichever comes first; • For patients without an established relationship with a practitioner, information was provided on potential primary care providers, such as health clinics, if available. b. For patients transferred to another inpatient facility, was necessary medical information ready at time of transfer and sent to the receiving facility with the patient? 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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	<ul style="list-style-type: none"> • even other short-term acute care hospitals. <p>Necessary medical information must be provided not only for patients being transferred, but also for those being discharged home, to make the patient’s physician aware of the outcome of hospital treatment or follow-up care needs. This is particularly important since the increasing use of hospitalists in the inpatient hospital setting means the patient’s physician may have had no interaction with the patient throughout the hospital stay.</p> <p>When the hospital provides the patient’s physician with necessary medical information promptly, among other things, this provides an opportunity for the patient’s physician to discuss with the hospital care team changes to the patient’s preadmission medication regimen or other elements of the post-discharge care plan about which the physician may have questions. Facilitating opportunities for such communication and dialogue enhances the likelihood of better patient outcomes after discharge.</p> <p>The “medical information” that is necessary for the transfer or referral includes, but is not limited to:</p> <ol style="list-style-type: none"> 1. Brief reason for hospitalization (or, if hospital policy requires a discharge summary for certain types of outpatient services, the reason for the encounter) and principal diagnosis; 2. Brief description of hospital course of treatment; 	<ol style="list-style-type: none"> c. When applicable, there is documentation in the medical record of providing the results of tests, pending at time of discharge, to the patient and/or post-hospital provider of care? 	

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	<p>3. Patient’s condition at discharge, including cognitive and functional status and social supports needed;</p> <p>4. Medication list (reconciled to identify changes made during the patient’s hospitalization) including prescription and over-the-counter medications and herbal. (Note, an actual list of medications needs to be included in the discharge information, not just a referral to an electronic list available somewhere else in the medical record.);</p> <p>5. List of allergies (including food as well as drug allergies) and drug interactions;</p> <p>6. Pending laboratory work and test results, if applicable, including information on how the results will be furnished;</p> <p>7. For transfer to other facilities,</p> <ul style="list-style-type: none"> • A copy of the patient’s advance directive, if the patient has one. <p>8. For patients discharged home:</p> <ul style="list-style-type: none"> • Brief description of care instructions reflecting training provided to patient and/or family or other informal caregiver(s); • If applicable, list of all follow-up appointments with practitioners with which the patient has an established relationship and which were scheduled prior to discharge, 		

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including who the appointment is with, date and time.

- If applicable, referrals to potential primary care providers, such as health clinics, if available, for patients with no established relationship with a practitioner.

The regulation requires transfer or referral “along” with necessary medical information.

- In the case of a patient being transferred to another inpatient or residential health care facility, the necessary information must accompany the patient to the facility.

However, in the case of a patient discharged home who is being referred for follow-up ambulatory care, the transmittal of the information to the patient’s physician may take place up to 7 days after discharge or prior to the first appointment for ambulatory care services that may have been scheduled, whichever comes first.

- If the patient’s physician is not yet able to accept the information electronically from the hospital, the hospital may provide the information to the patient with instructions to give this information to the physician at their next appointment.

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**For Information –
Not Required/Not to be Cited**

Scheduling of follow-up appointments for ambulatory care services by the hospital prior to discharge has been found to be an effective tool to ensure prompt follow-up and reduce the likelihood of a preventable readmission. This follow-up visit shortly after discharge provides an opportunity for the patient to address any issues or concerns experienced after the inpatient stay. It also provides an opportunity for the primary care physician or practitioner to review and reinforce the post-hospital plan of care with the patient, for rehabilitation therapy to begin in a timely manner, to clarify any concerns related to medication reconciliation or other adjustments to the patient’s pre-hospital regimen, etc.

It is recognized that hospitals have certain constraints on their ability to accomplish patient transfers and referrals:

- They must operate within the constraints of their authority under State law;
- A patient may refuse transfer or referral; or
- There may be financial barriers limiting a facility’s, agency’s, or ambulatory care service provider’s willingness to accept the patient. In such cases the hospital does not have financial responsibility for the post-acute care services. However, hospitals are expected to be knowledgeable about

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<p>15.03.24 Discharge Plan Reassessment. <i>The hospital must reassess the discharge planning process on an ongoing basis.</i></p> <p><i>The reassessment must include a review of discharge plans to ensure that they are responsive to the patient's discharge needs.</i></p> <p>§482.43(e)</p>	<p>resources available in their community to address such financial barriers, such as Medicaid services, availability of Federally Quality Health Centers, Area Agencies on Aging, etc., and to take steps to make those resources available to the patient. For example, in most states hospitals work closely with the Medicaid program to expedite enrollment of patients eligible for Medicaid.</p> <p>The hospital must reassess the effectiveness of its discharge planning process on an ongoing basis. Since the QAPI CoP at §482.21 requires the QAPI program to be hospital-wide, the discharge planning reassessment process is considered an integral component of the overall hospital QAPI program.</p> <p>The hospital must have a mechanism in place for ongoing reassessment of its discharge planning process.</p> <ul style="list-style-type: none"> • The reassessment process must include a review of discharge plans in closed medical records to determine whether they were responsive to the patient's post-discharge needs. • One indicator of the effectiveness of the discharge plan is whether or not the discharge was followed by a preventable readmission. • Accordingly, hospitals are expected to track their readmission rates and identify potentially preventable readmissions. 	<p style="text-align: center;"><u>DOCUMENT REVIEW AND INTERVIEW</u></p> <ol style="list-style-type: none"> 1. Review hospital policies and procedures to determine whether the discharge planning process is reassessed on an ongoing basis, i.e., at least quarterly. 2. Does the hospital's discharge planning reassessment policy include tracking and analysis of readmissions? <ul style="list-style-type: none"> • Do staff know how to obtain data on readmissions that enables them to review the discharge plans for the initial admission? Ask them to identify medical records for patients who were readmitted and to show you the documentation of the review of the discharge planning process for the initial admission. 3. Does the hospital QAPI program include an ongoing re-assessment of the discharge planning process including: 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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	<p>Typically readmissions at 7, 15, 30 days, or even longer, after discharge are tracked by analysts studying readmissions to short-term acute care hospitals.</p> <ul style="list-style-type: none"> Hospitals must choose at least one interval to track. Since there are National Quality Forum-endorsed readmissions measures that use a 30-day interval, and since such measures are permitted by law to be used by CMS for payment-related purposes, it might be prudent for a hospital to track its 30-day readmissions rate, but other intervals are permissible. It is understood that information on post-discharge admissions to other hospitals may not be readily available to hospitals, but all hospitals are expected to track readmissions to their own hospital, and to do so on an ongoing basis, i.e., at least quarterly. Hospitals may employ various methodologies to identify potentially preventable readmissions. There are proprietary products that, for example, use claims data to identify such cases. Hospitals are expected to document their methodology for tracking their readmissions rates. Once the hospital has identified potentially preventable readmissions, it is expected to conduct an in-depth review of the discharge planning process for a sample of such readmissions (at least 10% of potentially preventable readmissions, or 15 cases/quarter, whichever is larger is suggested but not required) in order to determine whether there was an 	<ul style="list-style-type: none"> Rate of re-admissions? The effectiveness of the discharge planning process for patient readmissions? <p>4. Does the assessment of readmissions include an evaluation of whether the readmissions were potentially preventable?</p> <ul style="list-style-type: none"> Is there evidence of in-depth analysis of a sample of discharge plans in cases where preventable readmissions were identified? Is there evidence that the hospital took action to address factors identified as contributing to preventable readmissions? 	

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	<p>appropriate discharge planning evaluation, discharge plan, and implementation of the discharge plan.</p> <ul style="list-style-type: none"> • Hospitals are also expected to follow up on trends identified through analysis of their readmissions, such as: <ul style="list-style-type: none"> • a concentration of readmissions related to post-surgical infections, • discharges from a particular service or unit, • discharges to a particular extended care facility or home health agency, • discharges with the same primary diagnosis on the first admission, etc. Such clustering or concentration may identify areas requiring more follow-up analysis and potential remedial actions. • Having identified factors that contribute to preventable readmissions, hospitals are expected to revise their discharge planning and related processes to address these factors. • Consistent with the requirements under the QAPI CoP, the hospital’s governing body, medical leadership and administrative leadership are all expected to ensure that identified problems are addressed, with further ongoing reassessment to 		

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achieve improvement.

The hospital's discharge planning process must be integrated into its QAPI program.

15.03.25 Continuity of Care Post-Discharge.

Facilities must have a discharge system in place to ensure the continuity of care of the patient post-discharge.

Discharge instructions must be prepared for each patient, and communicated to the clinical caregiver accepting responsibility for post-discharge care at the time of hospital discharge.

Organizations must ensure that there is confirmation of receipt of the discharge information by the independent licensed practitioner who will assume the responsibility for care after discharge. (NQF, #15, 2010)

PATIENT SAFETY INITIATIVE

The medical record must reflect that the information has been faxed, mailed or delivered in some fashion to the independent licensed practitioner assuming care of the patient after discharge. A fax transmittal sheet placed in the medical record is also acceptable.

OBSERVATION & CHART REVIEW

Review the medical record of recently discharged patients to ensure the existence of discharge instructions and confirmation of communication of the discharge instructions to the accepting provider / facility. Ensure that documentation supports that discharge information has been delivered to the accepting independent licensed practitioner.

Observe the discharge process for compliance with standard.

- 1 = Compliant
- 2 = Not compliant

Comment:

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<p>15.03.26 Discharge Instructions. The hospital must provide the inpatient or inpatient's representative with discharge instructions written in lay terminology at time of discharge. The discharge instructions must include the following elements:</p> <ol style="list-style-type: none"> 1. Reason for hospitalization and condition at the time of discharge. 2. Medications to be taken after discharge including, resuming pre-admission medications, how and when to take medications, and how to obtain medications. 3. Complications which may occur and actions to take should these happen post-discharge. 4. A list of follow-up appointments for tests and clinic visits, with dates, times and locations. 5. Organized services to be initiated following discharge. 6. Tests completed in the hospital with results pending at time of discharge and name of the clinician responsible for the results. 	<p>Inconsistent practices in the discharge process may result in unsafe outcomes. The discharge process is intended to provide patients with adequate information and necessary resources to improve or maintain their health during the post-hospital period and to prevent adverse events and unnecessary re-hospitalization.</p> <p>It has been reported that 50% of patients readmitted within 30-days of discharge had not seen their physician since the date of discharge. One strategy to reduce readmissions is for the hospital to make the first follow-up appointment for the patient prior to discharge.</p> <p>The facility is responsible for making appointments with the appropriate provider for follow-up clinical visits and tests after hospitalization. These appointments must be communicated, in writing, to the patient / caregiver at the time of discharge.</p> <p>Patient / caregiver understanding of the discharge instructions must be assessed and documented in the patient record.</p>	<p style="text-align: center;"><u>OBSERVATION, INTERVIEW, AND CHART REVIEW</u></p> <ol style="list-style-type: none"> 1. Review the medical record of recently discharged patients to ensure written discharge instructions contain the elements required. 2. Observe the discharge process for compliance with standard. 3. Interview patients / family re: education and understanding of the discharge plan, their diagnosis, medications and complications. 4. Review facility's data related to 30-day readmissions; review sample of readmitted patients for adequacy of the discharge plan and instructions. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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<p>7. List of relevant contact information (e.g., primary care providers, specialists, the pharmacy, and home health agencies, etc.).</p>			
<p>15.03.27 Discharge Checklist. The discharge process must include a checklist of the following activities:</p> <ol style="list-style-type: none"> 1. Educate patients and families about their diagnosis throughout the hospital stay. 2. Assess the patient’s understanding of the discharge plan in their own words. 3. Inform the patient and family of any tests completed in the hospital that have results pending at time of discharge; identify the clinician who will be responsible for results. 4. Schedule follow-up appointments and tests to be done following discharge. 5. Organize services to be initiated following discharge. 6. Confirm the medication plan. 	<p>Research has shown that the use of a checklist for planning discharge activities has decreased adverse events post-discharge and reduced the number of readmissions within 30 days after discharge. (Jack, Brian, et al. (2009). A Reengineered hospital discharge program to decrease re-hospitalization. <i>Annals of Internal Medicine</i>, 150(3): 178.)</p> <p>Further, studies report that one in five hospitalizations is complicated by a post-discharge adverse event as patients are often unprepared for discharge or do not understand their medications.</p> <p>A review of the literature has identified factors that contribute to hospital readmission including, but not limited to:</p> <ul style="list-style-type: none"> • Lack of a medication reconciliation resulting in unexplained medication discrepancies between pre-admission and post-discharge medication lists • Discharge medication prescription errors • Lack of information regarding pending tests results or the need for follow-up tests • Availability of the discharge summary has been received by the clinician at time of the first post- 	<p>CHART REVIEW AND DOCUMENT REVIEW</p> <ol style="list-style-type: none"> 1. Determine whether the facility utilizes a discharge checklist, which includes the identified eleven (11) elements. 2. Determine whether hospital policy has identified: <ul style="list-style-type: none"> • Patients at risk for adverse health consequences or readmission that potentially may benefit from a post-discharge telephone call; • Persons “qualified” to conduct the discharge follow-up telephone call. 3. Has the hospital developed discharge protocols for high-risk disease processes or medications? 4. If yes, has the protocol: <ul style="list-style-type: none"> • Been approved by the medical staff • Included follow-up visits, tests, medication reconciliation 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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<p>7. Reconcile the discharge plan with national guidelines and critical pathways when relevant.</p> <p>8. Review with the patient what to do if a problem occurs.</p> <p>9. Communicate the discharge summary to the healthcare providers who will be accepting responsibility for the patient's care.</p> <p>10. Give the patient written discharge instructions.</p> <p>11. Provide telephone follow-up two to three days after discharge for patients identified to be at risk for adverse health consequences upon discharge.</p>	<p style="text-align: center;">discharge visit</p> <p>Multiple initiatives have been published offering suggestions to reduce the rate of readmissions.</p> <ul style="list-style-type: none"> • With the Project RED (Reengineered Hospital Discharge Program) initiative, clinical pharmacists telephone patients 2 – 4 days after discharge to discuss medication-related concerns. Upon identification of problems, the patient's primary care physician is notified. <p>With pending payment penalties intended to reduce readmission rates, hospitals may elect to develop medical staff approved discharge protocols for specific disease processes known to be high-risk for adverse events or readmission, such as:</p> <ul style="list-style-type: none"> • Heart Failure (HF) • Stroke • Acute Myocardial Infarction (AMI) • Pneumonia • Venous thromboembolism (VTE) • Pulmonary embolism (PE) <p>Facilities may also consider development of medical staff discharge protocols for patients discharged with medications known to be a high-risk factor associated with adverse events or re-admission, such as:</p> <ul style="list-style-type: none"> • Corticosteroids • Antibiotics • Anticoagulants • Analgesics 	<ul style="list-style-type: none"> • Developed a script for the caller to identify conditions that require immediate evaluation including referral to the primary care physician or the Emergency Department? <p>5. Review the medical record to ensure attempts have been made to contact the patient 2 – 3 days post-discharge. It is appropriate to leave a generic message asking patient to return call when able. There should be documentation supporting this activity.</p>	

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	<ul style="list-style-type: none"> • Cardiovascular drugs <p>Hospital policy identifies those patients that may potentially benefit from a follow-up telephone call post discharge to avoid adverse health consequences or readmission.</p> <p>The medical staff approved discharge protocol should assign professionals qualified to conduct the discharge follow-up telephone call to the patient / patient's representative. Staff placing the calls should be familiar with the patient's discharge plan.</p> <p>The medical staff approved protocol should include:</p> <ul style="list-style-type: none"> • A list of inquiries regarding medications, diet, activity, wound care, follow-up appointments. • Reinforcement of education that was provided during the course of hospitalization. • A script for the caller to use to identify conditions that require immediate evaluation, including a referral to the primary care physician or a return to the Emergency Department. <p>National guidelines and critical pathways, regarding evidence-based practice for patient diagnosis and presentation should be used, when appropriate. The facility must reconcile the discharge plan with national guidelines and critical pathways when relevant.</p>		

PATIENT RIGHTS & DISCHARGE PLANNING

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	<p>The discharge planning process may include representatives from nursing, care management, social work, dietary, pharmacy, rehabilitation therapies, respiratory therapy, and other health care professionals along with the medical staff. The team approach ensures all post-discharge needs are identified.</p> <p>The facility discharge planning policy identifies the individuals that are qualified by education, title, experience, and training to perform the follow-up telephone calls. Often, a registered nurse, case manager, or a social worker is responsible for the follow-up telephone call. It is not mandatory that the bedside RN make the follow-up patient phone calls. However, this individual should be an RN with experience, knowledge and training to recognize potentially emergent situations when speaking with the patient.</p> <p>As the follow-up call is an assessment of high-risk patients, it would not be appropriate to have a secretary, unit clerk, or pharmacy technician to conduct the discharge follow-up telephone call.</p> <p>Recognizing the high volume of patients that experience medication-related adverse drug events or readmissions, facilities may include a well-qualified clinical pharmacist to conduct medication counseling and reconciliation at time of discharge with a follow-up telephone call within 48 hours of discharge.</p>		

NURSING DEPARTMENT

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>16.00.00 Condition of Participation: Nursing Services. <i>The hospital must have an organized Nursing Service that provides 24-hour Nursing services.</i></p> <p><i>The nursing services must be furnished or supervised by a registered nurse.</i></p> <p>§482.23</p>	<p>Nursing services are available 24 hours a day for inpatients. A registered nurse is available to plan, provide and/or supervise the nursing care of patients. The hospital must have an organized nursing service and must provide on premise nursing services 24 hours a day, 7 days a week with at least one registered nurse furnishing or supervising the service 24 hours a day, 7 days a week. (Exception: small rural hospitals operating under a waiver as discussed in §482.23(b)(1)).</p> <p>The Social Security Act (SSA) at §1861(b) states that nursing services must be furnished to inpatients and furnished by the hospital.</p> <p>The SSA at §1861(e) further requires that the hospital have a RN on duty at all times (except small rural hospitals operating under a nursing waiver).</p> <p>The nursing service must be a well-organized service of the hospital and under the direction of a registered nurse.</p> <p>The nursing service must be integrated into the hospital-wide QAPI plan.</p>	<p>DOCUMENT REVIEW AND INTERVIEW</p> <ol style="list-style-type: none"> Determine if the nursing service is integrated into the hospital-wide QAPI plan. Interview the chief nursing officer. Review the organizational chart(s) for nursing services in all locations where the hospital provides nursing services. Review job descriptions for all nursing personnel including the director’s position description. Verify that there is a hospital-employed registered nurse scheduled on every shift in every location where nursing care is provided. Verify that a hospital employed, unit based registered nurse is accountable for oversight of patient care for every shift and in every location where care is provided. Utilize care plans, medical records, patient interviews, investigative reports, staffing schedules, nursing policies and procedures, and QAPI activities to determine the adequacy of the department. Interview patients for information relative to the delivery of nursing services. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

NURSING DEPARTMENT

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
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OBSERVATION

Select at least one patient from every inpatient care unit.

1. Observe the nursing care in progress to determine the adequacy of staffing and to assess the delivery of care.
2. Other sources of information to use in the evaluation of the nursing services are:
 - nursing care plans,
 - medical records,
 - patients, family members,
 - accident and investigative reports,
 - staffing schedules,
 - nursing policies and procedures, and QAPI activities and reports.

16.00.01 Not Applicable.

16.00.02 Not Applicable.

NURSING DEPARTMENT

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>16.00.03 Nursing Organization. <i>The hospital must have a well-organized service with a plan of administrative authority and delineation of responsibilities for patient care.</i></p> <p><i>The director of the nursing service must be a licensed registered nurse. He or she is responsible for the operation of the service, including determining the types and numbers of nursing personnel and staff necessary to provide nursing care for all areas of the hospital.</i></p> <p>§482.23(a)</p>	<p>The hospital may have only one nursing service hospital-wide and the single nursing service must be under the direction of one RN.</p> <p>The director of the nursing service must be a currently licensed RN and he/she is responsible for the operation of the nursing service. The operation of the nursing service would include the quality of the patient care provided by the nursing service.</p> <p>The director of the nursing service must determine and provide the types and numbers of nursing care personnel necessary to provide nursing care to all areas of the hospital.</p> <p>The organization will include various configurations of the following hospital personnel as determined necessary by the hospital and the Director of Nursing:</p> <ul style="list-style-type: none"> • Assistant / Associate Director(s); • Supervisors / Coordinators; • Head Nurses / Nurse Managers; • Staff Nurses; • Unit Secretaries / Clerks; • Nurse's Aide / Orderlies. <p>The nurse executive is licensed in the state in which patient care is provided, supervised, or directed.</p> <p>The educational qualifications of the nurse executive are established at the facility level and must be appropriate to the scope and complexity of patient care services provided.</p>	<p style="text-align: center;">DOCUMENT REVIEW</p> <ol style="list-style-type: none"> 1. Review the organizational chart or plan for nursing services. Determine that the organizational chart(s) displays lines of authority that delegates responsibility within the nursing department. 2. Verify that the hospital has only one nursing service hospital-wide and the single nursing service is under the direction of one RN. 3. Review the position description. Determine the nursing director meets the requirements. 4. Read the position description for the director of nursing (DON) to determine that it delegates to the DON specific duties and responsibilities for operation of the service. 5. Verify that the director is currently licensed in accordance with state licensure requirements. 6. Verify that the DON is involved with or approved the development of the nursing service staffing policies and procedures. 7. Verify that the DON approves the nursing service patient care policies and procedures. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

NURSING DEPARTMENT

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>16.00.04 Staffing and Delivery of Care. <i>The nursing service must have adequate numbers of licensed registered nurses, licensed practical (vocational) nurses, and other personnel to provide nursing care to all patients as needed.</i></p> <p><i>There must be supervisory and staff personnel for each department or nursing unit to ensure, when needed, the immediate availability of a registered nurse for bedside care of any patient.</i></p> <p>§482.23(b)</p>	<p>The nurse executive is responsible for standards of nursing practice and standards of nursing care, nursing budget, policies and procedures for patient care and QAPI in clinical areas.</p> <p>The nursing executive participates in a collaborative interchange at the senior management level.</p> <p>The organizational chart explains the reporting responsibilities of the Assistant / Associate directors, head nurses/managers, staff nurses and nurse’s aides /techs to the nurse executive.</p> <p>The Nursing Service budget is based upon historical and projected data and indicates the minimum required staff and the flexible ranges for staffing.</p> <p>The nursing service must ensure that patient needs are met by ongoing assessments of patients’ needs and provides nursing staff to meet those needs. There must be sufficient numbers, types and qualifications of supervisory and staff nursing personnel to respond to the appropriate nursing needs and care of the patient population of each department or nursing unit.</p> <p>There must be a RN physically present on the premises and on duty at all times.</p> <ul style="list-style-type: none"> • Every inpatient unit / department / location within the hospital-wide nursing service must have adequate numbers of RNs physically present at each location to ensure the 	<p><u>DOCUMENT REVIEW, OBSERVATION & INTERVIEW</u></p> <ol style="list-style-type: none"> 1. There is evidence that the budget is approved by governance as part of the overall hospital budget. The budget is based upon reliable history and projections utilizing a system, which provides for at least one budgeted RN, per shift, per unit, unless a 24-hour nursing waiver has been granted. 2. Obtain copies of actual and planned staffing for inpatient units for the week prior to the survey, and for a full week six months prior to the survey. Verify: <ul style="list-style-type: none"> • There is at least one employed RN, each shift, for each organized inpatient unit. 3. Determine that there are written staffing 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

NURSING DEPARTMENT

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
	<p>immediate availability of a RN for the bedside care of any patient.</p> <p>A RN would not be considered immediately available if the RN was working on more than one unit, building, floor in a building, or provider (distinct part SNF, RHC, excluded unit, etc.) at the same time.</p> <p>Staffing schedules must be reviewed and revised as necessary to meet the patient care needs and to make adjustments for nursing staff absenteeism.</p>	<p>schedules which correlate to the number and acuity of patients.</p> <ol style="list-style-type: none"> 4. Verify that there is supervision of personnel performance and nursing care for each department or nursing unit. 5. To determine if there are adequate numbers of nurses to provide nursing care to all patients as needed, take into consideration: <ul style="list-style-type: none"> • Physical layout and size of the hospital; • Number of patients; • Intensity of illness and nursing needs; • Availability of nurses' aides and orderlies and other resources for nurses, e.g., housekeeping services, ward clerks etc.; • Training and experience of personnel; • Do not count personnel assigned to areas other than bedside patient care. 6. Review medical records to determine if patient care that is to be provided by nurses is being provided as ordered. 7. Is appropriate care being provided, or are deficiencies identified upon review of patient medical records? 	

NURSING DEPARTMENT

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>16.00.05 24-Hour Provision of Services. <i>The hospital must provide 24-hour nursing services furnished or supervised by a registered nurse, and have a licensed practical nurse or registered nurse on duty at all times, except for rural hospitals that have in effect a 24 –hour nursing waiver granted under §488.54(c) of 42 CFR 488.54.</i></p> <p>§482.23(b)(1)</p>	<p>The hospital must provide nursing services 24 hours a day, 7 days a week. An LPN can provide nursing services if an RN, who is immediately available for the bedside care of those patients, supervises that care.</p> <p>EXCEPTION: Section 488.54(c) sets forth certain conditions under which rural hospitals of 50 beds or fewer may be granted a temporary waiver of the 24-hour registered nurse requirement by the regional office.</p> <p>Rural is defined as all areas not delineated as “urbanized” areas by the Census Bureau, in the most recent census.</p> <p>Temporary is defined as a one year period or less and the waiver cannot be renewed.</p>	<p>DOCUMENT REVIEW</p> <p>Review the nurse staffing schedule for a one-week period. If there are concerns regarding insufficient RN coverage, review the staffing schedules for a second week period to determine if there is a pattern of insufficient coverage.</p> <p>Document daily RN coverage for every unit of the hospital.</p> <ul style="list-style-type: none"> Verify that there is at least one RN for each unit on each tour of duty, 7 days a week, 24 hours a day. Additional nurses may be required for vacation or absenteeism coverage. <p>EXCEPTION: If the hospital has a temporary waiver of the 24-hour RN requirement in effect, verify and document the following:</p> <ul style="list-style-type: none"> 50 or fewer inpatient beds. The character and seriousness of the deficiencies do not adversely affect the health and safety of patients. The hospital meets all the other statutory requirements in §1861(e)(1-8). The hospital has made and continues to make a good faith effort to comply with the 24 hour nursing requirement. <ul style="list-style-type: none"> Determine the recruitment efforts and methods used by the hospitals’ 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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administration by requesting copies of advertisements in newspapers and other publications as well as evidence of contact with nursing schools and employment agencies.

- Document that the salary offered by the hospital is comparable to three other hospitals, located nearest to the facility.
- The hospital’s failure to comply fully with the 24 hour nursing requirement is attributable to a temporary shortage of qualified nursing personnel in the area in which the hospital is located.
- A registered nurse is present on the premises to furnish the nursing service during at least the daytime shift, 7 days a week.
- On all tours of duty not covered by a registered nurse, a licensed practical (vocational) nurse is in charge.

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STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>16.00.06 <u>Licensure.</u> <i>The nursing service must have a procedure to ensure that the hospital nursing personnel for whom licensure is required have valid and current licensure.</i></p> <p>§482.23(b)(2)</p>	<p>The licensure verification process is in conformance with State Laws regarding copying / not copying the license. The process is applied to employee, agency, and contractual providers.</p> <p>The hospital’s procedure must ensure that all nursing personnel have valid and current licensure that complies with State licensure laws.</p> <p>Furthermore, the Condition of Participation (CoP) Compliance with Federal, State and local laws (<u>42 CFR §482.11</u>) requires the hospital to assure that personnel meet applicable standards (such as continuing education, certification or training) required by State or local law.</p>	<p style="text-align: center;"><u>DOCUMENT REVIEW</u></p> <ol style="list-style-type: none"> Review the nursing service licensure verification policies and procedures. Is licensure verified for each individual nursing services staff person for whom licensure is required? Determine the facility has a licensure verification mechanism that conforms with state mandates. Determine the licensure policy: <ul style="list-style-type: none"> Is employed for all individual employee and non-employee nursing personnel practicing in the hospital for whom licensure is required. <p style="text-align: center;"><u>FILE REVIEW</u></p> <p>Review hospital personnel records or records kept by the nursing service to determine that RNs, LPNs, and other nursing personnel for whom licensure is required have current valid licenses.</p>	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>
<p>16.00.07 <u>Not Applicable.</u></p>			
<p>16.00.08 <u>Not Applicable.</u></p>			

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STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>16.00.09 <u>Supervision of Care.</u> <i>A registered nurse must supervise and evaluate the nursing care for each patient.</i></p> <p>§482.23(b)(3)</p>	<p>An RN must supervise the nursing care for each patient.</p> <p>An RN must evaluate the care for each patient upon admission and when appropriate on an ongoing basis in accordance with accepted standards of nursing practice and hospital policy.</p> <p>Evaluation would include assessing the patient’s care needs, patient’s health status / conditioning, as well as the patient’s response to interventions.</p>	<p><u>DOCUMENT REVIEW</u></p> <p>Review staffing schedules and assignments. Determine:</p> <ol style="list-style-type: none"> 1. An RN is assigned to supervise and evaluate the nursing care furnished to each patient. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>
<p>16.00.10 <u>Plan of Care.</u> <i>The hospital must ensure that the nursing staff develops, and keeps current, a nursing care plan for each patient.</i></p> <p><i>The nursing care plan may be part of an interdisciplinary care plan.</i></p> <p>§482.23(b)(4)</p>	<p>Nursing care planning starts upon admission. It includes planning the patient’s care while in the hospital as well as planning for discharge to meet post-hospital needs.</p> <p>A nursing care plan is based on assessing the patient’s nursing care needs (not solely those needs related to the admitting diagnosis). The assessment considers the patient’s treatment goals and, as appropriate, physiological and psychosocial factors and patient discharge planning. The plan develops appropriate nursing interventions in response to the identified nursing care needs.</p> <p>The nursing care plan is kept current by ongoing assessments of the patient’s needs and of the patient’s response to interventions, and updating or revising the patient’s nursing care plan in response to assessments.</p>	<p><u>CHART REVIEW</u></p> <p>Review a sample of nursing care plans. Verify that the Nursing Care Plans:</p> <ol style="list-style-type: none"> 1. Are initiated as soon as possible after admission for each patient. 2. Describe patient goals and address, as appropriate, the physiological and psychosocial factors as well as discharge planning. 3. Are consistent with the attending Doctor of Medicine/Doctor of Osteopathic Medicine’s plan for medical care. 4. Are revised as the needs of the patient changes. 5. Are nursing care plans implemented in a 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

NURSING DEPARTMENT

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
	<p>The nursing care plan is part of the patient’s medical record and must comply with the medical records requirements at §482.24.</p> <p>Hospitals have the flexibility of developing the nursing care plan as part of a larger, coordinated interdisciplinary plan of care. This method may serve to promote communication among disciplines and reinforce an integrated, multi-faceted approach to a patient’s care, resulting in better patient outcomes. The interdisciplinary plan of care does not minimize or eliminate the need for a nursing care plan. It does, however, serve to promote the collaboration between members of the patient’s health care team.</p> <p>The required documentation for the nursing component of an interdisciplinary care plan remains the same.</p> <ul style="list-style-type: none"> • For other components, the hospital should follow the current documentation policies that it uses to document services provided by other disciplines, such as services provided by physical therapists, occupational therapists, speech-language pathologists, and others. • Documentation should follow the standards of practice for those disciplines in addition to any specific requirements that the hospital might want to establish. • The documentation must also comply with the requirements of the medical records 	<p>timely manner?</p> <p>6. Select a sample of nursing or interdisciplinary care plans. Approximately 6 – 12 plans should be reviewed. For each plan reviewed, with respect to the nursing care component:</p> <ul style="list-style-type: none"> • Was the plan initiated as soon as possible after admission for each patient? • Does the plan describe patient goals as part of the patient’s nursing care assessment and, as appropriate, physiological and psychosocial factors and patient discharge planning? • Is the plan consistent with the plan for medical care of the practitioner responsible for the care of the patient? • Is there evidence of reassessment of the patient’s nursing care needs and response to nursing interventions and, as applicable, revisions to the plan? • Was the plan implemented in a timely manner? 	

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requirement at §482.24. (77 FR 29049, May 16, 2012)

16.00.11 Care Assignments.

A registered nurse must assign the nursing care of each patient to nursing personnel in accordance with the patient's needs and the specialized qualifications and competence of the nursing staff available.

§482.23(b)(5)

A RN must make all patient care assignments.

The director of the nursing service and the hospital are to ensure that nursing personnel with the appropriate education, experience, licensure, competence and specialized qualifications are assigned to provide nursing care for each patient in accordance with the individual needs of each patient.

DOCUMENT REVIEW & INTERVIEW

Review the nursing assignments for at least three (3) weeks of staffing plans against the patient acuity to determine the requirements are met. Determine:

1. Did an RN made the assignments.
2. Assignments take into consideration the complexity of patient's care needs and the competence and specialized qualification of the nursing staff.

Ask the charge nurse what considerations are necessary when making staff assignments. Answers must include:

- Patient needs
- Complexity of patients
- Any special needs of individual patients
- Competence of nursing personnel
- Qualifications of nursing personnel
- Education of nursing personnel
- Experience of nursing personnel.

- 1 = Compliant
- 2 = Not Compliant

This standard is not met as evidenced by:

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16.00.12 Not Applicable.

16.00.13 Supervision of Non-Employee Staff.

Non-employee licensed nurses who are working in the hospital must adhere to the policies and procedures of the hospital.

The director of nursing service must provide for the adequate supervision and evaluation of the clinical activities of non-employee nursing personnel that occur within the responsibility of the nursing services.

§482.23(b)(6)

The hospital must ensure that there are adequate numbers of clinical nursing personnel to meet its patients nursing care needs.

In order to meet their patient’s needs, the hospital may supplement their hospital employed licensed nurses with volunteer and or contract nonemployee licensed nurses.

The hospital and the director of the nursing service are responsible for the clinical activities of all nursing personnel. This would include the clinical activities of all non-employee nursing personnel (contract or volunteer).

Non-employee licensed nurses who are working at the hospital must adhere to the policies and procedures of the hospital.

The hospital and the director of the nursing service are responsible for ensuring that non-employee nursing personnel know the hospital’s policies and procedures in order to adhere to those policies and procedures.

The hospital and the director of the nursing service ensure that each non-employee nursing care staff person is adequately supervised and that their clinical activities are evaluated. This supervision and evaluation of the clinical activities of each non-

DOCUMENT REVIEW

- Review the method for orienting non-employee licensed nurses to hospital policies and procedures. The orientation must include at least the following:
 - The hospital and the unit
 - Emergency procedures
 - Nursing service policies and procedures
 - Safety policies and procedures
- If the hospital uses non-employee nursing personnel, are they supervised by an RN who is a regular employee of the hospital?

FILE REVIEW

- Determine if non-employee personnel are appropriately oriented prior to providing care.
- Verify that non-employee personnel:
 - Are licensed in accordance with State law.
 - Are evaluated regularly.

OBSERVATION

- Observe the care provided by non-employee nursing personnel.
- Do they know and adhere to hospital policies?

1 = Compliant
 2 = Not Compliant

This standard is not met as evidenced by:

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employee nursing staff person must be conducted by an appropriately qualified hospital-employed RN.

- Do they know appropriate emergency procedures?
- Are they adequately supervised by an appropriately experienced hospital employed RN?
- Are their clinical activities being evaluated adequately?
- Are they licensed in accordance with State law?

INTERVIEW

1. Confirm with the director of nurses that a non-employee nurse’s performance is evaluated by the hospital at least once a year.
2. If the performance evaluation is not considered confidential, review two evaluations.

16.00.14 Not Applicable.

16.00.15 Not Applicable.

16.00.16 Not Applicable.

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STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>16.01.01 Preparation and Administration of Drugs.</p> <p>(1) <i>Drugs and biologicals must be prepared and administered in accordance with Federal and State laws, the orders of the practitioner or practitioners responsible for the patient’s care as specified under §482.12(c), and accepted standards of practice.</i></p> <p>(i) <i>Drugs and biological may be prepared and administered on the orders of other practitioners not specified under §482.12(c) only if such practitioners are acting in accordance with State law, including scope-of-practice laws, hospital policies, and medical staff bylaws, rules and regulations.</i></p> <p>(2) <i>All drugs and biologicals must be administered by, or under supervision of, nursing or other personnel in accordance with Federal and State laws and regulations, including applicable licensing requirements, and in accordance with the approved medical staff policies and procedures.</i></p>	<p>Drugs and biologicals must be prepared and administered in accordance with Federal and State laws.</p> <p>According to the Institute of Medicine of the National Academies, medication errors are among the most common medical errors, harming at least 1.5 million people each year.³</p> <p>It has been estimated that drug-related adverse outcomes were noted in nearly 1.9 million inpatient hospital stays (4.7 percent of all stays), and 838,000 treat-and-release ED visits (0.8 percent of all visits).⁴</p> <hr/> <p>3 Institute of Medicine. Preventing Medication Errors. Washington DC: The National Academies Press, 2007.</p> <p>4 Lucado, Jennifer, et al, <i>Medication-Related Adverse Outcomes in U.S. Hospitals and Emergency Departments</i>. Statistical Brief #109, April, 2011. Healthcare Cost and Utilization, Project, Agency For Healthcare Research and Quality, Rockville, MD.</p> <hr/> <p>Although technological advances in electronic order entry, medication administration, and electronic medical records hold a great deal of promise for decreasing medication errors, there are a multitude of human and environmental factors that will impact</p>	<p>CHART REVIEW AND OBSERVATION</p> <p>A. Verify that there is an effective method for the administration of drugs. Use the following indicators for assessing drug administration:</p> <ol style="list-style-type: none"> 1. Verify that there are policies and procedures approved by the medical staff and governing body concerning ordering of drugs and biologicals by practitioners. 2. Verify that there are policies and procedures approved by the medical staff covering who is authorized to administer medications, and that the policies are followed. 3. Verify nursing staff authorized to administer drugs and biological are practicing within their State-permitted scope of practice. 4. Are personnel other than nursing personnel administering drugs or biologicals? <ul style="list-style-type: none"> • If yes, determine if those personnel are administering drugs or biologicals in accordance with Federal and State laws and regulations, including scope of practice laws, hospital policy, and medical staff by-laws, rules and regulations. Use the above 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
§482.23(c) §482.23(c)(1) §482.23(c)(1)(i) §482.23(c)(2)	<p>their success. The increasing complexity of medical care and patient acuity present significant challenges that require an approach to medication administration that takes advantage of available technology while recognizing that it must be integrated into the medication administration work processes in a manner that meets the needs of patients and promotes their safety.</p> <p>The regulations at §482.23(c) and §482.23(c)(1) promote safety in the preparation and administration of drugs and biologicals to hospital patients by requiring preparation and administration by or under the supervision of nursing or other personnel in accordance with:</p> <ul style="list-style-type: none"> • Federal and State law; • Accepted standards of practice; • Orders of the practitioner(s) responsible for the patient’s care, as specified under §482.12(c) or of another practitioner as permitted under State law, hospital policy and medical staff bylaws, rules and regulations; and • Medical staff-approved policies and procedures. <p><u>Federal and State Law</u> Federal law regulates the approval and classification of drugs and biologicals. Individual States establish laws and regulations which specify the scope of practice for various types of licensed healthcare professionals,</p>	<p>procedures to determine compliance.</p> <ol style="list-style-type: none"> 5. Verify that there are policies and procedures approved by medical staff addressing the timing of medication administration. 6. Verify that the hospital has, consistent with its policies, identified medications: which are: <ol style="list-style-type: none"> a. Not eligible for scheduled dosing times; b. Eligible for scheduled dosing times and are time-critical; and c. Eligible for scheduled dosing times and are not time-critical. 7. Verify the hospital has established total windows of time that do not exceed the following: <ol style="list-style-type: none"> a. 1 hour for time-critical scheduled medications b. 2 hours for medications prescribed more frequently than daily, but no more frequently than every 4 hours; and c. 4 hours for medications prescribed for daily or longer administration intervals. 	

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STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
	<p>including which medications they may prescribe and administer, including controlled substances.</p> <p>Accepted Standards of Practice Hospital policies and procedures for the preparation and administration of all drugs and biologicals must not only comply with all applicable Federal and State laws, but also must be consistent with accepted standards of practice based on guidelines or recommendations issued by nationally recognized organizations with expertise in medication preparation and administration.</p> <p>Examples of such organizations include, but are not limited to:</p> <ol style="list-style-type: none"> 1. American Society of Health-System Pharmacists (http://www.ashp.org/default.aspx) 2. National Coordinating Council for Medication Error Reporting and Prevention (www.nccmerp.org); 3. Institute for Healthcare Improvement (http://www.ihl.org/ihl); 4. U.S Pharmacopeia (www.usp.org); 5. Institute for Safe Medication Practices, which offers guidelines specifically on timely medication administration, which can be found at: www.ismp.org/Newsletters/acutecare/articles/20110113.asp; 	<ol style="list-style-type: none"> 8. Verify that the hospital’s policy describes requirements for the administration of identified time-critical medications. Is it clear whether time-critical medications or medication types are identified as such for the entire hospital or are unit-, patient diagnosis-, or clinical situation-specific? <p>B. Review a sample of medical records to determine whether medication administration conformed to an authorized practitioner’s order, i.e., that there is an order from an authorized practitioner, or an applicable standing order, and that the correct medication was administered to the right patient at the right dose via the correct route, and that timing of administration complied with the hospital’s policies and procedures. Check that the practitioner’s order was still in force at the time the drug was administered.</p> <p>C. Observe the preparation of drugs and their administration to patients [medication pass] in order to verify that procedures are being followed.</p> <ol style="list-style-type: none"> 1. Is the patient’s identity confirmed prior to medication administration? 2. Are procedures to assure the correct 	

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	<p>6. Infusion Nurses Society (http://www.ins1.org).</p> <p>In addition, the Centers for Disease Control and Prevention (CDC) publishes evidenced-based practice guidelines and recommendations on medication preparation and administration practices, designed to reduce the risk of infection associated with these activities.</p> <p>Orders of an Authorized Practitioner Drugs must be administered in response to an order from a practitioner, or on the basis of a standing order which is appropriately authenticated subsequently by a practitioner. (See §482.23(c)(1) (ii) concerning standing orders.)</p> <p>Generally, the ordering practitioner is the practitioner(s) responsible for the care of the patient in accordance with §482.12(c). However, other practitioners not specified under §482.12(c) may write orders for the preparation and administration of drugs and biologicals, if they are acting in accordance with State law, including scope of practice laws, hospital policies and procedures, and medical staff bylaws, rules and regulations.</p> <p>This includes practitioners ordering outpatient services who do not have privileges in the hospital but who are permitted under their State scope of practice and authorized by hospital and medical staff policy to order outpatient services.</p>	<p>medication, dose, and route followed?</p> <p>3. If immediate-use CSPs are prepared outside of the pharmacy, are practices consistent with USP<797>?</p> <p>4. Are drugs administered in accordance with the hospital’s established policies and procedures for safe and timely medication administration?</p> <p>5. Does the nurse remain with the patient until oral medication is taken?</p> <p>D. Are patients assessed by nursing and/or other staff, per hospital policy, for their risk to their prescribed medications?</p> <p>E. Are patients who are at higher risk and/or receiving high-alert medications monitored for adverse effects?</p> <p>F. Are staff knowledgeable about intervention protocols when patients experience adverse medication-related events?</p> <p>G. Interview personnel who administer medication to verify their understanding of the policies regarding timeliness of medication administration.</p> <p>1. Are they able to identify time-critical and non-time-critical scheduled</p>	

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	<p>In accordance with standard practice, all practitioner orders for the administration of drugs and biologicals must include at least the following:</p> <ol style="list-style-type: none"> 1. Name of the patient; 2. Age and weight of the patients, to facilitate dose calculation when applicable. 3. Policies and procedures must address weight-based dosing for pediatric patients as well as in other circumstances identified in the hospital's policies. (Note that dose calculations are based on metric weight (kg, or g for newborns). <ul style="list-style-type: none"> • If a hospital permits practitioners to record weight in either pounds or using metric weight, the opportunity for error increases, since some orders would require conversion while others would not. Accordingly, hospitals must specify a uniform approach to be used by prescribing practitioners. • For example, a hospital could require all prescribers to use pounds or ounces and have the electronic ordering system or the pharmacy convert to metric); <ol style="list-style-type: none"> a. Date and time of the order; b. Drug name; c. Dose, frequency, and route; 	<p>medications? Medications not eligible for scheduled dosing times?</p> <ol style="list-style-type: none"> 2. Are they able to describe requirements for the timing of administration of time critical and non-time critical medications in accordance with the hospital's policies? 	

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- d. Dose calculation requirements, when applicable;
- e. Exact strength or concentration, when applicable;
- f. Quantity and/or duration, when applicable;
- g. Specific instructions for use, when applicable; and
- h. Name of the prescriber.

Medical Staff Approved Policies and Procedures

The hospital’s medical staff must approve policies and procedures for medication administration, consistent with the requirements of Federal and State law and accepted standards of practice. It is recommended that the medical staff consult with nurses, pharmacists, Quality Assessment and Performance Improvement program staff, and others in developing these policies and procedures.

The adopted policies and procedures must address key issues related to medication administration, which include but are not limited to:

A. Personnel Authorized To Administer Medication

§482.23(c)(2) requires that all drugs and biologicals are administered by, or under the supervision of, nursing or other personnel, in

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accordance with Federal or State law and approved medical staff policies and procedures. State law requirements include licensure requirements.

Policies and procedures must identify categories of licensed personnel and the types of medications they are permitted to prepare and administer, in accordance with state laws. The policies and procedures must also address education and training for all personnel preparing and administering drugs and biologicals.

Medication preparation and administration education and training is typically included in hospital orientation or other continuing education for nursing staff and other authorized healthcare personnel. Training or continuing education topics regarding medication preparation and administration may include but are not limited to the following:

- Safe handling and preparation of authorized medications;
- Knowledge of the indications, side effects, drug interactions, compatibility, and dose limits
- Equipment, devices, special procedures, and/or techniques required for medication administration;

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- Policies and procedures must address the required components of the training and if the training provided during hospital orientation imparts sufficient education or whether ongoing in-services or continuing education will be required to demonstrate competence.

B. Basic Safe Practices For Medication

Administration

The hospital’s policies and procedures must reflect accepted standards of practice that require the following be confirmed prior to each administration of medication (often referred to as the “five rights” of medication administration practice):

1. **Right Patient:** the patient’s identity— acceptable patient identifiers include, but are not limited to:
 - a. The patient’s full name; an identification number assigned by the hospital; or date of birth.
 - b. Identifiers must be confirmed by patient wrist band, patient identification card, patient statement (when possible) or other means outlined in the hospital’s policy.
 - c. The patient’s identification must be confirmed to be in agreement with the

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medication administration record and medication labeling prior to medication administration to ensure that the medication is being given to the correct patient.

2. **Right Medication:** the correct medication, to ensure that the medication being given to the patient matches that prescribed for the patient and that the patient does not have a documented allergy to it;
3. **Right Dose:** the correct dose, to ensure that the dosage of the medication matches the prescribed dose, and that the prescription itself does not reflect an unsafe dosage level (i.e., a dose that is too high or too low);
4. **Right Route:** the correct route, to ensure that the method of administration – orally, intramuscular, intravenous, etc., is the appropriate one for that particular medication and patient; and
5. **Right Time:** the appropriate time, to ensure adherence to the prescribed frequency and time of administration.

Note: the “5 rights” focus specifically on the process of administering medications. The medication process is generally recognized as consisting of five stages:

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- ordering/prescribing;
- transcribing and verifying;
- dispensing and delivering;
- administering; and
- monitoring / reporting.

Errors may occur in other components of the process, even when there is strict adherence to the “5 rights” of medication administration, for example when there has been a prescribing or a dispensing error. Hospitals are also expected to comply with requirements under the Pharmaceutical Services CoP at §482.25 and the patient safety requirements under the Quality Assessment and Performance Improvement CoP at §482.21, using a comprehensive systems approach to all components of the medication process.

Hospitals are encouraged to promote a culture in which it is not only acceptable, but also strongly encouraged, for staff to bring to the attention of the prescribing practitioner questions or concerns they have regarding medication orders. Any questions about orders for drugs or biologicals are expected to be resolved promptly, whether they arise prior to the preparation, dispensing, or administration of the medication.

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HEALTHCARE-ASSOCIATED INFECTIONS

Hospitals must also ensure staff adherence to accepted standards of practice required to prevent healthcare-associated infections related to medication preparation and/or administration. Adherence to these standards is assessed under the infection control CoP at 42 CFR 482.42, and details about the required practices are found in the Hospital Infection Control Worksheet.

Compounded sterile preparations (CSPs) may also be a source of healthcare-associated infection if proper precautions are not followed.

The applicable standards of practice for safe sterile compounding are, at a minimum, the standards published in The United States Pharmacopeia National Formulary Chapter <797> (“Pharmaceutical Compounding – Sterile Preparations”) and other relevant USP/NF Chapters (USP <797>).

- (See the guidance for §482.25(b)(1) for more information on the role of USP/NF standards and for discussion of the term “compounding.”)

Hospitals must ensure that they meet all currently accepted standards for safe preparation and administration for CSPs, whether they are the type of CSP that must be compounded in an aseptic pharmacy location

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that meets USP <797> standards for low, medium or high-level risk CSPs or are “immediate-use CSPs” prepared outside of the pharmacy.

IMMEDIATE-USE CSPs

Nurses commonly prepare sterile medications that are categorized by USP <797> as “immediate-use CSPs,” which are needed for immediate or emergency use for a particular patient and are not to be stored for anticipated needs.

The following USP <797> standards apply when preparing an immediate-use CSP:

1. Preparation of an immediate-use CSP must only involve “simple transfer of not more than three commercially manufactured...sterile nonhazardous products from the manufacturer’s original containers and not more than two entries into any one container or package (e.g. bag, vial) of sterile infusion solution or administration container/device;”
2. “Administration begins not later than one hour following the start of the preparation of the CSP (if not, the CSP must be appropriately discarded);”
3. Meticulous aseptic technique must be followed during all phases of preparation. If

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the CSP is not administered to the patient as soon as it is ready, “the finished CSP is under continuous supervision to minimize the potential for contact with non-sterile surfaces...,” contamination and/or confusion with other CSPs; and

4. “Unless immediately and completely administered by the person who prepared it or immediate and complete administration is witnessed by the preparer...,” the CSP must be labeled with at least:
 - a. Patient identification information;
 - b. The names and amounts of all ingredients;
 - c. The name or initials of the person who prepared it; and
 - d. The exact one hour “beyond use date” (see below).

A drug or biological is outdated after its expiration date, which is set by the manufacturer based on stability testing under specified conditions as part of the U.S. Food and Drug Administration’s (FDA) approval process. It should be noted that a drug or biological may become unusable prior to its expiration date if it has been subjected to conditions that are

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inconsistent with the manufacturer’s approved labeling.

BEYOND USE DATE (BUD)

1. A drug or biological is also outdated after its “beyond-use date” (BUD), which may be reached before the expiration date, but never later.

2. The BUD is the date and time after which the medication must not be used, stored or transported.

3. The BUD takes into account the specific conditions and potential for deterioration and microbial growth that may occur during or after the original container is opened, while preparing the medication for dispensing and administration, and/or during the compounding process if it is a compounded medication.

4. The BUD is to be based on information provided by the manufacturer, whenever such information is available. The hospital must maintain and implement policies and procedures that provide clear and consistent direction to pharmacy staff regarding how to determine a BUD when complete BUD information is not available from the manufacturer.

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5. The policies and procedures must be based on accepted professional principles which are equivalent to, or more stringent than, those described in the USP/NF (USP).³

6. According to Chapters <795> and <797> of the USP, the BUD must be safe for patients, and determined conservatively. The section in USP <797> entitled “Determining Beyond-Use Dates,” which addresses sterile compounding, notes that “the truly valid evidence for predicting beyond-use dating can be obtained only through product-specific experimental studies.” It provides an example of testing considered more appropriate for certain types of CSPs such as “CSPs with a narrow therapeutic index, where close monitoring or dose titration is required to ensure therapeutic effectiveness and to avoid toxicity....”

It also provides examples of important issues that a pharmacist must be able to critically interpret and evaluate when consulting literature sources in the process of determining a BUD; and distinguishes between reviewing literature specific to a particular drug, composition, concentration of ingredients, fill volume, container, storage conditions and duration of use, etc., versus merely reviewing available publications or tables. The former is the preferred

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approach, while the latter results in a “theoretical BUD,” which has an inherent likelihood of inaccuracy or error.

³ All references to “USP” herein are from: **United States Pharmacopeial Convention. USP on Compounding: A Guide for the Compounding Practitioner. Current with USP 37-NF32 through First Supplement. Rockville, MD: United States Pharmacopeial Convention, 2014.**

C. Timing of Medication Administration

Appropriate timing of medication administration must take into account the complex nature and variability among medications; the indications for which they are prescribed; the clinical situations in which they are administered; and the needs of the patients receiving them.

The chemical properties, mechanism of action, or therapeutic goals of some medications require administration at the exact time prescribed, or within a narrow window of its prescribed scheduled time, to avoid compromising patient safety or achievement of the intended therapeutic effect. However, the therapeutic effect of many other medications is uncompromised by a much broader window of time for administration.

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Consequently, the application of a uniform required window of time before or after the scheduled time for the administration of all medications, without regard to their differences, could undermine the ability of nursing staff to prioritize nursing care activities appropriately.

This could also result in staff work-arounds that jeopardize patient safety due to the imposition of unrealistic or unnecessary time constraints for medication administration. Instead, hospital policies and procedures must specifically address the timing of medication administration, based on the nature of the medication and its clinical application, to ensure safe and timely administration.

The policies and procedures must address at least the following:

1. Medications not eligible for scheduled dosing times;
2. Medications eligible for scheduled dosing times;
3. Administration of eligible medications outside of their scheduled dosing times and windows; and
4. Evaluation of medication administration timing policies, including adherence to them.

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D. Medications or Categories of Medication Not Eligible For Scheduled Dosing Times

The policies and procedures must identify medications or categories of medication which are not eligible for scheduled dosing times, either in general or in specific clinical applications.

These are medications that require exact or precise timing of administration, based on diagnosis type, treatment requirements, or therapeutic goals. The policies and procedures must reflect consideration of factors including, but not limited to, the pharmacokinetics of the prescribed medication; specific clinical applications; and patient risk factors.

Examples of medications that hospitals may choose to identify as not eligible for scheduled dosing times may include, but are not limited to:

- STAT doses (immediate);
- First time or loading doses (initial large dose of a drug given to bring blood, tissue or fluid levels to an effective concentration quickly);
- One-time doses; doses specifically timed for procedures;
- Time-sequenced doses; doses timed for serum drug levels;
- Investigational drugs; or

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- Drugs prescribed on an as needed basis (prn doses).

The policies and procedures must ensure timely administration of such medications. In addition they must specify if the policy for the administration of these medications will be applied hospital-wide or only for specific diagnosis types, hospital units or clinical situations.

E. Medications Eligible For Scheduled Dosing Times

Medications eligible for scheduled dosing times are those prescribed on a repeated cycle of frequency, such as once a day, BID (twice a day), TID (three times a day), hourly intervals (every 1, 2, 3 or more hours), etc.

The goal of this scheduling is to achieve and maintain therapeutic blood levels of the prescribed medication over a period of time.

Medication administration policies and procedures typically establish standardized dosing times for the administration of all 'scheduled' medications.

- For example, medications prescribed for BID (twice a day) administration might, under a given hospital's policies and procedures, be scheduled to be administered at 8am and 8pm.

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- Another hospital might choose to schedule BID medications at 7:30 am and 7:30 pm.
- Use of these standardized times facilitates the medication administration process, e.g., by providing to the hospital’s pharmacy that morning doses of all BID drugs must be dispensed and delivered to patient units in time for the scheduled administration.
- For the nursing staff, the scheduled administration time might prompt prioritization of additional activities that may be required, in the case of particular drugs, such as vital sign assessment or the collection and review of blood work, to ensure safe and timely medication administration.

Policies and procedures for medications eligible for scheduled dosing times must also address:

- first dose medications, including parameters within which nursing staff are allowed to use their own judgment regarding the timing of the first and subsequent doses, which may fall between scheduled dosing times;
- retiming of missed or omitted doses; medications that will not follow scheduled dosing times; and
- patient units that are not subject to following the scheduled dosing times.

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F. Time-Critical Scheduled Medications

Time-critical scheduled medications are those for which an early or late administration of greater than thirty minutes might cause harm or have significant, negative impact on the intended therapeutic or pharmacological effect.

Accordingly, scheduled medications identified under the hospital’s policies and procedures as time-critical must be administered within thirty minutes before or after their scheduled dosing time, for a total window of 1 hour.

It is possible for a given medication to be time-critical for some patients, due to diagnosis, clinical situation, various risk factors, or therapeutic intent, but not time-critical for other patients.

Therefore, hospital policies and procedures must address the process for determining whether specific scheduled medications are always time-critical, or only under certain circumstances, and how staff involved in medication administration will know when a scheduled medication is time-critical.

Examples of time-critical scheduled medications / medication types may include, but are not limited to:

- Antibiotics;
- Anticoagulants;

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- Insulin;
- Anticonvulsants;
- Immunosuppressive agents;
- Pain medication (non-IV);
- Medications prescribed for administration within a specified period of time of the medication order;
- Medications that must be administered apart from other medications for optimal therapeutic effect; or
- Medications prescribed more frequently than every 4 hours.

G. Non-Time-Critical Scheduled Medications

Non-time critical scheduled medications are those for which a longer or shorter interval of time since the prior dose does not significantly change the medication’s therapeutic effect or otherwise cause harm.

For such medications greater flexibility in the timing of their administration is permissible. Specifically:

- Medications prescribed for daily, weekly or monthly administration may be within 2 hours before or after the scheduled dosing time, for a total window that does not exceed 4 hours.

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- Medications prescribed more frequently than daily but no more frequently than every 4 hours may be administered within 1 hour before or after the scheduled dosing time, for a total window that does not exceed 2 hours.

H. Missed or Late Administration Of Medications

The hospital’s policies and procedures must address the actions to be taken when medications eligible for scheduled dosing times are not administered within their permitted window of time.

This includes doses which may have been missed due to the patient being temporarily away from the nursing unit, for example, for tests or procedures; patient refusal; patient inability to take the medication; problems related to medication availability; or other reasons that result in missed or late dose administration.

Likewise, policies and procedures must also outline guidelines for the administration and timing of new medications which are initiated between standardized dosing times.

These policies and procedures must identify parameters within which nursing staff are allowed to use their own judgment regarding the rescheduling of missed or late doses and when notification of the physician or other practitioner responsible for the care of the patient is required prior doing so. In either case, the reporting of

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medication errors that are the result of missed or late dose administration must be reported to the attending physician in accordance with requirements at §482.25(b)(6). See interpretative guidance §482.25(b)(6) for more details on internal reporting requirements.

I. Evaluation Of Medication Administration Timing

Hospitals must periodically evaluate their medication administration timing policies, including staff adherence to the policies, to determine whether they assure safe and effective medication administration.

Consistent with the QAPI requirements at 42 CFR 482.21(c)(2), medication errors related to the timing of medication administration must be tracked and analyzed to determine their causes. Based on the results of the evaluations of the policies and the medication administration errors, the medical staff must consider whether there is a need to revise the policies and procedures governing medication administration timing.

J. Assessment / Monitoring of Patients Receiving Medications

Observing the effects medications have on the patient is part of the multi-faceted medication administration process. Patients must be carefully monitored to determine whether the medication results in the therapeutically intended benefit, and to allow for early identification of adverse

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effects and timely initiation of appropriate corrective action.

Depending on the medication and route/delivery mode, monitoring may need to include assessment of:

- Clinical and laboratory data to evaluate the efficacy of medication therapy, to anticipate or evaluate toxicity and adverse effects. For some medications, including opioids, this may include clinical data such as respiratory status, blood pressure, and oxygenation and carbon dioxide levels;
- Physical signs and clinical symptoms relevant to the patient’s medication therapy, including but not limited to, somnolence, confusion, agitation, unsteady gait, pruritus, etc.

Certain types of medications are considered inherently high risk for adverse drug events. Although mistakes may or may not be more common with these drugs, the consequences of errors are often harmful, sometimes fatal, to patients. (See also the discussion of high-risk medications (typically referred to as “high-alert” medications) in the guidance for §482.25(b)). In addition, certain factors place some patients at greater risk for adverse effects of medication.

Factors including, but not limited to, age, altered liver and kidney function, a history of sleep apnea,

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patient weight (obesity may increase apnea or smaller patients may be more sensitive to dose levels of medications), asthma, history of smoking, drug-drug interactions, and first-time medication use may contribute to increased risk.

Consideration of patient risk factors as well as the risks inherent in a medication must be taken into account when determining the type and frequency of monitoring. Further, to enhance continuity of care/safe medication administration, it is essential to communicate all relevant information regarding patients' medication risk factors and monitoring requirements during hand-offs of the patient to other clinical staff, such as when patients are transferred internally from one unit to another, during shift report at change of shift, etc. This would apply to hand-offs involving not only to nursing staff, but also to any other types of staff who administer medications, e.g., respiratory therapists.

Adverse patient reactions, such as anaphylaxis or opioid-induced respiratory depression, require timely and appropriate intervention, per established hospital protocols, and must also be reported immediately to the practitioner responsible for the care of the patient. (See the guidance for §482.23(c)(5) and §482.25(b)(6), concerning reporting of adverse medication-related events.)

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An example of vigilant post-medication administration monitoring in the case of a high-alert medication where patient factors may increase risk would be regularly checking vital signs, oxygen level via pulse oximetry, and sedation levels of a post-surgical patient who is receiving pain medication via a patient controlled analgesia (PCA) pump. Narcotic medications, such as opioids, are often used to control pain but also have a sedating effect. Patients can become overly sedated and suffer respiratory depression or arrest, which can be fatal. Timely assessment and appropriate monitoring is essential in all hospital settings in which opioids are administered, to permit intervention to counteract respiratory depression should it occur. (See also the discussion of the requirements for intravenous medications at §482.23(c)(4))

As part of the monitoring process, staff are expected to include the patient's reports of his/her experience of the medication's effects. Further, when monitoring requires awakening the patient in order to assess effects of the medications, the patient and/or the patient's representative must be educated about this aspect of the monitoring process. In addition, hospitals are encouraged to educate the patient and his/her representative and/or family members about notifying nursing staff promptly when there is difficulty breathing or other changes that might be a reaction to medication.

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Hospital policies and procedures are expected to address how the manner and frequency of monitoring, considering patient and drug risk factors, are determined, as well as the information to be communicated at shift changes, including the hospital’s requirements for the method(s) of communication.

K. Documentation

Note that documentation of medication administration is addressed in the Medical Records CoP, at §482.24(c), which specifies the required content of the medical record.

Within this regulation §482.24(c)(vi) requires that the record contain:

“All practitioners’ orders, nursing notes, reports of treatment, medication records, radiology, and laboratory reports, and vital signs and other information necessary to monitor the patient’s condition.”

Documentation is expected to occur after actual administration of the medication to the patient; advance documentation is not only inappropriate, but may result in medication errors. Proper documentation of medication administration actions taken and their outcomes is essential for planning and delivering future care of the patient. See the guidance for the various parts of §482.24(c) concerning documentation in the

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medical record. Deficiencies in documentation would be cited under the applicable Medical Records regulation.

Accepted standards of practice include maintaining compliance with applicable Federal and State laws, regulations (including all the hospital Conditions of Participation (CoP) such as Pharmacy, Medical Records, Patients' Rights, QAPI), and guidelines governing drug and biological use in hospitals, as well as, any standards and recommendations promoted by nationally recognized professional organizations.

16.01.02 Not Applicable.

16.01.03 Medication Orders.

- *Drugs and biologicals may be prepared and administered on the orders contained within pre-printed and electronic standing orders, order sets, and protocols for patient orders only if such orders meet the requirements of §482.12(c)(3).*
- *With the exception of influenza and pneumococcal vaccines, which may be administered per physician-approved hospital policy after an assessment of*

All orders for drugs and biologicals, with the exception of influenza and pneumococcal vaccines, must be documented and signed by a practitioner who is responsible for the care of the patient, as specified under §482.12(c), or who is another practitioner who is authorized by hospital policy and medical staff bylaws, rules and regulations, and who is acting in accordance with State law, including scope of practice laws.

Flu and Pneumonia Vaccines

Influenza and pneumococcal vaccines may be administered per physician-approved hospital policy, i.e., hospital policy approved by the physician members of the medical staff. There must be an

DOCUMENT REVIEW & CHART REVIEW

1. Review the hospital's policy for drug and biological orders. Does it require that all administration of drugs or biologicals be based on either an applicable standing order or the order of a practitioner who is responsible for the care of the patient or otherwise authorized by hospital policy medical staff policy and in accordance with State law to write orders?
2. Interview nursing staff to determine whether they initiate medications in accordance with standing orders. Are they familiar with the hospital's policies and procedures for using

- 1 = Compliant
- 2 = Not Compliant

This standard is not met as evidenced by:

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<p><i>contraindications, orders for drugs and biologicals must be documented and signed by a practitioner who is authorized to write orders by hospital policy and in accordance with State law, and who is responsible for the care of the patient as specified under §482.12(c).</i></p> <ul style="list-style-type: none"> • <i>Orders for drugs and biologicals may be documented and signed by other practitioners not specified under §482.12(c) only if such practitioners are acting in accordance with State law, including scope of practice laws, hospital policies, and medical staff bylaws, rules, and regulations.</i> <p>§482.23(c)(1)(ii) §482.23(c)(3) §482.23(c)(3)(iii)</p>	<p>assessment of contraindications prior to administration of the vaccine(s). There is no requirement for authentication by a practitioner when influenza and pneumococcal vaccines are administered to a patient in accordance with hospital policy and State law.</p> <p>Standing Orders Nurses or other personnel authorized by hospital policy and in accordance with State law may administer drugs and biologicals in accordance with pre-printed and electronic standing orders, order sets, and protocols for patient orders, collectively referred to in this guidance as “standing orders,” to address well-defined clinical scenarios involving medication administration.</p> <p>The requirements governing the hospital’s development and use of standing orders are found at the Medical Records CoP, under §482.24(c)(3). For the nursing services requirement under §482.23(c)(1) (ii), compliance assessment focuses on whether nurses comply with the hospital’s established standing orders policies and procedures when administering drugs or biological in accordance with a standing order.</p>	<p>standing orders? Are they following the policies and procedures? Ask to see the protocol for a standing order used by nursing staff, and ask nursing staff to explain how their practice conforms to the protocol.</p> <ol style="list-style-type: none"> 3. Review a sample of open and closed patient medical records. Although the regulation applies to both inpatient and outpatient medical records, the sample should be weighted to include more inpatient records. 4. Determine whether all orders for drugs and biologicals, with the exception of influenza and pneumococcal vaccines, are included in the patient’s medical record and authenticated by a practitioner who is authorized to write orders by hospital and medical staff policy and in accordance with State law, and who is responsible for the care of the patient. 5. Determine whether all standing orders which were initiated by a nurse were authenticated by an authorized practitioner. 6. Determine whether all orders for drugs and biologicals contain the required elements. 7. Verify that the prescribing practitioner has reviewed and authenticated the orders in accordance with medical staff policy and/or 	

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applicable State laws.

16.01.04 Verbal Orders.

If verbal orders are used, they are to be used infrequently.

§482.23(c)(3)(i)

Verbal orders, if used, must be used infrequently. This means that the use of verbal orders must not be a common practice.

Verbal orders pose an increased risk of miscommunication that could contribute to a medication or other error, resulting in a patient adverse event.

Verbal orders should be used only to meet the care needs of the patient when it is impossible or impractical for the ordering practitioner to write the order or enter it into a computer (in the case of a hospital with an electronic prescribing system) without delaying treatment. Verbal orders are not to be used for the convenience of the ordering practitioner. (71 FR §68679)

Hospitals are expected to develop appropriate policies and procedures that govern the use of verbal orders and minimize their use, policies which:

- Describe situations in which verbal orders may be used as well as limitations or prohibitions on their use;
- Provide a mechanism to establish the identity and authority of the practitioner issuing a verbal order;

DOCUMENT REVIEW, CHART REVIEW, AND INTERVIEW

1. Are there policies and procedures in place to minimize the use of verbal orders?
2. Interview direct care staff to determine whether actual practice is consistent with verbal order policies and procedures.
3. Review both open and closed patient medical records for the use of verbal orders.
4. Were the policies and procedures for the use of verbal orders followed?
5. Does the number of verbal orders found in the sampled records suggest routine use, which the regulations do not permit? The number of verbal orders is not in itself evidence of noncompliance, but should result in more focused analysis. For example:
 - a. Is there a pattern to the use of verbal orders? Some patterns might make sense – e.g., for orders entered between midnight and 7a.m., it might be plausible that it was impossible for the prescribing practitioner to write / computer-enter the order. On the other hand, if one patient care unit has a high proportion of

- 1 = Compliant
 2 = Not Compliant

This standard is not met as evidenced by:

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- List the elements required for inclusion in the verbal order process;
- Define the types of personnel who may issue and receive verbal orders; and
- Establish protocols for clear and effective communication and verification of verbal orders.

The content of verbal orders must be clearly communicated. CMS expects nationally accepted read-back verification practice to be implemented for every verbal order. (71 FR §68680)

As required by §482.24(b), all verbal orders must be promptly documented in the patient’s medical record and signed by the individual receiving the order.

verbal orders, while another does not, this might be a flag for inconsistent implementation of the hospital’s policies and procedures for verbal orders.

- b. Are verbal orders used frequently for certain types of situations, and if so, is it reasonable to assume that it is impossible or impractical for the prescribing practitioners to write / enter the orders in such situations?
- c. Do certain practitioners use verbal orders frequently? From the limited number of records sampled it may be difficult to detect trends related to specific practitioners, but if a surveyor finds such evidence, further investigation is warranted to determine if it is evidence of noncompliance.

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<p>16.01.05 <u>Accepting Verbal Orders.</u> <i>When verbal orders are used, they must only be accepted by persons who are authorized to do so by hospital policy and procedures consistent with Federal and State law.</i></p> <p>§482.23(c)(3)(ii)</p>	<p>A verbal order for drugs and biologicals may only be accepted by an individual who is permitted by Federal and State law and hospital policy to accept verbal orders.</p> <p>Consistent with the requirements of §482.24(b), the person who received the verbal order must promptly document it in the medical record.</p>	<p><u>DOCUMENT REVIEW, CHART REVIEW, AND INTERVIEW</u></p> <ol style="list-style-type: none"> 1. Determine whether the hospital has policies and procedures, consistent with Federal and State law, governing who is authorized to accept verbal orders. 2. Review open and closed patient medical records containing verbal orders for drugs and biologicals. <ul style="list-style-type: none"> • Determine whether the orders were accepted and documented by authorized hospital personnel. 3. Interview several direct care staff to determine if they are permitted to take verbal orders for drugs and biologicals, and determine whether such staff have been authorized to do so in accordance with hospital policy. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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<p>16.01.06 Administration of Blood Products & IV Medications. <i>Blood transfusions and intravenous medications must be administered in accordance with State law and approved medical staff policies and procedures.</i></p> <p>§482.23(c)(4)</p>	<p>Intravenous (IV) medications and blood transfusions must be administered in accordance with State law and approved medical staff policies and procedures. Further, many of the medications included in the high-alert categories are administered intravenously. (See also the discussion of high-risk/high-alert medications in the guidance for §482.25(b).)</p> <p>HOSPITAL POLICIES AND PROCEDURES: BLOOD TRANSFUSIONS AND IV MEDICATIONS Hospital policies and procedures for blood transfusions and IV medications must be based on accepted standards of practice, and must address at least the following:</p> <p>1. Vascular Access Route Patients may require a form of vascular access to deliver blood or medications, either venous or arterial, based on the desired treatment plan. Safe administration of blood transfusions and IV medications includes the correct choice of vascular access.</p> <p>IV medications, such as fluids, antibiotics, and chemotherapy, may require specific types of access, such as peripheral or central catheters versus implanted port devices, based on the medication’s chemical properties or safety concerns.</p> <ul style="list-style-type: none"> Hospital policies and procedures must address which medications can be given intravenously via what type of access. 	<p>DOCUMENT REVIEW, FILE REVIEW, AND CHART REVIEW</p> <ol style="list-style-type: none"> Verify the hospital has a special training program for administering blood transfusions and intravenous medications. Training should include: <ul style="list-style-type: none"> Fluid and electrolyte balance; Blood components; and Venipuncture techniques, demonstrations and supervised practice. Interview nursing staff on different units who administer IV medications and blood transfusions. Are staff knowledgeable with respect to: <ol style="list-style-type: none"> Venipuncture techniques; Safe medication administration practices, including general practices applying to all types of medications and practices concerning IV tubing and infusion pumps; Maintaining fluid and electrolyte balance; Patient assessment for risk related to IV medications and appropriate monitoring; Early detection and intervention for IV opioid-induced respiratory depression in post-operative patients; 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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	<p>2. <u>Other Patient Safety Practices</u> In addition to the basic safe practices that apply to all medication administration (See the discussion of safe medication administration practices, and medication administration in general, at §482.23(c)), there are additional safe practices specific to IV medication administration that require consideration, including but not limited to, the following:</p> <ul style="list-style-type: none"> • Tracing invasive lines and tubes prior to administration to ensure the medication is to be administered via the proper route (for example, peripheral catheter versus epidural catheter connections); • Avoiding forcing connections when the equipment offers clear resistance; • Verifying proper programming of infusion devices (concentrations, flow rate, dose rate). <p>3. <u>Patient Monitoring</u> As discussed in the medication administration guidance for §§482.23(c)(1), (c)(1)(i) and (c)(2), patients must be monitored for the effects of medications. To the extent that IV medications have a more rapid effect on the body, it is important that staff administering medications understand each medication and its monitoring requirements.</p>	<p>f. With respect to blood transfusions:</p> <ul style="list-style-type: none"> • Blood components; • Process for verification of the right blood product for the right patient; and • Transfusion reactions: identification, treatment, and reporting requirements. <p>3. Review the files for a sample of staff who administer blood products and IV medications, for evidence that competency was assessed and training was provided as appropriate.</p> <p>4. If able, observe blood transfusion and IV medication administration to assess staff adherence to accepted standards of practice.</p> <ul style="list-style-type: none"> a. Were safe medication administration practices used? b. Was the transfused patient correctly identified and matched to the correct blood product prior to administration? c. Was the appropriate access used for IV medications? d. Were appropriate steps taken with regard to IV tubing and infusion 	

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	<p>Policies and procedures for IV medication administration must address appropriate IV medication monitoring requirements, including assessment of patients for risk factors that would influence the type and frequency of monitoring.</p> <ul style="list-style-type: none"> For example: a 50 year old patient with a history of renal failure is receiving IV vancomycin to treat a wound infection. The hospital policy for IV antibiotics, including vancomycin, requires the patient’s kidney function to be monitored daily with blood draws. Based on review of the lab results, a practitioner responsible for the care of the patient would be expected to determine on a timely basis whether or not the antibiotic dose needs to be adjusted to protect kidney function or prevent drug toxicity while achieving the desired therapeutic effects. Staff administering the medication would be expected to review the lab results as well, and to raise with a practitioner responsible for the care of the patient any concerns they might have about whether an adjustment in the medication is needed. <p>HOSPITAL POLICIES AND PROCEDURES: PATIENT MONITORING</p> <p>Hospital policies and procedures related to monitoring patients receiving IV medications are expected to address, but are not limited to, the following:</p>	<p>pumps?</p> <ul style="list-style-type: none"> e. Are patients being monitored post-infusion for adverse reactions? <p>5. If staff appear to not be following accepted standards of practice for patient risk assessment related to IV medications, particularly opioids, and appropriate monitoring of patients receiving IV medications and/or blood transfusions,</p> <ul style="list-style-type: none"> review policies and procedures for IV medication administration and blood transfusion to determine if they address safe practices considerations. <p>6. Review a sample of medical records of patients that received a blood transfusion and/or IV medications.</p> <ul style="list-style-type: none"> a. Are blood transfusions and IV medications administered in accordance with State law and approved hospital policies and medical staff policies and procedures? b. Determine the identity of staff who administered blood components and/or IV medications and review their employee records. <ul style="list-style-type: none"> Do they have documented special training? 	

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	<p>1. <u>Monitoring for Fluid & Electrolyte Balance</u> Whenever IV medications and blood transfusions are administered, the patient may become at risk for fluid and electrolyte imbalance. Hospital policies and procedures must address monitoring and treatment for fluid and electrolyte imbalances that may occur with blood transfusions and IV medications.</p> <p>2. <u>Monitoring Patients Receiving High-alert Medications, Including IV Opioids</u> Policies and procedures related to IV medication administration must address those medications the hospital has identified as high-alert medications and the monitoring requirements for patients receiving such drugs intravenously.</p> <ul style="list-style-type: none"> At a minimum, hospitals are expected to address monitoring for over-sedation and respiratory depression related to IV opioids for post-operative patients. <p><u>OPIOIDS</u> Opioids are a class of medication used frequently in hospitals to treat pain. The sedating effects of opioids make it difficult at times to properly assess the patient’s level of sedation. It can be erroneously assumed that patients are asleep when they are actually exhibiting progressive symptoms of respiratory compromise - somnolence, decreased respiratory rate, and decrease in oxygen levels. These symptoms, if unrecognized, can progress to respiratory</p>	<p>7. Are blood transfusions and IVs administered by personnel who are trained and working within their scope of practice in accordance with State law and hospital and Medical Staff policies?</p> <p>8. Review personnel files of staff that administered blood transfusions and IV medications. Is there evidence that the competency of these staff was assessed with respect to:</p> <ol style="list-style-type: none"> Maintaining fluid and electrolyte balance; Venipuncture techniques; With respect to blood transfusions: <ol style="list-style-type: none"> Blood components; Blood administration procedures per hospital policy, State law, and nationally recognized standards of practice; Patient monitoring requirements, including frequency and documentation of monitoring; Process for verification of the right blood product for the right 	

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	<p>depression and even death.</p> <p>Certain characteristics, in addition to those discussed in the medication administration guidance for §§482.23(c)(1), (c)(1)(i) and (c)(2), place patients receiving opioids at higher risk for oversedation and respiratory depression. These additional factors include, but are not limited to³:</p> <ul style="list-style-type: none"> • Snoring or history of sleep apnea • No recent opioid use or first-time use of IV opioids • Increased opioid dose requirement or opioid habituation • Longer length of time receiving general anesthesia during surgery • Receiving other sedating drugs, such as benzodiazepines, antihistamines, sedatives, or other central nervous system depressants • Preexisting pulmonary or cardiac disease • Thoracic or other surgical incisions that may impair breathing <hr/> <p>³ Jarzyna D., Junquist C., Pasero C., et al. American Society for Pain Management Nursing - Guidelines on Monitoring for Opioid-Induced Sedation and Respiratory Depression. Pain Management Nursing, Vol 12, No. 3 (September), 2011: pp 118-145</p>	<p>patient; and</p> <p>f. Transfusion reactions: Identification, treatment, and reporting requirements.</p>	

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Of Particular Concern Are Patients Receiving IV Opioids Post-Operatively.

The effects of IV opioids in post-operative patients must be monitored vigilantly via serial assessments of pain, respiratory status, and sedation levels.

Hospitals must have policies and procedures related to the use of high-alert medications, including IV opioids for post-operative patients.

1. Policies and procedures must address, at a minimum, the process for patient risk assessment, including who conducts the assessments, and, based on the results of the assessment, monitoring frequency and duration, what is to be monitored, and monitoring methods.

2. The policies and procedures must also address whether and under what circumstances practitioners prescribing IV opioids are allowed to establish protocols for IV opioid administration and monitoring that differ from the hospital-wide policies and procedures.

3. The frequency of the serial assessments and duration of the monitoring timeframe for post-operative patients receiving IV opioids must be determined based on at least the following considerations:
 - Patient risk for adverse events;
 - Opioid dosing frequency and IV delivery method. (push or patient-controlled analgesia (PCA));

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- Duration of IV opioid therapy.

Regardless of the above factors, at a minimum monitoring must include the following:

1. Vital signs (blood pressure, temperature, pulse, respiratory rate)
2. Pain level;
3. Respiratory status;
4. Sedation level; sedation levels are important indicators for the clinical effects of opioids. Sedation is a useful assessment parameter to observe the effects of opioids since sedation typically precedes respiratory depression⁴. See the blue box below for information on sedation assessment methods.

⁴ Institute for Safe Medication Practices (ISMP), Medication Safety Alert – Fatal PCA Adverse Events Continue to Happen...Better Patient Monitoring is Essential to Prevent Harm. May 30, 2013.

NURSING ASSESSMENT

In addition to vigilant nursing assessment at appropriate intervals, hospitals may choose to use technology to support effective monitoring of patients’ respiratory rate and oxygen levels. The assessment and monitoring process must be explained to the patient and/or the patient's representative, to communicate the rationale for vigilant monitoring, including that it might be necessary to awaken the patient in order to assess

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effects of the medications. In addition, hospitals are encouraged to educate the patient and his/her representative and/or family members about notifying nursing staff promptly when there is difficulty breathing or other changes that might be a reaction to medication.

Adverse patient reactions require timely and appropriate intervention, per established protocols, and must also be reported immediately to the practitioner responsible for the care of the patient. (See the guidance for §482.23(c)(5) and §482.25(b)(6), concerning reporting of adverse medication-related events.)

BLOOD COMPONENTS AND BLOOD ADMINISTRATION PROCEDURES

According to the U.S. Department of Health and Human Services, 13,785,000 units of whole blood and red blood cells were transfused in the United States in 2011⁵.

The collection, testing, preparation, and storage of blood and blood components are regulated by the Food and Drug Administration. However, administration of blood products via transfusion is governed by §482.23(c)(4). Blood transfusions can be life-saving. However, like IV medications, blood transfusions are not without risk of harm to patients.

Transfusion reactions and/or errors can be fatal. In addition to the safe practices and other safety

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considerations that apply to all IV medication administration, policies and procedures must address blood administration procedures that are consistent with accepted standards of transfusion practice, including but not limited to:

1. Confirming the following prior to each blood transfusion:
 - a. the patient’s identity
 - b. verification of the right blood product for the right patient

2. The standard of practice calls for two qualified individuals, one of whom will be administering the transfusion, to perform the confirmation.

3. Requirements for patient monitoring, including frequency and documentation of monitoring.

4. How to identify, treat, and report any adverse reactions the patient may experience during or related to transfusion.

⁵ The 2011 National Blood Collection and Utilization Survey Report. Retrieved September 27,2013 from <http://www.hhs.gov/ash/bloodsafety/2011-nbcus.pdf>

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STAFF TRAINING AND COMPETENCIES

Intravenous (IV) medications and blood transfusions must be administered by qualified personnel, regardless of whether they are practitioners or non-practitioners.

Generally IV medications and blood transfusions are administered to patients by registered nurses (RNs), consistent with State law governing scope of practice, and approved medical staff policies and procedures.

- Among other things, personnel must be able to demonstrate competency in venipuncture, in accordance with State law and hospital policy. If other types of vascular access are utilized, staff must have demonstrated competency in appropriate usage, care, and maintenance.

- Staff must also be trained in early detection of and timely intervention for IV opioid-induced over-sedation and respiratory depression.

Education and training regarding these procedures are typically included in the nurse’s hospital orientation.

- Content of the training must address each required component of the approved medical staff policies and procedures.

- Nursing staff who receive training for intravenous medication administration and/or blood transfusion administration

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during hospital orientation or during other continuing education programs would meet the requirements of this regulation.

- Other non-physician personnel, for example, licensed practical nurses or licensed vocational nurses, with demonstrated competence may also administer IV medications and blood transfusions if they are acting in accordance with State law, including scope of practice law, and the hospital’s approved medical staff policies and procedures. (77 FR 29050, May 16, 2012)
- For non-practitioners, the appropriate competencies must be documented in the qualified staff person’s employee record.
- All State law and scope of practice requirements must be met regarding the administration of intravenous medications and blood transfusions, as applicable.

The appropriate competencies must be documented in the qualified staff person’s employee record.

Content of the training is based on nationally recognized standards for intravenous medication administration and blood transfusion and must address at least the following:

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1. Fluid and electrolyte balance;
2. Venipuncture techniques, including both demonstration, and supervised practice; and,
3. Blood transfusion training:
 - Blood components;
 - Blood administration procedures based on hospital policy, State law, and nationally recognized standards of practice;
 - Requirements for patient monitoring, including frequency and documentation of monitoring;
 - The process for verification of the right blood product for the right patient; and
 - Identification and treatment of transfusion reactions.

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<p>16.01.07 Adverse Drug Reactions, Transfusion Reactions & Medical Error Reporting. <i>There must be a hospital procedure for reporting transfusion reactions, adverse drug reactions, and errors in administration of drugs.</i></p> <p>§482.23(c)(5)</p>	<p><u>ADVERSE DRUG REACTIONS AND DRUG ADMINISTRATION ERRORS</u> There is a similar but more detailed and prescriptive requirement concerning internal hospital reporting of adverse drug reactions, drug administration errors and incompatibilities under the Pharmaceutical Services CoP at §482.25(b)(6). Therefore, it is not necessary for hospitals to establish a different procedure in the case of adverse drug reactions and drug administration errors for such events when nurses administer drugs or transfusions. Consult the guidance for §482.25(b)(6) to see what must be reported, to whom, and in what timeframe.</p> <p>Failure to make required reports concerning adverse drug reactions and errors in administration of drugs should be cited under §482.23(c)(5) when the drug was administered by a nurse, as well as under §482.25(b)(6).</p> <p><u>TRANSFUSION REACTIONS</u> Transfusion reactions can occur during or after a blood transfusion. A patient’s immune system recognizes the foreign blood product and attempts to destroy the transfused cells. Incompatible blood products are typically the cause of transfusion reactions. Symptoms may include back pain, bloody urine, hives, chills, fainting, dizziness, fever, flank pain, and skin flushing. More serious complications may include acute kidney failure, anemia, respiratory distress, shock and even death. Transfusion reactions are serious and can be life-threatening.</p>	<p><u>DOCUMENT REVIEW</u></p> <ol style="list-style-type: none"> Review the procedure for reporting transfusion reactions to determine that the requirements are met. Review incident reports or other documents to validate the procedure is implemented and monitored through the QAPI program. For adverse drug events and medication administration errors, follow the survey procedures for §482.25(b)(6). <p>Deficiencies are to be cited under both §482.23(c)(5) and §482.25(b)(6) when the drug or transfusion related to an adverse drug reaction, transfusion reaction or medication administration error relates to a drug or transfusion administered by a nurse.</p> <ol style="list-style-type: none"> Request the hospital policy and procedure for internal reporting of transfusion reactions. Interview nursing staff responsible for administering blood transfusions to determine whether they are familiar with and comply with the hospital’s policies. Ask to see if there are any transfusion-related incident reports. <ul style="list-style-type: none"> Is there evidence that the transfusion reaction was reported 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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POLICIES AND PROCEDURES

The hospital must have policies and procedures in place for the internal reporting of transfusion reactions.

1. The policies must include procedures for reporting transfusion reactions immediately to the practitioner responsible for the care of the patient.

2. The transfusion reaction must also be reported to the hospital-wide quality assessment performance improvement program as an adverse event, in accordance with the QAPI CoP at 42 CFR 482.21(c)(2).

3. The transfusion reaction must be documented in the patient's medical record, including the prompt notification of the responsible practitioner.

immediately to the practitioner responsible for the patient's care?

- Was it reported to the hospital's QAPI program?

16.01.08 Not Applicable.

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<p>16.01.09 Self-Administration of Medications: Hospital-Issued Medications. <i>The hospital may allow a patient (or his or her caregiver/support person where appropriate) to self-administer both hospital-issued medications and the patient’s own medications brought into the hospital, as defined and specified in the hospital’s policies and procedures.</i></p> <p><i>If the hospital allows a patient to self-administer specific hospital-issued medications, then the hospital must have policies and procedures in place to:</i></p> <p>(A) <i>Ensure that a practitioner responsible for the care of the patient has issued an order, consistent with hospital policy, permitting self-administration.</i></p> <p>(B) <i>Assess the capacity of the patient (or the patient’s caregiver/support person where appropriate) to self-administer the specified medication(s).</i></p> <p>(C) <i>Instruct the patient (or the patient’s support person where appropriate) in the safe and accurate administration of the</i></p>	<p>Hospitals have the option of establishing a program for self-administration by patients, or, when applicable, patient caregivers or support persons, of hospital-issued medications. The existence of this regulatory option does not mean that a hospital must offer medication self-administration programs or that a patient has a right to self-administer their medications.</p> <p>A hospital program for patient self-administration of hospital-issued medications could be beneficial for the appropriate patients if the proper precautions are taken in designing and implementing such a program.</p> <p>Generally such a program would apply only to inpatients, but there may be circumstances under which a hospital finds it appropriate to permit self-administration of hospital-issued medications by outpatients or their caregivers/support persons.</p> <p>Among the potential benefits of medication self-administration, teaching patients or their caregivers/support persons adherence to the proper medication regimen could reduce hospital inpatient length of stay and also might have a positive effect on continued compliance with the regimen after discharge, potentially avoiding an emergency department visit or inpatient readmission secondary to post-hospital patient medication administration errors and noncompliance.</p> <p>Hospitals have the discretion to establish policies</p>	<p><u>DOCUMENT REVIEW, MEDICAL RECORD REVIEW, AND OBSERVATION</u></p> <p>If the hospital permits patient self-administration of hospital-issued medications:</p> <ol style="list-style-type: none"> 1. Ask the hospital to identify current inpatients for whom self-administration of hospital-issued medications is permitted. <ul style="list-style-type: none"> • Interview of several of these patients (or their caregivers/support persons when applicable) to verify that they received instruction on how to administer their medications. 2. Interview nurses caring for the selected patients. Ask them: <ol style="list-style-type: none"> a. What the applicable hospital policies and procedures are regarding supervision of self-medication. b. How they assess a patient’s (or patient’s caregiver/support person’s) capacity to self-administer medication. If they have concerns, how do they communicate them to the responsible practitioner? Does their hospital permit nurses to return to nurse administration of medications in response to temporary reduction in patient capacity or absence of the patient’s caregiver/support person? If so, how do the nurses make this assessment? 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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<p><i>specified medication(s).</i></p> <p>(D) <i>Address the security of the medication(s) for each patient.</i></p> <p>(E) <i>Document the administration of each medication, as reported by the patient (or the patient’s caregiver/support person where appropriate), in the patient’s medical record.</i></p> <p>§482.23(c)(6) §482.23(c)(6)(i) §482.23(c)(6)(i)(A) §482.23(c)(6)(i)(B) §482.23(c)(6)(i)(C) §482.23(c)(6)(i)(D) §482.23(c)(6)(i)(E)</p>	<p>providing for different levels of patient self-administration, and may make these levels across-the-board, patient-specific, or medication-specific. For example, a hospital may choose whether or not a nurse must be present to supervise the self-administration, and whether this supervision requirement could vary according to the type of medication or the capacity of the individual patient (or the patient’s caregiver/support person).</p> <p>A hospital may also determine through its policies and procedures whether supervision requirements must be addressed in the practitioner’s order or whether this may be left to the discretion of the nurse who assesses the patient.</p> <p>A hospital may choose to exclude certain medications from patient self-administration, for example, because they pose too great a medication security challenge, or because the manner in which they must be administered does not lend itself to safe self-administration. (77 FR 29052, May 16, 2012) It must be clear in the hospital’s policies and procedures whether it has established such a policy and what kind of limitations it has established for its program of patient self-administration of hospital-issued medications.</p> <p>It is expected that the medical staff, nursing and pharmacy departments are to collaborate in developing policies and procedures governing self-administration of hospital-issued medications which</p>	<p>c. How they instruct a patient (or patient’s caregiver/support person’s) in medication self-administration.</p> <p>d. How self-administered medications are secured.</p> <p>e. How they document self-administration of medications.</p> <p>f. To provide a copy of the hospital’s policies and procedures. Are they following the policies and procedures?</p> <p>3. Review the medical records for the selected patients. Is there documentation of:</p> <p>a. An order for self-administration of specific medication(s).</p> <p>b. A nurse assessment of the patient’s (or patient’s caregiver/support person’s) capacity to self-administer medication.</p> <p>c. Documentation of nurse instruction to the patient or (or patient’s caregiver/support person) in safe and appropriate techniques for self-administration of medication.</p> <p>d. Documentation of self-administration times and doses, as reported by the patient or (or patient’s caregiver/support</p>	

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	<p>are approved by the governing body.</p> <p><u>REQUIRED ELEMENTS OF A SELF-ADMINISTRATION PROGRAM:</u> If the hospital chooses to develop programs for self-administration of hospital-issued medications by patients (and/or their caregiver/support persons), the following must be in place:</p> <ol style="list-style-type: none"> <u>An order allowing the patient to administer hospital-issued medications.</u> The order must be consistent with the hospital’s policy concerning self-administration of hospital-issued medications and be written by a practitioner who is responsible for the care of the patient and who is authorized to order medications, in accordance with hospital policies and procedures, State law, including scope of practice laws, and medical staff by-laws, rules, and regulations. <u>A documented assessment of the capacity of the patient (or their caregiver/support person) to successfully administer medications for which self-administration has been authorized.</u> Nurses are expected to exercise their clinical judgment and to inform the practitioner responsible for the care of the patient about any reservations the nurse might have about an individual patient’s (or caregiver/support person’s) capacity to safely self-administer medications. 	<p>person) or directly observed by a nurse.</p> <ol style="list-style-type: none"> Do the hospital’s policies and procedures for self-administration of hospital-issued medications address: <ol style="list-style-type: none"> Limitations on medications not eligible for self-administration or patient conditions which exclude self-administration; Orders for self-administration of medication; Requirements, if any, for supervision of self-administration; Assessment of self-medication capacity; Instruction in self-medication; Security of self-administered medications; and Documentation of self-administration. 	

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The assessment must be documented and must highlight the findings that are affirmative – i.e., support patient-self-administration – and negative – i.e., call into question patient self-administration. The nurse is also expected to document any discussions with the practitioner responsible for the care of the patient regarding the nurses’ concerns about patient’s (or caregiver/support person’s) capacity to safely self-administer medications.

Hospitals may, as a matter of policy, permit a nurse to return to nurse administration for particular doses of a medication for which there is a self-administration order, without a discussion with the responsible practitioner if, based on the nurse’s assessment, the patient’s capacity has been temporarily diminished and there is no caregiver/support person who is assisting the patient with self-administration of medication. For example, a patient who has just had an invasive test or procedure may not be fully alert for a period thereafter, or the parent of a minor patient, who is administering medications to the patient may for whatever reasons not be available and a scheduled medication dose is close to being overdue.

3. Instruction in self-administration.

As part of the assessment of the patient’s self-administration capacity, nurses are expected to identify the patient’s (or the patient’s

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caregiver/support person’s) education and/or training needs. These needs may be related to type of medication, unique individual medication requirements, delivery route, dosage and scheduling, equipment (e.g. syringes, pill-cutters, measuring containers, etc.) intravenous access, potential adverse side effects and what to do if they occur, infection control measures, storage, medication disposal, among others. Education and training needs, and how they were addressed, must be documented in the medical record.

4. Security of the self-administered medications.

The security of a patient’s self-administered medications is extremely important, but does not lend itself well to a one-size-fits-all regulatory requirement. There are Federal and State laws, including the Pharmaceutical Services CoP, which require a higher level of security for certain medications (for example, controlled substances). Hospitals are expected to comply with these already-established requirements and laws, and generally should not include such medications as part of a patient self-administration program.

Note that Patient-controlled Analgesia (PCA) pumps are a special variant of patient self-administration. Such pumps allow patients, within tightly controlled, pre-determined parameters with respect to dosage and minimum time intervals between doses, to release an intravenous dose of a controlled substance pain

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medication that has been pre-loaded into the PCA pump in a manner that prevents tampering by an unauthorized person. PCA pumps are considered secure despite their use of controlled substances.

PCA pumps allow for the self-administration of intravenous (IV) medications to patients. See the interpretive guidelines for §482.23(c)(4) concerning assessment and monitoring requirements for post-surgical patients receiving IV opioids, including via patient-controlled analgesia (PCA) pumps, in and out of the post-anesthesia care and intensive care units. Hospitals are also free to exclude other medications besides controlled substances from their patient self-administered medication programs when the hospital has concerns over its capacity to address the safety and security of these other medications for patients.

A hospital may choose to have a policy where it maintains a list of medications that it excludes from self-administration entirely, due to security concerns. It may choose to have a policy that addresses the security of a particular medication on a patient-by-patient basis. Or it may establish a policy that is a combination of both of these approaches to medication security. (77 FR 29052, May 16, 2012)

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5. Documentation of medication administration.
 Under the regulation, a nurse must document the self-administration of a medication. In cases where the nurse directly supervised the self-administration, the nurse is expected to indicate that the medication administration was observed and confirmed. On the other hand, where direct nurse supervision is not required, the nurse is required to document only what the patient, or the patient’s caregiver/support person, reports to the nurse as to the time and amount of medication administered. Nurses are expected to assess whether the reports of the patient or patient’s caregiver/support person indicate, with respect to timing and dosage, that the patient is receiving the medication as ordered.

16.01.10 Self-Administration of Medications: Medications Brought into the Hospital.

If the hospital allows a patient to self-administer his or her own specific medications brought into the hospital, then the hospital must have policies and procedures in place to:

(A) *Ensure that a practitioner responsible for the care of the patient has issued an order, consistent with hospital policy,*

Hospitals have the option of establishing a program for self-administration by patients, or, when applicable, patient caregivers or support persons, of medications the patient brings himself or herself to the hospital. The existence of this regulatory option does not mean that a hospital must offer medication self-administration programs or that a patient has a right to retain and self-administer medications they bring with them from home.

A hospital program for patient self-administration of medications the patient brings from home could be beneficial for the appropriate patients if the proper

DOCUMENT REVIEW, MEDICAL RECORD REVIEW AND OBSERVATION

If the hospital permits patient self-administration of medications brought from home:

1. Ask the hospital to identify current inpatients for whom self-administration of medications brought from home is permitted.
2. Interview of several of these patients (or their caregivers/support persons when applicable) to ask if that they received instruction on how to self-administer their medications consistent with hospital policy.

- 1 = Compliant
- 2 = Not Compliant

This standard is not met as evidenced by:

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<p><i>permitting self-administration of medications the patient brought into the hospital.</i></p> <p>(B) <i>Assess the capacity of the patient (or the patient’s caregiver/support person where appropriate) to self-administer the specified medication(s) and also determine if the patient (or the patient’s caregiver/support person where appropriate) needs instruction in the safe and accurate administration of the specified medication(s).</i></p> <p>(C) <i>Identify the specified medication(s) and visually evaluate the medication(s) for integrity.</i></p> <p>(D) <i>Address the security of the medication(s) for each patient.</i></p> <p>(E) <i>Document the administration of each medication, as reported by the patient (or the patient’s caregiver/support person where appropriate), in the patient’s medical record.</i></p> <p>§482.23(c)(6)(ii) §482.23(c)(6)(ii)(A)</p>	<p>precautions are taken in designing and implementing such a program. Generally such a program would apply only to inpatients, but there may be circumstances under which a hospital finds it appropriate to permit self-administration of medications that outpatients or their caregivers/support persons bring with them.</p> <p>Among the potential benefits of permitting self-administration of medications the patient brings from home is that problems are avoided related to the hospital’s formulary not including a particular medication that a patient needs to continue to take during his/her hospital stay, and the patient prefer to avoid medication substitution. The hospital also gains an opportunity to identify suboptimal patient medication administration techniques for these drugs and to provide instruction designed to ensure that the patient is administering his/her medications properly.</p> <p>Hospitals have the discretion to establish policies providing for different levels of patient self-administration, and may make these levels across-the-board, patient-specific, or medication-specific.</p> <ul style="list-style-type: none"> • For example, a hospital may choose whether or not a nurse must be present to supervise the self-administration, and whether this supervision requirement could vary according to the type of medication or the capacity of the individual patient (or the patient’s caregiver / support person). 	<p>3. Interview nurses caring for the selected patients. Ask them:</p> <ol style="list-style-type: none"> a. What the applicable hospital policies and procedures are regarding supervision of self-medication. b. How they assess a patient’s (or patient’s caregiver/support person’s) capacity to self-administer medication. If they have concerns, how do they communicate them to the responsible practitioner? c. Does their hospital permit nurses to return to nurse administration of medications in response to temporary reduction in patient capacity or absence of the patient’s caregiver/support person? If so, how do the nurses make this assessment? d. How they instruct a patient (or patient’s caregiver/support person’s) in safe and proper medication self-administration when educational needs have been identified. e. How self-administered medications are secured? f. How they document self-administration of medications. 	

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§482.23(c)(6)(ii)(B) §482.23(c)(6)(ii)(C) §482.23(c)(6)(ii)(D) §482.23(c)(6)(ii)(E)	<p>A hospital may also determine through its policies and procedures whether supervision requirements must be addressed in the practitioner’s order or whether this may be left to the discretion of the nurse who assesses the patient.</p> <p>A hospital may choose to exclude certain medications from patient self-administration, for example, because they pose too great a medication security challenge. It must be clear in the hospital’s policies and procedures whether it has established such a policy and what kind of limitations it has established for its program of patient self-administration of medications the patient brings from home.</p> <p>It is expected that the medical staff, nursing and pharmacy departments are to collaborate in developing policies and procedures for self-administration of medications the patient brings from home which are approved by the governing body.</p> <p><u>REQUIRED ELEMENTS OF A SELF-ADMINISTRATION PROGRAM:</u></p> <p>If the hospital chooses to develop programs for self-administration of medications brought from home by patients (and/or their caregiver/support persons), the following must be in place:</p> <p>1. <u>An order allowing the patient to administer medications brought from home.</u> The order must be consistent with the hospital’s policy concerning self-administration of</p>	<p>g. To provide a copy of the hospital’s policies and procedures. Are they following the policies and procedures?</p> <p>4. Review the medical records for the selected patients. Is there documentation of:</p> <p>a. An order for self-administration of specific medication(s).</p> <p>b. A nurse assessment of the patient’s (or patient’s caregiver/support person’s) capacity to self-administer medication and identification of whether or not there are educational needs that have been met.</p> <p>c. Documentation of the identification and visual assessment of medications brought from home.</p> <p>d. Documentation of self-administration times and doses, as reported by the patient or (or patient’s caregiver/support person) or directly observed by a nurse.</p> <p>5. Do the hospital’s policies and procedures for self-administration of medications brought from home address, consistent with the regulatory requirements, the following:</p> <p>a. Limitations on medications eligible for self-administration or patient conditions</p>	

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	<p>medications brought from home and be written by a practitioner who is responsible for the care of the patient and who is authorized to order medications, in accordance with hospital policies and procedures, State law, including scope of practice laws, and medical staff by-laws, rules, and regulations.</p> <p>2. A documented assessment. A documented assessment of the capacity of the patient (or their caregiver/support person) to successfully administer the medication(s) specified in the order, including a determination whether the patient (or their caregiver/support person) needs instruction in the safe and accurate administration of the specified medication(s).</p> <p>Nurses are expected to exercise their clinical judgment and to inform the practitioner responsible for the care of the patient about any reservations the nurse might have about an individual patient's (or caregiver/support person's) capacity to safely self-administer medications.</p> <p>The assessment must be documented and must highlight the findings that are affirmative – i.e., support patient-self-administration – and negative – i.e., call into question patient self-administration.</p>	<p>which exclude self-administration;</p> <p>b. Orders for self-administration of medications brought from home;</p> <p>c. Requirements, if any, for supervision of self-administration;</p> <p>d. Assessment of self-medication capacity, including identification of educational needs and how they are to be met;</p> <p>e. Identification and visual inspection for integrity of self-administered medications brought from home;</p> <p>f. Security of self-administered medications; and</p> <p>g. Documentation of self-administration in the medical record?</p>	

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The nurse is also expected to document any discussions with the practitioner responsible for the care of the patient regarding the nurses' concerns about patient's (or caregiver/support person's) capacity to safely self-administer medications. (77 FR 29052, May 16, 2012)
Hospitals may, as a matter of policy, permit a nurse to return to nurse administration for particular doses of a medication for which there is a self-administration order, without a discussion with the responsible practitioner if, based on the nurse's assessment, the patient's capacity has been temporarily diminished and there is no caregiver/support person who is assisting the patient with self-administration of medication.

- For example, a patient who has just had an invasive test or procedure may not be fully alert for a period thereafter, or the parent of a minor patient, who is administering medications to the patient may for whatever reasons not be available and a scheduled medication dose is close to being overdue.

As part of the assessment of the patient's self-administration capacity, nurses are expected to identify whether the patient (or the patient's caregiver/support person) needs instruction in the safe and accurate administration of the specified medication(s).

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Even though the patient has been taking the medication at home, the patient (or the patient’s caregiver/support person) may not be using optimal administration techniques. Patient needs may be related to type of medication, unique individual medication requirements, delivery route, dosage and scheduling, equipment (e.g. syringes, pill-cutters, measuring containers, etc.) intravenous access, potential adverse side effects and what to do if they occur, infection control measures, storage, medication disposal, among others. Education and training needs identified, and how they were addressed, must be documented in the medical record.

3. Identification/visual evaluation for integrity.

Hospitals must have policies and procedures addressing how they will identify the medications the patient has brought from home. Identification is important because the label on the patient’s medication container may not accurately reflect the contents. Further, the medication might have expired or have not been stored correctly in the patient’s home, requiring hospitals to at least conduct a visual inspection to see if the medication appears to have retained its integrity. It is recognized that a visual inspection for integrity may not be definitive, but the regulation does not require use of more complex methods.

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- 4. Security of the self-administered medications.**
 The security of a patient’s self-administered medications is extremely important, but does not lend itself well to a one-size-fits-all regulatory requirement. There are Federal and State laws, including the Pharmaceutical Services CoP, which require a higher level of security for certain medications (for example, controlled substances). Hospitals are expected to comply with these already-established requirements and laws, and generally should not include such medications as part of a patient self-administration program. Hospitals are also free to exclude other medications besides controlled substances from their patient self-administered medication programs when the hospital has concerns over its capacity to address the safety and security of these other medications for patients.

A hospital may choose to have a policy where it maintains a list of medications brought from home that it excludes from self-administration entirely, due to security concerns. It may choose to have a policy that addresses the security of a particular medication on a patient-by-patient basis. Or it may establish a policy that is a combination of both of these approaches to medication security.

- 5. Documentation of medication administration.**
 Under the regulation, a nurse must document the self-administration of a medication. In cases

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where the nurse directly supervised the self-administration, the nurse is expected to indicate that the medication administration was observed and confirmed. On the other hand, where direct nurse supervision is not required, the nurse is required to document only what the patient, or the patient's caregiver/support person, reports to the nurse as to the time and amount of medication administered.

Nurses are expected to assess whether the reports of the patient or patient's caregiver/support person indicate, with respect to timing and dosage, that the patient is receiving the medication as ordered.

16.02.00 Not Applicable.

16.02.01 Not Applicable.

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<p>16.02.02 <u>Patients at Risk.</u> Patients at-risk for developing the following complications are identified on admission or during the hospital stay:</p> <ol style="list-style-type: none"> 1. Pressure ulcers 2. Deep vein thrombosis (DVT/ venous thromboembolism (VTE) 3. Aspiration 4. Malnutrition 5. Fall Risk / Prevention 	<p style="text-align: center;"><u>PATIENT SAFETY INITIATIVE</u></p> <p>The medical complications of pressure ulcers, DVT/VTE, aspiration, malnutrition and falls can be prevented with proactive risk assessment, thereby improving outcomes and the quality of care for at-risk patients.</p> <p>Implement a facility wide “falls program” using evidence based interventions to prevent and reduce patient fall-related injuries.</p> <p>The “fall program” must be reviewed at least annually for efficiency and effectiveness.</p> <p>Suggested added information:</p> <ul style="list-style-type: none"> • Risk assessments must be documented in the medical record. • Those patients who have been identified to be at risk must have related care plans and preventative measures put in place. 	<p style="text-align: center;"><u>DOCUMENT REVIEW & CHART REVIEW</u></p> <p>Review the admission assessment policy. Examine ten medical records.</p> <p>Verify:</p> <ol style="list-style-type: none"> 1. The admission assessment policy addresses the five (5) required risk assessments and defines when reassessment would be required. The policy must also include a plan, process or intervention to be implemented to prevent complications in at-risk patients. 2. The medical record contains risk assessments for each of the five (5) required elements have been completed on admission and periodically as indicated by patient status change throughout the admission. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>
<p>16.02.03 <u>Standards Availability.</u> Nursing staff have access to clinical and administrative policies and procedures.</p>	<p>Staff are knowledgeable regarding how to access policies and procedures.</p> <p>Policies, procedures, and Standards of Practice are consistent with local, State and Federal laws and regulations governing nursing practice.</p> <p>Standards of Practice reflect evidenced-based practices, when applicable. References to national</p>	<p style="text-align: center;"><u>DOCUMENT REVIEW</u></p> <ol style="list-style-type: none"> 1. Interview staff. Determine they are knowledgeable regarding the availability of clinical and administrative policies and procedures. 2. Review policies and procedures and Standards of Practice. Determine: <ul style="list-style-type: none"> • These documents have been approved 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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practice groups such as the Association of Operating Room Nurses (AORN) are cited.

Standards and policies are reviewed at least every three (3) years and approved by the Chief Nursing Officer.

within the past three (3) years.

- References to national practice groups are cited, as applicable.

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**17.00.00 Condition of Participation:
Respiratory Services.**

The hospital must meet the needs of the patients in accordance with acceptable standards of practice.

The following requirements apply if the hospital provides respiratory care services.

§482.57

This is an optional hospital service.

If a hospital provides care to patients who require respiratory care services, the hospital must meet the needs of those patients, in accordance with acceptable standards of practice.

However, if a hospital provides any degree of respiratory care to its patients, the hospital must comply with the requirements of this Condition of Participation.

Acceptable standards of practice include compliance with applicable standards that are set forth in Federal or State laws, regulations or guidelines, as well as standards and recommendations promoted by nationally recognized professional organizations. (e.g., American Medical Association, American Association for Respiratory Care, American Thoracic Association, etc.).

The hospital’s respiratory services must be integrated into its hospital-wide QAPI program.

DOCUMENT REVIEW & OBSERVATION

1. Determine if the hospital provides any degree of respiratory care services.
2. **Determine that the type and amount of respiratory care provided** meets the needs of the **patients and is delivered** in accordance with accepted standards of practice.
3. **Determine if the hospital’s** respiratory services are integrated into its hospital-wide QAPI program.

- 1 = Compliant
- 2 = Not Compliant
- Chapter not applicable in this facility

This standard is not met as evidenced by:

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<p>17.00.01 <u>Organization & Staffing.</u> <i>The organization of the respiratory care services must be appropriate to the scope and complexity of the services offered.</i></p> <p>§482.57(a)</p>	<p>The hospital must provide the appropriate equipment and types and numbers of qualified personnel necessary to furnish the services offered by the hospital in accordance with acceptable standards of practice.</p> <p>The scope of diagnostic and/or therapeutic respiratory services offered by the hospital should be defined in writing and approved by the Medical Staff.</p>	<p style="text-align: center;"><u>DOCUMENT REVIEW</u></p> <ol style="list-style-type: none"> 1. Review the hospital’s organizational chart to determine the relationship of respiratory care services to other services provided by the hospital. 2. Review the hospital policies and procedures to verify that the scope of the diagnostic and/or therapeutic respiratory care services provided is defined in writing and approved by the Medical Staff. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>
<p>17.00.02 <u>Medical Director.</u> <i>There must be a director of respiratory care services who is a doctor of medicine or osteopathic medicine with the knowledge, experience and capabilities to supervise and administer the service properly.</i></p> <p><i>The director may serve on either a full time or part time basis.</i></p> <p>§482.57(a)(1)</p>	<p>The service director must be a doctor of medicine or a doctor of osteopathic medicine and must demonstrate through education, experience and specialized training that he/she has the qualifications necessary to supervise and administer the service properly, appropriate to the scope and complexity of services offered.</p> <p>The physician providing medical direction (full time, part time) is knowledgeable of pulmonary (and cardiology) practices and techniques to lead and advise the cardiopulmonary staff.</p> <p>If the director serves on a part-time basis, the time spent directing the department should be appropriate to the scope and complexity of services provided.</p>	<p style="text-align: center;"><u>INTERVIEW</u></p> <p>Interview leaders and staff regarding the role and oversight activities conducted by the director.</p> <p>Verify:</p> <ol style="list-style-type: none"> 1. A medical director has been appointed and he/she has fixed lines of authority and delegated responsibility for operation of the service. 2. The time spent by the Medical Director directing the department is appropriate to the scope and complexity of services provided. <p style="text-align: center;"><u>FILE REVIEW</u></p> <p>Review the service director’s credentialing file to determine that he/she is a MD or DO and has the necessary education, experience and specialized</p>	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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training to supervise and administer the service properly.

17.00.03 Staffing & Qualifications.

There must be adequate numbers of respiratory therapists, respiratory therapy technicians, and other personnel who meet the qualifications specified by the medical staff, consistent with State law.

§482.57(a)(2)

There must be sufficient personnel available to respond to the respiratory care needs of the patient population being served.

INTERVIEW

Interview **respiratory care** staff regarding services provided, schedules, and availability of respiratory care staff throughout the day and week to determine that the number and type of staff available is appropriate to the volume and types of treatments furnished. If needed, review staffing and on-call schedules.

- 1 = Compliant
- 2 = Not Compliant

This standard is not met as evidenced by:

FILE REVIEW

1. Review a sample of personnel files for respiratory care staff to determine that the personnel meet the qualifications specified by the medical staff, consistent with State law.
2. Review personnel files to validate current licensure, training and experience as required.

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<p>17.00.04 Policies & Procedures. <i>Services must be delivered in accordance with medical staff directives.</i></p> <p>§482.57(b)</p>	<p>There should be written policies for the delivery of respiratory care services that are developed and approved by the medical staff. The hospital must be in compliance with the written directives / policies.</p> <p>Appropriate to the scope of services provided, the written policies should address at least the following:</p> <ol style="list-style-type: none"> 1. Equipment assembly, operation, and preventive maintenance; 2. Safety practices, including infection control measures for equipment, sterile supplies, biohazardous waste, posting of signs, and gas line identification; 3. Handling, storage, and dispensing of therapeutic gases to both inpatients and outpatients; 4. Cardiopulmonary resuscitation; 5. Procedures to follow in the advent of adverse reactions to treatments or interventions; 6. Pulmonary function testing; 7. Therapeutic percussion and vibration; 8. Bronchopulmonary drainage; 9. Mechanical ventilatory and oxygenation support; 10. Aerosol, humidification, and therapeutic gas 	<p style="text-align: center;"><u>DOCUMENT REVIEW</u></p> <ol style="list-style-type: none"> 1. Review policies and procedures to assure that all required policies are current and approved by the medical staff. 2. Observe practice to assure practice is reflective of policy requirements. 3. Review medical records to assure appropriate documentation in the medical record, in accordance with hospital policies. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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administration;

11. Storage, access, control, administration of medications and medication errors;
12. Procedures for obtaining and analyzing blood samples (e.g., arterial blood gases);
13. Procedure for reporting medication errors and adverse drug events; and
14. Patient care documentation requirements.

17.00.05 Qualified Staff.

Personnel qualified to perform specific procedures and the amount of supervision required for personnel to carry out specific procedures shall be designated in writing.

§482.57(b)(1)

The hospital must have written policies to address, at a minimum:

- Each type of respiratory care service provided by the hospital;
- The qualifications, including job title, licensure consistent with State law, education, training and experience of personnel authorized to perform each type of respiratory care service and whether they may perform it without supervision; and
- The type of personnel qualified to provide the direct supervision.

DOCUMENT REVIEW

Review treatment logs, job descriptions of respiratory care staff, and policies and procedures to determine the following:

1. Duties and responsibilities of staff;
2. Qualifications and education required, including licensure, consistent with State law;
3. Specialized training or experience needed to perform specific duties.
4. **All required policies are current and approved by the medical staff.**

- 1 = Compliant
 2 = Not Compliant

This standard is not met as evidenced by:

RESPIRATORY CARE

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<p>17.00.06 Clinical Laboratory Testing. <i>If blood gases or other clinical laboratory tests are performed in the respiratory care unit, the unit must meet the applicable requirements for laboratory services specified in §482.27.</i></p> <p>§482.57(b)(2)</p>	<p>Refer to standards in Chapter 22, Laboratory Services standards.</p> <p>The hospital must have written policies to address:</p> <ol style="list-style-type: none"> 1. Qualifications of personnel responsible for performing proficiency tests. 2. Training requirements for performing proficiency tests. 3. Proficiency testing procedures. 4. Role of the medical director of respiratory care services. 5. Reporting proficiency test results to the hospital QAPI Program and others, as necessary. 	<p style="text-align: center;"><u>DOCUMENT REVIEW</u></p> <ol style="list-style-type: none"> 1. Each location where laboratory testing is conducted must have or be operating under a current CLIA certificate. 2. Review policies and procedures to assure that all required policies are current and approved by the medical staff. 	<p style="text-align: center;"> <input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant </p> <p>This standard is not met as evidenced by:</p>
<p>17.00.07 Services Provided. <i>Services must only be provided under the orders of a qualified and licensed practitioner who is responsible for the care of the patient, acting within his or her scope of practice under State law, and who is authorized by the hospital's medical staff to order the services in accordance with hospital policies and procedures and State laws.</i></p> <p>§482.57(b)(3)</p>	<p>Respiratory care services must be ordered by a qualified and licensed practitioner who is responsible for the care of the patient.</p> <p>The practitioner must have medical staff privileges:</p> <ul style="list-style-type: none"> • to write orders for these services or, • for outpatient services, if hospital policy permits acceptance of orders from outside practitioners, the practitioner's order must meet the requirements at 482.54(c) (see standard 31.00.11). 	<p style="text-align: center;"><u>CHART REVIEW</u></p> <ol style="list-style-type: none"> 1. Review medical records of patients receiving respiratory care services. <ul style="list-style-type: none"> • Determine who wrote the orders for the respiratory care services. • Determine if the practitioner is responsible for the care of the patient and privileged to write orders for respiratory care services. • Verify the practitioner meets hospital medical staff policy criteria to order 	<p style="text-align: center;"> <input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant </p> <p>This standard is not met as evidenced by:</p>

RESPIRATORY CARE

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	<p>For practitioners who have medical staff privileges, such privileges must be granted in a manner consistent with the State’s scope of practice law, as well as with hospital policies and procedures governing respiratory care services developed by the medical staff.</p> <p>Practitioners who may be granted privileges to order respiratory care services include physicians, and may also, in accordance with hospital policy, include:</p> <ul style="list-style-type: none"> • Nurse Practitioners, • Physicians’ Assistants, • Clinical Nurse Specialists, • Certified Registered Nurse Anesthetists, and • Certified Nurse Midwives <p>as long as they meet the parameters of this requirement.</p> <p>Although the following licensed professionals are also considered practitioners, in accordance with Section 1842(b)(18)(C) of the Social Security Act, they generally would not be considered responsible for the care of the patient with regard to respiratory care services or qualified to order respiratory care services:</p> <ul style="list-style-type: none"> • Clinical social worker (Section 1861(hh)(1) of the Act and as defined in 42 CFR §410.71); • Clinical psychologist (for purposes of Section 	<p>services as well as State law for ordering respiratory care services.</p> <p>2. Does the hospital permit acceptance of orders from outside practitioners who do not practice at the hospital?</p> <ul style="list-style-type: none"> • If so, evaluate for compliance with 482.54(c) (see standard 31.00.11). 	

RESPIRATORY CARE

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
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- 1861(ii) of the Act); or
- Registered dietitian or nutrition professional.

17.00.08 Respiratory Care Services Orders.

All respiratory care services orders must be documented in the patient’s medical record in accordance with the requirements at §482.24.

§482.57(b)(4)

The patient’s medical record must contain documentation of all respiratory care services ordered.

The medical record entries must comply with regulations at 42 CFR §482.24.

CHART REVIEW

Review a sample of patient medical records who received respiratory care services.

- Determine whether the respiratory care services orders are legible, complete, dated, timed, authenticated, and meet all other medical record requirements as specified at §484.24.

- 1 = Compliant
- 2 = Not Compliant

This standard is not met as evidenced by:

17.00.09 Therapeutic Medical Gases.
Policies and procedures describe all aspects of the use of therapeutic medical gases.

There are descriptions of medical gas storage, handling, dispersing, use, and the logging of routine periodic oxygen purity checks.

Compliance with policies must be demonstrated.

DOCUMENT REVIEW

1. Review documentation of the results of the purity tests from the original acceptance report, and whenever the medical gas system is breached.
2. The piped-in medical gases are to be considered as a utility system (see Physical Environment).
3. Policies address storage, handling, dispensing, use, and documentation requirements for therapeutic medical gases.

- 1 = Compliant
- 2 = Not Compliant

This standard is not met as evidenced by:

OBSERVATION

Verify compliance with storage, handling, dispersing, use, and documentation requirements for therapeutic medical gases.

RESPIRATORY CARE

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>17.00.10 <u>Adverse Drug Reactions & Medication Errors.</u> The various types of potential adverse drug reactions are described in writing along with processes to follow when such may occur.</p> <p>Adverse drug reactions and medication errors will be reported with departmental QAPI data to the Quality Committee and to the Pharmacy and Therapeutics Committee and is analyzed for patterns, trends and opportunities for improvement.</p>	<p>The policy is congruent with the pharmaceutical service definition for, and response to, adverse responses to medication administration.</p>	<p style="text-align: center;"><u>INTERVIEW & DOCUMENT REVIEW</u></p> <ol style="list-style-type: none"> 1. The service adverse drug reaction policy must support / enhance that from pharmacy. 2. Review the minutes of the Pharmacy and Therapeutics Committee (function) and the QAPI Committee (function). Determine that the minutes acknowledge reported reactions / errors. 3. Interview staff to verify the process for reporting drug reactions and medication errors. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>
<p>17.00.11 <u>Not Applicable.</u></p>			
<p>17.00.12 <u>Equipment Availability.</u> Resuscitative, ventilatory, and oxygenation devices are available for all sizes of patients that could be served by the organization.</p>	<p>Sufficient inventory exists to meet the predictable needs of the patient population.</p> <p>Arrangements exist to supplement this inventory to accommodate unusual census changes.</p>	<p style="text-align: center;"><u>OBSERVATION</u></p> <p>Observe for variety of needed supplies and equipment.</p> <p>Interview staff to determine that suitable arrangements exist to augment equipment needs.</p>	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

RESPIRATORY CARE

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>17.00.13 Assessment. Respiratory care patients receive a prompt assessment of their functional ability.</p> <p>Policies describe the timelines and characteristics of a respiratory assessment.</p>	<p>Other than in an emergency, an assessment is ordinarily completed within four (4) hours of receipt of the:</p> <ul style="list-style-type: none"> • Inpatient order • Upon the initial visit for outpatients <p>In no case does the non-urgent inpatient assessment occur any later than twenty-four (24) hours after receipt of the order.</p> <p>An initial assessment shall be conducted prior to any treatment administration.</p>	<p><u>CHART REVIEW</u></p> <p>Review ten patient records, including two outpatients. Determine that the records describe the timeliness and characteristics of an assessment.</p>	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

CARDIOVASCULAR SERVICES, INTERVENTIONAL RADIOLOGY, AND ENDOSCOPY SERVICES

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
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**CARDIOVASCULAR SERVICES,
INTERVENTIONAL RADIOLOGY
SERVICES, AND
ENDOSCOPY SERVICES.**

This chapter applies to:

- Cardiovascular Services
- Interventional Radiology Services
- Endoscopic Services

Chapter not applicable in this facility

18.00.01 Organizational Structure: Scope of Service.
The hospital provides services appropriate to the scope and complexity of services available at the facility.

The scope and complexity of services offered are specified in writing and approved by the medical staff and governing body.

- The scope of service statement identifies:
- inpatient and outpatient procedures offered
 - patient eligibility criteria for services
 - hours of operation
 - location of services
 - categories and qualifications of personnel

Organizational charts / documents indicate the clinical leadership and organizational relationship to the Surgical Services, Anesthesia Services, and Radiology Services, as appropriate.

DOCUMENT REVIEW

1. **Determine the scope of service statement:**
 - Identifies the services provided
 - Lists the patient eligibility criteria for procedures provided
 - Has been approved by the medical staff within the past three (3) years
2. **Determine the organizational chart reflects the integration of services to other services provided by the hospital.**

Score at 30.00.01

This standard is not met as evidenced by:

CARDIOVASCULAR SERVICES, INTERVENTIONAL RADIOLOGY, AND ENDOSCOPY SERVICES

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>18.00.02 Location. Invasive cardiology, Interventional Radiology, and Endoscopy Services may be provided in the "main" Operating Room or in remote locations, as long as these locations are properly designed and equipped for the procedures performed.</p>	<p>The location is not of concern, provided that principles of surgical asepsis and care are not compromised.</p> <p>The location is properly designed and equipped for the procedures being performed.</p> <p>The services must also comply with all applicable hospital standards (i.e. anesthesia, infection control, governing body, medical staff, nursing, physical environment, pharmacy services, etc.).</p> <p>Department policies for remote locations are authored, coauthored, or approved by the Imaging, Anesthesia, and Surgical Services supervisors.</p>	<p align="center"><u>OBSERVATION</u></p> <ol style="list-style-type: none"> 1. Observe for the physical provision of the required elements listed. 2. Policies comply with those approved by the medical staff of the Surgical Services, Anesthesia Services, and Radiology Services. 3. Policies have been reviewed and approved by the medical staff within the past three (3) years. 	<p>Score at 30.00.01</p> <p>This standard is not met as evidenced by:</p>
<p>18.00.03 Physical Environment. Whether the service is "stand alone" or integrated with another service / program, there shall be adequate provision for the following:</p> <ol style="list-style-type: none"> 1. Reception / waiting / toilet areas for patients, family / companions; 2. Patient registration - this may be integrated with general registration; 3. Private interview area for discussion anticipated procedures and accomplishing preadmission testing / teaching; 	<p>The hospital must maintain a sanitary environment to avoid sources and transmission of infections and communicable diseases. All areas of the hospital must be clean and sanitary.</p> <p>The service areas are designed in such a manner that respects:</p> <ol style="list-style-type: none"> 1. The patient's right to receive care in a safe environment, and 2. The patient's right to personal privacy. 	<p align="center"><u>OBSERVATION</u></p> <ol style="list-style-type: none"> 1. Determine the required elements are provided. 2. Determine the patient's rights are respected, as defined. 	<p>Score at 15.01.17</p> <p>This standard is not met as evidenced by:</p>

CARDIOVASCULAR SERVICES, INTERVENTIONAL RADIOLOGY, AND ENDOSCOPY SERVICES

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>4. Private dressing rooms for patients;</p> <p>5. Provision for safekeeping of patient clothing - mechanisms for valuable protection;</p> <p>6. Preparation / holding;</p> <p>7. The patient’s right to privacy (visual / auditory) is respected, which may include segregation of pre and post procedure patients; and</p> <p>8. Post-procedure observation / holding.</p>			
<p>18.00.04 Instrumentation Availability. Instruments, supplies, and equipment are sufficient in quantity so that movement is minimized during cases.</p> <p>IUSS (“Immediate Use Steam Sterilization” formerly known as flash sterilization) is utilized only for emergencies.</p> <p>The facility follows IUSS criteria and guidelines for sterilization.</p>	<p>The design of operating and invasive procedures rooms is such that personnel and supply movement is such that "clean" areas are protected from contamination. Signage, or "red" lines, may be utilized to denote "clean" from general traffic areas.</p> <p>Sterile packages are not subjected to dust accumulation, moisture, or other potential sources of contamination.</p> <p>Quality controls are in place to assure "fresh" strength disinfectants while maintaining employee safety.</p>	<p><u>OBSERVATION AND DOCUMENT REVIEW</u></p> <ol style="list-style-type: none"> 1. Determine that general and "clean" areas are clearly identified. 2. Determine that staff adheres to traffic rules. Movement in and out of the area is minimized. 3. Determine that shipping cartons are neither stored in the clean storage area nor on the floor. 4. Determine that sterile packages are intact 	<p>Score at 30.00.13</p> <p>This standard is not met as evidenced by:</p>

CARDIOVASCULAR SERVICES, INTERVENTIONAL RADIOLOGY, AND ENDOSCOPY SERVICES

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>Processed instruments are protected from surface / airborne contamination.</p>	<p>The facility adopts criteria and practices in accordance with manufacturer’s instructions and national guidelines such as CDC, CDC-HICPAC, AORN, AAMI, and etc.</p>	<p>and protected from dust, moisture, and other sources of contamination.</p> <p>5. Determine that the sterilization log demonstrates that IUSS (flash sterilization) is used only for emergency purposes.</p> <p>6. Determine the facility utilizes IUSS guidelines.</p> <p>7. Determine the staff utilizes safety measures with the chemicals disinfectants / cold sterilant products. These products are labeled and reflect current dates.</p>	
<p>18.00.05 Standards of Practice. The services and care provided are consistent with the standards established for Surgical Services, Anesthesia Services, and Radiology Services of this manual, as applicable.</p>	<p>Services are provided in accordance with acceptable standards of practice and must meet professionally approved standards for safety and personnel qualifications.</p> <p>Staff is trained to identify and respond to life threatening conditions.</p> <p>Policies are reviewed and approved by the medical staff at least every three (3) years.</p>	<p align="center"><u>DOCUMENT REVIEW</u></p> <p>Review department policies.</p> <p>1. Determine the level of integration with the Radiology Services, Surgical Services, and Anesthesia Services of the hospital.</p> <p>2. Determine the department standards of practice are consistent with the Surgical Services and Anesthesia Services of the hospital, e.g., draping, setting up the back table, patient safety standards, etc.</p>	<p>Score at 30.00.09</p> <p>This standard is not met as evidenced by:</p>

CARDIOVASCULAR SERVICES, INTERVENTIONAL RADIOLOGY, AND ENDOSCOPY SERVICES

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>18.00.06 Staffing. There must be adequate numbers of qualified medical, nursing, and other personnel available to meet the needs of the patient.</p>	<p>The facility defines the number of staff needed to ensure safe and efficient provision of care.</p> <p>The type and qualifications of staff is based on the type of patients treated and complexity of treatment provided.</p>	<p align="center"><u>INTERVIEW</u></p> <p>Interview department manager and staff regarding services provided to determine that the number and type of staff available is appropriate to the volume and types of treatments furnished. If needed, review staffing schedules.</p>	<p>Score at 30.00.01</p> <p>This standard is not met as evidenced by:</p>
<p>18.00.07 Supervision of Care. A Registered Nurse (RN) plans and supervises the care of each operative patient.</p>	<p>The facility defines the type of staff required to meet the needs of the patient.</p> <ol style="list-style-type: none"> The circulating nurse, if appropriate for the services provided, must be a registered nurse. LPNs and ORTs serving as scrub nurses will be under the supervision of a RN who is immediately available to physically intervene and provide care. Operative records will indicate which RN assessed and planned the perioperative care for each invasive procedure patient. If a case is circulated by other than an RN, the operative record will be co-authored by the RN who was immediately available. <p>The hospital, in accordance with state law and acceptable standards of practice, must establish the qualifications required for RNs who perform (RN) circulating duties and LPNs and surgical technologists who assist with circulating duties.</p>	<p><u>CHART REVIEW, OBSERVATION & INTERVIEW</u></p> <ol style="list-style-type: none"> Determine that an RN plans and supervises the perioperative care. If LPNs and surgical technologists (STs) assist with circulating duties, verify that they do so in accordance with applicable State laws and medical staff approved policies and procedures. 	<p>Score at 30.00.04</p> <p>This standard is not met as evidenced by:</p>

CARDIOVASCULAR SERVICES, INTERVENTIONAL RADIOLOGY, AND ENDOSCOPY SERVICES

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>18.00.08 Moderate Sedation. The use of moderate sedation (Conscious Sedation) is limited to qualified individuals.</p>	<p>Moderate sedation (conscious sedation) is the responsibility of the ordering practitioner; thus there is to be evidence that this technique is included in the privilege delineation for those practitioners.</p> <p>The administration of moderate sedation (Conscious Sedation) is limited to qualified individuals and is included in the privilege delineation for those practitioners.</p> <p>There may be requirements, established through Anesthesia Services policies, to document the advanced training and competencies of the Registered Nurses who give the medications and/or monitor patients having moderate sedation (conscious sedation).</p>	<p align="center"><u>FILE REVIEW</u></p> <p>Review at least three anesthesia provider files. Verify:</p> <ol style="list-style-type: none"> 1. The qualifications including current certification with verifications are present in the files of the reviewed practitioners. 2. Review the credential files for those providers who administer moderate sedation. The qualifications including current privileges are present in the files of the reviewed practitioners. 	<p>Score at 30.01.03</p> <p>This standard is not met as evidenced by:</p>
<p>18.00.09 Moderate Sedation: Monitoring the Patient. Medical staff and departmental policies identify the types of cases wherein a qualified registered nurse shall be assigned to monitor the patient due to the use of moderate sedation.</p> <p>Department policies will be the same as those utilized in the operating room, and all other clinical locations where moderate sedation is provided.</p>	<p>The definition of "moderate sedation (conscious sedation)" is noted in Anesthesia Services (see standard 30.01.01).</p> <p>Anesthesia services throughout the hospital (including all departments in all campuses and offsite locations where anesthesia services are provided) must be organized into one Anesthesia Service.</p> <p>The medical staff defines the qualifications and competencies expected of the RN who monitors the patient during moderate sedation. These monitoring activities may be provided by either a Registered Nurse or a CRNA.</p>	<p align="center"><u>DOCUMENT REVIEW</u></p> <ol style="list-style-type: none"> 1. Determine the medical staff has identified the types of cases that require a qualified RN to monitor the patient due to use of moderate sedation. 2. Determine that competency mechanisms exist for the RN who monitors moderate sedation. 	<p>Score at 30.01.03</p> <p>This standard is not met as evidenced by:</p>

CARDIOVASCULAR SERVICES, INTERVENTIONAL RADIOLOGY, AND ENDOSCOPY SERVICES

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>18.00.10 Moderate Sedation: Assisting With the Procedure. The proceduralist shall have an assistant assigned whenever moderate sedation is administered; this assistant may be another physician, RN, LPN/LVN, or technician.</p>	<p>There may be requirements, within Anesthesia policies, to document the advanced training and competencies of the Registered Nurses who give the medications and/or monitor patients having moderate sedation (conscious sedation).</p> <p>MONITORING If the drugs utilized are beyond anxiolytic there is an expectation that a specific qualified individual is responsible for monitoring the effect(s) of the drugs; this requires the undivided attention of that nurse.</p> <p>The monitoring RN cannot:</p> <ul style="list-style-type: none"> • be the nurse assisting with the procedure, nor • serve as the circulating nurse in the room. <p>The "monitoring" RN may be counted as the "RN planning and supervising nursing care" for the patient.</p> <p>A non-RN may be assigned to assist with the procedure, as defined by the facility.</p>	<p><u>DOCUMENT REVIEW AND CHART REVIEW</u></p> <ol style="list-style-type: none"> 1. Determine that policy requires moderate cases to have a minimum of two (2) staff: <ul style="list-style-type: none"> • one (1) to monitor and • one (1) to assist the physician. 2. Determine that policy identifies the qualifications of the assistant assigned to monitor the patient during sedation 3. Verify that the RN monitoring the patient under conscious sedation is not functioning as the assistant or circulating nurse during the procedure. 	<p>Score at 30.01.03</p> <p>This standard is not met as evidenced by:</p>

CARDIOVASCULAR SERVICES, INTERVENTIONAL RADIOLOGY, AND ENDOSCOPY SERVICES

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>18.00.11 Preoperative Assessment. The medical record contains a current history and physical.</p> <p>The proceduralist performs a preoperative evaluation of the patient and updates the history and physical prior to the procedure.</p>	<p>Self-explanatory.</p>	<p align="center"><u>CHART REVIEW</u></p> <p>Review medical records.</p> <ol style="list-style-type: none"> Determine the presence of a current history and physical. Determine the presence of the preoperative assessment. 	<p align="center">Score at 10.01.07</p> <p align="center">This standard is not met as evidenced by:</p>
<p>18.00.12 Post-Procedure Report. A post-procedure report will be required on all records including outpatient records.</p> <p>The content will include:</p> <ol style="list-style-type: none"> Name of the specific procedure performed Pre- and post-procedure diagnosis Type of anesthesia administered Complications, if any Description of the findings, techniques used, and tissue removed or altered Outcome of the treatment or procedure 	<p>Self-explanatory.</p>	<p align="center"><u>CHART REVIEW</u></p> <p>Review medical records.</p> <ul style="list-style-type: none"> Determine the presence and content of the Post-Procedure report. 	<p align="center">Score at 10.01.18</p> <p align="center">This standard is not met as evidenced by:</p>

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- 7. Disposition of the case
- 8. Provisions for follow-up care for an outpatient surgery patient

18.00.13 Outpatient Discharge Requirement.

Outpatient surgical / invasive procedure patients, who have had other than local or topical anesthesia shall have a responsible **person** to provide transportation following the procedure, **except those exempted by the practitioner who performed the procedure.**

Arrangements for **transportation** by a responsible **person** shall be **clarified by** staff, prior to initiation of the procedure.

The outpatient who has had anesthesia / moderate sedation may **have** delayed responses to these agents **which impact judgment and personal safety.** For **patient safety**, it is essential that provisions for **the patient’s discharge are made prior to the procedure.**

Transportation may be provided by someone known to the patient or through other arrangements, as deemed appropriate by the facility. These arrangements are documented in the medical record.

INTERVIEW AND CHART REVIEW

1. **Determine that staff can articulate the facility’s discharge practices.**
2. **Review medical records for patients discharged following outpatient surgery / procedure.**
 - Determine there is documentation that a **responsible person transported** the patient **following the procedure, or the exemption to this requirement is documented by the physician performing the procedure.**

Score at 30.03.01

This standard is not met as evidenced by:

CARDIOVASCULAR SERVICES, INTERVENTIONAL RADIOLOGY, AND ENDOSCOPY SERVICES

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>18.00.14 <u>Discharge Instructions.</u> Outpatient surgical / invasive procedure patients, and their families / companions are provided with instructions regarding post-procedure management in a language that the patient or responsible accompanying individual can understand.</p> <p>Post-procedure instructions include at least:</p> <ol style="list-style-type: none"> 1. Post-procedure sign and symptoms that may be expected. 2. Post-procedure sign and symptoms that require notification of the physician and/or immediate attention. 3. The mechanism to utilize in the event of post-procedure problems when the physician cannot be notified; 4. The date and time to next see a physician for follow-up care; 5. Pain management and treatment; 6. Changes in diet and medication, as appropriate; 	<p>The medical record contains documentation that post-procedure instructions were provided to the patient or family.</p>	<p align="center"><u>CHART REVIEW</u></p> <ul style="list-style-type: none"> • Determine that the medical record contains documentation that post-procedure care instructions were provided. 	<p>Score at 30.03.02</p> <p>This standard is not met as evidenced by:</p>

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- 7. Alterations in activity,
- 8. Management of wounds or devices.

18.00.15 Outpatient Follow-up Calls.
 Outpatient surgical / invasive procedure patients are contacted, when possible, by the facility within 24 to 72 hours post-procedure to determine their status.

The hospital policy identifies patients to be “at risk” that should receive a follow-up call to assess the clinical well-being post-surgery.

Mechanisms are established to determine patient status following discharge.

1. A process is in place to document these follow-up calls. **The clinical evaluation information obtained from post-discharge follow-up telephone calls is recorded in the medical record.**
2. **Information obtained from these calls is tracked and reported to the QAPI program in order to identify opportunities for improving the outpatient program. Adverse events may include, but are not limited to:**
 - Pain management issues
 - Bleeding
 - Returns to the Emergency Department
3. Patient satisfaction with the facilities and the service can also be assessed; **however, this information is not ordinarily recorded in the**

INTERVIEW & CHART REVIEW

1. Interview staff to determine **what** process is implemented.
2. Determine the medical records contain documentation of these follow-up calls.
3. Determine that there is a **mechanism** to review **and trend outcome or process issues as a result of the follow-up calls.** Determine if **the findings are reported to the QAPI Committee.**

Score at 30.03.03

This standard is not met as evidenced by:

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medical record.

Facilities may determine the time frame, which is "best" for their population. (Some patients return to school or work so rapidly that contact may not be possible.)

DIAGNOSTIC RADIOLOGY AND RADIATION THERAPY SERVICES

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19.00.00 Condition of Participation: Radiological Services.

The hospital must maintain, or have available, diagnostic radiological services.

If therapeutic services are also provided, they, as well as the diagnostic services, must meet the professionally approved standards for safety and personnel qualifications.

§482.26

Hospitals must offer diagnostic radiologic services and may also offer therapeutic radiologic services.

No matter where they are furnished in the hospital (including all departments on all campuses and off-site locations) radiologic services must satisfy professionally approved standards for safety and personnel qualifications.

Hospitals are expected to take a consistent approach in their policies and procedures for radiologic services safety and personnel qualifications throughout the hospital. This may be accomplished in several ways, including by having one organized radiologic service under the direction of the radiologist who supervises all ionizing radiology services (see §482.26(c)(1)), or by the governing body ensuring a uniform approach to radiologic services that are offered in multiple departments of the hospital.

WHAT IS INCLUDED IN RADIOLOGIC SERVICES?

Radiologic services encompass many different modalities used for the purpose of diagnostic or therapeutic medical imaging and radiation therapy. Each type of technology yields different information about the area of the body being studied or treated, related to possible disease, injury, or the effectiveness of medical treatment. All the

OBSERVATION, DOCUMENT REVIEW, CHART REVIEW, & INTERVIEW

1. Verify that radiological services are integrated into the hospital-wide QAPI program.
2. **Determine** the diagnostic radiology services offered by reviewing the scope of service statements.

- 1 = Compliant
 2 = Not Compliant

This standard is not met as evidenced by:

DIAGNOSTIC RADIOLOGY AND RADIATION THERAPY SERVICES

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modalities use some form of radiation, which is a term for energy waves or particles that pass through a medium, such as light or radio signals through the air. Some of these modalities (radiography, computed tomography, fluoroscopy) utilize ionizing radiation, which has enough energy to potentially cause damage to DNA, while others (ultrasound, magnetic resonance imaging) use other forms of non-ionizing radiation to view the human body in order to diagnose, monitor, or treat medical conditions.

Most of the definitions and terms referred to in this guidance are based on technical information available on the U.S. Food and Drug Administration’s (FDA) website, located at

<http://www.fda.gov/Radiation-EmittingProducts/default.htm> or from the Radiologic Society of North America’s (RSNA) website, located at <http://www.radiologyinfo.org>

DIAGNOSTIC & THERAPEUTIC RADIOLOGIC SERVICES

Diagnostic and therapeutic radiologic services may use the same modalities, but for different purposes.

Diagnostic services are performed to determine a specific cause of the medical problem with which the patient presents (e.g., fractured bone, occluded artery, tumor), while therapeutic services are performed to treat a specific problem (e.g., stenting of an artery or embolization of a blood vessel,

DIAGNOSTIC RADIOLOGY AND RADIATION THERAPY SERVICES

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lithotripsy of a renal stone, external beam radiation therapy to a cancerous tumor).

Regardless of the purpose of the radiologic services, the risks to the patient and staff, if applicable, depend on the modality used, the length of the study/procedure, the size of the patient, the specifics of the device being used, and other factors.

MODALITIES THAT USE IONIZING RADIATION

A. Radiography (X-rays) is a technique for generating and recording an x-ray pattern for the purpose of providing the user with a static image(s) after termination of the exposure. During a radiographic procedure, an x-ray beam is passed through the body. A portion of the x-ray is absorbed or scattered by the body's internal structure and the remaining x-ray pattern is transmitted to a detector, so that an image may be recorded for later evaluation. The recording of the pattern may occur on film or through electronic means (digital). X-rays are used to diagnose or treat patients by displaying images of the internal structure(s) of the body to assess the presence or absence of disease, foreign objects, and structural damage or anomaly.

Some common examples include:

- Verification of correct placement of invasive catheters, tubes, or devices;

DIAGNOSTIC RADIOLOGY AND RADIATION THERAPY SERVICES

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- Orthopedic evaluations for fractured or dislocated bones;
 - Chest x-ray to identify common conditions, such as congestive heart failure or pneumonia;
 - Evaluations of radio-opaque foreign bodies in soft tissues; and
 - Mammography.
- B. Dual-energy X-ray absorptiometry (DEXA) is a form of medical imaging that uses very small amounts of ionizing radiation to measure bone mineral density and determine an individual's risk for bone fractures or establish the diagnosis of osteoporosis. The amount of radiation used is less than one-tenth the dose of a traditional chest X-ray and less than one day's exposure to natural radiation.
- C. Computed Tomography (CT) scanning, also called computerized axial tomography (CAT) scanning, is a medical imaging procedure that uses x-rays to show cross-sectional images of the body. A CT imaging system produces cross-sectional images or "slices" of areas of the body, like the slices in a loaf of bread. During a CT scan, a patient undergoes several consecutive and simultaneous X-rays that can be configured as a three dimensional reconstruction of the part of the body that is being imaged. Thus, a CT scan delivers more ionizing radiation to the patient than radiography. CTs are better able to

DIAGNOSTIC RADIOLOGY AND RADIATION THERAPY SERVICES

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distinguish between different types of tissues in the body than radiography and, given its ability to image large areas over a short period of time, CT offers significantly improved resolution of many different structures in a variety of spatial configurations.

Often a CT scan will be performed using x-ray dye or contrast agent, which can be administered by mouth or by vein. This technique further helps to identify the intestines or vasculature, which can assist with the diagnosis of disease or injury.

Some common examples include:

- CT of the brain to distinguish between an ischemic or hemorrhagic stroke;
- CT of the abdomen and pelvis to evaluate for internal bleeding following trauma;
- CT of the chest to determine the presence of a pulmonary embolus; and
- CT of the aorta with intravenous contrast agent to determine a ruptured aneurysm.

D. Fluoroscopy is a type of medical imaging that shows a continuous x-ray image on a monitor, much like an x-ray movie. It is used to diagnose or treat patients by displaying the movement of a body part, or of an instrument or x-ray dye (contrast agent) through the body.

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Fluoroscopy is used in many types of examinations and procedures. Some examples include:

- Barium upper GI (gastrointestinal) series and enemas (to view movement through the GI tract);
- Catheter insertion (to direct the placement of a catheter in a blood vessel);
- Orthopedic surgery (to view fracture treatments); and
- Angiography (to determine if there are blockages in arteries).

The amount of ionizing radiation that a patient and the medical staff receive during the procedure depends on the procedure's length and complexity.

RADIATION THERAPY

Ionizing radiation can also be used for therapeutic purposes, in which the energy is utilized to directly kill cancerous cells.

External beam therapy (EBT) is a method to deliver a beam of high-energy x-rays to a patient's tumor. The beam is generated outside the patient and is targeted at the tumor site. The goal is to deposit the energy to kill the cancer cells while sparing the normal tissue. EBT is often used to treat cancers of the breast, head and neck, prostate, lung, and brain. It also can be used to provide palliative care for painful sites of metastases to bone.

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Brachytherapy is a type of radiation therapy in which radioactive material is placed directly inside or next to the tumor. This type of therapy allows for a higher dose of radiation to treat a smaller area and in a shorter time than with EBT. It can be either temporary, in which the radioactive material is placed inside or near a tumor for a specified amount of time, often via a catheter; or permanent, in which radioactive seeds or pellets are placed near or inside a tumor and left there permanently, eventually decaying so that the radioactivity diminishes to nothing. Brachytherapy is often used to treat solid tumors, including prostate, breast, and gallbladder cancer.

RADIOLOGIC SERVICES MODALITIES THAT DO NOT USE IONIZING RADIATION

A. ULTRASOUND

Ultrasound imaging (sonography) uses high-frequency sound waves to view soft tissues, such as muscles and internal organs. Because ultrasound images are captured in real-time, they can show movement of the body's internal organs as well as blood flowing through blood vessels. This imaging modality has no documented evidence of dangers to the patient or staff administering it, however, caution about the frequency of use has been encouraged, particularly in the imaging of fetuses. Ultrasound imaging is used in many types of examinations and procedures.

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Some examples include:

- Doppler ultrasound (to visualize blood flow through a blood vessel);
- Echocardiogram (to view the heart);
- Fetal ultrasound (to view the fetus in pregnancy);
- Ultrasound-guided biopsies of suspicious masses;
- Doppler fetal heart rate monitors (to listen to the fetal heart beat); and
- Lithotripsy to break up kidney stones; this procedure uses high energy sound waves (shock waves), but there is minimal risk to the patient and staff from this form of energy. Pre- and post-procedure radiographs are taken of the patient, which confer the same risk as a standard X-ray of that part of the body.

B. Magnetic resonance imaging (MRI) is a medical imaging procedure that uses strong magnetic fields and radio waves to produce cross-sectional images of organs and internal structures in the body. Because the signal detected by an MRI machine varies depending on the water content and local magnetic properties of a particular area of the body, different tissues or substances can be distinguished from one another in the study image.

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MRI can give different information about structures in the body than can be obtained using a standard x-ray, ultrasound, or computed tomography (CT) exam. For example, an MRI study of a joint can provide detailed images of ligaments and cartilage, which are not visible using other modalities. In some cases, an MRI contrast agent is given by vein to show internal structures or abnormalities more clearly.

In most MRI devices, an electric current is passed through coiled wires to create a temporary magnetic field in a patient’s body. (In open-MRI devices, permanent magnets are used.) Radio waves are sent from and received by a transmitter/receiver in the machine, and these signals are used to produce digital images of the area of interest.

MRI scans facilitate diagnosis or monitoring of treatments for a variety of medical conditions, including:

- Abnormalities of the brain and spinal cord;
- Tumors, cysts, and other abnormalities in various parts of the body;
- Injuries or abnormalities of the joints;
- Certain types of heart problems;
- Diseases of the liver and other abdominal organs;
- Causes of pelvic pain in women (e.g., fibroids, endometriosis); and
- Suspected uterine abnormalities in women

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undergoing evaluation for infertility.

The hospital’s radiological services, including any contracted services, must be integrated into its hospital-wide QAPI program.

The elements of the Condition’s regulatory language (the Condition “stem” statement) are close, but not identical, to those found in the standards at §§482.26(a) and (b). We have, therefore, repeated elements of this Condition regulatory language in the Tags for both §§482.26(a) and (b), in order to permit citation of deficiencies that are specific to requirements found in the Condition stem statement at either the standard or condition level, as appropriate.

The manner or degree of noncompliance with the requirements of this Condition and its component standards must be evaluated to determine whether there is substantial noncompliance with the Condition, warranting a Condition-level citation.

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<p>19.00.01 Scope of Service. <i>The hospital must maintain, or have available, diagnostic radiologic services....</i></p> <p><i>The hospital must maintain, or have available, radiology services according to the needs of the patients.</i></p> <p>§482.26(a)</p>	<p><u>MANDATORY AND OPTIONAL RADIOLOGIC SERVICES</u></p> <p>The hospital must maintain, or have available, diagnostic radiological services according to the needs of the volume and types of patients the hospital serves.</p> <p>“Maintain” in this context means furnishing radiologic services on-site, while having them available means providing access to radiologic services even when they are not furnished on-site.</p> <p>For example:</p> <ul style="list-style-type: none"> It would not be uncommon for a psychiatric hospital to maintain on-site relatively limited or no radiologic services, while making more extensive diagnostic services available under arrangement, at a site outside the psychiatric hospital. On the other hand, a short-term acute care hospital with a busy emergency department that handles trauma, stroke, and other complex medical and surgical cases would be expected to maintain on-site a wider range of diagnostic radiologic services that are ready to be furnished when needed. <p>A hospital’s diagnostic radiologic services must be maintained or available at all times.</p> <p>Multi-campus hospitals must have diagnostic radiologic services that can be furnished when</p>	<p><u>DOCUMENT REVIEW & OBSERVATION</u></p> <p>With respect to assessing whether the diagnostic radiologic services meet the needs of the hospital’s patients:</p> <ol style="list-style-type: none"> Ask the hospital for evidence of the scope and complexity of its diagnostic radiologic services. Ask how the hospital has determined that the services meet the needs of its patients. Verify that the hospital either maintains or makes available diagnostic radiologic services that can be provided promptly when needed. If the hospital has an emergency department, are diagnostic radiologic services maintained or available at all times to support the emergency department? If the diagnostic radiologic services are not on the same campus as the hospital’s emergency department, same-day surgery, inpatient locations, or other areas where services dependent upon radiologic services are provided: <ul style="list-style-type: none"> Ask the hospital how it ensures that services are furnished within clinically required timeframes. Does the hospital have an arrangement 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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	<p>needed in a clinically appropriate timeframe for each location providing inpatient, same-day surgery, and emergency services.</p> <p>The scope and complexity of diagnostic radiological services maintained or available must be specified in writing, in order to demonstrate how the hospital meets the needs of its patients.</p> <p>Therapeutic radiologic services are optional, but if they are offered, must also comply with the Radiologic Services requirements.</p> <p>Radiological services may be provided by the hospital directly utilizing its own staff, or through a contractual arrangement.</p> <p>The hospital is responsible for ensuring that the services meet all the requirements of this regulation, regardless of whether they are provided directly or under arrangement. Diagnostic radiologic services provided under arrangement may be provided either on the hospital's campus or in an adjacent or other nearby, readily accessible facility so long as the services, including those required on an urgent or emergent basis, can be furnished within clinically appropriate timeframes.</p> <p>Increasingly, hospitals are also separating the performance of radiologic studies, which may be done on-site or at a readily accessible facility off the hospital's campus, from the interpretation of the</p>	<p>with an off-site facility to furnish diagnostic services when needed?</p> <p>6. How does the hospital ensure that staff authorized to interpret diagnostic studies are ready to furnish services within clinically required timeframes, either on-site or through telecommunications media that permit remote review and interpretation of studies?</p>	

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studies, which can be performed remotely by a teleradiology practitioner in a timely fashion.

- This practice is acceptable, so long as the teleradiology practitioner is privileged in accordance with the requirements of the Governing Body (§482.12) and Medical Staff (§482.22) CoPs.

19.00.02 Safety for Patients and Personnel.

If therapeutic services are also provided, they, as well as the diagnostic services, must meet professionally approved standards for safety and personnel qualifications.

The radiologic services, particularly ionizing radiology procedures, must be free from hazards for patients and personnel.

§482.26(b)

The hospital must adopt and implement radiologic services policies and procedures that provide safety for affected patients and hospital personnel and which are consistent with accepted professional standards for radiologic services.

IONIZING RADIOLOGY PROCEDURES

Radiologic services modalities that use ionizing radiation have increased the ability to detect disease or injury early enough for a medical problem to be managed, treated, or cured. When applied and performed appropriately, these radiologic studies or procedures can maintain or improve health and save lives.

X-ray energy used in radiologic services also has a potential to harm living tissue. The most significant risks are:

- Cataracts and skin damage, but only at very high levels of radiation exposure; and
- An increase in the possibility that a person

OBSERVATION, DOCUMENT REVIEW, AND INTERVIEW

Verify that there are written hospital policies and procedures and protocols for specific radiologic services modalities that are based on identified professionally approved standards, and which address the ALARA principle as well as the other safety and risk-reduction measures discussed in the guidance.

1. Ask for evidence that safety protocols are reviewed periodically and, if applicable, updated.
2. Determine if the radiologic services staff are familiar with the policies and procedures related to safety in general and specific clinical protocols.
3. Observe whether the policies and procedures are followed when radiologic services are delivered to patients.

- 1 = Compliant
 2 = Not Compliant

This standard is not met as evidenced by:

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	<p>exposed to x-ray energy will develop cancer later in life. The risk of developing cancer from radiologic services radiation exposure is generally very small, and it depends on at least three factors—the amount of the radiation dose, the age of the person exposed, and the sex of the person exposed:</p> <ul style="list-style-type: none"> ○ The lifetime risk of cancer increases the larger the dose and the more x-ray studies or procedures a patient undergoes; ○ The lifetime risk of cancer is larger for a patient who received x-rays at a younger age than for one who receives them at an older age; and ○ Women are at a somewhat higher lifetime risk than men for developing radiation-associated cancer after receiving the same exposures at the same ages. <p><u>MRI:</u> MRIs are useful when a soft tissue injury or disease process is suspected and are generally considered at low risk of causing harm to patients or staff.</p> <p>However, they also are not entirely risk-free. Potential risks include projectile risk of magnetic objects being sucked into the main magnet, thermal</p>	<ul style="list-style-type: none"> • Ask for the protocol(s) for one or more studies/procedure(s) you observed and check if they were followed. <ol style="list-style-type: none"> 4. Verify that radiologic services staff are trained at appropriate intervals to ensure that they are operating the equipment according to manufacturer’s instructions and hospital policy 5. Verify that radiologic services staff know how to respond to adverse events. 6. Confirm that areas where radiologic services are provided are equipped with the equipment or materials to immediately respond to an adverse event. 7. Ask the radiologist who supervises ionizing radiologic services how the hospital monitors the quality and safety of radiologic services. 8. Verify that adverse events are analyzed for their causes and that preventive actions are taken (deficiencies to be cited both here and under the applicable QAPI citation). 	

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injury and burns, adverse effects on devices and leads implanted in patients, and hearing damage.

PROVISION OF SERVICES IN ACCORDANCE WITH PROFESSIONALLY APPROVED STANDARDS FOR SAFETY

1. All radiological services provided by the hospital, including both diagnostic and, if offered, therapeutic services, must be provided in accordance with acceptable standards of practice, including standards for safety.

2. Professionally approved standards include maintaining compliance with applicable Federal and State laws and regulations governing radiological services, including, but not limited to, facility licensure and/or certification requirements.

3. Professionally approved standards also include the recommendations or guidelines promulgated by expert governmental agencies, such as the U.S. Food and Drug Administration, as well as those issued by nationally recognized professional organizations, such as the American Medical Association, American College of Radiology, Radiological Society of North America, The Alliance for Radiation Safety in Pediatric Imaging, American Society of Radiologic Technologists, the American College of Cardiology, the American College of Neurology,

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the American College of Physicians, etc.

4. Generally, there are different standards for different imaging modalities used to provide radiologic services; there may also be different standards for diagnostic versus therapeutic uses, as well as for pediatric versus adult patients, etc. For example, the American College of Radiology has separate diagnostic radiology guidance documents for general radiology, CT, MRI, and ultrasound, among others.

5. The hospital must be able to document the source standards that form the basis for its policies and procedures for each of its radiologic services modalities and/or settings.
 - For example, if one organization’s standards are used for mammography services, another’s for CT services, another’s for MRI, and another’s for pediatric X-rays, this must be clearly indicated.

6. In order to ensure safety and freedom from hazards, the hospital’s radiologic services policies and procedures must include, but are not limited to, provisions addressing the following:
 - a. For ionizing radiation services, application of the fundamental principle of As Low as Reasonably Achievable or ALARA, which is

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- defined by the U.S. Environmental Protection Agency (EPA) as “A principle of radiation protection philosophy that requires that exposures to ionizing radiation be kept as low as reasonably achievable, economic and social factors being taken into account.
- b. The protection from radiation exposure is ALARA when the expenditure of further resources would be unwarranted by the reduction in exposure that would be achieved.” (Federal Guidance Report No. 14, Radiation Protection Guidance for Diagnostic and Interventional X-ray Procedures, p. 100, November, 2014). Although CMS does not interpret or enforce EPA guidance, the ALARA principle is considered an accepted standard of practice for ionizing radiation services to which hospitals must adhere.
 - c. Written protocols developed or approved by the radiologist responsible for the radiologic services, in conjunction with other qualified radiologic services personnel (e.g., a medical physicist, radiologic technologists, patient safety officers, etc.) designed to ensure that diagnostic studies and therapeutic procedures are routinely performed in a safe manner, utilizing parameters and specifications that are appropriate to the

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ordered study/procedure.

- d. The hospital must ensure that protocols for the various types of ionizing radiation diagnostic or therapeutic imaging modalities are designed to minimize the amount of radiation while maximizing the yield and producing diagnostically acceptable image quality.
- e. Existing protocols must be reviewed periodically and updated as needed. The rationale and details for changes to technical parameters must be documented.

**For Information Only –
Not Required/Not to be Cited**

Hospitals are encouraged to follow the recommendation in the EPA’s Guidance Report No. 14 concerning patient radiation dosage.

The report says “As the ICRP [International Commission on Radiological Protection] has stated, ‘Provided that the medical exposures of patients have been properly justified and that the associated doses are commensurate with the medical purpose, it is not appropriate to apply dose limits or dose constraints to the medical exposure of patients, because such limits or constraints would often do more harm than

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good' (ICRP 2007b).

While dose limits do not apply to medical exposures, radiation doses to patients should always be optimized. All responsible parties should always strive to minimize patient irradiation to the dose that is necessary to perform the procedure with adequate image quality.

The recommendation against establishing absolute dose limits should not discourage a facility from implementing diagnostic reference levels for imaging and interventional procedures. Exceeding these levels should prompt a review of practice at the facility as a quality assurance measure.

Dose notification and alert values for CT, notification levels for use during interventional procedures, and trigger levels for follow-up after interventional procedures are also appropriate QA measures [emphasis added]...(EPA Guidance Report No. 14, p.6)

- f. Policies and protocols to identify patients at high risk for adverse events for whom the radiologic study or procedure might be contraindicated, e.g., pregnant women, individuals with known allergies to contrast agents, individuals with implanted devices,

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etc. Policies would address the steps to be taken, and by which personnel, if an order is written for a radiologic study or procedure for an individual identified in the radiologic services policies as potentially at high risk (e.g., notify the ordering physician, cancel the procedure personally, etc.).

- g. Specific requirements related to procedures to mitigate radiation hazards are discussed in the guidance for §482.26(b)(1).
- h. Procedures to address risks associated with modalities that do not use ionizing radiation.

For example, with respect to MRI:

- Measures to prevent magnetic materials from being closer than is safe to the MRI suite, per nationally recognized guidelines;
- If equipment and supplies, such as fire extinguishers and oxygen tanks, are located in the MRI area, they are MR-safe, i.e., they are non-ferromagnetic;
- Provision of adequate and effective hearing protection to patients, staff and others who might be in the MRI suite while the scans are taking place; and
- Measures to reduce the risk of thermal

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injuries/burns during MRI. This would include, but is not limited to, screening patients to identify those who may have metallic tattoos or metal in them, proper patient positioning, ensuring implants are MR Conditional, checking for electrically conductive materials that might be in close proximity to the patient and taking the appropriate precautions, and instructing the patient to immediately report any burning sensations experienced during the scan.

- i. Training required by personnel permitted to enter areas where radiologic services are provided.
- j. Training and, as applicable, qualifications, required for personnel who perform diagnostic imaging studies or therapeutic procedures utilizing radiologic services equipment. This includes proper operation of equipment per manufacturer’s instructions and hospital policy.
- k. Areas where radiologic services are provided must be equipped with the necessary equipment or materials to immediately respond to potential adverse events. This could include, but is not limited to, things like a crash cart, emergency stop mechanisms, cleaning and decontamination

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agents if applicable, etc.

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Hospitals are encouraged to also address the following in their Radiologic Services:

- Encouraging physicians and other practitioners with privileges to order radiologic studies or procedures that utilize ionizing radiation to consider both the benefits and risks of the procedures.
- Recording and tracking the dosing patients receive. There are several nationally recognized quality assurance programs designed to assist health care providers in developing and maintaining this data, including, but not limited to:
 - The Alliance for Safety in Pediatric Imaging (www.imagegently.org)
 - The Conference of Radiation Control Program Directors
 - The American College of Radiology data registry (<http://nrdr.acr.org>)
 - The Nationwide Evaluation of X-ray Trends (NEXT program)

Further, although the EPA’s Guidance Report No. 14 was developed by an Interagency Working Group on Medical Radiation specifically to

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provide guidance to Federal facilities that use diagnostic and interventional X-ray equipment, it should also be useful to non-Federal medical facilities and hospitals are encouraged to review it. The Guidance Report addresses the following topics:

- Radiation Safety Standards and General Concerns
- Structural Shielding and Door Interlock Switches
- Requesting and Performing Studies Involving X-rays
- Technical Quality Assurance
- General Guidelines for Clinical Imaging, organized into separate sections for Medical and Dental, and further broken down by modality
- Imaging Informatics
- Recommendations for Facility Action

MEDICAL PHYSICISTS

1. According to the American Association of Physicists in Medicine, the practice of Medical Physics means the use of principles and accepted protocols of physics to ensure the correct quality, quantity, and placement of radiation during the performance of a radiological procedure.

2. Hospitals are not required under the regulations to have a medical physicist on staff or under

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contract.

3. However, since radiologic services are required to be free from hazards to patients and hospital personnel, hospitals must ensure that qualified personnel, whether or not they are medical physicists, develop and carry out protocols and test, calibrate, and maintain radiologic services equipment and that there is a reliable means to validate the results.

**For Information Only –
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Definition of a Medical Physicist
 An example of a definition of and qualifications for a medical physicist is provided by the American Association of Physicists in Medicine:

“For the purpose of providing clinical professional services, a Qualified Medical Physicist (QMP) is an individual who is competent to independently provide clinical professional services in one or more of the subfields¹ of medical physics. The subfields of medical physics are:

- Therapeutic Medical Physics
- Diagnostic Medical Physics
- Nuclear Medicine Physics
- Medical Health Physics

.... A Qualified Medical Physicist meets each of the following credentials:

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- Has earned a master’s and/or doctoral degree in physics, medical physics, biophysics, radiological physics, medical health physics, or equivalent disciplines from an accredited college or university; and
- Has been granted certification in the specific subfield(s) of medical physics with its associate medical health physics aspects by an appropriate national certifying body and abides by the certifying body’s requirements for continuing education.”
<http://www.aapm.org/org/default.asp>

**For Information Only –
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The responsibilities of the medical physicist in a hospital may include:

- Protection of the patient and others from potentially harmful or excessive radiation;
- Establishment, with the approval of the Director of Radiologic Services, of adequate protocols to ensure accurate patient dosimetry;
- Measurement and characterization of radiation;
- Determination of delivered dose;
- Promotion of procedures necessary to ensure image quality;
- Development and direction of quality assurance programs; and assistance to other

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healthcare professionals in optimizing the balance between the beneficial and deleterious effects of radiation.

Hospitals are also encouraged to involve a medical physicist in the calibration of the radiologic services equipment and monitoring of radiation dosage exposures to staff.

QAPI

Consistent with the requirements under the Quality Assessment and Performance Improvement (QAPI) CoP at 42 CFR 482.21, the hospital must monitor the quality and safety of radiologic services.

Examples of indicators of potential quality and safety problems could include, but are not limited to:

- Improper patient preparation, such as inadequate intravenous access or lack of pre-medication, such that procedures must be cancelled or reordered;
- Repeats of the same studies in the hospital for the same patient within a short time span, which may be an indicator of poor image quality; or
- Diagnostic imaging studies or therapeutic procedures performed in a manner inconsistent with the applicable hospital written protocol.

Under the QAPI CoP, hospitals are required to undertake improvement activities in areas that

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represent high risk, high volume, or problem-prone areas.

- Problems identified in radiologic services may meet these criteria.
- In addition, adverse events related to radiologic services must be analyzed for their causes, and preventive actions must then be undertaken.
- Deficiencies identified related to tracking, analyzing, and addressing adverse event and quality indicator data and performance improvement activities must be cited under the applicable QAPI standards.

19.00.03 Shielding.

Proper safety precautions must be maintained against radiation hazards.

This includes adequate shielding for patients, personnel, and facilities, as well as appropriate storage, use and disposal of radioactive materials;

§482.26(b)(1)

The hospital must adopt and implement written policies and procedures to ensure safety from radiation hazards.

The policies and procedures must include, but are not limited to, consideration of the following:

- **Clear and easily recognizable signage identifying hazardous radiation areas;**
- **Limitations on access to areas containing radiologic services equipment.**
- **Appropriate use of shielding, including:**

OBSERVATION

1. Verify that **personal shielding, supplies and equipment** are properly maintained and routinely inspected by the hospital.
2. Verify that hazardous **radiation** materials are **clearly labeled, properly** stored in a safe manner **in the requisite containers, and disposed of in the appropriate manner.**
3. **Determine if the proper shielding is applied to a patient who is undergoing a procedure using ionizing radiation.**

- 1 = Compliant
 2 = Not Compliant

This standard is not met as evidenced by:

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	<ul style="list-style-type: none"> • Types of personal protective shielding (e.g., lead aprons, lead gloves, protective eyewear, thyroid shields, portable individualized lead panels, stationary barriers) to be used, under what circumstances, for patients, including high-risk patients as identified in radiologic services policies and procedures, patient family members or support persons who may be needed to be with the patient during a study or procedure, and hospital personnel; • Lead and concrete barriers built into the walls and other structures of the imaging areas; • Identification and use of appropriate containers to be used for various radioactive materials, if applicable, when stored, in transport between locations within the hospital, in use, and during/after disposal. <p>ADDITIONAL POLICIES The hospital policies must establish safety standards for at least the following:</p> <ol style="list-style-type: none"> 1. Labeling of radioactive materials, waste, and hazardous areas. 2. Transportation of radioactive materials between locations within the hospital. 3. Security of radioactive materials, including determining who may have access to radioactive 	<ol style="list-style-type: none"> 4. Determine if staff members appropriately extricate themselves from the immediate exposure field while performing a study or procedure using ionizing radiation. 5. Determine if staff wear shielding as appropriate, per hospital policy. 6. Verify the required policies have been approved by the medical staff within the past three (3) years. 	

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- materials and controlling access to radioactive materials.
4. Testing of equipment for radiation hazards.
 5. Maintenance of personal radiation monitoring devices.
 6. Proper storage of radiation monitoring badges when not in use.
 7. Storage of radio nuclides and radiopharmaceuticals as well as radioactive waste.
 8. Disposal of radionuclides, unused radiopharmaceuticals, and radioactive waste.
 9. Methods of identifying pregnant patients.
 10. Periodic inspections of radiology equipment are conducted, current and problems identified are corrected in a timely manner.
 11. Personnel are competent to use radiological equipment and perform procedures.
- The hospital must implement and ensure compliance with its established safety standards.

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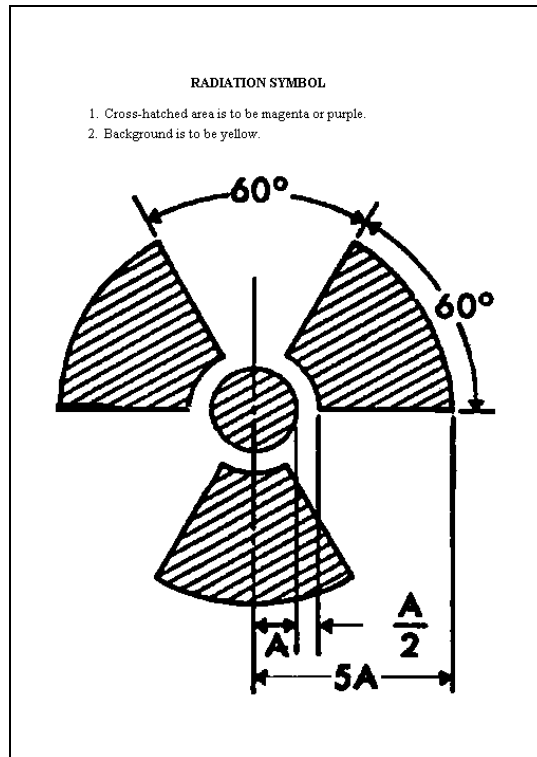
The Occupational Health and Safety Administration (OSHA) has requirements for protecting hospital staff from radiation exposure, some of which are summarized below:

- “For information about exposure limits see: 29 CFR 1910.1096, Ionizing Radiation Standard. The standard also requires:.....

- Each radiation area shall be conspicuously posted with a sign or signs bearing the radiation caution symbol, with the wording ‘Caution Radiation Area’ [29 CFR 1910.1096(e)(2)]”

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This document also discusses other tools to prevent radiation exposure.

See:
<https://www.osha.gov/SLTC/etools/hospital/clinical/radiology/radiology.html#Radiation>

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<p>19.00.04 Equipment Inspections. <i>Periodic inspection of equipment must be made and hazards identified must be promptly corrected.</i></p> <p>§482.26(b)(2)</p>	<p>As a reminder, although hospitals are required to comply with applicable OSHA requirements, surveyors conducting surveys on behalf of CMS do not interpret or assess compliance with the requirements of OSHA or other Federal Agencies. Surveyors do assess compliance with Medicare requirements that may overlap or duplicate OSHA requirements.</p> <hr/> <p>The hospital must have policies and procedures in place to ensure that periodic inspections of radiology equipment are conducted, current and that problems identified are corrected in a timely manner.</p> <p>Equipment includes not only devices used to deliver diagnostic or therapeutic radiologic services, but also:</p> <ul style="list-style-type: none"> • Exposure meters, badges, or personal radiation monitoring devices used by staff, as well as • Equipment the hospital uses to inspect or calibrate devices used to deliver diagnostic or therapeutic radiologic services. <p>The hospital must ensure that equipment is inspected in accordance with manufacturer’s instructions and Federal and State laws, regulations, and guidelines, and hospital policy, as applicable.</p>	<p align="center"><u>DOCUMENT REVIEW</u></p> <ol style="list-style-type: none"> 1. Review the inspection records (logs) to verify that periodic inspections are conducted in accordance with manufacturer’s instructions, Federal and State laws, regulations, and manufacturer’s instructions. 2. Verify that inspection and maintenance activities were performed by qualified individuals. 3. Verify that the maintenance logs show documentation of the calibration upon installation and after major upgrades or servicing. 4. Review with the appropriate personnel the inspection schedule and the mechanism for identifying hazards, including accurate dosimetry determinations with phantom patients, as applicable. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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INSPECTIONS PERFORMED BY QUALIFIED PERSONNEL

Inspections and maintenance, including correction of identified hazards, must be performed by qualified employees (e.g., medical physicists, qualified biomedical technicians, etc.) or through contractual arrangements with vendors with appropriate expertise.

Hospitals must follow the manufacturer’s instructions as to how to inspect and maintain radiologic equipment. This includes acceptance testing (i.e., upon initial installation and after major upgrades) as well as ongoing inspection and maintenance.

Documentation of preventive maintenance, quality control tests, service records, and major software/hardware upgrades must be maintained by the hospital and be readily available for inspection.

The hospital must have a system in place, to identify and remedy equipment hazards in a timely manner. This system must include, but is not limited to:

- Periodic and consistent calibration of equipment and,

- For equipment using ionizing radiation, monitoring of dosimetry parameters with phantoms to ensure that an accurate dose of radiation is delivered per the applicable protocol.

5. Determine that any problems identified through the testing and maintenance program are properly corrected in a timely manner and the correction is maintained over time.

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In addition, hospitals must also have a system to track all modifications made to the equipment that would significantly impact the accuracy of the dosage delivered.

- Any adverse events related to over- or under-dosing must be identified and addressed.

<p>For Information Only – Not Required/Not to be Cited</p> <p>Requirements for Manufacturers Re: Instructions that Must be Made Available</p> <p>Below is an FDA summary of its requirements for manufacturers of x-ray systems to make available to purchasers and, upon request, to other parties, information related to maintenance of the following types of systems:</p> <ul style="list-style-type: none"> • For all diagnostic x-ray systems, manufacturers are required to provide to purchasers, and, upon request, to others at a cost not to exceed the cost of publication and distribution, manuals or instruction sheets that include technical and safety information (21 CFR 1020.30(h)). This information must include a schedule of the maintenance necessary to keep the equipment in compliance with §§1020.30, 1020.31, 1020.32, and 1020.33 (21 CFR

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1020.30(h)(1)(ii). Manufacturers are also required to provide to assemblers, and, upon request, to others at a cost not to exceed the cost of publication and distribution, instructions for assembly, installation, adjustment, and testing of specified components of diagnostic x-ray systems adequate to ensure that the products will comply with applicable provisions of §§1020.30, 1020.31, 1020.32, and 1020.33, when assembled, installed, adjusted, and tested as directed (21 CFR 1020.30(g)).

- In addition to the requirements applicable to all diagnostic x-ray systems, there are also other requirements for specific systems:
- Manufacturers of fluoroscopic x-ray systems manufactured on or after June 10, 2006 are required to provide a schedule of maintenance for any system instrumentation associated with the display of air kerma information necessary to maintain the displays of air kerma rate and cumulative air kerma within the limits of allowed uncertainty specified by 21 CFR 1020.32(k)(6). And, if the capability for user calibration of the display is provided, adequate instructions for such calibration must be supplied (21 CFR 1020.30(h)(6)(i)).
- Manufacturers of computed tomography (CT)

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systems are required to provide a specific phantom or phantoms for quality assurance testing of specific system parameters on these systems (21 CFR 1020.33(d)(1)), and

- instructions on the use of the phantom(s), including a schedule of testing appropriate for the system and allowable variations for the indicated parameters (21 CFR 1020.33(d)(2)).
- Manufacturers of cabinet x-ray systems are required to provide purchasers, and others, upon request, at a cost not to exceed the cost of preparation and distribution, manuals and instructions. These documents must include, among other technical and safety information, a schedule of maintenance necessary to keep the system in compliance with 21 CFR 1020.40 (21 CFR 1020.40(c)(9)(i)).
- Cabinet x-ray systems that are intended to be assembled or installed by the purchaser must be accompanied by instructions for assembly, installation, adjustment and testing of the cabinet x-ray adequate to ensure that the system is in compliance with the applicable provisions of 21 CFR 1020.40 when assembled, installed, adjusted and tested as directed (21 CFR 1020.40(c)(9)(ii)).

19.00.05 Exposure Meters.

This requirement applies to radiologic services

OBSERVATION, DOCUMENT REVIEW, AND

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<p><i>Radiation workers must be checked periodically, by the use of exposure meters or badge tests, for amount of radiation exposure.</i> §482.26(b)(3)</p>	<p>personnel, as well as other hospital employees who may be regularly exposed to radiation due to working near radiation sources. This could include certain nursing and maintenance staff.</p> <p>The types or locations of employees who require monitoring for radiation exposure must be identified in the policies and procedures for the radiologic services developed or approved by the radiologist who supervises the services, in conjunction with the appropriately qualified radiation safety personnel.</p> <p>The monitoring of staff exposure must be documented by qualified personnel.</p> <p>Hospitals are expected to educate staff who are monitored for radiation exposure about the appropriate use of the monitoring meters or badges (or through use of a “personal radiation monitoring device,” which employs modern technology for the same measurement purpose).</p> <p>Hospitals must educate staff on the importance of tracking their radiation exposure over various timeframes, such as the most recent month and year, as well as their cumulative exposure through work.</p> <p>Staff also must be educated about the appropriate storage of the meters and/or badges as well as the procedures to follow if the exposure device exceeds cumulative dosage parameters specified per hospital policy.</p>	<p align="center"><u>INTERVIEW,</u></p> <ol style="list-style-type: none"> Verify that staff being monitored have been trained about the appropriate use and storage of their badges/meters. <ul style="list-style-type: none"> Are staff knowledgeable about their personal radiation exposure over various timeframes? Observe whether staff in categories or locations identified for monitoring have radiation-detecting meters or badges and that they appropriately wear and store them. Review records to verify that monitoring of staff exposure is documented. Ask the hospital what steps it takes if staff exposure exceeds parameters established per hospital policy. <ul style="list-style-type: none"> Can the hospital provide examples, or, if it asserts there have been no cases in the prior 12 – 24 months, do its records support this? 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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The hospital is expected to proactively monitor staff cumulative dosage and take appropriate steps if an individual staff member’s cumulative dosage level exceeds parameters specified per hospital policy.

**For Information Only –
Not Required/Not to be Cited**

The Occupational Safety and Health Administration (OSHA) has requirements for protecting hospital staff from radiation exposure, some of which are summarized below:

- “For information about exposure limits see: 29 CFR 1910.1096, Ionizing Radiation Standard. The standard also requires:.....
- Every employer shall supply appropriate personnel monitoring equipment, such as film badges, pocket chambers, pocket dosimeters, or film rings, and shall require the use of such equipment [29 CFR 1910.1096(d)(2)]
- Employers shall maintain records of the radiation exposure of all employees for whom personnel monitoring is required under paragraph (d) of this section and advise each employee of his individual exposure at least yearly.....

See:

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<https://www.osha.gov/SLTC/etools/hospital/clinical/radiology/radiology.html#Radiation>

As a reminder, although hospitals are required to comply with applicable OSHA requirements, surveyors conducting surveys on behalf of CMS do not interpret or assess compliance with the requirements of OSHA or other Federal Agencies.

Surveyors do assess compliance with Medicare requirements that may overlap or duplicate OSHA requirements.

19.00.06 Orders.

Radiologic services must be provided only on the order of practitioners with clinical privileges or, consistent with State law, of other practitioners authorized by the medical staff and the governing body to order the services.

§482.26(b)(4)

The medical staff and the governing body determine the necessary qualifications and clinical privileges that practitioners must have to order diagnostic radiologic studies or therapeutic procedures.

For outpatient services, the governing body and medical staff may also authorize practitioners who do not have hospital privileges to order such studies or procedures, as permitted under State law.

- For example, a hospital may decide that it will routinely accept orders from physicians in the communities it services for outpatient diagnostic studies, regardless of whether those physicians have privileges to practice in the hospital. See the guidance for §482.54(c) for more information on requirements related to outpatient orders

CHART REVIEW

1. Review medical records to determine that there is an order for all radiologic services, and that the order was dated/timed and authenticated by an authorized practitioner prior to the diagnostic study or therapeutic procedure being performed.
2. Observe whether a radiologic technologist confirms that there is an order from an authorized practitioner and reviews information included in the order before beginning a study or procedure.

- 1 = Compliant
- 2 = Not Compliant

This standard is not met as evidenced by:

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from practitioners who do not hold privileges to practice at the hospital.

The order must include information for the radiologic technologist about the study or procedure to be performed, and the technologist is expected to review this information prior to implementing the order.

<p>For Information Only – Not Required/Not to be Cited</p> <p>Hospitals are strongly encouraged, but not required, to develop standard formats for practitioner’s orders for radiologic services that clearly document the diagnostic or therapeutic purpose of the study/procedure, as well as any other pertinent information that may lead to altering the dose of radiation, including, but not limited to:</p> <ul style="list-style-type: none"> • Indication (reason) for the study/procedure • Previous imaging studies of the body part(s) under investigation; • Additional relevant radiation exposure; and • Previous adverse events (e.g., over- or underexposure of dosing, allergic reaction to contrast dye) during radiologic procedures. <p>In addition, hospitals are encouraged to adopt policies to ensure that the radiation technologist performing the study/procedure confirms the order with the ordering practitioner if there are</p>
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any concerns about its appropriateness.

19.00.07 Physicist Inspections.

A radiation physicist, or equivalent, conducts inspections to identify hazards.

Equipment is maintained in a safe manner.

Equipment is **included on** a regular preventive maintenance schedule.

At least annual equipment inspections are conducted. The findings from inspections are corrected promptly.

The procedures for compliance with regulatory agencies are to be approved at least annually by the physicist or regulatory agency authority.

The physicist is to monitor doses administered to patients; validity and quantitative results; and absorbed doses of radiation in individual patients (as requested by the director).

INTERVIEW & DOCUMENT REVIEW

Verify:

1. Reports indicating that a physicist or regulatory agency authority has inspected the facility at periods no more than twelve months apart.
2. Any hazards were corrected immediately.
3. Preventive maintenance schedules for equipment.

- 1 = Compliant
 2 = Not Compliant

This standard is not met as evidenced by:

19.00.08 Equipment Output Monitoring.

All radiation producing equipment emits radiation within acceptable limits. The output of this equipment is measured at least annually.

Records of the radiation output are maintained.

Each radiation producing equipment is monitored for the level of radiation it emits at various settings; it is to be within acceptable limits, at least annually.

DOCUMENT REVIEW & OBSERVATION

- Verify that equipment emission / output testing is documented for each piece of equipment under 19.00.07.

- 1 = Compliant
 2 = Not Compliant

This standard is not met as evidenced by:

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<p>19.00.09 <u>Approval of Policies & Procedures.</u> All radiation safety policies and procedures are approved by the radiation safety committee.</p>	<p>The radiation safety committee reviews and approves all policies within the organization relating to radiation safety at least every three (3) years.</p>	<p style="text-align: center;"><u>DOCUMENT REVIEW</u></p> <p>Verify that the policies and procedures have received approval from the radiation safety committee within the past three (3) years.</p>	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>
<p>19.00.10 <u>Personnel.</u> §482.26(c)</p>	<p>The hospital must ensure that specific radiology personnel requirements are met.</p>	<p>Score based on the results of scoring standards 19.00.11 & 19.00.13.</p>	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>
<p>19.00.11 <u>Medical Supervision.</u> <i>A qualified full-time, part-time, or consulting radiologist must supervise the ionizing radiology services and must interpret only those radiologic tests that are determined by the medical staff to require a radiologist's specialized knowledge.</i></p> <p><i>For purposes of this section, a radiologist is a doctor of medicine or osteopathy who is qualified by education and experience in radiology.</i> §482.26(c)(1)</p>	<p>The regulation defines a radiologist as a doctor of medicine (MD) or doctor of osteopathy (DO) who is qualified by education and experience in radiology.</p> <p>The medical staff must establish the specific criteria related to education and experience that must be met in order to be privileged as a radiologist in the hospital.</p> <p>IONIZING RADIOLOGIC SERVICES Ionizing radiologic services offered throughout the hospital must be under the supervision of a radiologist, who may be part-time, full-time, or consulting.</p>	<p style="text-align: center;"><u>INTERVIEW, DOCUMENT AND FILE REVIEW</u></p> <ol style="list-style-type: none"> 1. Review the medical staff privileging criteria for a radiologist. 2. Review the credentialing and privileging file of the supervising radiologist to verify that he or she meets the qualifications established by the medical staff and has been granted privileges as a radiologist. <ul style="list-style-type: none"> • If the supervising radiologist is a part-time employee or consultant, ask him/her how much time/week is spent on supervising ionizing radiologic 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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This may be accomplished in several ways, including:

- By having one organized radiologic service under the direction of the supervising radiologist, or
- By the governing body ensuring a uniform approach to ionizing radiologic services that are offered in multiple, separately organized departments of the hospital which collaborate with the supervising radiologist in developing their department-specific protocols for ensuring that these services are free from hazards for patients and personnel.

The supervising radiologist, including, if applicable, a consultant who provides such supervision, must be privileged as a radiologist at the hospital. The extent of radiologic services provided by the hospital determines whether the supervising radiologist must carry out these responsibilities full or part-time.

POLICY

For diagnostic radiologic services using ionizing radiation, policies and procedures must, in addition to the requirements addressed in other portions of the radiologic services CoP, identify which types of radiologic tests require interpretation by a radiologist, as opposed to another type of practitioner holding privileges; the hospital's medical staff must approve this policy.

services.

- Is there any evidence of problems within the radiologic services that suggest lack of supervision?
3. Determine whether the medical staff has reviewed and approved a policy identifying the types of diagnostic radiologic tests (studies) that require interpretation by a radiologist.

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TELERADIOLOGY

When interpretation of radiologic tests (studies) is provided via telemedicine, the radiologist interpreting the radiological test must be licensed and/or meet the other applicable standards that are required by State or local laws in the state where the hospital (and, therefore, the patient) is located.

The requirements concerning granting of privileges to teleradiologists are addressed in the medical staff (§482.22) and governing body (§482.12) Conditions of Participation.

The radiology director shall be:

- Knowledgeable of imaging and therapy service practices in order to lead and advise those providing and requesting services

- A member of the Professional Medical Staff who maintains regular contact with administration and participates in Medical Staff activities.

Supervision of the radiology services may only be performed by a radiologist who is a member of the medical staff. Supervision should include at least the following:

- 1) Ensuring that radiology reports are signed by the practitioner who interpreted them;

- 2) Assigning duties to radiology personnel appropriate to their level of training, experience, and licensure if applicable;

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- 3) Enforcing infection control standards;
- 4) Ensuring that emergency care is provided to patients who experience an adverse reaction to diagnostic agents in the radiology service;
- 5) Ensuring that files, scans, and other image records are kept in a secure area and are readily retrievable; and
- 6) Training radiology staff on how to operate the equipment safely, perform tests offered by the facility and on the management of emergency radiation hazards and accidents.

19.00.12 Personnel Requirements.

The qualifications, training, functions, and responsibilities of imaging and therapy personnel are specified by the service director and approved by the physician director of the service.

Professional criteria, Federal and State regulations (and licensing acts) guide the requirements for staff.

A radiologic technologist (therapist, if appropriate) is on duty, or available "on call" at all times.

INTERVIEW & FILE REVIEW

1. Determine that facility standards of practice for staff correlate to the listed guidelines.
2. Determine that a technologist / therapist is available to accomplish requested tests and needed procedures.
3. Verify through review of employee files that the qualifications, training, functions and responsibilities for each staff member are defined and reflected in the file.

- 1 = Compliant
- 2 = Not Compliant

This standard is not met as evidenced by:

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<p>19.00.13 <u>Qualified Personnel.</u> <i>Only personnel designated as qualified by the medical staff may use the radiological equipment and administer procedures.</i></p> <p>§482.26(c)(2)</p>	<p>The medical staff must develop policies, consistent with State law, that govern the designation of all personnel who are qualified to use the radiologic equipment and perform diagnostic or therapeutic studies or procedures.</p> <p>Qualifications must include appropriate training and demonstrated competence in the use of equipment and administration of procedures prior to being designated as qualified.</p> <p>Only designated individuals may use the equipment and perform studies or procedures.</p> <p>There should be written policies, developed and approved by the medical staff, consistent with State law, to designate which personnel are qualified to use the radiological equipment and administer procedures.</p> <p>The use of the radiologic equipment includes, but is not limited to, functions such as operating the equipment according to the manufacturer’s instructions and hospital policy, and interfacing with specialized technology as needed.</p> <p>In addition to a radiologist, and although not specifically mentioned in the regulations, radiologic technologists are typically involved in the delivery of radiologic services in a hospital.</p>	<p align="center"><u>INTERVIEW, FILE REVIEW, AND OBSERVATION</u></p> <ol style="list-style-type: none"> 1. Verify that the medical staff established criteria for personnel who use radiologic services equipment and perform studies or procedures. 2. Determine which staff are using which pieces of radiological equipment. Review their personnel folders to determine if they meet the qualifications established by the medical staff for the tasks they perform. 3. Verify that radiologic services staff are periodically trained and reassessed for competence to ensure that they are operating the equipment according to manufacturer instructions and hospital policy and know how to respond to adverse events related to their use of the equipment. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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Radiologic technologists are medical personnel who typically perform diagnostic imaging examinations and administer radiation therapy treatments, as permitted under State law. They are educated in anatomy, patient positioning, examination techniques, equipment protocols, radiation safety, radiation protection, and basic patient care.

All radiologic technologists using radiologic equipment or performing studies/procedures must be designated to do so. Personnel also need to know how to respond to adverse events that may occur during a radiologic study or procedure.

Hospitals are expected to regularly reassess staff competency and to provide periodic training needed to keep staff skills up-to-date.

The hospital must document training completion dates and evidence of satisfactory competence. Staff that complete training but cannot demonstrate satisfactory competence must not be permitted to use radiologic equipment and/or administer procedures.

19.00.14 Order Requirement.

Each request for imaging services shall contain the reason(s) for the examination.

The order for an imaging examination shall include the pertinent reason(s) for conducting the procedure to ensure the proper services are provided.

DOCUMENT REVIEW

- Review requests in Radiology Services Department to verify compliance; review other records as necessary.

- 1 = Compliant
 2 = Not Compliant

This standard is not met as evidenced by:

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<p>19.00.15 Record Maintenance. <i>Records of radiologic services must be maintained.</i></p> <p>(1) The radiologist or other practitioner who performs radiology services must sign reports of his or her interpretations.</p> <p>(2) The hospital must maintain the following for at least 5 years:</p> <p style="margin-left: 20px;">(i) <i>Copies of reports and printouts.</i></p> <p style="margin-left: 20px;">(ii) <i>Films, scans, and other image records, as appropriate.</i></p> <p>§482.26(d) §482.26(d)(1) §482.26(d)(2) §482.26(d)(2)(i) §482.26(d)(2)(ii)</p>	<p>The hospital must maintain records for all radiologic procedures performed. At a minimum, the records must include:</p> <ol style="list-style-type: none"> 1. The orders for the services, 2. Copies of reports and printouts, and 3. Any films, scans, digital or other image records, as appropriate. <p>Radiology films, image records, scans, digital files, reports, and printouts must be secure and properly stored for at least five years. If State law requires a longer period, the hospital must comply, but surveyors do not assess compliance with State law requirements as part of the Federal survey.</p> <p>Patient radiologic services records are considered patient medical records and the hospital must comply with the requirements of the medical records CoP (§482.24). The standards in Chapter 10, Medical Records Services also apply.</p> <p>All reports of studies must be signed by the radiologist or other authorized practitioner (in the case of studies not designated as requiring a radiologist to interpret them) who reads and evaluates the findings of the study. Acceptable forms of signature include paper signatures as well as electronic signatures.</p> <p>The hospital should have written policies and procedures that ensure the integrity of authentication and protect the privacy of radiology records.</p>	<p style="text-align: center;"><u>CHART REVIEW</u></p> <ol style="list-style-type: none"> 1. Verify that the medical record storage and security standards for all radiology reports and films comply with those defined in Chapter 10, Medical Records Services. 2. Determine whether the hospital maintains radiologic services records for at least 5 years after the study or procedure. (Assess them for compliance with the Medical Records CoP at §482.24 at the same time, but make sure to cite general medical record noncompliance under that CoP.) 3. Request records for all different imaging modalities furnished by the hospital, to determine if the procedure for maintaining the records is consistent among all the radiologic services. 4. Review radiologic records to determine that reports of studies are signed by the radiologist or other authorized practitioner (in the case of studies not designated as requiring a radiologist to interpret them) who read and evaluated the findings of the study. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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19.00.16 Not Applicable.

19.00.17 Qualified Physicians.

Interpretations of imaging / therapy procedures are performed only by a qualified individual with Medical Staff delineated clinical privileges for such.

Only individuals who have demonstrated their qualifications are granted the authority to interpret diagnostic studies or perform therapeutic procedures.

The author authenticates reports.

FILE REVIEW

Determine that individuals who interpret imaging examinations or perform therapeutic procedures have been granted delineated privileges for such.

- 1 = Compliant
 2 = Not Compliant

This standard is not met as evidenced by:

19.00.18 Contrast Media.

The organization will utilize validated protocols to evaluate patients who are at risk for contrast media-induced renal failure and utilize a clinically appropriate method for reducing risk of renal injury based on the patient's kidney function evaluation.

PATIENT SAFETY INITIATIVE

Many radiologic procedures utilize iodine-containing contrast media. Adverse events resulting from the intravenous administration of contrast dye include allergic reactions, anaphylaxis, and kidney damage.

Contrast media-induced renal failure rarely occurs in patients with normal kidney function, but patients with pre-existing renal insufficiency or other conditions (e.g., diabetic nephropathy, dehydration, congestive heart failure, or concurrent administration of nephrotoxic drugs) are at risk for renal failure when given iodine-containing contrast media.

Screening protocols have been developed to identify patients who need baseline kidney function assessment (e.g., serum creatinine testing) and risk-reduction precautions such as the use of low osmolar contrast media.

DOCUMENT REVIEW

Review organizational policies on the prevention of contrast media-induced nephropathy to validate that it defines the risk-assessment process and defines the method utilized for risk-reduction.

- 1 = Compliant
 2 = Not Compliant

This standard is not met as evidenced by:

CHART REVIEW

Review a sampling of patient records. Determine the following are available:

1. Documentation of the assessment **of risk for contrast media-induced renal failure**; and
2. Implementation of risk reduction interventions.

Requirements to meet standard compliance are as follows:

1. Explicit organizational policies and procedures should be in place regarding the prevention of contrast media-induced nephropathy.
2. Ensure that the patient undergoing IV contrast procedures is hydrated sufficiently according

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to standard protocol

Implementation approaches to be considered are as follows:

1. Check the serum creatinine level prior to scheduling a contrast study in a patient who has uncertain kidney function.
2. Use low osmolar contrast media to prevent contrast media-induced renal failure in a patient with impaired renal function.

19.00.19 Not Applicable.

19.00.20 Labeling of Radiographs.

The organization has implemented a standardized protocol to prevent the mislabeling of radiographs.

Minimally, the protocol includes:

1. Flash / marking of x-ray images with the correct patient information in the darkroom (if applicable)
2. Mark "left" or "right" on each radiographic image to prevent misinterpretation on the light box.

PATIENT SAFETY INITIATIVE

Self-explanatory.

DOCUMENT REVIEW, OBSERVATION & INTERVIEW

1. **Determine that the facility has a protocol addressing all required elements.** Review the protocol for compliance.
2. Observe the process to validate implementation.

- 1 = Compliant
 2 = Not Compliant

This standard is not met as evidenced by:

EMERGENCY SERVICES

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EMERGENCY SERVICES DEPARTMENT.

The provision of emergency services is an optional service for Medicare participation, but may be required by State law or regulation or the State’s hospital licensing requirements.

If the facility does not have an emergency department, score provision of emergency services for patients in Chapter 1, Administration **of the Organizational** Environment, Standards 01.02.01 through 01.02.04.

Chapter not applicable in this facility

20.00.00 Condition of Participation: Emergency Services.
The hospital must meet the emergency needs of patients in accordance with acceptable standards of practice.

§482.55

The hospital must meet the emergency needs of its patients in accordance with 482.12(f) even if it chooses not to provide emergency services in a dedicated emergency department.

If the hospital provides emergency services, the hospital must comply with all the requirements of this Condition of Participation and provide those services in accordance with acceptable standards of practice.

The hospital’s emergency services must be integrated into the hospital-wide QAPI program.

The facility Written Plan for the provision of care and services identifies the level of emergency services provided. This usually is patterned after Federal or State guidelines for "trauma" designations. Facilities which offer specialty services only, and very small - isolated facilities may opt to list their level of emergency service as "triage, stabilize and transport" providing only very basic levels of emergency care.

DOCUMENT REVIEW

1. Verify that the facility statements regarding scope of service identify / classify the level of emergency services to be provided.
2. Verify that the hospital’s emergency services are integrated into the hospital-wide QAPI program.
3. If this Condition is determined to be out of compliance, the standard in chapter one in regards to the provision of emergency services must also be scored out.

1 = Compliant
 2 = Not Compliant

This standard is not met as evidenced by:

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<p>20.00.01 <u>Medical Staff Leadership.</u> <i>If emergency services are provided at the hospital,</i></p> <ul style="list-style-type: none"> • <i>The services must be organized under the direction of a qualified member of the Medical Staff.</i> <p>§482.55(a); §482.55(a)(1)</p>	<p>If emergency services are provided at the hospital, the hospital must ensure that specific emergency services organization and direction requirements are met.</p> <p>The hospital's emergency services must be under the direction of a qualified member of the hospital's medical staff.</p> <p>The hospital's medical staff establishes criteria for the qualifications for the director of the hospital's emergency services in accordance with state law and acceptable standards of practice.</p> <p>A single emergency services director must be responsible for the hospital's emergency services.</p>	<p style="text-align: center;"><u>FILE REVIEW & INTERVIEW</u></p> <ol style="list-style-type: none"> 1. Verify that a single physician member of the Medical Staff has been designated as Physician Director of the Emergency Service. 2. Verify that emergency services are organized under the direction of a qualified member of the medical staff. 3. Verify the medical staff has established the qualifications for the emergency services director. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>
<p>20.00.02 <u>Integration.</u> <i>If emergency services are provided at the hospital,</i></p> <ul style="list-style-type: none"> • <i>The services must be integrated with other departments of the hospital.</i> <p>§482.55(a)(2)</p>	<p>The hospital's emergency service/department must be integrated with the other departments of the hospital such as surgical services, lab, ICU, diagnostic services, etc.</p> <p>The hospital must demonstrate that its emergency services are truly integrated into its other departments. The integration must be such that the hospital can immediately make available the full extent of its patient care resources to assess and render appropriate care for an emergency patient.</p>	<p style="text-align: center;"><u>INTERVIEW & DOCUMENT REVIEW</u></p> <ul style="list-style-type: none"> • Verify that there are established procedures to assure integration with hospital services, including laboratory, radiology, and operating services to provide continuity of care. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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Emergency Services integration would include at a minimum:

- Coordination and communication between the Emergency Department and other hospital services / departments;

- Physical access for emergency department patients to the services, equipment, personnel, and resources of other hospital departments / services;

- The immediate availability of services, equipment, personnel, and resources of other hospital departments / services to emergency patients; and

- That the provision of services, equipment, personnel and resources of other hospital departments / services to emergency department patients is within timeframes that protect the health and safety of patients and is within acceptable standards of practice, including:
 - The length of time it takes to transport the emergency patient from the ED to another hospital department where needed interventions or diagnostic services will be rendered.

 - The length of time it takes to deliver equipment or supplies, or for the staff from other departments to travel from their

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location to the emergency department in order to provide needed interventions, tests, care, or services.

Time is critical in the provision of emergency care. The hospital must be able to demonstrate how the hospital's other departments provide emergency patients the care and services needed within safe and appropriate times.

In emergency care situations, the time needed to provide the patient with appropriate diagnostic and care interventions can have a significant effect on the patient. Delays in diagnosis and the provision of needed interventions is likely to adversely affect the health and safety of patients who require emergency care. Therefore, a hospital that cannot demonstrate integration of its emergency services with its other departments (including radiological services, OR, intensive care, laboratory, etc) would not be in compliance with the Emergency Services CoP.

URGENT CARE SERVICES

Many hospitals offer urgent care services on the hospital campus or in provider-based clinics in the communities they serve. **Those clinics must be in compliance with the hospital CoP.**

Hospitals may organize their urgent care clinics as part of their outpatient department or emergency services department. An urgent care clinic that:

- The hospital holds out to the public as

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<p>20.00.03 Policies & Procedures. <i>If emergency services are provided at the hospital,</i></p> <ul style="list-style-type: none"> <i>Policies and procedures governing medical care provided in the Emergency Service are established by and are a continuing responsibility of the Medical Staff.</i> <p>§482.55(a)(3)</p>	<p>providing only urgent care services and possibly other services;</p> <ul style="list-style-type: none"> Clearly advises the public that the urgent care clinic is not an emergency services department; and Does not meet the EMTALA definition of dedicated emergency department; would be evaluated for compliance with the integration requirement in the Outpatient Services CoP (§482.54(a)) rather than the integration requirement in the Emergency Services CoP. <p>In most urgent care situations, the time, qualified personnel, equipment, and other resources needed to provide the patient with appropriate diagnostic and care interventions are less than needed in emergency situations.</p> <p>The hospital’s medical staff must establish policies and procedures governing the medical care provided in the emergency service or emergency department. The medical staff must have had ongoing / continuing assessment of the medical care provided in the emergency service or department.</p> <p>Emergency service or emergency department policies must be current and revised as necessary based on the ongoing monitoring conducted by the medical staff and the emergency service or department QAPI activities.</p>	<p><u>DOCUMENT REVIEW</u></p> <ol style="list-style-type: none"> Verify that procedures and policies for emergency medical services (including triage of patients) are established, evaluated, and updated on an ongoing basis. Verify that the Emergency Services maintains a current Manual of Policies and Procedures, which have been collaboratively developed, established, evaluated, updated, and approved by the Professional Medical Staff. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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These policies and procedures are developed in collaboration with the Nursing Staff assigned to the service. Emergency Service policies and procedures comply with Federal, State and Local laws and are reflective of current guidelines for trauma and crises practices as promulgated by emergency medical and nursing organizations.

3. **Determine the policies have been approved by the medical staff within the last three (3) years.**

20.00.04 Required Policies & Procedures.

The Emergency Services policies address, at a minimum:

1. The mechanism for initial evaluation and triage of patients. (See §489.20 and §489.24 for EMTALA Standards.)
2. The mechanisms for providing sufficient diagnostic and stabilization services for persons whose care will be managed by transfer to another acute care facility;
3. The determination of the level of service to be provided is under the direction of a physician member of the Staff;
4. The assessment of each patient by a Registered Nurse;

No patient is denied access to evaluation and care based upon inability to pay.

The majority of the required policies are straightforward. Note that item #5 may be inclusive of services which are impacted by federal, state, or local laws; that is, persons presenting with alleged/suspected abuse, neglect, violence, animal bites, industrial injury, burns, etc., which require mandated reporting and collection / preservation of evidence.

Determine that there is a mechanism for patient encounter reviews. The process includes:

1. Persons (including visitors) presenting at an area of a hospital on the hospital’s main campus other than a dedicated ED must receive a Medical Screening Exam (MSE) only if they request, or have a request made on their behalf, for examination or treatment for what may be an Emergency Medical Condition (EMC).
2. Where there is no verbal request, a request will nevertheless be considered to exist if a prudent

DOCUMENT REVIEW

1. Determine that the policies address the eight (8) **required elements**.
2. Determine that there is a policy which defines the process to evaluate and conduct a Medical Screening Examination (MSE) in non-ED main campus locations.

- 1 = Compliant
- 2 = Not Compliant

This standard is not met as evidenced by:

OBSERVATION & INTERVIEW

- Verify that there is compliance with all required policies.

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<p>5. The provision of services appropriate to the assessed needs of the patient, which results in a disposition plan;</p> <p>6. The mechanisms for evaluating the quality and appropriateness of emergency services provided;</p> <p>7. Provision of care for disasters; and</p> <p>8. The mechanism for management of medical emergencies in non-Emergency Department (ED) settings on the hospital main campus, unless present in a non-Emergency Services hospital policy.</p>	<p>layperson observer would conclude, based on the person’s appearance or behavior, that the person needs emergency examination or treatment.</p>		
<p>20.00.05 Personnel. <i>The hospital must ensure the emergency services personnel requirements are met.</i></p> <p><i>The emergency services must be supervised by a qualified member of the medical staff.</i></p> <p>§482.55(b) §482.55(b)(1)</p>	<p>A qualified member of the medical staff must supervise the provision of emergency services.</p> <p>Since §482.55(a)(1) requires that emergency services must be organized under the direction of a qualified member of the medical staff, the requirement for supervision at §482.55(b)(1) must be distinguished from the prior requirement.</p> <ul style="list-style-type: none"> In this context, “supervision” implies a more immediate form of oversight by a qualified member of the medical staff during all times the 	<p style="text-align: center;"><u>FILE REVIEW</u></p> <ol style="list-style-type: none"> Verify that a qualified member of the medical staff is physically present in the Emergency Department and available to supervise the provision of emergency services at all times the hospital offers emergency services. Verify that a qualified member of the medical staff is designated to supervise emergency services. Verify the medical staff has established 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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	<p>hospital makes emergency services available.</p> <ul style="list-style-type: none"> A supervisor may be briefly absent from the emergency department, but is expected to be in the hospital and immediately available to provide direction and/or direct care during the operating hours of the emergency department. <p>The medical staff must establish criteria, in accordance with State law, regulations, and guidelines, delineating the qualifications a medical staff member must possess in order to be granted privileges for the supervision of the provision of emergency care services.</p> <p>Qualifications include necessary education, experience and specialized training, consistent with state law and acceptable standards of practice.</p>	<p>qualifications for medical staff to be granted privileges for the supervision of emergency care services.</p>	
<p>20.00.06 Personnel: Staffing & Staff Qualifications. <i>There must be adequate medical and nursing personnel qualified in emergency care to meet the written emergency procedures and needs anticipated by the facility.</i></p> <p>§482.55(b)(2)</p>	<p>The hospital must staff the emergency department with the appropriate numbers and types of professionals and other staff who possess the skills, education, certifications, specialized training and experience in emergency care to meet the written emergency procedures and needs anticipated by the facility.</p> <p>The hospital must determine the categories and numbers of MD/DOs, specialists, RNs, EMTs and emergency department support staff the hospital needs to meet its anticipated emergency needs.</p>	<p>DOCUMENT REVIEW AND INTERVIEW</p> <ol style="list-style-type: none"> Verify that there are sufficient medical and nursing personnel qualified in the needs anticipated by the facility. There are specific duties assigned for emergency care personnel and a clear chain of command. Interview staff to determine that they are knowledgeable, within their own level of participation in emergency care including: <ul style="list-style-type: none"> Parenteral administration of electrolytes, fluids, blood and blood components. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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	<p>The medical staff must establish criteria, in accordance with State law and regulations and acceptable standards of practice delineating the qualifications required for each category of emergency services staff (e.g., emergency physicians, specialist MD/DO, RNs, EMTs, mid-level practitioners, etc.).</p> <p>As a suggested prudent practice the hospital should conduct periodic assessments of its emergency needs in order to anticipate the policies, procedures, staffing, training, and other resources that may be needed to address likely demands.</p> <p>Additionally, the hospital should work cooperatively with Federal, State, and local emergency preparedness agencies and officials in order to identify likely risks to the community (e.g., natural disasters, mass casualties, terrorist acts, etc.), to anticipate demands and resources needed by the hospital emergency services, and to develop plans, methods and coordinating networks to address those anticipated needs.</p> <p>Medical Staff policies define coverage of the service, either by call back or by coverage; this may be by physicians who are contracted. In any case, there are specific delineations for emergency practices for all staff providing care and services.</p> <p>Depending upon the case load and complexity of the service, nursing staff may be assigned to the service or</p>	<ul style="list-style-type: none"> • Care and management of injuries to extremities and central nervous system. • Prevention of contamination and cross infection. 	

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may be "on call" from another area; in any event, each patient presenting for service has his/her emergency nursing needs planned and supervised by a Registered Nurse.

20.00.07 Staff Training.

Staff providing emergency services have training and experience in providing care to the types of patients anticipated by the facility.

Staff orientation schedules and ongoing education programs are designed to enhance documented competencies appropriate to the level of participation for each provider in the foci of care which is probable for the facility.

INTERVIEW & DOCUMENT REVIEW

1. Determine that Medical and Nursing Staff have identified core competencies and mechanisms for enhancing these.
2. Determine that mechanisms have been established to evaluate ongoing competencies, such as by means of "skills" testing and/or certifications.

- 1 = Compliant
 2 = Not Compliant

This standard is not met as evidenced by:

At a minimum, staff are competent in accomplishing rapid assessment and developing intervention plans, as appropriate to the facility mission, for emergencies relating to:

Staff competencies shall relate to:

- A. Cardiac crises
- B. Obstetric / gynecologic crises
- C. Orthopedic / Neurologic crises
- D. Endocrine crises
- E. Psychiatric crises
- F. Substance abuse
- G. Childhood diseases and conditions
- H. Trauma: highway, industrial,

1. Triage
2. Parenteral administration of electrolytes, fluids, blood and blood components
3. Care and management of injuries to the extremities and the central nervous system
4. Principles of asepsis and the reduction of potential cross infections
5. Cardio-pulmonary resuscitation
6. Emotional support and intervention to persons in crises situations

FILE REVIEW

Verify through file review that staff competency validation has been **completed** and is appropriate for the scope of services and type of patients served.

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school, domestic

- I. Epidemiologic crises
- J. Pain management

20.00.08 Records.

There is a record for each patient presented for emergency services.

Specific issues to be addressed include:

- A. Onset and duration of entry complaint;
- B. Time and method of arrival;
- C. Triage status upon arrival;
- D. Treatment attempted prior to arrival;
- E. Assessment(s), problem list(s), plan(s);
- F. Testing results, and treatment rendered;
- G. Patient responses to treatment;
- H. Disposition of the case

Multidisciplinary Assessments and Plans of Care outline principles that apply to the emergency setting.

In addition to the Assessment and Medical Record’s Principles, certain characteristics are unique to the Emergency Services Record. The facility provides the necessary systems to record these data.

Emergency Services Records are copied, as appropriate, to the physician who will be providing follow-up care.

A discharge summary is required on all patient medical records, including outpatient records.

CHART REVIEW

1. Determine that the format for documenting emergency services care incorporates the principles noted in **Chapter 10, Medical Records Services** and those in this element.
2. Determine that a mechanism exists to provide legible and timely copies of Emergency Care Records to the physician providing follow-up care.

- 1 = Compliant
- 2 = Not Compliant

This standard is not met as evidenced by:

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- I. Further care needs, with plan for same; and
- J. Time and condition at discharge.

20.00.09 Emergency Room Log.

Permanent logs shall be maintained of persons seeking emergency care. These may be manual or electronic; periodically, electronic records are “backed up” to ensure the integrity of the information in the event of computer failure.

The data maintained in the Permanent Register of Emergency Care Patients provides useful data to the facility for long range planning. Additionally, the data may be utilized in determining statistical sampling for quality and utilization management studies.

DOCUMENT REVIEW

1. Determine that a permanent register of emergency registrants exists and that all parameters are included.
2. If the register is electronic, determine that the information is periodically backed up so as to preserve the integrity of the register from computer failure.

- 1 = Compliant
- 2 = Not Compliant

This standard is not met as evidenced by:

The register provides data regarding:

- A. Date, time, and mode of arrival
- B. Age, sex, and name of patient
- C. Nature of complaint
- D. Name of physician responsible for care
- E. Brief description of services provided
- F. Disposition (treated / released, admitted to facility, transferred to another acute facility, or death in ER)

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G. Condition on discharge

H. Time of discharge

20.00.10 Change in Treatment Plan Log.

A separate log shall be maintained as part of the quality management program for the emergency service.

The log provides information about patients whose initial treatment plan later required modification based upon significant variation in the final interpretation of radiographic, cardiographic or laboratory findings.

Maintenance of the Treatment Log is the responsibility of the physician director with the assistance of the emergency nurse manager.

This log may be sequestered in the service area if such is requested by the facility Risk Manager.

DOCUMENT REVIEW

Review the Treatment Log.

Determine:

- The three required recall situations (radiographic, cardiographic, and laboratory findings) are actively maintained with outcomes of such recalls noted (contact made / not made.)

- 1 = Compliant
- 2 = Not Compliant

This standard is not met as evidenced by:

ENDOSCOPIC SERVICES

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THIS CHAPTER HAS BEEN RETIRED

REFER TO CHAPTER 18

LABORATORY SERVICES

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<p><u>Laboratory Services.</u> Each laboratory within a hospital and each lab service location or reference laboratory used by a hospital shall be certified under the 42 CFR §493 Clinical Laboratory Improvement Amendments (CLIA).</p> <p>The requirements listed below relate to the Medicare Conditions of Participation for Hospitals. They do not represent a full survey of Laboratory Services.</p> <p>22.00.00 Condition of Participation: <u>Laboratory Services - Scope of Services.</u> <i>The hospital must maintain, or have available, adequate laboratory services to meet the needs of its patients.</i></p> <p><i>The hospital must ensure that all laboratory services provided to its patient are performed in a facility certified in accordance with part §493 of 42 CFR 493.</i></p> <p>§482.27</p>	<p>See the description of HFAP accreditation program for clinical laboratories under CLIA located at the end of this chapter.</p> <p>The hospital must maintain or have available laboratory services whenever its patients need those services.</p> <p>The hospital may make laboratory services available directly, through contractual agreements, or through a combination of direct and contractual services. The scope and complexity of the hospital laboratory service must be adequate to meet the needs of its patients.</p> <p>The hospital must maintain, or have available, adequate laboratory services to meet the needs of its patients at each campus or off-campus location of the hospital. All laboratory services, whether direct or contractual, whether conducted in a lab or in another location, must be provided in accordance with Clinical Laboratory Improvement Act (CLIA) requirements.</p>	<p style="text-align: center;"><u>DOCUMENT REVIEW</u></p> <ul style="list-style-type: none"> • Determine the total number of laboratories, the location of each laboratory, and every location where laboratory procedures are performed. • Verify that the laboratory service and all laboratory locations are integrated into the hospital-wide QAPI program. • If laboratory services are contracted, verify that the review of the quality of those services is integrated into the hospital-wide QAPI Program. 	<p style="text-align: center;"> <input type="checkbox"/> 1= Compliant <input type="checkbox"/> 2= Not Compliant </p> <p>This standard is not met as evidenced by:</p>

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Every hospital laboratory service must be operating under a current CLIA certificate appropriate to the level of services performed.

The hospital’s laboratory services, including any contracted services, must be integrated into its hospital-wide QAPI program.

Patient laboratory results and all other laboratory clinical patient records are considered patient medical records and the hospital must comply with the requirements of the Medical Records CoP.

22.00.01 Accreditation / Certification of Laboratory Services.

The hospital must have laboratory services available, either directly or through a contractual agreement with a certified laboratory that meets requirements of Part 493 of 42 CFR §493 (CLIA).

§482.27(a)

Laboratory testing including Point of Care (POC) may be performed in the main laboratory, ancillary laboratories throughout the facility, or in areas such as respiratory therapy, cardiopulmonary, emergency room, intensive care units, and nursing units.

The CLIA certification may be accomplished by having one certificate for the entire hospital’s laboratory services, by having one certificate for each laboratory, or by the hospital having a mixture. Whatever the arrangement, all laboratory services must be provided in accordance with CLIA requirements and under a current CLIA certificate, even when those laboratory services take place outside of a lab.

INTERVIEW & OBSERVATION

Request evidence that each clinical area performing testing within the hospital, or reference laboratory used by the hospital, has been accredited / certified under 42 CFR §493 (CLIA).

A CLIA certificate and proof of accreditation should evidence this.

1. Determine which services are provided directly by the facility and which are provided through contractual agreements.
2. Determine if the referral laboratory is CLIA certified for the appropriate test specialty.

- 1= Compliant
- 2= Not Compliant

This standard is not met as evidenced by:

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22.00.02 Emergency Service Availability.

Emergency laboratory services must be available 24 hours a day

§482.27(a)(1)

The hospital must provide emergency laboratory services 24 hours a day, 7 days a week.

These onsite emergency services may be provided directly by the hospital or through onsite contracted laboratory services. Emergency lab services include collection, processing, and provision of results to meet a patient's emergency laboratory needs.

MULTIPLE HOSPITAL CAMPUSES

In a hospital with multiple hospital campuses, these emergency laboratory services must be available onsite 24/7 at each campus.

The medical staff must determine which laboratory services are to be immediately available to meet the emergency laboratory needs of patients who may be currently at the hospital or those patients who may arrive at the hospital in an emergency condition. The emergency laboratory services (procedures, tests,

3. If the hospital provides laboratory services in multiple locations, verify that all laboratory services are operating under a current CLIA certificate.
4. Examine records and determine if the services, including emergency services, are provided in accordance with the hospital's policies.

DOCUMENT REVIEW AND INTERVIEW

Determine the hours of availability for laboratory services.

1. Verify that emergency laboratory services are available onsite 24/7.
2. Is the scope of services available consistent with needs defined by the medical staff?
3. Verify that the scope of required emergency testing onsite has been defined by the medical staff.
4. Review the written description of the emergency laboratory services. Review records (including accession records, worksheets, and test reports) to verify the 24-hour availability of emergency services and that those services are provided when required.

- 1= Compliant
- 2= Not Compliant

This standard is not met as evidenced by:

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personnel) available should reflect the scope and complexity of the hospital's operation and be provided in accordance with Federal and State law, regulations and guidelines and acceptable standards of practice.

OFF-CAMPUS LOCATIONS

At a hospital with off-campus locations the medical staff must determine which, if any, laboratory services must be immediately available to meet the emergency laboratory needs of the patients who are likely to seek care at each off-campus location.

The emergency laboratory services available must reflect the scope and complexity of the hospital's operations at the location and be provided in accordance with Federal and State law, regulations and guidelines and acceptable standards of practice.

The services must be available during the hours of operation of that location.

22.00.03 Laboratory Services Description.

A written description of services provided must be available to the medical staff and other staff as appropriate.

§482.27(a)(2)

The written description of available laboratory services is reviewed and approved by the medical staff at least every three (3) years and more often, as necessary.

INTERVIEW & OBSERVATION

1. **Verify the existence of a written** description of 1= Compliant 2= Not Compliant
the laboratory services provided, including those furnished on routine and stat basis (either directly or under an arrangement with an **arrangement with an** outside facility).
2. Verify that the description of services is accurate and current.

This standard is not met as evidenced by:

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3. The description should include turnaround time for test results and inclusion into the medical record. Availability of results must be timely and complete to provide accurate information to all practitioners providing care.
4. Verify that the written description is available to medical staff and unit based staff.

22.00.04 Tissue Specimens.

The laboratory must make provision for proper receipt and reporting of tissue specimens.

§482.27(a)(3)

The laboratory must have written instructions for the collection, preservation, transportation, receipt, and reporting of tissue specimen results.

INTERVIEW & DOCUMENT REVIEW
Review tissue records (accession records, worksheets, and test reports) to determine whether the laboratory follows the written protocol.

- 1= Compliant
 2= Not Compliant

This standard is not met as evidenced by:

22.00.05 Required Tissue Examination.

The medical staff and a pathologist must determine which tissue specimens require a macroscopic (gross) examination and which require both macroscopic and microscopic examinations.

§482.27(a)(4)

Laboratory written policies, approved by the medical staff and a pathologist, must state:

- 1) which tissue specimens require a macroscopic examination, and
- 2) which tissue specimens require both macroscopic and microscopic examination.

DOCUMENT REVIEW

1. Verify that the hospital has a written policy for examination requirements.
2. Review the written policies and tissue reports to assure that tissue specimens are examined in accordance with the written policies.
3. Verify that the policies are in accordance with these requirements and other Federal and State laws, regulations, and guidelines.

- 1= Compliant
 2= Not Compliant

This standard is not met as evidenced by:

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<p>22.01.01 Potentially Infectious Blood and Blood Components.</p> <p>(1) Potentially human immunodeficiency virus (HIV) infectious blood and blood components. <i>Potentially HIV infectious blood and blood components are prior collections from a donor –</i></p> <p>(i) <i>Who tested negative at the time of donation but tests reactive for evidence of HIV infection on a later donation;</i></p> <p>(ii) <i>Who tests positive on the supplemental (additional, follow-up testing required by FDA; and</i></p> <p>(iii) <i>For whom the timing of seroconversion cannot be precisely estimated.</i></p> <p>(2) Potentially hepatitis C virus (HCV) infectious blood and blood components. <i>Potentially HCV infectious blood and blood components are the blood and blood components identified in 21 CFR §610.47.</i></p> <p>(3) Services furnished by an outside</p>	<p>This regulation requires the hospital to have a system in place to take appropriate action when notified that blood or blood components it received are at increased risk of transmitting HIV or HCV.</p>	<p>DOCUMENT REVIEW</p> <ol style="list-style-type: none"> Review the policy reflecting the process for handling HIV or HCV blood components. <ul style="list-style-type: none"> Determine the policy contains all of the required content. Review the documentation following notification of an infectious unit. Was the policy followed? 	<p><input type="checkbox"/> 1= Compliant <input type="checkbox"/> 2= Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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blood collecting establishment.

If a hospital regularly uses the services of an outside blood collecting establishment, it must have an agreement with the blood collecting establishment that governs the procurement, transfer, and availability of blood and blood components.

The agreement must require that the blood collecting establishment notify the hospital –

- (i) Within 3 calendar days if the blood collecting establishment supplied blood and blood components collected from a donor who tested negative at the time of donation but tests reactive for evidence of HIV or HCV infection on a later donation or who is determined to be at increased risk for transmitting HIV or HCV infection;*
- (ii) Within 45 days of the test, of the results of the supplemental (additional, more specific) test for HIV or HCV, as relevant, or other follow-up testing required*

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by FDA;

(iii) *Within 3 calendar days after the blood collecting establishment supplied blood and blood components collected from an infectious donor, whenever records are available, as set forth at 21 CFR §610.48(b)(3).*

(4) Quarantine of blood and blood components pending completion of testing.

If the blood collecting establishment (either internal or under an agreement) notifies the hospital of the reactive HIV or HCV screening test results, the hospital must determine the disposition of the blood or blood component and quarantine all blood and blood components from previous donations in inventory.

(i) *If the blood collecting establishment notifies the hospital that the result of the supplemental (additional, more specific) test or other follow-up testing required by FDA is negative, absent other*

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informative test results, the hospital may release the blood and blood components from quarantine.

- (ii) *If the blood collecting establishment notifies the hospital that the result of the supplemental (additional, more specific) test or other follow-up testing required by FDA is positive, the hospital must –*
 - (A) *Dispose of the blood and blood components; and*
 - (B) *Notify the transfusion recipients as set forth in paragraph (b)(6) of **42 CFR 482.27**.*
- (iii) *If the blood collecting establishment notifies the hospital that the result of the supplemental (additional, more specific) test or other follow-up testing required by FDA is indeterminate, the hospital must destroy or label prior collections of blood or blood components held in quarantine as set forth at 21*

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CFR §610.46(b)(2),
 §610.47(b)(2), and
 §610.48(c)(2)

(5) **Recordkeeping by the hospital.** *The hospital must maintain –*

(i) *Records of the source and disposition of all units of blood and blood components for at least 10 years from the date of disposition in a manner that permits prompt retrieval; and*

(ii) *A fully funded plan to transfer these records to another hospital or other entity if such hospital ceases operation for any reason.*

(6) **Patient notification.**

If the hospital has administered potentially HIV or HCV infectious blood or blood components (either directly through its own blood collecting establishment or under an agreement) or released such blood or blood components to another entity or appropriate individual, the hospital must take the following actions:

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(i) *Make reasonable attempts to notify the patient, or to notify the attending physician, or the physician who ordered the blood or blood component and ask the physician to notify the patient, or other individual as permitted under paragraph (b)(10) of this section, that potentially HIV or HCV infectious blood or blood components were transfused to the patient and that there may be a need for HIV or HCV testing and counseling.*

(ii) *If the physician is unavailable or declines to make the notification, make reasonable attempts to give this notification to the patient, legal guardian or relative.*

(iii) *Document in the patient’s medical record the notification or attempts to give the required notification.*

(7) Time frame for notification.

(i) For donors tested on or after February 20, 2008.

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For notifications resulting from donors tested on or after February 20, 2008 as set forth at 21 CFR §610.46 and 21 CFR §610.47 the notification effort begins when the blood collecting establishment notifies the hospital that it received potentially HIV or HCV infectious blood and blood components. The hospital must make reasonable attempts to give notification over a period of 12 weeks unless—

(A) The patient is located and notified; or

(B) The hospital is unable to locate the patient and documents in the patient’s medical record the extenuating circumstances beyond the hospital’s control that caused the notification timeframe to exceed 12 weeks.

(ii) For donors tested before February 20, 2008.

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For notifications from donors tested before February 20, 2008 as set forth at 21 CFR §610.48(b) and (c), the notification effort begins when the blood collecting establishment notifies the hospital that it received potentially HCV infectious blood and blood components.

The hospital must make reasonable attempts to give notification and must complete the actions within 1 year of the date on which the hospital received notification from the outside blood collecting establishment.

(8) Content of notification.

The notification must include the following information:

- (i) A basic explanation of the need for HIV or HCV testing and counseling.*
- (ii) Enough oral or written information so that an informed decision can be made about whether to obtain*

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HIV or HCV testing and counseling.

(iii) A list of programs or places where the person can obtain HIV or HCV testing and counseling, including any requirements or restrictions the program may impose.

(9) Policies and procedures.

The hospital must establish policies and procedures for notification and documentation that conform to Federal, State, and local laws, including requirements for the confidentiality of medical records and other patient information.

(10) Notification to legal representative or relative.

If the patient has been adjudged incompetent by a State court, the physician or hospital must notify a legal representative designated in accordance with State law.

If the patient is competent, but State law permits a legal representative or relative to receive the information on the patient's

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behalf, the physician or hospital must notify the patient or his or her legal representative or relative.

For possible HIV infectious transfusion recipients that are deceased, the physician or hospital must inform the deceased patient’s legal representative or relative. If the patient is a minor, the parents or legal guardian must be notified.

(11) Applicability.

HCV notification requirements resulting from donors tested before February 20, 2008, as set forth at 21 CFR §610.48 will expire on August 24, 2015.

§482.27(b)

22.01.02 Exposure Resulting in HIV Conversion.

In any event of HIV conversion, the hospital will notify the appropriate public health officials.

Hospital policy outlines the procedure for notifying public health officials.

DOCUMENT REVIEW

Look for written policies. If such an incident occurred look for compliance with policies.

- 1= Compliant
- 2= Not Compliant

This standard is not met as evidenced by:

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<p>22.01.03 General Blood Safety Issues. <i>For look-back activities only related to new blood safety issues that are identified after August 24, 2007, hospitals must comply with FDA regulations as they pertain to blood safety issues in the following areas:</i> (1) <i>Appropriate testing and quarantining of infectious blood and blood components.</i> (2) <i>Notification and counseling of recipients that may have received infectious blood and blood components.</i></p> <p>§482.27(c)(1) §482.27(c)(2)</p>	<p><u>LOOK-BACK REQUIREMENTS</u> The hospital must establish, maintain, and follow an appropriate system for the following actions:</p> <ol style="list-style-type: none"> 1. You must quarantine all previously collected in-date blood and blood components that has tested reactive for evidence of HIV/HCV infection, except for pooled blood components intended solely for further manufacturing into products that are manufactured using validated clearance procedures, when notified by the collecting establishment. 2. You must release from quarantine, destroy, or relabel quarantined in-date blood and blood components consistent with the results of the supplemental (additional, more specific) test performed, or the results of the reactive screening test if there is no available supplemental test that is approved by the FDA, or if an IND or IDE, is exempted for such use by the FDA. 3. When the supplemental test for HIV/HCV is positive or when the screening test is reactive and there is no available supplemental test that is approved by FDA, or if under an IND or IDE is exempted for such use by FDA, you must notify transfusion recipients of previous collections of blood and blood components at increased risk of transmitting HIV/HCV infection, or the recipient’s physician of record or a legal representative or relative if the recipient is a minor, deceased, 	<p><u>DOCUMENT REVIEW</u></p> <ol style="list-style-type: none"> 1. Review the facilities policies and procedures to determine an appropriate system for look-back requirements is in place. 2. Verify the policy is followed. (Reference CFR §610.46 AND CFR §610.47) 	<p><input type="checkbox"/> 1= Compliant <input type="checkbox"/> 2= Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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adjudged incompetent by a state court, or, if the recipient is competent but state law permits a legal representative or relative to receive information on behalf of the recipient. You must make reasonable attempts to perform the notification within 12 weeks after receiving the supplemental test results for evidence of HIV/HCV infection from the collecting establishment, or after receiving the donor’s reactive screening test result for HIV/HCV.

22.02.01 Point of Care Testing.

When the facility performs blood gases or other laboratory tests in the respiratory care unit or any other unit in the facility they shall meet the applicable requirements for the general laboratory services.

Other laboratory tests include any Point of Care (POC) test performed in any nursing or ancillary department.

INTERVIEW, OBSERVATION, & DOCUMENT REVIEW

1. Determine if the respiratory unit or other units in the facility are under the policies and review of the general laboratory manager or an individual designated by the medical director listed on the applicable CLIA certificate.
2. Verify that all laboratory testing done outside the lab is overseen by the lab, and meets all requirements for competency testing, quality control, and monitoring.

- 1= Compliant
 2= Not Compliant

This standard is not met as evidenced by:

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<p>23.00.00 Condition of Participation: Nuclear Medicine Services. <i>If the hospital provides nuclear medicine services, those services must meet the needs of the patients in accordance with acceptable standards of practice.</i></p> <p>§482.53</p>	<p>This is an optional hospital service.</p> <p>However, if a hospital provides any degree of nuclear medicine services to its patients, it must comply with the requirements of this Condition of Participation.</p> <p>If nuclear medicine services are provided under arrangement, the governing body must ensure that the services are provided in a safe and effective manner, in accordance with §482.12(e).</p> <p>Nuclear medicine services must be provided in accordance with acceptable standards of practice.</p> <p>Acceptable standards of practice include maintaining compliance with applicable Federal and State laws, regulations and guidelines governing the use of nuclear medicine, including facility licensure and/or certification requirements, as well as any standards and recommendations promoted by nationally recognized professional organizations (e.g., the American Medical Association, American College of Radiology, etc.).</p> <p>The hospital’s nuclear medicine services must be integrated into its hospital-wide QAPI program.</p> <p><u>WHAT IS NUCLEAR MEDICINE AND WHAT IS IT USED FOR?</u> Nuclear medicine uses radioactive material to</p>	<p style="text-align: center;"><u>DOCUMENT REVIEW, INTERVIEW & OBSERVATION</u></p> <p>Determine if the hospital provides nuclear medicine services. If nuclear medicine services are offered, determine the type(s) of services provided and the location where each service is provided.</p> <ol style="list-style-type: none"> 1. Determine that appropriate equipment and types and numbers of qualified personnel are provided to furnish services consistent with the scope and accepted standards of practice. 2. Determine the organization has the required policies, procedures, documents, and practices to minimize hazards to patients and personnel. 3. Determine the organization has conducted inspections and testing, as required. 4. Determine that the hospital’s nuclear medicine services are integrated into the hospital-wide QAPI program. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant <input type="checkbox"/> NA =Chapter Not Applicable in this facility</p> <p>This standard is not met as evidenced by:</p>

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diagnose or treat a variety of diseases and conditions.

DIAGNOSTIC NUCLEAR MEDICINE

When a diagnostic nuclear medicine study is performed, a patient inhales, swallows, or is injected with a small amount of a radiopharmaceutical that accumulates in a specific organ or area of the body. A radiopharmaceutical is a drug that contains a radioactive component. The energy emitted by the radioactive material is detected by a device, processed and measured by a computer, and then displayed as an image on a screen or on film that is then interpreted by a radiologist specially trained in nuclear medicine or another type of physician with specialized training as a nuclear medicine physician. The image(s) provide details on both the structure and function of organs and tissues.

For some studies, nuclear medicine techniques can be combined with other medical imaging devices, such as CT scans or MRIs, in which the same machine can deliver, detect, and process several types of images at the same time. The technique of combining various imaging modalities is called hybrid imaging. Hybrid imaging can provide more precise information and accurate diagnoses and is predominantly used in the diagnosis and treatment of cancer.

Nuclear medicine diagnostic imaging scans are commonly performed to:

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- Visualize heart blood flow and function, e.g., a cardiac stress test or myocardial perfusion scan; this is the most frequent use of nuclear medicine diagnostic imaging.
- Diagnose blood clots in the lungs (pulmonary emboli) with a ventilation/perfusion (V/Q) scan;
- Identify areas of infection, inflammation, or cancer metastases with a bone scan;
- Localize lymph nodes prior to surgery;
- Determine gastrointestinal tract muscle function by measuring time for swallowing and emptying;
- Determine the functioning and perfusion of many other organs, including the thyroid gland, kidneys, brain, and gall bladder

THERAPEUTIC NUCLEAR MEDICINE

Nuclear medicine can also be used to treat various diseases and conditions. For these types of procedures, a specific radiopharmaceutical agent is used to deliver a specific amount of radioactivity to a targeted cell type or organ. The energy emitted by the radioactive agent incapacitates or kills the diseased cells of that targeted tissue, and thus limits the exposure of healthy tissue to radioactivity.

Examples of therapies that use nuclear medicine include (but are not limited to):

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- Radioactive iodine to treat hyperthyroidism (Graves' disease);
- Radioactive antibodies that target specific forms of lymphoma;
- Radioactive agents to relieve pain in areas of bony metastases.

The manner or degree of noncompliance with the requirements of this Condition and its component standards must be evaluated to determine whether there is substantial noncompliance with the Condition, warranting a Condition-level citation.

However, the regulatory language concerning provision of nuclear medicine services in a manner that meets the needs of the patients in accordance with acceptable standards of practice appears only in the condition "stem" statement of this CoP. This does not mean, however, that deficiencies related to these requirements must automatically be cited at the condition level.

To facilitate, when appropriate, citation of deficiencies associated with these requirements at the appropriate level, Tag A-1025 must be used for condition-level citations, while Tag A-1026 must be used for standard-level citations related to the stem statement language.

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<p>23.00.01 Organization & Staffing. <i>The organization of the nuclear medicine service must be appropriate to the scope and complexity of the services offered.</i></p> <p>(1) There must be a director who is a doctor of medicine or osteopathy qualified in nuclear medicine.</p> <p>(2) The qualifications, training, functions and responsibilities of the nuclear medicine personnel must be specified by the service director and approved by the medical staff.</p> <p>§482.53(a) §482.53(a)(1) §482.53(a)(2)</p>	<p>The hospital must provide the appropriate equipment and types and numbers of qualified personnel necessary to furnish the services offered by the hospital in accordance with acceptable standards of practice.</p> <p>The scope of nuclear medicine services offered by the hospital should be defined in writing, and approved by the Medical staff.</p> <p>The scope of nuclear medicine services offered by the hospital, including which types of diagnostic studies and/or therapeutic procedures are provided, where they are provided in the hospital, and the appropriately-trained staff and equipment needed to provide these services must be specified in writing.</p> <p>Hospitals may choose to provide nuclear medicine services in one location or at several different locations in the hospital, including, but not limited to, inpatient and outpatient locations of the radiology, cardiology, and oncology departments. The organization of the nuclear medicine service must encompass the full scope and complexity of nuclear services offered throughout the hospital.</p> <p>MEDICAL DIRECTOR for NUCLEAR MEDICINE The hospital is required to have a director responsible for nuclear medicine services offered throughout the hospital.</p>	<p><u>DOCUMENT REVIEW, INTERVIEW, AND OBSERVATION</u></p> <p>Review the hospital policies and procedures.</p> <ol style="list-style-type: none"> Determine whether the scope of the nuclear medicine services offered is specified in writing. Determine whether there are nuclear medicine policies developed by the director of nuclear medicine governing provision of these services in every part of the hospital offering nuclear medicine services. Determine the organization has a Medical Director of the Nuclear Medicine department. Verify that the hospital has a written description of the qualifications of the nuclear medicine services director. Review the service director’s file to verify that he/she is a MD or DO and has the necessary education, experience and specialized training in nuclear medicine, per the hospital’s written policies. Verify that the qualifications, training, functions and responsibilities of the various categories of nuclear medicine staff the hospital uses are specified by the director and approved by the medical staff. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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	<p>The director must be a doctor of medicine (MD) or osteopathy (DO) and must demonstrate through education, experience and specialized training that he/she is qualified in nuclear medicine. Nuclear medicine physicians utilize radioactive materials to diagnose and treat disease either by interpreting the images created by radioisotopes or by prescribing and evaluating therapeutic interventions involving radiopharmaceuticals.</p> <p>Typically these MDs/DOs initially specialize in radiology or internal medicine and then complete subspecialty training in nuclear medicine.</p> <p>The hospital must describe in writing the qualifications it requires for the director of nuclear medicine services.</p> <p><u>OTHER NUCLEAR MEDICINE PERSONNEL</u> Although not mentioned specifically in the regulation, there are several different categories of personnel that may typically be involved in the provision of nuclear medicine services, including (but not limited to):</p> <ul style="list-style-type: none"> • Nuclear medicine pharmacists: these individuals are pharmacists who specialize in preparing, dispensing, and distributing radiopharmaceuticals; • Nuclear medicine technologists: these individuals are trained to administer radioactive 	<p>7. Review personnel files for a sample of nuclear medicine staff to determine if they meet the prescribed qualifications and have received ongoing training as required in the hospital's policies and procedures.</p>	

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materials and perform the specific imaging procedures and often process the images for interpretation; and

- Nuclear medicine physicists.

The hospital must specify in writing the qualifications, training, functions and responsibilities of each category of personnel used by the hospital, whether personnel are employees or contractors, in the delivery of nuclear medicine services.

The written specifications must be developed by the Director and approved by the hospital's medical staff.

Qualifications include at a minimum, job title, education, experience, specialized training, and licensure/certification, consistent with any applicable Federal and State law.

The specifications must also address ongoing training for personnel.

23.00.02 Not Applicable.

23.00.03 Not Applicable.

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<p>23.00.04 Delivery of Service. <i>Radioactive materials must be prepared, labeled, used, transported, stored, and disposed of in accordance with acceptable standards of practice.</i></p> <p><i>There is proper storage and disposal of radioactive material.</i></p> <p>§482.53(b) §482.53(b)(2)</p>	<p>The hospital must establish, in writing, and implement policies and procedures addressing the use of radioactive materials within the hospital.</p> <p>The policies and procedures must be based on acceptable standards of practice for the medical use of radioactive materials and must address, at a minimum:</p> <ol style="list-style-type: none"> 1. Security of radioactive materials at every stage and location of their use within the hospital, including determining who may have access to them, implementing procedures to control access, and a system to track the receipt, usage and disposal of all radioactive materials; 2. Safe storage of radioactive materials, including radioactive waste awaiting disposal outside the hospital; 3. Clear, recognizable labeling of radioactive materials, waste, and hazardous areas in all locations of the hospital, including during the preparation of such materials, if applicable; 4. Safe and secure transport of radioactive materials between locations within the hospital; 5. Safe handling with the appropriate personal and container protections, as applicable, by personnel who prepare and administer radiopharmaceuticals within the hospital; 	<p><u>DOCUMENT REVIEW, OBSERVATION, & INTERVIEW</u></p> <ol style="list-style-type: none"> 1. Verify through observation and document review that radioactive materials are prepared, labeled, used, transported, stored, and disposed of in accordance with hospital policies that are based on acceptable standards of practice. <ul style="list-style-type: none"> • Verify that radioactive materials, including radioactive waste, have appropriate storage and disposal. 2. Ask the hospital to demonstrate how it limits access to radioactive materials at all times. 3. Verify that the hospital maintains accurate records of the receipt, distribution, and disposal of radioactive materials, including radiopharmaceuticals. 4. If the hospital prepares radiopharmaceuticals on site, observe the preparation to verify that proper safety precautions are utilized to protect staff from excess radiation and once prepared, stored in appropriate containers. If the radiopharmaceuticals are obtained from an outside source, verify that the receipt and storage are appropriately tracked. 5. Verify that a clear, recognizable label for 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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	<p>6. Protection of patients from radiation hazards, including screening for high-risk patients (for example, possible pregnancy, multiple nuclear medicine studies, children, etc.);</p> <p>7. Maintenance and proper use of personal radiation monitoring devices (dosimeters) for staff working in the vicinity of radiopharmaceuticals, according to manufacturer’s instructions, particularly regarding the appropriate placement of the dosimeter on the body, as indicated on the dosimeter;</p> <p>8. Safe and secure disposal of radioactive waste, including unused but unneeded radioactive materials as well as, when extra precautions are applicable, human waste products.</p>	<p>nuclear material is appropriately displayed in all relevant areas throughout the hospital and on all radioactive materials.</p> <p>6. Verify that safety precautions are followed in the operations of the nuclear medicine service and that personnel and patients maintain and wear appropriate body shielding (e.g., lead aprons, lead gloves, thyroid shields) when appropriate.</p> <p>7. Observe a staff member deliver a nuclear medicine procedure to a patient, paying particular attention to adherence to hospital safety protocols during the delivery of the radiopharmaceutical.</p> <p>8. Through interview and observation, determine if staff use their dosimeters according to manufacturer’s instructions, particularly in the appropriate placement of the dosimeter on the body, as indicated on the dosimeter.</p> <p>9. Ask the responsible staff to demonstrate how they ensure safe transport of radioactive materials in the hospital.</p> <p>10. Interview the responsible staff to determine whether the appropriate container protection devices—e.g., lead for gamma emitters—are being utilized for storage and</p>	

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23.00.05 In-House Preparation of Radiopharmaceuticals.

In-house preparation of radio pharmaceuticals is by, or under the supervision of, an appropriately trained registered pharmacist or doctor of medicine or osteopathic medicine.

§482.53(b)(1)

If the hospital prepares radio pharmaceuticals **in-house, such preparation** must be performed by, or supervised by, a registered pharmacist or MD/DO who is qualified through education, experience and training, in the preparation of radio pharmaceuticals, consistent with Federal and State law.

This allows other appropriately trained hospital staff to prepare in-house radiopharmaceuticals under the oversight of a registered pharmacist or doctor of medicine or doctor of medicine. **This means it is no longer required that a supervising physician or pharmacist must be present when radio-pharmaceuticals are being prepared. It is no longer**

administration of radioactive materials.

11. Ask staff to show the policy for disposal methods for radioactive waste or unused material and to explain how they ensure that these procedures are followed.
12. Determine how the hospital disposes of unneeded radio nuclides and radio pharmaceuticals.
 - Are these methods in accordance with Federal and State laws, regulations and guidelines?
 - Are the methods described in hospital policy?

DOCUMENT REVIEW & OBSERVATION

1. If radio pharmaceuticals are prepared in-house, determine that the preparation is performed by, or supervised by, a registered pharmacist or MD/DO who is qualified through education, experience and training, consistent with Federal and State law.
2. **Determine that the facility policies address the identification, qualification, and training of professionals eligible to:**
 - Prepare radiopharmaceuticals and
 - Provide supervision of nuclear medicine personnel and the in-house preparation

- 1 = Compliant
- 2 = Not Compliant

This standard is not met as evidenced by:

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	<p>required to have the physical presence in the hospital at all times by one of these professionals, particularly during off-hours when such a professional would not be routinely present.</p> <p>POLICIES AND PROCEDURES</p> <ol style="list-style-type: none"> 1. Hospitals must establish policies and procedures for in-house preparation of radiopharmaceuticals, including by nuclear medicine technologists under supervision. 2. The policies and procedures must identify the qualifications, roles and responsibilities of staff preparing radiopharmaceuticals under supervision. 3. Hospitals are expected to develop policies and procedures with respect to supervision of nuclear medicine technologists and the in-house preparation of radiopharmaceuticals. 4. CMS anticipates that most hospitals will follow the supervision recommendations of the Society of Nuclear Medicine and Molecular Imaging, but there is no mandate that every hospital does so. (79 FR 27120, May 12, 2014) <p>Recommendations are available at: http://www.snmmi.org/files/docs/NMT%20SOP%20Clinical%20Performance%20Standards%20June%202013.pdf</p> <p>If a hospital is not following this guidance, then it must be able to explain the basis for the</p>	<p>of pharmaceuticals.</p> <ol style="list-style-type: none"> 3. Determine that the facility has adopted evidence-based guidelines regarding the in-house preparation of radiopharmaceuticals. 4. Review personnel records of pharmacists, MDs/DOs and nuclear medicine personnel involved in the preparation and supervision of radio pharmaceuticals to verify they have required qualifications per State law and hospital policy. 5. Verify the hospital has policies regarding the supervision of nuclear medicine personnel and the in-house preparation of radio pharmaceuticals. 6. Ask the supervising pharmacist or MD/DO how technicians who prepare radio pharmaceuticals are supervised. Are the supervision policies based on the 12 recommendations of the Society of Nuclear Medicine and Molecular Imaging? If not, what is the basis for the supervision policies? <ul style="list-style-type: none"> • Ask what policies/procedures the hospital uses to assure proper preparation. • Ask what guidelines the hospital relies upon for radio pharmaceutical preparation. 	

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supervision policies and procedures it has developed.

- 5. Policies are reviewed and approved by the medical staff at least every three (3) years.

COMPETENCIES

The hospital must ensure that all staff who are involved in the preparation and/or supervision of radiopharmaceuticals are trained and demonstrate competencies in accordance with acceptable standards of practice.

23.00.06 Not Applicable.

23.00.07 Shielding Requirements.

Adequate shielding will be provided to protect patients, personnel, and the facility from radiation exposure.

Appropriate devices are readily available and used to reduce the potential of radiation overexposure for patients, staff, equipment, and building. There is suitable shielding in areas where patients and staff could be exposed to radiation.

Proper storage containers and/or handling procedures are used for radioactive materials and waste.

Precautions are taken to protect patients who may be pregnant. (The facility determines what ages are vulnerable.)

DOCUMENT REVIEW AND OBSERVATION

Verify:

1. Policies and procedures are in place regarding shielding and other safety devices.
2. Criteria have been developed for determining persons who are vulnerable to pregnancy.
3. Aprons and other shields are checked at least annually for cracks or more frequently if mandated by state law.
4. Verify that protective devices are readily available and used by the staff.

- 1 = Compliant
- 2 = Not Compliant

This standard is not met as evidenced by:

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<p>23.00.08 <u>Monitoring of Exposure.</u> Personnel, who are at risk for exposure to radiation, are monitored for levels of radiation.</p>	<p>Personnel identified to be “at risk” are issued and consistently wear exposure meters or badge tests to measure radiation exposure.</p> <p>Monthly radiation exposure checks are conducted.</p> <p>Exposure records for each person are maintained and readily accessible. Radiological personnel as well as other employees determined to be at risk have access to their exposure reports.</p> <p>A physicist or qualified radiologist shall review the records. Results of the findings are to be reviewed and approved by the hospital radiation safety group and the safety team.</p>	<p style="text-align: center;"><u>DOCUMENT REVIEW</u></p> <ol style="list-style-type: none"> 1. Determine if the facility has identified other staff beyond the nuclear medicine department to be "at risk." 2. Confirm that a physicist or radiologist has reviewed and signed each employee radiation exposure reports. 3. Determine staff knowledge of these procedures and the results of their tests. 4. Verify that the exposure results are reviewed by an appropriate hospital safety group. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>
<p>23.00.09 <u>Nuclear Regulatory Commission Licensure.</u> All isotopes shall be handled in accordance with Nuclear Regulatory Commission (NRC) regulations.</p>	<p>Federal, state, and local regulations governing radiation safety are adopted and implemented for protection from ionizing radiation.</p> <p>Licenses from regulatory bodies are readily available.</p>	<p style="text-align: center;"><u>INTERVIEW AND DOCUMENT REVIEW</u></p> <ol style="list-style-type: none"> 1. Verify policies are in congruence with the standard and there is compliance. 2. Determine that the licenses are current. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

NUCLEAR MEDICINE SERVICES

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<p>23.00.10 Laboratory Testing. <i>If laboratory tests are performed in the nuclear medicine service, the service must meet the applicable requirement for laboratory services specified in §482.27.</i></p> <p>§482.53(b)(3)</p>	<p>Any laboratory tests performed in connection with nuclear medicine services must comply with the hospital Condition of Participation of laboratory services, including a requirement to comply with 42 CFR Part 493, which establishes the Clinical Laboratory Improvement Act (CLIA) requirements for laboratories.</p> <p>All in-vitro tests and all in-vivo procedures classified under radio bioassay must be performed in accordance with the requirements of §482.27 including quality control calibration and record retention, etc.</p> <p>See chapter 22, Laboratory Services, for applicable standards.</p>	<p style="text-align: center;"><u>DOCUMENT REVIEW</u></p> <ol style="list-style-type: none"> 1. Review the nuclear medicine department against all standards in Chapter 22, if lab tests are being performed in the nuclear medicine service. 2. The applicable survey procedures for the laboratory services Condition of Participation must be used. 3. Verify that the nuclear medicine lab has a CLIA license, as appropriate. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>
<p>23.00.11 Facilities. <i>Equipment and supplies must be appropriate for the types of nuclear medicine services offered and must be maintained for safe and efficient performance.</i></p> <p><i>The equipment must be--</i></p> <ol style="list-style-type: none"> (1) Maintained in safe operating condition; and (2) Inspected, tested and calibrated at least annually by qualified personnel. 	<p>The nuclear medicine service must use equipment and supplies that are designed and, when applicable, approved to be used in conjunction with radioactive materials.</p> <p>Equipment must be maintained so that it operates safely to minimize hazards to patients and hospital personnel as much as possible. Accordingly, it must be inspected, tested, and calibrated by personnel with the necessary qualifications.</p> <p>Personnel may be either hospital employees or contracted. Personnel must follow the manufacturer’s quality assurance instructions for</p>	<p style="text-align: center;"><u>OBSERVATION, INTERVIEW, AND DOCUMENT REVIEW</u></p> <ol style="list-style-type: none"> 1. Does the hospital have documentation that indicates that the equipment and supplies it uses in nuclear medicine services are appropriate for use with radioactive materials? 2. Is the hospital able to demonstrate how personnel, whether employees or contractors, who inspect, test, calibrate, and maintain nuclear medicine services equipment are qualified to do so? 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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<p>§482.53(c) §482.53(c)(1) §482.53(c)(2)</p>	<p>acceptance testing (upon installation and after major upgrades) and maintenance testing.</p> <p>The hospital must have a policy and procedure for staff who operate the equipment to follow if they suspect a malfunction.</p> <p>Inspections, testing and calibration must occur at least annually unless required to be more frequent according to the manufacturer’s instructions. The findings from inspections are corrected promptly.</p> <p>The nuclear medicine service must function in accordance with applicable Federal and State regulations and guidelines governing radiation safety.</p> <ul style="list-style-type: none"> • For more information, see 21 CFR Subpart J, “Radiological Health,” and 10 CFR, Chapter 1, Part 20, “U.S. Nuclear Regulatory Commission Standards for Protection Against Ionizing Radiation.” <p>Reagents must be labeled to ensure proper identification, use, storage and safe handling and date of preparation and assay.</p>	<p>3. Review equipment maintenance records.</p> <ul style="list-style-type: none"> ○ Verify that equipment is tested, calibrated and otherwise maintained at least annually, following the manufacturer’s recommended procedures. ○ Verify that if the manufacturer requires more frequent than annual testing and maintenance that the hospital adheres to the manufacturer’s prescribed schedule. <p>4. Ask nuclear medicine services staff who operate equipment what they would do if they suspected a malfunction.</p> <ul style="list-style-type: none"> ○ Does the hospital have a policy to address this and are staff familiar with it? 	

23.00.12 Not Applicable.

NUCLEAR MEDICINE SERVICES

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>23.00.13 <u>Handling & Disposal of Radium Elements.</u> Procedures clearly define handling and disposal methods for radium elements, their disintegration products, and radioactive isotopes.</p>	<p>Mechanisms are established and implemented for proper handling and removal of the hazardous elements of radiation materials and wastes.</p>	<p><u>DOCUMENT REVIEW AND OBSERVATION</u></p> <ol style="list-style-type: none"> 1. Verify that policies and procedures address the handling and removal of radioactive materials within the facility. 2. Verify compliance with the policies on handling and storage. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>
<p>23.00.14 <u>Approval of Policies & Procedures.</u> All radiation safety policies and procedures are approved by the Radiation Safety and the Radiation Safety Committee (Team).</p>	<p>The Safety Team and the Radiation Safety subcommittee reviews and approves all policies within the organization relating to radiation safety at least every three (3) years.</p>	<p><u>DOCUMENT REVIEW</u></p> <p>Verify:</p> <ol style="list-style-type: none"> 1. Policies and procedures have received approval from the Safety Team and the Radiation Safety subcommittee within the past three (3) years. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>
<p>23.00.15 <u>Order Requirements.</u> Each request for nuclear medicine services shall contain the reason(s) for the examination.</p>	<p>Orders for a nuclear medicine exam shall include the pertinent reason(s) for conducting the procedure to insure that the proper services are being provided.</p>	<p><u>DOCUMENT REVIEW</u></p> <ul style="list-style-type: none"> • Review requests in the radiology services department to verify compliance; review other records as necessary. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

NUCLEAR MEDICINE SERVICES

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>23.00.16 <u>Medical Record Requirements.</u> <i>The hospital must maintain signed and dated reports of nuclear medicine interpretations, consultations and procedures.</i></p> <p>(1) <i>The hospital must maintain copies of nuclear medicine reports for at least 5 years.</i></p> <p>(2) <i>The practitioner approved by the medical staff to interpret diagnostic procedures must sign and date the interpretation of these tests.</i></p> <p>§482.53(d) §482.53(d)(1) §482.53(d)(2)</p>	<p>The hospital must maintain records for all nuclear medicine procedures performed.</p> <p>Nuclear medicine patient records, including interpretations, consultations, and procedures are patient medical records and the hospital must comply with the Medical Records CoP (§482.24).</p> <p>Nuclear medicine patient records, like all patient medical records, must be maintained for at least five years. If State law requires a longer period, the hospital must comply, but surveyors do not assess compliance with State law requirements as part of the Federal survey.</p> <p>Each report of an interpretation of a nuclear medicine diagnostic study must be signed and dated by the practitioner who made the interpretation, as authorized by the medical staff.</p> <p>Deficient nuclear medicine medical records practices related to these two requirements must be cited under this regulation; depending on the specific facts, citation under the Medical Records CoP might also be appropriate.</p> <p>Bulls-eye films and other nuclear image records shall be maintained so as to be readily produced upon request for at least five years.</p>	<p><u>OBSERVATION, INTERVIEW AND CHART REVIEW</u></p> <ol style="list-style-type: none"> 1. Observe the record storage for sufficient record retention space, organization, ability to retrieve, and security. 2. Verify compliance with all applicable standards in Chapter 10, Medical Records. 3. Verify that copies of nuclear medicine reports are maintained for at least 5 years. 4. Verify that reports of nuclear medicine interpretations are signed and dated only by the practitioner who interpreted the study's results, as authorized by the medical staff to perform these interpretations. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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23.00.17 Not Applicable.

23.00.18 Not Applicable.

23.00.19 Documentation Requirements.

The hospital must maintain records of the receipt and distribution of radiopharmaceuticals.

§482.53(d)(3)

Hospitals receive their radiopharmaceuticals from manufacturers, either for further in-house preparation, or ready to use.

Regardless of the source of the material, the hospital must have records that track the movement of the radiopharmaceuticals upon receipt, throughout the hospital.

The records must specify:

- 1. The type of radiopharmaceutical;**
- 2. The location in the hospital where it was received, stored and dispensed;**
- 3. The amount received or dispensed at each location;**
- 4. The staff member receiving or dispensing; and**
- 5. When applicable, how/when it is disposed of and by whom. This would also include, when applicable, the type and amount of any radiopharmaceuticals returned to the source vendor.**

DOCUMENT REVIEW & INTERVIEW

1. Review the records relating to the inventory, administration, and disposal. Request the most recent documentation for the delivery of radiopharmaceuticals. Verify:
 - a. All radio pharmaceuticals and radionuclides that entered the facility are still in the inventory or transferred via administration to a patient or disposal.
 - b. Radionuclides are not delivered during non-business hours and left unsecured.
 - c. The hospital maintains accurate records of the receipt and distribution of radio pharmaceuticals.
2. **Ask the hospital to demonstrate how it maintains accurate records of the receipt and distribution of radiopharmaceuticals at all locations throughout the hospital.**
3. **Ask what the hospital’s policy is for frequency of review of the records; is there evidence that the hospital complies with its policy?**

- 1 = Compliant
 2 = Not Compliant

This standard is not met as evidenced by:

NUCLEAR MEDICINE SERVICES

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	<p>6. Additional information, including special transport instructions or precautions, may be included.</p> <p>The hospital must also have policies and procedures that address how often it reviews these records and how it reconciles discrepancies between inventory on hand and records of receipt, distribution, use, disposal and/or return to the source vendor.</p> <p>Records are kept of radiopharmaceuticals and radionuclides from the point of entering the facility to the points of administration and final disposal.</p> <p>The records are to indicate:</p> <ul style="list-style-type: none"> (1) the date received method of receipt, (2) activity, (3) identity of recipients, (4) dates of administration, and (5) dates of disposal. 	<ul style="list-style-type: none"> 4. Ask the hospital to explain how it addresses discrepancies in the records. 5. What actions does it take to determine whether there are errors in the records versus unaccounted for loss of materials? 6. If applicable, what further actions does it take to locate unaccounted for radioactive materials? 7. If applicable, what further actions does it take to prevent future recordkeeping errors? 	
<p>23.00.20 Qualified Ordering Practitioners. <i>Nuclear medicine services must be ordered by practitioners whose scope of Federal or State licensure and whose defined privileges allow such referrals.</i></p> <p>§482.53(d)(4)</p>	<p>Nuclear medicine services may only be ordered by practitioners holding privileges that permit them to do so, consistent with State scope of practice law.</p> <p>However, for outpatient services, consistent with the provisions of §482.54, the governing body and medical staff may also authorize practitioners who do not have hospital clinical privileges to order such studies or procedures, as permitted under State law.</p>	<p><u>DOCUMENT REVIEW, CHART REVIEW, & INTERVIEW</u></p> <p>Review service policies and several outpatient requisitions to determine congruence with this element, and with Medical Staff Bylaws, Rules / Regulations.</p> <ul style="list-style-type: none"> 1. Determine there is congruence between this element and the Medical Staff Bylaws, Rules and Regulations. 	<ul style="list-style-type: none"> <input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant <p>This standard is not met as evidenced by:</p>

NUCLEAR MEDICINE SERVICES

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>23.00.21 <u>Standard: Nuclear Medicine Services.</u> <i>If the hospital provides nuclear medicine services, those services must meet the needs of the patients in accordance with acceptable standards of practice.</i></p> <p>§482.53</p>	<p>Nuclear medicine services must be provided in accordance with acceptable standards of practice. Acceptable standards of practice include maintaining compliance with applicable Federal and State law and regulations governing the use of nuclear medicine, including facility licensure requirements, as well as standards and recommendations promoted by nationally recognized professional organizations.</p> <p>Examples of nationally recognized professional organizations in the area of nuclear medicine include, but are not limited to, organizations such as the American College of Radiology, the Radiological Society of North America, the Society of Nuclear Medicine and Molecular Imaging, the American Society of Nuclear Cardiology, and the American Association of Physicists in Medicine.</p> <p>If nuclear medicine services are provided under arrangement, the governing body must, in accordance with §482.12(e), ensure that the services</p>	<p>2. Verify that nuclear medicine services are ordered only by practitioners who have privileges to do so or, for outpatient services when authorized consistent with the provisions of §482.54, by other practitioners authorized to do so by the medical staff, consistent with Federal and State law.</p> <p><u>DOCUMENT REVIEW, CHART REVIEW, AND INTERVIEW</u></p> <p>If nuclear medicine services are offered, determine the type(s) of services provided and the location where each service is provided.</p> <ol style="list-style-type: none"> 1. Ask the director of nuclear medicine services how the hospital ensures that the services are provided in accordance with acceptable standards of practice. 2. Can the director point to accepted guidelines or State or other Federal law that support the hospital’s nuclear medicine policies and procedures? 3. Can the director explain how the hospital’s policies, procedures, and protocols are consistent with ALARA principles? 4. Observe one or more nuclear medicine studies to determine whether the staff 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

NUCLEAR MEDICINE SERVICES

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
	<p>are provided in a manner that complies with the requirements of the nuclear medicine CoP.</p> <p><u>MINIMIZING THE RISKS OF NUCLEAR MEDICINE</u> Nuclear medicine studies and procedures provide useful diagnostic information and targeted therapies for patients. However, since they use radioactive materials that produce high energy, there are also risks associated with the exposure to radioactivity. Specifically, the risk involves exposure to ionizing radiation, which is a form of energy given off by atomic particles that can cause damage to DNA in various living tissues.</p> <p>The most significant risks include, but are not limited to:</p> <ul style="list-style-type: none"> • A small increase in the possibility that a person exposed to ionizing radiation will develop cancer later in life. <p>The risk of developing cancer from nuclear medicine radiation exposure is generally small and depends on at least three factors—the amount of the radiation dose, the age of the patient or staff member at the time of the exposure, and the sex of the person exposed:</p> <ul style="list-style-type: none"> • The lifetime risk of cancer increases the larger the dose and the greater the number of studies or treatments involving radioactivity which he/she undergoes; 	<p>follows the hospital’s protocols for that study. Ask the staff after the observation to show you the applicable protocol and explain how they complied with it.</p> <p>Surveyor: After reviewing all CMS requirements:</p> <ul style="list-style-type: none"> • Identification of CMS standard-level deficiencies within the Condition of Participation should be cited here if non-compliance does not rise to the Condition level. • Do NOT include HFAP standard deficiencies. 	

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- The lifetime risk of cancer is larger for a patient who received exams that involve radioactivity at a younger age, since less mature cells are more radiosensitive; and
- Women are at somewhat higher lifetime risk than men for developing radiation-associated cancers after receiving the same exposures at the same age.

In order to minimize the risks of ionizing radiation and maximize patient safety during nuclear medicine studies and procedures, hospitals are expected to apply the fundamental principle of “As Low as Reasonably Achievable” or “ALARA,” which is defined by the U.S. Environmental Protection Agency (EPA) as “A principle of radiation protection philosophy that requires that exposures to ionizing radiation be kept as low as reasonably achievable, economic and social factors being taken into account.

The protection from radiation exposure is ALARA when the expenditure of further resources would be unwarranted by the reduction in exposure that would be achieved.” (Federal Guidance Report No. 14, Radiation Protection Guidance for Diagnostic and Interventional X-ray Procedures, p. 100, November, 2014)Although CMS does not interpret or enforce EPA guidance, the ALARA principle is considered an accepted standard of practice for nuclear medicine that hospitals must adhere to.

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Hospitals are expected to be able to demonstrate how they incorporate ALARA into their nuclear medicine services.

They are also expected to have nuclear medicine policies and procedures that take into consideration classes of patients who may be at higher risk for over-exposure, as well as the radiation exposure of staff when preparing, storing, transporting, administering and disposing of radioactive materials.

<p>For Information Only – Not Required/Not to be Cited</p> <p>Hospitals are encouraged to develop protocols for the use of radiopharmaceuticals designed to achieve an optimal balance between minimizing the amount of radiation exposure while maximizing the diagnostic image quality or therapeutic benefit.</p> <p>The risk of excessive exposure for both patients and staff can be reduced by designing and implementing nuclear medicine study protocols that:</p> <ul style="list-style-type: none"> • Minimize the distance between the source of radiation and its target; and • Follow published guidelines for administered activity, i.e., the amount of radiation administered by the radiopharmaceutical.
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QAPI:

In addition, the hospital’s nuclear medicine services must be integrated into its hospital-wide Quality Assessment and Performance Improvement (QAPI) program, as required by §482.21.

Consistent with these requirements, the hospital must monitor the quality and safety of nuclear medicine services.

Examples of nuclear medicine indicators of potential quality and safety problems could include, but are not limited to:

- Incidents of improper patient preparation, such as inadequate intravenous access or lack of pre-medication, such that procedures must be cancelled or reordered;
- Incidents of the wrong radiopharmaceutical being used, i.e., not the radiopharmaceutical prescribed for the patient, or of the wrong dose of the prescribed radiopharmaceutical being administered, or of use of the wrong route of administration for the prescribed radiopharmaceutical.
- Repeats of the same diagnostic studies within a short time span, which may be an indicator of poor image quality; or
- Diagnostic studies or therapeutic procedures

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performed in a manner inconsistent with the applicable hospital written protocol.

In addition, the hospital is also required under the QAPI CoP to track medical errors and adverse events related to nuclear medicine services.

- Adverse events related to nuclear medicine services must be analyzed for their causes, and preventive actions must then be undertaken.
- Deficiencies identified related to tracking, analyzing and addressing adverse event and quality indicator data and performance improvement activities must be cited under the applicable QAPI standards.

NUTRITIONAL SERVICES

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>24.00.00 Condition of Participation: Food & Dietetic Services. <i>The hospital must have organized dietary services that are directed and staffed by adequate qualified personnel.</i></p> <p><i>However, a hospital that has a contract with an outside food management company may be found to meet this Condition of Participation if the company has a dietician who serves the hospital on a full-time, part-time, or consultant basis, and if the company maintains at least the minimum standards specified in this section and provides for constant liaison with the hospital medical staff for recommendations on dietetic policies affecting patient treatment.</i></p> <p>§482.28</p>	<p>The services can be provided directly or by a contracted food management group.</p> <p>The hospital’s food and dietetic services must be organized, directed and staffed in such a manner to ensure that the nutritional needs of the patients are met in accordance with practitioners’ orders and acceptable standards of practice.</p> <p>The hospital should have written policies and procedures that address at least the following:</p> <ol style="list-style-type: none"> 1. Availability of a diet manual and therapeutic diet menus to meet patients’ nutritional needs; 2. Frequency of meals served; 3. System for diet ordering and patient trays delivery; 4. Accommodation of non-routine occurrences (e.g., parenteral nutrition (tube feeding), total parenteral nutrition, peripheral parenteral nutrition, change in diet orders, early/late trays, nutritional supplements, etc); 5. Integration of the food and dietetic service into the hospital-wide QAPI and Infection Control programs; 6. Guidelines for acceptable hygiene practices of food service personnel; and 	<p><u>DOCUMENT REVIEW, OBSERVATION, AND INTERVIEW</u></p> <p>The survey of the Food and Dietetic Services standards (including staff qualifications, transportation, food safety, and whether the hospital is meeting the nutritional needs of its patients) is coordinated by one surveyor. However, each surveyor, as he/she conducts his/her survey assignments, should assess the hospital’s compliance with the Food and Dietetic Services standards.</p> <p>Score the Condition based on scoring results from the remainder of the chapter.</p>	<p><input type="checkbox"/> 1 =Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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7. Guidelines for kitchen sanitation.

The same standards apply whether the food and dietetic services are provided by the hospital directly, through a contractual agreement, or by off-site vendor.

The hospital must be in compliance with Federal and State licensure requirements for food and dietary personnel as well as food service standards, laws and regulations.

24.00.01 Organization.
§482.28(a)

The hospital must ensure that the specific food and dietetic services organization requirements are met.

Score this standard based on the results of scoring from standards 24.00.02 through 24.00.05.

- 1 =Compliant
- 2 = Not Compliant

This standard is not met as evidenced by:

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STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>24.00.02 Food & Dietetic Services. <i>The hospital must have a full-time employee who:</i></p> <p>(i) <i>Serves as director of the food and dietetic services,</i></p> <p>(ii) <i>Is responsible for daily management of the dietary services, and</i></p> <p>(iii) <i>Is qualified by experience or training.</i></p> <p>§482.28(a)(1) §482.28(a)(1)(i) §482.28(a)(1)(ii) §482.28(a)(1)(iii)</p>	<p>The service director must be a full-time employee who has been granted the authority and delegated responsibility by the hospital’s governing body and medical staff for the operation of the dietary services.</p> <p>This authority and delegated responsibility includes, the daily management of the service, implementing training programs for dietary staff, and assuring that established policies and procedures are maintained that address at least the following:</p> <ol style="list-style-type: none"> Safety practices for food handling Emergency food supplies Orientation, work assignments, supervision of work and personnel performance Menu planning, purchasing of foods and supplies, and retention of essential records (e.g., cost, menus, personnel, training records, QAPI reports, and etc.), Nutritional Services QAPI program <p>The service director must demonstrate, through education, experience and/or specialized training, the qualifications necessary to manage the service, appropriate to the scope and complexity of the food service operations.</p>	<p><u>INTERVIEW, DOCUMENT REVIEW, AND FILE REVIEW</u></p> <ol style="list-style-type: none"> Verify that the director of food and dietetic services is a full-time employee. Review the service director’s job description to verify that it is position-specific and that responsibility and authority for the direction of the food and dietary service has been clearly delineated. Review the service director’s personnel file to verify that he/she has the necessary education, experience, and training to manage the service, appropriate to the scope and complexity of food service operations. Verify the Nutrition Services is integrated with the hospital-wide QAPI program. 	<p><input type="checkbox"/> 1 =Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

NUTRITIONAL SERVICES

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The Food Service Director may or may not be a Registered Dietitian. It is not required that the Food Service Director report to a Registered Dietitian.

Food Service Directors in a transitional role will be evaluated on a case-by-case basis. Temporary reporting structures will be acceptable only if active recruitment for an appropriately qualified candidate is in progress.

24.00.03 Dietitian Services.

There must be a qualified dietitian,

- *full-time,*
- *part-time or*
- *on a consultant basis.*

§482.28(a)(2)

A qualified dietitian must supervise the nutritional aspects of patient care.

Responsibilities of a hospital dietitian may include, but are not limited to:

- Approving patient menus and nutritional supplements;
- Patient, family, and caretaker dietary counseling;
- Performing and documenting nutritional assessments and evaluating patient tolerance to therapeutic diets when appropriate;
- Collaborating with other hospital services (e.g., medical staff, nursing services, pharmacy service, social work service, etc.) to plan and implement patient care as necessary in meeting the nutritional needs of the patients; and
- Maintaining pertinent patient data necessary to

FILE REVIEW AND INTERVIEW

1. Review **the dietitian’s** personnel files to determine **that he/she is qualified based on education, experience, specialized training, and, if required by State law, is licensed, certified, or registered by the State.**
2. If the dietitian is not full time, determine that the number of hours spent working is appropriate to serve the nutritional needs of the patients, **and that the hospital makes adequate provisions for coverage with the dietitian is not available.**

- 1 =Compliant
 2 = Not Compliant

This standard is not met as evidenced by:

NUTRITIONAL SERVICES

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>24.00.04 Staffing Qualifications. <i>There must be administrative and technical personnel competent in their respective duties.</i></p> <p>§482.28(a)(3)</p>	<p>recommend, prescribe, or modify therapeutic diets as needed to meet the nutritional needs of the patients.</p> <p>Qualification is determined on the basis of education, experience, specialized training, State licensure or registration when applicable, and maintaining professional standards of practice.</p> <p>If the qualified dietitian does not work full-time, and when the dietitian is not available, the hospital must make adequate provisions for dietary consultation that meets the needs of the patients. The frequency of consultation depends on the total number of patients, their nutritional needs and the number of patients requiring therapeutic diets or other nutritional supplementation.</p> <p>Administrative and technical personnel must be competent in their assigned duties. This competency is demonstrated through education, experience and specialized training appropriate to the task(s) assigned. Personnel files should include documentation that the staff member has the required qualifications and is competent in their respective duties.</p> <p>Dietetic administrative personnel may include diet clerk or secretarial positions.</p> <p>Dietetic technical personnel may include certified or</p>	<p><u>OBSERVATION AND DOCUMENT REVIEW</u></p> <p>1. Review personnel files for both administrative and technical staff. Determine they have appropriate credentials as required and have received adequate training and are competent in their respective duties.</p> <ul style="list-style-type: none"> • Duties are consistent with assignments in the service. • There is evidence of appropriate credentials, adequate training, and 	<p><input type="checkbox"/> 1 =Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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	<p>noncertified dietary positions. For dietetic technicians who provide technical support under the supervision of RDs, it is preferred that these are registered through the Commission on Dietetic Registration as “Dietetic Technician, Registered” (DTR).</p> <p>Food Service personnel include those staff responsible for food preparation, the tray line, and dish machine operators.</p>	<p>competency evaluations for both administrative and technical personnel.</p> <p>2. Visit the kitchen to observe personnel. Check assignment sheets for staffing.</p> <ul style="list-style-type: none"> • Determine there is ample staff to meet the nutritional needs of patients. 	
24.00.05 <u>Not Applicable.</u>			
<p>24.00.06 <u>Diets: Menus Must Meet the Needs of Patients.</u> <i>Individual patient nutritional needs must be met in accordance with recognized dietary practices.</i></p> <p>§482.28(b) §482.28(b)(1)</p>	<p>Each hospital patient for whom the hospital is providing one or more meals or nutrition must have their nutritional needs met in a manner that is consistent with recognized dietary practices.</p> <p>Affected patients include all inpatients and those patients in observation status whose stay is sufficiently long that they must be fed. According to the U.S. Department of Agriculture’s (USDA) Food and Nutrition Center the nationally recognized source for recommended dietary intakes allowances is the Institute of Medicine Food and Nutrition Board’s Dietary Reference Intakes (DRIs), which are designed to provide recommended nutrient intakes for use in a variety of settings.</p> <p>The DRIs are a set of four reference values:</p> <p>1. Recommended Dietary Allowance (RDA) is the</p>	<p style="text-align: center;">INTERVIEW AND DOCUMENT REVIEW</p> <p>1. Can the dietician demonstrate how the menus meet the nutritional needs of patients? For example, does the service rely upon DRIs, including RDAs, in developing menus?</p> <p>2. Can the dietician demonstrate patients are assessed for special nutritional needs and how the hospital assures the needs of those with specialized needs are met?</p> <p>3. When observing care in inpatient units (or observation units where meals are provided) ask staff how patients are assessed for nutritional needs.</p> <ul style="list-style-type: none"> • Ask them how they monitor patients identified as having specialized needs. 	<p><input type="checkbox"/> 1 =Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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	<p>average daily dietary intake of a nutrient that is sufficient to meet the requirement of nearly all (97-98%) healthy persons.</p> <p>2. Adequate Intake (AI) for a nutrient is similar to the Estimated Safe and Adequate Daily Dietary Intakes (ESADDI) and is only established when an RDA cannot be determined. Therefore a nutrient either has an RDA or an AI. The AI is based on observed intakes of the nutrient by a group of healthy persons.</p> <p>3. Tolerable Upper Intake Level (UL) is the highest daily intake of a nutrient that is likely to pose no risks of toxicity for almost all individuals. As intake above the UL increases, risk increases.</p> <p>4. Estimated Average Requirement (EAR) is the amount of a nutrient that is estimated to meet the requirement of half of all healthy individuals in the population.</p> <p>USDA provides access to an interactive DRI tool and DRI tables at: http://fnic.nal.usda.gov/dietary-guidance/dietary-reference-intakes</p> <p>THERAPEUTIC DIETS Meeting individual patient nutritional needs may include the use of therapeutic diets. Therapeutic diets refer to a diet ordered as part of the patient's treatment for a disease or clinical condition, to</p>	<ul style="list-style-type: none"> • Is there evidence that therapeutic diets are provided as ordered? <p>4. Does the sample of patient records being reviewed include patients identified with special nutritional needs? If not, ask to see records for several such patients. Determine if there is evidence of monitoring the dietary intake and nutritional status of patients identified as having special nutritional needs.</p>	

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eliminate, decrease, or increase certain substances in the diet (e.g., sodium or potassium), or to provide mechanically altered food when indicated.

Patients must be assessed for their risk for nutritional deficiencies or need for therapeutic diets and/or other nutritional supplementation.

Examples of patients who may have specialized dietary needs and may require a more detailed nutritional assessment include, but are not limited to:

- All patients requiring artificial nutrition by any means (i.e., enteral nutrition (tube feeding), total parenteral nutrition, or peripheral parenteral nutrition);
- Patients whose medical condition, surgical intervention, or physical status interferes with their ability to ingest, digest or absorb nutrients;
- Patients whose diagnosis or presenting signs/symptoms indicates a compromised nutritional status (e.g., anorexia nervosa, bulimia, electrolyte imbalances, dysphagia, malabsorption, end stage organ diseases, etc.);
- Patients whose medical condition can be adversely affected by their nutritional intake (e.g., diabetes, congestive heart failure, patients taking certain medications, renal diseases, etc.).

Patients who refuse the food served should be

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<p>24.00.07 Diet Orders. <i>All patient diets, including therapeutic diets, must be ordered by a practitioner responsible for the care of the patient, or by a qualified dietitian or qualified nutrition professional as authorized by the medical staff and in accordance with State law governing dietitians and nutrition professionals.</i></p> <p>§482.28(b)(2)</p>	<p>offered substitutes that are of equal nutritional value in order to meet their basic nutritional needs.</p> <p>PLAN OF CARE The care plan for patients identified as having specialized nutritional needs must address those needs as well as monitoring of their dietary intake and nutritional status.</p> <p>The methods and frequency of monitoring could include one or more of the following, as well as other methods:</p> <ul style="list-style-type: none"> • Patient weight (BMI, unintended weight loss or gain) • Intake and output • Lab values <p>Patient diets, including therapeutic diets, must be provided in accordance with orders from a practitioner responsible for the care of the patient, or by a qualified dietitian or qualified nutrition professional who is permitted to order diets under State law and authorized to do so by the medical staff.</p> <p>Diets must be based on an assessment of the patient’s nutritional and therapeutic needs and documented in the patient’s medical record (including documentation about the patient’s tolerance to any therapeutic diet ordered).</p> <p>DIET-ORDERING PRIVILEGES</p>	<p><u>DOCUMENT REVIEW AND CHART REVIEW</u></p> <ol style="list-style-type: none"> 1. Review patient records to verify that diet orders are provided as prescribed by: <ul style="list-style-type: none"> • the practitioner(s) responsible for the care of the patient, • a qualified dietician, or • qualified nutrition professional. 2. If diet orders are prescribed by a dietitian or other nutrition professional, review their records to verify that he or she was appointed to the medical staff with diet- 	<p><input type="checkbox"/> 1 =Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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	<p>The hospital’s governing body may choose, when permitted under State law and upon recommendation of the medical staff, to grant qualified dietitians or qualified nutrition professionals diet-ordering privileges.</p> <p>A. QUALIFIED DIETICIAN</p> <ul style="list-style-type: none"> In many cases State law determines what criteria an individual must satisfy in order to be a “qualified dietician;” State law may define the term to mean a “registered dietician” registered with a private organization, such as the Commission on Dietetic Registration, or State law may impose different or additional requirements. <p>B. QUALIFIED NUTRITIONIST</p> <ul style="list-style-type: none"> Terms such as “nutritionists,” “nutrition professionals,” “certified clinical nutritionists,” and “certified nutrition specialists” are also used to refer to individuals who are not dietitians, but who may also be qualified under State law to order patient diets. It is the responsibility of the hospital to ensure that individuals are qualified under State law before appointing them to the medical staff or granting them privileges to order diets. <p>If the hospital chooses NOT to grant diet-ordering</p>	<p>ordering privileges, or was granted diet-ordering privileges without being appointed to the medical staff.</p> <p>3. Ask the hospital how it determines whether the dietician/nutrition professional is qualified under state law.</p> <p>4. Review staff records to verify that dietitians/nutrition professionals demonstrate the required qualifications.</p>	

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privileges to dietitians or other nutrition professionals, even when permitted under State law, the patient’s diet must be prescribed by a practitioner responsible for the patient’s care. In this situation, a dietician or nutrition professional who does not have privileges to order diets may nevertheless assess a patient’s nutritional needs and provide recommendations or consultations for patients to a practitioner responsible for the care of the patient.

24.00.08 Diet Manual.

A current therapeutic diet manual approved by the dietitian and medical staff must be readily available to all medical, nursing and food service personnel.

§482.28(b)(3)

The therapeutic diet manual **must be** approved by the dietitian and the Medical Staff within the last three (3) years. The publication or revision date of the approved therapeutic diet manual must not be greater than 5 years old.

The therapeutic diet manual (or copies of it) must be available to all medical, nursing and food service personnel.

Preferred Diet Manuals

The “**Academy Of Nutrition And Dietetics** Nutrition Care Manual” is the preferred therapeutic diet manual. This **Academy Of Nutrition And Dietetics** publication is accessible online at www.eatright.org and <http://www.nutritioncaremanual.org>

The “**Academy Of Nutrition And Dietetics** Pediatric Manual of Clinical Dietetics, 2nd Edition” (hard copy) is the preferred pediatric diet manual.

INTERVIEW & DOCUMENT REVIEW

Determine **the Therapeutic Diet Manual is current – and -**

1. Has been approved by both the medical staff and a **qualified** Dietitian within the past three (3) years.
2. **Is in accordance with** current national standards, **such as RDA or DRI.**
3. **Is readily available to MD/DOs, nursing and food service personnel.**
4. Is accessible at each nursing station for nursing and medical staff, and is also available to food service and dietetic staff.
5. Includes the **different types** of therapeutic diets routinely ordered at the facility

- 1 =Compliant
- 2 = Not Compliant

This standard is not met as evidenced by:

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	<p>Also acceptable, if recommended by the Registered Dietitian and approved by the medical staff, are:</p> <ol style="list-style-type: none"> 1. Diet manuals prepared by state dietetic associations. 2. Supplementary specialized manuals. <p><u>Emergency Plan</u> A plan is in place to ensure the diet manual is readily available in the event of a power outage, internet / intranet interruptions, or computer failure. Staff is trained in these alternative methods.</p>	<ol style="list-style-type: none"> 6. Is consistently used as guidance for ordering and preparing patient diets. 7. Staff is knowledgeable of alternate methods of accessing the diet manual. 	
24.00.09 <u>For Future Use</u>			
<p>24.00.10 <u>Nutrition Counseling & Education.</u> Patients and their families are counseled, as appropriate, on the therapeutic diet regime, food - drug interactions, and nutrition-related topics.</p>	<p>Nutrition counseling is provided to achieve knowledge regarding healthy food choices consistent with the ordered therapeutic diet.</p> <p>Food or drug products, which may result in interference or interaction, are taught in a manner that the patient (family) can understand.</p> <p>Patient education materials are often prepared by various hospital disciplines. Materials relating to therapeutic diets or food-drug interactions are developed in collaboration with a registered dietitian.</p>	<p style="text-align: center;"><u>INTERVIEW AND DOCUMENT REVIEW</u></p> <p>Determine the Standards of Practice and mechanisms utilized for patient (family) teaching.</p> <p>Verify that food - drug interaction teaching aids have been conjointly devised by nutrition and pharmacy services even if these are utilized by nursing staff. Teaching aids are available in the language of the patient.</p> <p style="text-align: center;"><u>CHART REVIEW</u></p> <p>Review 10 appropriate patient records to verify documentation of education on nutrition counseling and/or food-drug interactions.</p>	<p><input type="checkbox"/> 1 =Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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<p>24.00.11 Outcomes Management/ Quality Assessment Performance Improvement Systems. For both food service and clinical nutrition services a process is in place to monitor, improve and report quality and outcomes of services provided.</p>	<p>Food Service Directors and Registered Dietitians are accountable to implement systems to reliably measure quality and outcomes of food and nutrition services, to act on those results as needed and to report results to stakeholders.</p> <p>A comprehensive outcomes management / QAPI program is in place and consists of the following:</p> <ol style="list-style-type: none"> 1. National benchmarks are utilized as appropriate. 2. Integrated into the facility wide quality and outcomes initiatives program. 3. The program identifies and analyzes causes of less than optimal performance and outcomes. <p>Nutrition Services monitoring to consider:</p> <ol style="list-style-type: none"> 1. Implementation of the four steps of the Nutrition Care Process and Screening. 2. Effectiveness of the nutrition screening and referral system. 3. A risk analysis / audit procedure to determine the accuracy of meals / nutrition served to patients are as prescribed. <p>For more information, refer to “Academy of Nutrition and Dietetics Outcomes Management Publications.”</p>	<p style="text-align: center;"><u>DOCUMENT REVIEW</u></p> <p>Verify that policies and procedures define systems for measuring quality and outcomes of services.</p> <p>Verify documentation of a minimum of two QAPI projects:</p> <ol style="list-style-type: none"> 1. One (1) food service initiative; and 2. One (1) nutrition service initiative. <p>Verify the food service and clinical nutrition services participate in the facility wide QAPI program.</p> <p style="text-align: center;"><u>INTERVIEW</u></p> <p>Interview staff about the quality and outcomes projects, methodology, results, and refinements to services made.</p>	<p><input type="checkbox"/> 1 =Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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24.00.12 Emergency Preparedness Plan.

The Emergency Preparedness Plan of the facility addresses methods for ensuring the nutritional needs of patients and personnel during an internal or external emergency or disaster.

The hospital emergency preparedness plan describes the strategies for ensuring nutritional needs are met during situations in which hospital services or utilities are disrupted. The plan outlines methods for meeting the nutritional needs of patients, visitors, and personnel while awaiting evacuation or the return to normal hospital operations.

It is recommended that hospitals work with the community leaders when developing the emergency plan. In the event of a community disaster, the hospital will need priority status for the delivery of fuel, food, water, and other supplies.

During a disaster, the facility may experience a disruption in one or multiple services, such as:

- a. Loss of water, gas, fuel, or electricity;
- b. Equipment failure, e.g., dishwashing machines, pumps, refrigeration, cooking appliances; and
- c. Disruption with the delivery and grocery and food preparation items.

The emergency preparedness plan anticipates the possible disruptions and prepares strategies, in advance, for ensuring continuity of services.

For example, how would the hospital meet patient nutritional needs in the event of:

- a. A loss of electricity / power? Alternative methods for heating foods and water used for cooking should be identified.

DOCUMENT REVIEW

Verify:

- The hospital Emergency Preparedness Plan addresses methods for ensuring the nutritional needs of patients and personnel are met during internal and external emergencies, including major disruption of delivery and sanitation infrastructures.

- 1 =Compliant
- 2 = Not Compliant

This standard is not met as evidenced by:

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- b. A disruption with delivery of food products? The facility might choose to:
- 1) Obtain agreements with food suppliers for priority grocery delivery
 - 2) Calculate the volume of food, drinking water, paper products, and utensils needed to feed the patients, staff, and visitors for at least three (3) days.
 - 3) Store a 3-day inventory of:
 - Fresh and frozen foods
 - Dairy products
 - Drinking water
 - Paper products
 - Special dietary requirements, e.g., diabetic, Kosher, and vegetarian diets

24.01.01 Food Service Department: General Requirements.

The Food Service department is governed by current policies.

The Food Service Department (Food Service) collaborates with other departments as necessary to ensure the needs of their patients are met.

Food Service has a policy manual in place. Policies are reviewed minimally every three (3) years and revised as necessary.

DOCUMENT REVIEW

Verify:

1. Policies reflect collaborative efforts between Food Service and other departments, e.g., Pharmacy and patient care services.
2. Policies are reviewed every three (3) years and revised as necessary.

- 1 = Compliant
 2 = Not Compliant

This standard is not met as evidenced by:

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<p>24.01.02 Policy Requirements: Tube Feedings. Food Service policies address the role of the department regarding the storage, distribution, and administration of enteral / tube feedings.</p>	<p>The Food Service department collaborates with Dietetic Service, patient care services, and Pharmacy, as applicable, in development of policies relative to enteral / tube feedings, specifically:</p> <ol style="list-style-type: none"> Storage Distribution Administration 	<p style="text-align: center;"><u>DOCUMENT REVIEW</u></p> <p>Verify:</p> <ol style="list-style-type: none"> The required policies are in place. Policies reflect collaboration between Food Service, Dietetic Service, patient care services, and Pharmacy, as applicable. 	<p><input type="checkbox"/> 1 =Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>
<p>24.01.03 Policy Requirements: Food Preparation & Storage in Patient Care Areas. Processes are in place relative to food storage centers located in the patient care areas. Minimally, policies must address:</p> <ol style="list-style-type: none"> Rotation of stock and supplies. Checking for outdated supplies. Cleaning frequency and procedures for all food preparation work areas and equipment. Measuring and recording temperatures of refrigerators and freezers. Storage, refrigeration, preparation, and heating of nutrition supplements, infant 	<p>Food products must be maintained in a manner that ensures an acceptable level of safety and quality. The Food Service Department collaborates with patient care services in development of policies relative food and nutrition supplements stored on the patient care units.</p> <p>The Infection Control Committee reviews policies relative to the food product safety and the cleaning of food centers and refrigerators in all patient care areas.</p> <p>A process is in place to communicate food product expiration / discard dates; this process is consistently practiced throughout the facility.</p> <p>A process is in place to monitor and remove supplies prior to expiration.</p> <p>Food and products are stored at least six (6) inches off the floor.</p> <p>Cleaning products and paper products are stored away from food. Horizontal surfaces are clean and free of</p>	<p style="text-align: center;"><u>DOCUMENT REVIEW</u></p> <p>Verify:</p> <ol style="list-style-type: none"> Required policies are in place and current. Food safety policies have been approved by the Infection Control Committee. Policies reflect collaboration between Food Service and patient care services. <p style="text-align: center;"><u>OBSERVATION</u></p> <p>Verify:</p> <ol style="list-style-type: none"> Food products and supplements are maintained in a safe manner. Food items are stored properly and labeled. There are no medications stored in food refrigerators. The food preparation work area and equipment are clean. Separate refrigerators are provided, as required. 	<p><input type="checkbox"/> 1 =Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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<p>formulas, breast milk, and patient food brought from home.</p> <p>6. Labeling of food items with patient name, room number, and expiration date.</p> <p>7. A separate and designated refrigerator for each of the following:</p> <p style="margin-left: 20px;">a. Patient food</p> <p style="margin-left: 20px;">b. Employee food</p> <p style="margin-left: 20px;">c. Breast milk, as applicable</p> <p style="margin-left: 20px;">d. Medications that must be stored at a cool temperature</p>	<p>crumbs.</p> <p>Cleaning Policies are in place that describe the frequency, procedure, and persons responsible for cleaning food preparation work areas and equipment including floors, counter tops, refrigerators and freezer units, microwave ovens, coffee pots, and toasters.</p> <p>Refrigerator Temperatures:</p> <ol style="list-style-type: none"> 1. Check and record food refrigerator temperatures at least daily. (Checking and recording temperatures is not required for employee food refrigerators.) 2. Desired temperatures: <ul style="list-style-type: none"> • Refrigerator temperature range: Between 32° - 40° Fahrenheit (0° – 5° Celsius). • Freezer temperature range: Between minus 10° and minus 0.4° Fahrenheit (minus 23° to minus 18° Celsius). 3. The refrigerator log provides space to document the date, time, temperature, and person recording the temperature. The desired refrigerator temperature is indicated on the log. 4. A process is in place to repair the refrigerator in a timely manner if the temperature should fall out of range. Thirty (30) minutes following the repair, recheck the temperature to ensure the proper temperature has been achieved. 	<ol style="list-style-type: none"> 4. Refrigerator temperatures are maintained within safety guidelines. (Standard requirement does not apply to employee refrigerators.) 5. Processes for food preparation and storage are consistently followed in all areas of hospital, e.g., the main hospital kitchen, Occupational Therapy, and nursing units. 	

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<p>24.01.04 Preparation & Storage of Formula & Breastmilk. Processes are in place that ensures infant formula and breastmilk are properly stored and prepared in accordance with nationally accepted guidelines.</p> <p>Policies are in place to ensure infant safety, including:</p> <ol style="list-style-type: none"> 1. Guidelines for ordering infant formulas. 2. Guidelines that govern acceptable ingredients that may be added to infant formulas. 3. Guidelines for aseptic infant formula preparation techniques. 4. Storage, preparation, and temperature control of breastmilk and infant formula products. 5. Patient safety with heating breast milk and infant formula. 6. Personnel responsible and qualified to prepare infant formula. 7. Cleaning / autoclaving of 	<p>For facilities with an infant patient population, the organization adopts nationally accepted and recognized clinical practice standards such as the Academy of Nutrition and Dietetics’s “Guidelines for Preparation of Formula and Breastmilk in Health Care Facilities.” (2003)</p> <p>Aseptic technique is used for all infant formula preparations.</p> <p>Preferably, there is a separate room used exclusively for the preparation of infant formula, breastmilk, and infant enteral feedings. When there is no formula room, a dedicated clean space with handwashing facilities must be available to allow for the aseptic preparation of infant formulas.</p> <p>Refrigerators and Freezers</p> <ol style="list-style-type: none"> 1. As breast milk is both a food and a body fluid it cannot be stored in refrigerators designated for food or medication storage. 2. A separate refrigerator is dedicated for storage of infant feedings. Unless prohibited by state law, it is acceptable to store breastmilk and formula in the same refrigerator. 3. Refrigeration must be able to chill ingredient water and cool prepared formula to 4° C (40° F). <p>Infant Formula Storage: Prepared infant formula must not be frozen. Refrigerator temperatures for storing infant formula</p>	<p style="text-align: center;"><u>DOCUMENT REVIEW & OBSERVATION</u></p> <p>Verify:</p> <ol style="list-style-type: none"> 1. The required policies are in place. 2. There is a dedicated clean space with handwashing facilities for preparation of infant formulas. 3. Infant formula and breastmilk is stored and prepared in a safe manner. 	<p><input type="checkbox"/> 1 =Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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<p>equipment used in formula preparation.</p> <p>8. Indications, use, and sanitation of enteral feeding pump equipment.</p>	<p>are maintained at:</p> <ul style="list-style-type: none"> • 40° Fahrenheit or lower • 4° Celsius or lower <p>Breast Milk Storage:</p> <ol style="list-style-type: none"> 1. Refrigerator temperatures for storing breast milk are maintained between: <ul style="list-style-type: none"> • 35° to 40° Fahrenheit • 2° and 4° Celsius 2. Freezer temperatures for storing breast milk are maintained: <ul style="list-style-type: none"> • At minus 4° Fahrenheit or lower • At minus 20° Celsius or lower <p>Infant Formula Preparation:</p> <ol style="list-style-type: none"> 1. Written formulations are developed and maintained in the infant formula preparation room. The written formulations shall be verified for accuracy, preferably by a registered dietitian trained in infant formulation preparation. 2. Medications and electrolytes should not be added to formulas in the formula preparation area. 3. Single use bottles and nipples should be used for infant feedings. 4. When available and appropriate, commercially prepared sterile ready-to-feed and liquid concentrate formulas should be used for infant 		

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feedings.

- Processes are in place to sanitize utensils used with infant formula preparation. Measuring cups, spoons, and blenders are sanitized. When oil is added to infant formula for additional fat calories, per physician order, the use of a disposable spoon is acceptable.

Use of Powdered Formula:

- Powdered formula should only be used when commercially prepared sterile liquid formula is not available.
- Powdered formula must be measured by weight.
- Commercially** prepared sterile water should be used for infant formula preparation.

Storage of Infant Formula Products

- All opened formula products, including liquid concentrate, powders, and additives, should be labeled with expiration date and time.
- Opened, ready-to-feed formula and house-prepared formula may be stored in bulk containers and refrigerated for up to 24-hours.
- Prepared infant formula must not be frozen.

Breastmilk

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1. Human milk must be stored in food-grade plastic or glass containers.
2. Containers must be labeled with the names of the infant and mother, medical record number, and date and time of pumping.
3. The breastmilk expressed by each mother is stored in a separate bin to discourage misadministration and cross-contamination.
4. Breastmilk shall be warmed or thawed under warm running water. Microwaves and hot water should never be used to warm breastmilk.
5. Thawed breast milk must be used within 24 hours. Do not refreeze thawed or fortified breast milk.
6. Fortified breast milk should be used within 24 hours.

24.01.05 **Not Applicable.**

24.01.06 **Not Applicable.**

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<p>24.01.07 <u>Trash Disposal.</u> Policies are in place for the following processes:</p> <ol style="list-style-type: none"> 1. Storage and disposal of grease, food waste, and biohazardous waste. 2. Containment, handling, transporting, and removal of trash. 3. Covering, labeling, frequency of emptying, and securing trashcans and lids. 4. Daily washing of trashcans. 	<p>The term “trash” refers to common garbage as well as biohazardous waste.</p> <p>In the Food Service department, typically this includes grease, food waste, and paper / packaging materials. On occasion, a patient tray may return to the department with biohazardous wastes such as soiled dressings, dentures, needles, and syringes.</p> <p>The facility has policies established relative to containing, covering, labeling, securing, storing, and transporting trashcans in accordance with state and local regulations (see Chapter 11 of this manual).</p> <p>This practice is consistently implemented throughout the Food Service department.</p>	<p style="text-align: center;"><u>DOCUMENT REVIEW & OBSERVATION</u></p> <p>Determine that required policies are in place.</p> <p>Verify through observation that staff adhere to the policies relative to trash disposal and removal. Ensure that garbage does not present a health hazard.</p> <p>Verify:</p> <ol style="list-style-type: none"> 1. Required policies are in place. Practice is consistent with policies. 2. Trash is contained, covered, and labeled consistent with hospital policy. 	<p><input type="checkbox"/> 1 =Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>
<p>24.01.08 <u>Physical Environment.</u> Processes are in place for the following:</p> <ol style="list-style-type: none"> 1. Food and non-food items are stored separately. 2. All food containers are covered. 3. Food containers are labeled with the contents and the date prepared. 4. Foods are within their expiration dates. 	<p>Chemicals, cleaning products, mops and brooms are to be stored separately from foods, utensils, pots / pans, plates / bowls, serving trays, or paper products.</p> <p>Paper products including napkins, plates, cups must not be stored in food preparation areas.</p> <p>All food packages that are not currently being used are to be covered and/or sealed to protect from contamination and/or evaporation.</p> <p>All food containers are to be labeled with the name of the product stored in it.</p>	<p style="text-align: center;"><u>DOCUMENT REVIEW</u></p> <p>Verify that Food Service policies and employee orientation both cover the listed issues.</p> <p style="text-align: center;"><u>OBSERVATION</u></p> <p>During the kitchen walk-through, observe for adherence to these principles.</p> <p>Verify:</p> <ol style="list-style-type: none"> 1. Food products and supplements are maintained in a safe manner. Food items are stored properly and labeled with contents and either “date opened / date prepared” or “expiration / discard date.” Staff is 	<p><input type="checkbox"/> 1 =Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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5. Loose scoops are not stored in the bulk food containers.	All opened food containers are labeled to indicate the “date opened / date prepared” or “expiration / discard date” consistent with hospital policy.	knowledgeable of labeling practices.	
6. Supplies are off the floor.	All perishable foods that have passed their expiration date are removed from availability.	2. Refrigerators and freezers are in good working order. Humidity is controlled.	
7. Refrigerator / freezer door seals and water pipes are in good working order. Humidity is controlled to prevent / reduce mold growth.	All expired foods are discarded promptly. Scoop handles become contaminated when handled; thus, storage of scoops in bins may contaminate the stored food. The scoops may be kept in the bin if arranged so the handles hang above the food, or in accordance with state and local health department requirements.	3. Hand washing facilities are in the immediate proximity of the food preparation area.	
8. Soap, paper towels, and a sink for hand washing are readily available for staff working in the food preparation area.		4. Food transport vehicles are clean and in good working order.	
9. Food transport vehicles are clean and in good working order.	Staff working in the food preparation area have sinks for hand washing, soap, and paper towels readily available. The location of the sink does not allow splashing onto food, the preparation table, or utensils. Foot operated sinks are preferred.	5. Ceiling tiles are intact and stain free.	
10. Ceiling tiles are intact and stain-free.	The Food Service department environment avoids sources of infection: 1. Walls and floors are clean and kept free of cracks and holes. 2. Ceiling tiles are in place and secure. 3. Supplies are stored at least six (6) inches off the floor per FDA requirement. 4. Floors in all areas of food storage and		

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preparation are clean. Floors under the storage shelves are free of dust and crumbs.

5. Refrigerator and freezer doors, walls, and floors are free of cracks and holes.
 - a. Door seals and water pipes are in good working order.
 - b. Humidity is controlled.
 - c. Ceiling fans in refrigerators / freezers are dust free.

Food Transport Vehicles:

Food transport vehicles are clean and functioning. The hot food section heats properly; the cold food section is chilled.

Flammables

Flammables, such as containers of propane gas used for outdoor grilling, are not stored in the kitchen area.

24.01.09 Lighting, Ventilation, & Temperature Control.

Observe for the following:

1. Food products are stored under appropriate conditions (e.g., time, temperature, packaging, location), consistent with nationally accepted guidelines (i.e., Food and Drug Administration (FDA), United

Ventilation Hood Systems & Filters:

1. Processes are in place to ensure proper ventilation throughout the food preparation area. Usually, the hospital maintenance department provides oversight for these processes.
2. Ventilation of sufficient capacity is provided to keep the area free of excessive heat, steam,

INTERVIEW & OBSERVATION

Verify that Food Service policies and employee orientation both cover the listed issues.

During the kitchen walk through, observe for adherence to these principles. Observe the receiving, food preparation, cooking, cooling, and reheating flow of food, if possible.

- 1 =Compliant
 2 = Not Compliant

This standard is not met as evidenced by:

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<p>States Department of Agriculture (USDA), Hazard Analysis and Critical Control Point (HACCP), and etc.)</p> <p>2. The air supply should flow from clean (food preparation) to dirty (cleanup / garbage);</p> <p>3. Daily temperatures are consistent with USDA guidelines and recorded for refrigerator and freezer units;</p> <p>4. Hot foods are maintained at appropriate temperatures;</p> <p>5. If dish machines are utilized, dish machine temperatures are recorded for each cycle;</p> <p>6. Food preparation areas have adequate lighting; and</p> <p>7. Ceiling light bulbs are shielded.</p>	<p>condensation, vapors, obnoxious odors, smoke, and fumes.</p> <p>3. Ventilation hood systems or other grease extracting equipment shall be designed to prevent grease or condensation from dripping onto food, equipment, and utensils. Ventilation hoods should be readily removable for cleaning and replacement if not designed to be cleaned in place.</p> <p>4. Intake and exhaust air ducts shall be cleaned and filters changed so they are not a source of contamination by dust, dirt, and other materials.</p> <p>5. The air supply flows from clean to dirty areas of the kitchen.</p> <p>6. Dust is not permitted to accumulate around the ventilation grills.</p> <p><u>Food Temperature Danger Zone</u> The food temperature danger zone is between 41° F and 135° F. To avoid bacterial growth:</p> <ol style="list-style-type: none"> 1. Store cold foods at 41° Fahrenheit (5° Celsius) or less. 2. Hot foods should be held and stored at 135° Fahrenheit (60° Celsius) or greater. <p><u>Maintain Proper Refrigerator / Freezer</u></p>	<p>Verify:</p> <ol style="list-style-type: none"> 1. Proper ventilation and air flow is provided throughout the food service area. Ventilation hoods and filters are clean and free of dust and grease. 2. Refrigerator and freezer temperatures are maintained according to guidelines. Daily records are in place. 3. Dishwasher temperatures are maintained per guidelines. Temperature recordings are in place for the wash and rinse cycles. Dishes, glassware, and utensils are free of water spots. 4. There is adequate lighting in the food preparation area. Ceiling light bulbs are shielded. 	

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Temperatures:

1. There are daily records of food refrigerator and freezer temperatures. Such records are to be maintained for all patient food regardless of the location of the equipment or the department / service distributing the product.
2. The log provides space to document the date, time, and person recording the temperature. The desired refrigerator / freezer temperature is indicated on the log.
3. **The internal temperature for refrigerators / freezers are checked and recorded consistent with State and public health rules and regulations, but at least daily.**
4. A process is in place for adjusting refrigerators in a timely manner when the temperature is out of range. The temperature is rechecked following adjustments.
5. If food is above 45 degrees, discard it. If frozen food has thawed, do not refreeze.

Refrigerator Temperatures:

Refrigerator temperatures should be maintained:

1. Between 32° – 40° Fahrenheit (0° to 5° Celsius) for all refrigerated goods.
2. For fresh meat, poultry, and seafood: 30° – 34° Fahrenheit (minus 1° to 1° Celsius).

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Freezer Temperatures:

Freezer temperatures should be maintained:

1. Between minus 10° to minus 0.4° Fahrenheit (minus 23° to minus 18° Celsius) for dairy, ice cream, frozen vegetables, meat, poultry and seafood.

2. For ice cream in scooping cabinets: Between minus 0.4° to 10° Fahrenheit (minus 18° to minus 12° Celsius).

Dishwashing Machines:

Records are kept of the dishwater temperatures at each cycle.

1. Dish machine temperatures should remain:
 - a. Above 155° Fahrenheit (55° Celsius) during the wash cycle.

 - b. Above 180° Fahrenheit (72° Celsius) on the rinse cycle.

 - c. EXCEPTION: The rinse cycle of the dish machine can be at least 160° Fahrenheit if there is some form of chlorination additive supplied to the rinse cycle.

2. When the rinse cycle temperature is too low, the plates, glasses, and flatware will not air dry, which is the optimal sanitation condition. The presence of “water spots” on dishes, glasses, flatware, pots

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and pans is an indication of improper drying techniques.

3. Towel drying dishes, glasses, flatware, pots and pans is not acceptable as this can be a source of cross-contamination.

Lighting:

There is sufficient lighting in the food handling area to ensure safety.

Light Bulbs:

1. The FDA (Food and Drug Administration) requires ceiling light bulbs to be shielded, coated, or otherwise shatter-resistant in areas where there is food, clean equipment, and utensils.
2. Shielding of light bulbs is not required in areas that are used only for storing food in unopened packages if:
 - The integrity of the packages cannot be affected by broken glass falling onto them.
 - The packages are capable of being cleaned of debris from broken bulbs before the packages are opened.

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<p>24.01.10 Staff Education. Food Service personnel are trained and function within the scope of the respective job description.</p>	<p>Job descriptions for food service personnel list the full scope of responsibilities.</p> <p>Food Service personnel, including contract staff and volunteers, receive an orientation and monthly training consistent with state and local public health regulations.</p> <p>The orientation and training, as appropriate to the job description, addresses relevant policies, including:</p> <ol style="list-style-type: none"> 1. Employee health policies: <ol style="list-style-type: none"> a. Mandatory self-reporting procedures related to hazardous health issues. b. Personnel with hazardous health issues, e.g., open skin lesions, respiratory infections, or gastroenteritis, are prohibited from handling food. 2. Personal hygiene and hand-washing 3. Sanitation, food safety (food preparation and storage), physical environment, prevention of cross contamination, and infection control practices. 	<p style="text-align: center;"><u>FILE REVIEW</u></p> <p>Review orientation and ongoing training curricula, schedules, attendance, and competency assessments.</p> <p>Verify:</p> <ol style="list-style-type: none"> 1. Appropriateness of orientation / training material. 2. Training is provided on an ongoing basis consistent with state and local regulations. <p style="text-align: center;"><u>INTERVIEW & OBSERVATION</u></p> <p>Through observation and interviewing, determine:</p> <ul style="list-style-type: none"> • Staff have received proper training, e.g., sanitation techniques, employee health policies. 	<p><input type="checkbox"/> 1 =Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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<p>24.01.11 <u>Staff Hygiene & Health.</u> There are policies and procedures regarding the personal hygiene and health of food service employees.</p>	<p>Food Service policies are in place and provide guidelines. These include but are not limited to the following:</p> <ol style="list-style-type: none"> 1. Hairnets / bonnets, gloves, hand-washing facilities, aprons, and other devices are utilized on an ongoing basis. 2. Employees with open skin lesions and respiratory infections are not assigned to food preparation. 	<p style="text-align: center;"><u>DOCUMENT REVIEW & INTERVIEW</u></p> <p>Verify:</p> <ol style="list-style-type: none"> 1. Employee Health program has met these specific food service requirements. 2. Personal hygiene practices are consistent with policies. 	<p><input type="checkbox"/> 1 =Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>
<p>24.01.12 <u>China & Utensils.</u> China, glassware, and utensils must be of an acceptable level of safety and quality.</p>	<p>Policies describe the actions to be taken by staff to discard chipped and damaged utensils.</p> <p>Damaged dishes, glassware, utensils, and pitted cookware are discarded.</p> <p>Water spots on dishes and utensils indicate improper drying temperatures or methods.</p>	<p style="text-align: center;"><u>OBSERVATION</u></p> <p>Verify:</p> <ol style="list-style-type: none"> 1. There are no chipped or damaged china, glassware, utensils, or pitted cookware. 2. Unglazed china is not used. 3. Dishes and utensils are clean and without water spots. 	<p><input type="checkbox"/> 1 =Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>
<p>24.01.13 <u>Traffic Control.</u> Traffic through the food preparation area is limited to authorized personnel wearing appropriate sanitation garb.</p>	<p>Policies and practices prohibit non-departmental staff from entering food preparation areas during production without measures taken to reduce potential contamination of food products.</p> <p>These measures are the same requirements as for nutrition staff. Non-dietary service individuals shall receive prior authorization before entering a food preparation area.</p>	<p style="text-align: center;"><u>OBSERVATION</u></p> <p>Verify that practice conforms with policy:</p> <ol style="list-style-type: none"> 1. Traffic through the food preparation area is limited. 2. All individuals in the food preparation area have proper identification and protective gear, per hospital policy. (This includes surveyors who may be requested to wear a hair net, etc.) 	<p><input type="checkbox"/> 1 =Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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Policies are in place to control traffic through the food preparation area. These include:

1. Identification of authorized and non-authorized personnel.
2. Use of hairnets / bonnets and other protective clothing to be worn by all individuals entering the area.

24.01.14 For Future Use.

24.01.15 Local Health Standards.

The Food Service is in compliance with state and local health standards.

The Food Service Department meets all applicable codes and guidelines relating to the health and safety of the patients, staff, and visitors.

Copies of the State / local food codes are available in the Food Service Department.

All state and local health department inspection reports are available for review. There is evidence the identified deficiencies have been corrected and improvement sustained.

DOCUMENT REVIEW & OBSERVATION

Verify:

1. State/local food preparation codes are available in the department.
2. Review current health department inspection report. Deficiencies have been corrected and improvements sustained.

- 1 =Compliant
 2 = Not Compliant

This standard is not met as evidenced by:

24.01.16 Infection Control.

Policies must address the following:

- A. Provision of a safe environment consistent with nationally recognized infection control precautions for the prevention of food-borne pathogens/illness,

This regulation requires the hospital to develop, implement and maintain an infection control program for the prevention, control, and investigation of infections and communicable diseases of patients and personnel.

Food preparation equipment and utensils are cleaned,

DOCUMENT REVIEW

Review Infection Control Committee minutes to determine that food service issues are included in evaluation of compliance issues.

Verify that all required infection control policies are in place and approved by the Infection Control

- 1 =Compliant
 2 = Not Compliant

This standard is not met as evidenced by:

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<p>including care of utensils, use of cutting boards, temperature control, etc.</p> <p>B. Isolation procedures and requirements for delivery of and disposal of food products.</p> <p>C. Methods for monitoring and evaluating practices of sanitation.</p> <p>D. Employee health policies regarding infectious diseases and specifically those infected or ill employees, including contract workers and volunteers, must not render food service and/or must not report to work.</p> <p>E. Recalls of food products.</p> <p>F. Identifying, investigating, and reporting infections and outbreaks of disease related to food consumption in both employees and patients.</p>	<p>sanitized, and stored in a manner that prevents cross-contamination. To avoid cross-contamination, a separate cutting board is used for each of the following. Boards are sanitized following use.</p> <p>Preferably, cutting boards are color coded to denote the exclusive use for:</p> <ol style="list-style-type: none"> 1. Dairy products 2. Fruit and vegetables 3. Raw poultry and meats <p>A process is in place to ensure can openers are clean. The cutting or piercing parts of electric can openers are removable to facilitate cleaning and replacement.</p> <p>A process is in place for cleaning ice cream machines. There is an ongoing pest extermination process within the hospital. This can be by hospital employees or by a contracted outside service.</p> <p>The facility has a process for monitoring and evaluating sanitation practices in the food preparation area, such as the USDA Hazard Analysis and Critical Control Point (HACCP) program.</p> <p>Below is the website to access this information. https://fsrio.nal.usda.gov/haccp-0</p> <p>Employee health policies are in place relative to food handlers including a process for self-reporting illness.</p>	<p>Committee.</p> <p style="text-align: center;"><u>OBSERVATION</u></p> <p>Observe for implementation of the policies. Verify:</p> <ol style="list-style-type: none"> 1. The food preparation and serving area is a safe and clean environment. 2. A process is in place for monitoring and evaluating sanitation practices, such as the USDA HACCP program. 	

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The facility has policies established that outline procedures for:

1. Prevention of cross-contamination
2. Cafeteria self-serve buffets
3. Money handling
4. Proper glove use, e.g., Food preparation and handling, tray setup and distribution, food serving, tray clean-up and disposal, indications for changing gloves (such as after touching skin, hair, money).

References:

The U.S. Food and Drug Administration, “2005 Food Code” for the U.S. Department of Health and Human Services, available at: <http://www.fda.gov/food/guidanceregulation/retailfoodprotection/foodcode/ucm2016793.htm>

PHARMACY SERVICES/MEDICATION USE

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>25.00.00 Condition of Participation: Pharmaceutical Services. <i>The hospital must have pharmaceutical services that meet the needs of the patients.</i></p> <p><i>The institution must have a pharmacy directed by a registered pharmacist or a drug storage area under competent supervision.</i></p> <p><i>The medical staff is responsible for developing policies and procedures that minimize drug errors. This function may be delegated to the hospital's organized pharmaceutical service.</i></p>	<p>A hospital must provide pharmaceutical services that meet the needs of its patients. The services must include either a pharmacy that is directed by a pharmacist, or, when appropriate, a drug storage area that is competently supervised.</p> <p>The hospital's medical staff is responsible for developing pharmaceutical policies and procedures that minimize the potential for medication errors, but may delegate this function to the pharmaceutical service.</p> <p>The manner or degree of noncompliance with the requirements of this Condition and its component standards must be evaluated to determine whether there is substantial noncompliance with the Condition, warranting a Condition-level citation.</p>	<p><u>INTERVIEW, OBSERVATION, DOCUMENT REVIEW, & CHART REVIEW</u></p> <ol style="list-style-type: none"> Interview the Chief Pharmacist or the individual delegated to fulfill the functions. <ul style="list-style-type: none"> Determine that either the medical staff has developed policies and procedures regarding the management of pharmaceuticals or that this function is fulfilled by the pharmacy service. Verify that the purpose of pharmaceutical policies and procedures is to minimize drug errors. <ul style="list-style-type: none"> Review the pharmaceutical policies and procedures, the hospital's formulary and, if there is a pharmacy and therapeutic committee, the minutes of the committee meetings. Does a multidisciplinary committee composed of representatives from nursing, pharmacy, administration and medicine develop policies and procedures? Are there policies and procedures to minimize drug errors? Are policies and procedures reviewed and amended based on: <ul style="list-style-type: none"> Facility-generated reports of adverse drug events; 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>
<p>§482.25</p>	<p>Provision of pharmaceutical services must meet the needs of the patients' therapeutic goal by promoting a safe medication use process that ensures optimal selection of medications, dose, dosage form, frequency, route, duration of therapy and that substantially reduces or eliminates adverse drug events and duplication of treatment.</p> <p>The hospital's pharmacy must be directed by a registered pharmacist. If a drug storage area is used instead of a pharmacy at any location providing pharmacy services that storage area must be under competent supervision in accordance with State and</p>		

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	<p>Federal law.</p> <p>Pharmaceutical Services would include:</p> <ul style="list-style-type: none"> • The procuring, manufacturing, compounding, packaging, dispensing, ordering, distributing, disposition, use, and administering of all medications, biologicals, chemicals and the use of medication related devices. • Provision of medication-related information to hospital health care professionals and patients necessary to optimize therapeutic outcomes. • Provision of pharmaceutical care. Pharmaceutical care is defined as the direct, responsible provision of medication-related care for the purpose of achieving definite outcomes that improve a patient’s quality of life while minimizing patient risk. <p>Functions of Pharmaceutical Care are the:</p> <ul style="list-style-type: none"> • Collection and organization of patient-specific information; • Determination of the presence of medication-therapy problems both potential and actual; • Summary of the patient’s medication related health care needs; • Identification and specification of pharmacotherapeutic goals; 	<ul style="list-style-type: none"> • Facility QAPI activities pertaining to pharmaceutical care; • Evaluation of external alerts and/or recommendations from national associations; and • Evaluation of literature for new technologies or successful practices that have demonstrated enhanced medication safety in other organizations. <p>6. Is the staff familiar with the medication-related policies and procedures?</p> <p>7. Is there a method to periodically review and evaluate the actual implementation of pharmaceutical policies and procedures by staff?</p> <p>8. Upon review of patient clinical record are issues with regard to provision of pharmaceutical services identified? Is the facility aware of the issues? Was there a failure to implement a policy and procedure?</p> <p>9. Are pharmacists an integral component of pharmaceutical care?</p> <p>10. Verify that the hospital’s pharmacy service is integrated into its hospital-wide QAPI</p>	

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program.

- Development of a pharmacotherapeutic regimen;
- Implementation of a monitoring plan in collaboration with the patient, if applicable, and other health care professionals;
- Monitoring the effects of the pharmacotherapeutic regimen; and
- Redesigning the regimen and monitoring plan as indicated.

POLICIES AND PROCEDURES

Medication errors are a substantial source of morbidity and mortality in the hospitalized setting. Therefore, the development of policies and procedures to minimize medication errors should be based on accepted professional principles; external alerts and proactive review of facility reported and reviewed adverse drug events. It is important to flag new types of mistakes and continually improve and refine things, based on what went wrong.

The hospital’s medical staff must develop policies and procedures to minimize drug errors, but may delegate this function to the hospital’s organized pharmaceutical service.

Policies and procedures to minimize drug errors should include:

1. High-alert medications: dosing limits,

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	<p>administration guidelines, packaging, labeling and storage;</p> <p>2. Limiting the variety of medication-related devices and equipment. For example limit the types of general-purpose infusion pumps to one or two;</p> <p>3. Availability of up-to-date medication information;</p> <p>4. Availability of pharmacy expertise. Pharmacist available on-call when pharmacy does not operate 24 hours a day;</p> <p>5. Standardization of prescribing and communication practices to include:</p> <ul style="list-style-type: none"> ○ Avoidance of dangerous abbreviations; ○ All elements of the order – dose, strength, units (metric), route, frequency, and rate; ○ Alert systems for look-like and sound-alike drug names; ○ Use of facility approved pre-printed order sheets whenever possible. <p>6. That orders to “resume previous orders” are prohibited;</p> <p>7. A voluntary, non-punitive, reporting system to monitor and report adverse drug events (including medication errors and adverse drug reactions);</p>		

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	<p>8. The preparation, distribution, administration and proper disposal of hazardous medications;</p> <p>9. Drug recalls;</p> <p>10. That patient-specific information is readily accessible to all individuals involved in provision of pharmaceutical care. The patient information must be sufficient to properly order, prepare, dispense, administer and monitor medications as appropriate;</p> <p>11. Identification of when weight-based dosing for pediatric populations is required; and</p> <p>12. Requirements for review and revision based on facility-generated reports of adverse drug events and QAPI activities.</p> <p>The hospital should have policies and procedures to actively identify potential and actual adverse drug events. Proactive identification could include; direct observation of medication administration, review of patient’s clinical records, identification of patient signals that would warrant immediate review of patient’s medication therapy and implementation of medication use evaluation studies.</p> <p>The hospital should have a means to incorporate external alerts and/or recommendations from national associations and governmental agencies for review</p>		

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and facility policy and procedure revision consideration. National associations could include:

- Institute for Safe Medications Practice,
- National Coordination Council for Medication Error Reporting and Prevention and
- Joint Commission for Accreditation of Health Care Facilities, Sentinel Event Reports.

Governmental agencies may include:

- Food and Drug Administration,
- Med Watch Program, and
- Agency for Health Care Research and Quality.

The hospital’s pharmacy services must be integrated into its hospital-wide QAPI program.

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<p>25.00.01 STANDARD: Pharmacy Services. <i>The hospital must have pharmaceutical services that meet the needs of the patients.</i></p> <p>§482.25</p>	<p>WHAT IS INCLUDED IN PHARMACEUTICAL SERVICES?</p> <p>Pharmaceutical services encompass the functions of procuring, storing, compounding, re-packaging, and dispensing all medications, biologicals, chemicals and medication-related devices within the hospital. They also include providing medication-related information to care professionals within the hospital, as well as direct provision of medication-related care.</p> <p>MEETING PATIENT NEEDS Hospitals must provide pharmaceutical services that meet the needs of their patients.</p> <ul style="list-style-type: none"> The scope and complexity of pharmaceutical services available in the hospital must be consistent with the volume and types of patients the hospital serves. Except in unusual circumstances, the pharmaceutical service is expected to make available in a timely manner the volume and types of medications typically needed. <p>These would be those medications typically prescribed by the hospital’s practitioners for hospital patients receiving inpatient services, surgical services, diagnostic services involving medications as a component of testing, and outpatient drug therapies administered while the patient is in the hospital.</p>	<p>INTERVIEW AND DOCUMENT REVIEW</p> <ol style="list-style-type: none"> Ask the hospital for evidence of the scope and complexity of its pharmaceutical services. Ask how the hospital has determined that the services meet the needs of its patients. Ask unit nursing staff if prescribed medications are routinely available and timely. If there are reports of frequent delays or other problems, probe further with the director of pharmaceutical services. <p>Surveyor Instructions:</p> <ul style="list-style-type: none"> After reviewing all CMS standard-level requirements for this chapter, identification of CMS standard-level deficiencies within the Condition of Participation should be cited here if the non-compliance does not rise to the Condition level. Do NOT include HFAP-standard deficiencies with this decision. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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Not every hospital is expected to offer the same level of pharmaceutical services. For example:

- It would not be uncommon for a psychiatric hospital to maintain a relatively limited pharmaceutical service, due to minimal need for compounding, and/or dispensing multiple types and forms of medications and biologicals.
- On the other hand, a short-term acute care hospital with a busy oncology outpatient service and other complex medical and surgical departments would be expected to provide a wider range of pharmaceutical services that are ready to be furnished when needed.

25.00.02 Licensure.

Each pharmacy location is licensed as required by State law.

If the pharmacy provides retail outpatient dispensing it is also licensed for this activity, if required.

Most states require hospital pharmacies to be licensed separately from the facility. Some states require retail pharmacy licenses for outpatient dispensing even if this is limited to employee prescriptions.

OBSERVATION

Verify that the license(s) is/are current and prominently posted.

Often, states require reissue in the event of a change in pharmacy director. If required by the state, the license(s) is posted.

- 1 = Compliant
- 2 = Not Compliant

This standard is not met as evidenced by:

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<p>25.00.03 <u>Permits & Certifications.</u> Permits and certifications required by law are current for all pharmacy locations. These are located within the pharmacy area and posted, if required by law.</p>	<p>Permits may include but are not limited to:</p> <ul style="list-style-type: none"> • Drug Enforcement Agency; • State controlled substance; • Tax free alcohol; and/or • Pharmacist preceptor for intern practitioners. 	<p style="text-align: center;"><u>OBSERVATION</u></p> <p>Verify:</p> <ol style="list-style-type: none"> 1. Permits and certifications are current and posted for all pharmacy locations. 2. Permits exist for all required activities. 3. If required by the state, permits are posted. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>
<p>25.00.04 <u>Pharmacy Management & Administration.</u> <i>The medical staff is responsible for developing policies and procedures that minimize drug errors. This function may be delegated to the hospital's organized pharmaceutical service.</i></p> <p><i>The pharmacy or drug storage area must be administered in accordance with accepted professional principles.</i></p> <p>§482.25(a)</p>	<p>The hospital may utilize a unit dose system, individual prescription, floor stock system or a combination of these systems, properly stored.</p> <p>Pharmaceutical services must be administered in accordance with accepted professional principles. Accepted professional principles includes compliance with applicable Federal and State laws, regulations, and guidelines governing pharmaceutical services, as well as, standards or recommendations promoted by nationally recognized professional organizations, such as those found in the U.S. Pharmacopeia/National Formulary (USP/NF).</p> <p>The hospital's pharmacy service must ensure safe and appropriate procurement, storage, preparation, dispensing, use, tracking and control, and disposal of medications and medication-related devices throughout the hospital, for both inpatient and outpatient services.</p>	<p style="text-align: center;"><u>DOCUMENT REVIEW</u></p> <ol style="list-style-type: none"> 1. Are the policies and procedures consistent with accepted professional principles? 2. Does the hospital have a means to incorporate external alerts and/or recommendations from national associations and governmental agencies for review and facility policy and procedure revision consideration? 3. Is the hospital's organized pharmaceutical services responsible for the procurement, distribution and control of all medication products used in the hospital (including medication-related devices) for inpatient and outpatient care? 4. If the hospital has a drug storage area instead of a pharmacy, does it use only drugs 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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	<p>Hospitals may choose how to set up the pharmaceutical services utilizing various methods including, but not limited to:</p> <ul style="list-style-type: none"> • A unit dose system (i.e.; single unit package, dispensed in most ready to administer form possible), • Individual prescription (i.e.; instruction for a single patient, written by a medical practitioner for a medication or treatment), • Floor stock system (i.e.; storage of pharmaceutical and over-the-counter drugs on the patient care unit), or • A combination of these systems, as long as they are properly stored. <p>HOSPITALS WITH ONLY A DRUG STORAGE AREA However, hospitals with only a drug storage area must only use drugs that are pre-packaged and need no further preparation beyond that required at the point of care.</p> <p>POLICIES AND PROCEDURES The hospital must develop, implement and periodically review and revise as needed policies and procedures governing provision of pharmaceutical services.</p> <p>The regulation makes the hospital’s medical staff responsible for the policies and procedures, but also</p>	<p>that are pre-packaged and need no further preparation beyond that required at the point of care?</p> <ol style="list-style-type: none"> 5. Is there evidence that the hospital’s medical staff has either adopted pharmaceutical services policies and procedures, or has delegated this task to the pharmaceutical services? 6. Can the pharmacy director provide evidence that the policies and procedures are consistent with accepted professional principles? 7. Can the pharmacy director provide evidence that policies and procedures address key areas to prevent medication errors? 8. Is there evidence of training staff on applicable pharmaceutical policies and procedures? 9. Is there a process in place to monitor adherence to policies and procedures? 	

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permits the medical staff to delegate this function to the hospital’s pharmaceutical services.

The policies and procedures must reflect accepted professional pharmacy principles, and the pharmacy director must be able to identify the source(s) used when developing and adopting the policies and procedures.

- There must also be a process to train staff on the applicable policies and procedures and to monitor their adherence.

Policies and Procedures for Minimizing Drug Errors

Medication errors are a substantial source of morbidity and mortality risk in the hospitalized setting. Therefore, hospitals must take steps to prevent, identify, and minimize these errors. These steps must be based on accepted professional principles. This includes not only ensuring that the pharmacy processes conform to of accepted standards of pharmacy practice but also proactively identifying and reviewing Adverse Drug Events (ADE) that occur.

Pharmacies also need to be aware of external alerts to real or potential pharmacy-related problems in hospitals.

The pharmaceutical services policies and procedures must be designed to minimize drug errors and are expected to address:

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1. **High-Alert Medications:**
 High-alert medications are considered inherently high risk for adverse drug events. High alert drugs may include controlled medications, medications not on the approved FDA list, medications with a narrow therapeutic range, psychotherapeutic medications, look-alike/sound-alike medications and those new to the market or new to the hospital. Although mistakes may or may not be more common with these drugs, the consequences of errors are often harmful, sometimes fatal, to patients. Examples of ways to minimize high alert medication errors include, but are not limited to, the following: dosing limits, administration guidelines, packaging, labeling and storage.

2. **Investigational Medications (Research):**
 Hospitals that conduct research involving investigational medications must have a policy and procedure in place to ensure that investigational medications are safely controlled and administered.

Procedures for the use of investigational medications include, but are not limited to, the following:

- A written process for reviewing, approving, supervising and monitoring investigational medications specifying that when pharmacy services are provided, the pharmacy controls the storage, dispensing, labeling, and

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distribution of the investigational medication.

3. Adherence to professional standards of practice for all compounding, packaging dispensing and drug disposal activities;
4. Standardizing medication-related devices and equipment where feasible. For example, limit the types of general-purpose infusion pumps to one or two;
5. Availability of up-to-date medication information and pharmacy expertise on-call when pharmacy does not operate 24 hours a day;
6. Standardization of prescribing and communication practices to include:
 - a. Avoidance of dangerous abbreviations;
 - b. All elements of the order – dose, strength, units (metric), route, frequency, and rate;
 - c. Alert systems for look-like and sound-alike drug names;
 - d. Use of facility approved pre-printed order sheets whenever possible.
 - e. Prohibition of orders to “resume previous orders;”

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- f. Availability of patient-specific information to all individuals involved in provision of pharmaceutical services. The patient information must be sufficient to properly order, prepare, dispense, administer and monitor medications as appropriate;
- g. Identification of when weight-based dosing for pediatric populations is required; and
- h. A voluntary, non-punitive, reporting system to monitor and report adverse drug events (including medication errors and adverse drug reactions);
- i. Monitoring drug alerts and/or recalls. The hospital should have a means to incorporate external alerts and/or recommendations from national associations and governmental agencies for review and facility policy and procedure revision consideration. National associations could include Institute for Safe Medications Practice and National Coordinating Council for Medication Error Reporting and Prevention. Governmental agencies may include: Food and Drug Administration, Med Watch Program; and
- j. The hospital’s pharmacy services must be integrated into its hospital-wide QAPI program and therefore, it is important to

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flag new types of mistakes and continually improve and refine policies and procedures as a result of analyses of errors and adverse events.

25.00.05 Management.

The hospital... must have a pharmacy directed by a registered pharmacist or a drug storage area under competent supervision....

A full time, part time, or consulting pharmacist must be responsible for developing, supervising, and coordinating all of the activities of the pharmacy services.

§482.25
§482.25(a)(1)

Pharmaceutical services offered throughout the hospital must be under the direction of a pharmacist, who may be full-time, part-time, or consulting.

- This is required even in the case of a hospital that has a drug storage area instead of a pharmacy.

The director must have documented training or expertise in hospital pharmacy practice and management.

The hospital must have written criteria for the qualifications of the pharmacy director in accordance with the scope of services provided.

The extent of pharmaceutical services provided by the hospital determines whether a part-time director of the services is sufficient.

- Depending on the volume and complexity of the hospital's services, oversight may not require full-time on-site management at the hospital's pharmacy, but may be accomplished through regularly scheduled visits, and/or use of telecommunications in accordance with federal

FILE REVIEW, DOCUMENT REVIEW, & INTERVIEW

- Does the hospital have a pharmacist who has been appointed to direct the pharmaceutical services?
 - Is there evidence in the pharmacist's file that he/she satisfies the criteria?
- Are there written criteria for the qualifications of the pharmacist director?
 - Is there evidence in the pharmacist's file that he/she satisfies the criteria?
- If the hospital has a drug storage area in lieu of a pharmacy, is there evidence the storage area is under competent supervision?
- Review the pharmaceutical services Director's file to verify that he or she meets the qualifications established by the medical staff.
- If the Director is a part-time employee or consultant, ask him/her how much time/week is spent on developing, supervising and coordinating pharmaceutical

- 1 = Compliant
- 2 = Not Compliant

This standard is not met as evidenced by:

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	<p>and state law and accepted professional principles.</p> <ul style="list-style-type: none"> If the hospital does not have a full-time pharmacist, it must be able to provide evidence of how a part-time or consulting pharmacist is able to perform all functions relating to developing, supervising and coordinating all pharmacy services activities. <p>In general, hospital pharmacies are staffed with registered pharmacists and pharmacy technicians who perform various functions, including, but not limited to, compounding, labeling, and dispensing of various drugs and biologicals.</p> <p>There may be instances of small hospitals that do not have a pharmacy but utilize a drug storage area for dispensing pre-packaged drugs only.</p> <ul style="list-style-type: none"> If the hospital has a drug storage area in lieu of a pharmacy, the day-to-day operations of pharmaceutical services must be under the supervision of an individual who, if not a pharmacist, nevertheless has documented competency to oversee compliance with all the pharmaceutical services regulatory requirements (e.g., security, access to locked areas, etc.). The hospital must establish in writing the qualifications of the drug storage area supervisor. 	<p>services.</p> <ol style="list-style-type: none"> Determine there is a current state licensure for all pharmacists, including the director, serving the facility. Review the implementation of the Pharmacy Director's responsibilities by: <ul style="list-style-type: none"> Reviewing minutes of meetings (if any) with facility staff regarding pharmaceutical services; Reviewing the job description or the written agreement to see that the responsibilities of the pharmacist are clearly defined and include development supervision and coordination of all the activities of pharmacy services; Determining whether the Pharmacy Director / Manager routinely evaluates the performance and competency of pharmacy personnel? Ask the pharmacy director to describe how policies and procedures related to pharmaceutical services are developed, approved, and implemented. What is his/her role in this process? Is there any evidence of problems within the 	

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<p>25.00.06 Staffing. <i>The pharmaceutical service must have an adequate number of personnel to ensure quality pharmaceutical services, including emergency services.</i></p> <p>§482.25(a)(2)</p>	<p>Likewise, if a hospital has remote locations or satellites that rely on the pharmacy of the main campus and maintain only drug storage area(s) on-site, there must be competent day-to-day supervision of those storage area(s), under the overall direction of the pharmacist who manages the hospital's pharmaceutical services.</p> <p>The job description or the written agreement for the responsibilities of the pharmacist director should be clearly defined and include development, supervision and coordination of all the activities of pharmacy services, including active leadership of those committees responsible for establishing medication-related policies and procedures.</p> <p>Professional criteria, Federal and State regulations (and licensing acts) guide the facility requirements for staff.</p> <p>There must be sufficient personnel to respond to the pharmaceutical needs of the patient population being served.</p> <p>The pharmaceutical services staff must be sufficient in types, numbers, and training to provide quality services, including 24 hour, 7-day emergency coverage, or there is an arrangement for emergency services, as determined by the needs of the patients and as specified by the medical staff.</p>	<p>pharmaceutical services that suggest lack of supervision?</p> <p><u>DOCUMENT REVIEW, INTERVIEW, & OBSERVATION</u></p> <p>Determine:</p> <ol style="list-style-type: none"> The pharmaceutical services staff is sufficient in number and training to provide quality services, including 24 hour, 7-day emergency coverage, or there is an arrangement for emergency services, as determined by the needs of the patients and as specified by the medical staff. There are sufficient personnel to provide accurate and timely medication delivery, ensure accurate and safe medication administration and to provide appropriate 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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	<p>The number of pharmacists and/or the number of hours of services provided by pharmacists at the hospital, or at each location of the hospital that provides pharmaceutical services, must meet and be in accordance with the needs of its patients and accepted professional principles (as previously defined), and reflect the scope and complexity of the hospital’s pharmaceutical services.</p> <p>There must be sufficient numbers and types of personnel to provide accurate and timely medication delivery, ensure accurate and safe medication administration and to provide appropriate clinical services as well as the participation in continuous quality improvement programs that meet the needs of the patient population being served.</p>	<p>clinical services as well as the participation in continuous quality improvement programs that meet the needs of the patient population being served.</p>	
<p>25.00.07 Scheduled Drugs. <i>Current and accurate records must be kept of the receipt and disposition of all scheduled drugs.</i></p> <p>§482.25(a)(3)</p>	<p>A "perpetual" inventory is maintained. Distribution and movement of scheduled drugs throughout the facility is controlled and records are maintained and reconciled. Destruction and waste records are maintained and monitored.</p> <p>Components of a record system to maintain current and accurate records of the receipt and disposition of scheduled drugs include:</p> <ol style="list-style-type: none"> 1. Accountability procedures to ensure control of the distribution, use, and disposition of all scheduled drugs. 	<p><u>DOCUMENT REVIEW, INTERVIEW & OBSERVATION</u></p> <ol style="list-style-type: none"> 1. Review a sample of (6) narcotic balance sheets representative of anesthesia, ER, GI lab, pharmacy, and from nursing care units. Observe for witnessed waste / destruction and balanced inventory. 2. Select two drugs from the inventory and complete a drug count with a registered nurse or pharmacist. 3. Determine if there is a record system in place 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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	<p>2. Records of the receipt and disposition of all scheduled drugs must be current and must be accurate.</p> <p>3. Records trace the movement of scheduled drugs throughout the service.</p> <p>4. The pharmacist is responsible for determining that all drug records are in order and that an account of all scheduled drugs is maintained and reconciled.</p> <p>5. The record system, delineated in policies and procedures, tracks movement of all scheduled drugs from the point of entry into the hospital to the point of departure either through administration to the patient, destruction or return to the manufacturer. This system provides documentation on scheduled drugs in a readily retrievable manner to facilitate reconciliation of the receipt and disposition of all scheduled drugs.</p> <p>6. All drug records are in order and an account of all scheduled drugs is maintained and any discrepancies in count are reconciled promptly.</p> <p>7. The hospital system is capable of readily identifying loss or diversion of all controlled substances in such a manner as to minimize the time frame between the actual loss or diversion to the time of detection and determination of the extent of loss or diversion.</p>	<p>that provides information on controlled substances in a readily retrievable manner.</p> <p>4. Review the records to determine that they trace the movement of scheduled drugs throughout the service.</p> <p>5. Determine if there is a system, delineated in policies and procedures, that tracks movement of all scheduled drugs from the point of entry into the hospital to the point of departure either through administration to the patient, destruction or return to the manufacture. Determine if this system provides documentation on scheduled drugs in a readily retrievable manner to facilitate reconciliation of the receipt and disposition of all scheduled drugs.</p> <p>6. Determine if the pharmacist is responsible for determining that all drug records are in order and that an account of all scheduled drugs is maintained and periodically reconciled.</p> <p>7. Is the hospital system capable of readily identifying loss or diversion of all controlled substances in such a manner as to minimize the time frame between the actual losses or diversion to the time of detection and determination of the extent of loss or diversion?</p> <p>8. Determine if facility policy and procedures</p>	

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	8. Facility policies and procedures should minimize scheduled drug diversion.	minimize scheduled drug diversion.	
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25.00.08 Space Requirements.
There is adequate space allocated to enhance the security of inventories.

Sufficient space permits the orderly storage of inventories.

Separate storage for Schedule II drugs exists.

OBSERVATION

Interview staff to determine their familiarity with pharmacy-related policies and procedures.
Verify:
1. Space allocation allows for orderly storage of inventory.

2. Schedule II inventory is stored separately and double locked.

1 = Compliant
 2 = Not Compliant

This standard is not met as evidenced by:

25.00.09 Scope of Service.
The hospital provides pharmaceutical services appropriate to the scope of service of the facility.

The patient mix and acuity drive the scope of services.

DOCUMENT REVIEW & OBSERVATION

Observe physical space, equipment. Review the scope of service statement.
Verify:
1. The scope of service statement identifies the needs of the patients served.

2. Pharmaceutical services are appropriate to meet the needs of patients.

1 = Compliant
 2 = Not Compliant

This standard is not met as evidenced by:

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<p>25.01.01 Medication Control & Distribution. <i>In order to provide patient safety, drugs and biologicals must be controlled and distributed in accordance with applicable standards of practice consistent with Federal and State law.</i></p> <p>§482.25(b)</p>	<p>Drugs and biologicals must be controlled and distributed in accordance with applicable Federal and State laws and regulations, and in accordance with applicable standards of practice. Applicable standards of practice include compliance with all Federal and State laws, regulations, and guidelines, as well as, standards and recommendations promoted by nationally recognized professional organizations that apply to pharmaceutical care and the control and distribution of drugs and biologicals.</p> <p>The procedures established to prevent unauthorized usage and distribution must provide for an accounting of the receipt and disposition of drugs subject to the Comprehensive Drug Abuse Prevention and Control Act of 1970.</p> <p>Other sources of additional guidelines could include, but are not limited to: American Society of Health-System Pharmacists, American College of Clinical Pharmacy, American Pharmacists Association, United States Pharmacopeia, etc.</p> <div style="border: 1px solid black; padding: 5px; margin-top: 20px;"> <p>Note re: US Pharmacopeia/National Formulary (USP/NF) According to the Federal Food, Drug and Cosmetic Act (FCDA), the official compendia of the United States for excipients, drug substances, and drug products is the USP/NF. It is published every year in November by the United States Pharmacopeial</p> </div>	<p><u>DOCUMENT REVIEW & OBSERVATION</u></p> <ol style="list-style-type: none"> 1. Are questions regarding medication orders resolved with the prescriber and a written notation of these discussions documented in the patient’s medical record or pharmacy copy of the prescriber’s order? 2. Does the hospital retrieve and remove medications available for patient use when the hospital has been informed of a drug recall? 3. Are medication orders routinely reviewed by the pharmacy before the first dose? What evidence can the hospital present that such reviews take place? 4. Does the hospital pharmacy have a system for monitoring the effects of medication therapies for cases specified per hospital policy? 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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Convention (<http://www.usp.org/>) and includes two supplements published in February and June.

The USP is a not-for-profit, non-governmental organization that since 1820 has established quality standards for, among other things, drug substances, drug products and compounded preparations. Congress established a role for USP standards in the adulteration provision of the 1906 Food and Drug Act. That role was expanded in the modern Food, Drug and Cosmetic Act (FDCA) beginning in 1938, with a role for USP compendial standards for naming and identity; strength, quality, and purity; and packaging and labeling, in both the adulteration and misbranding provisions of FDCA. (See, for example, §501(b) of the FDCA regarding compendial standards for strength, quality and purity, §502(g) for compendial standards for packaging and labeling). Under the FDCA, a drug with a name recognized in the USP/NF must comply with compendial identity standards, or be deemed adulterated, or misbranded, or both. To avoid being deemed adulterated, such drugs must also comply with compendial standards for strength, quality, and purity, unless labeled to show all respects in which the drug differs.

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The hospital must have a process in place for medication orders to be received in the pharmacy and dispensed in a safe and timely manner.

Safe dispensing of medications must be in accordance with accepted standards of practice and includes, but is not limited to, the following:

1. Implementing systems such as dose limits, pre-printed orders, special labeling, or double checks to minimize adverse drug events, especially for high alert medications;

2. Reviewing all medication orders (except in emergency situations) for appropriateness by a pharmacist before the first dose is dispensed. A process is established for resolving questions with the prescribing practitioner and the discussion and outcome are documented in the patient’s medical record or pharmacy copy of the prescriber’s order;

This review should include:

- a. Therapeutic appropriateness of a patient’s medication regimen;

- b. Therapeutic duplication in the patient’s medication regimen;

- c. Appropriateness of the drug, dose, frequency, and route of administration;

- d. Real or potential medication-medication,

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medication-food, medication-laboratory test and medication-disease interactions;

- e. Real or potential allergies or sensitivities; and
- f. Other contraindications.

RECALLED OR DISCONTINUED MEDICATIONS

Medications dispensed by the hospital are retrieved when recalled or discontinued by the manufacturer or the Food and Drug Administration (FDA) for safety reasons.

- Policies and procedures that address the use of medications brought into the hospital by patients or their families when self-administration of medications is permitted by hospital policy; and
- Having a system in place to reconcile medications that are not administered (e.g., left in the patient’s medication drawer) when the pharmacy inventories patient medications or restocks patient medications. For example, did the patient refuse the medication, was there a clinical or treatment reason the medication was not used, or was the medication not used due to an error?

MONITORING THE EFFECTS OF MEDICATIONS

The pharmaceutical service may be responsible for monitoring the effects of medication(s) specified per

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hospital policy to assure medication therapy is appropriate and minimizes the occurrence of adverse events. Typically this occurs with anticoagulant therapy and antibiotics prescribed for the pharmacy to establish or adjust the dosage (i.e.; “pharmacy to dose” order). In such cases, the pharmacy’s monitoring process includes:

- a. Clinical and laboratory data to evaluate the efficacy of medication therapy to anticipate or evaluate toxicity and adverse effects;
- b. Physical signs and clinical symptoms relevant to the patient’s medication therapy;
- c. Assessing the patient’s own perceptions about side effects, and, when appropriate, perceived efficacy.

(See also the Nursing CoP discussion regarding monitoring of patients at §482.23(c)(4)).

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<p>25.01.02 Supervision of Pharmacy Activities. <i>All compounding, packaging, and dispensing of drugs and biologicals must be under the supervision of a pharmacist and performed consistent with State and Federal laws.</i></p> <p>§482.25(b)(1)</p>	<p>All pharmaceutical services involving compounding, packaging, or dispensing of drugs and biologicals must be conducted by or under the supervision of a registered pharmacist and performed consistent with State and Federal laws.</p> <p>The hospital must adopt and implement written policies and procedures to ensure all medications are prepared by authorized personnel.</p> <p>COMPOUNDED PREPARATIONS Hospitals use many medications that need to be reconstituted, mixed or which otherwise may be considered “compounded” preparations.</p> <p>Some may be compounded in the hospital pharmacy and/or the hospital may obtain some or all from external sources. The external sources could include:</p> <ul style="list-style-type: none"> • Manufacturers, • Registered outsourcing facilities, and/or • Compounding pharmacies. <p>Regardless of the source, if accepted standards for safe compounding are not met, compounded medications may contain less or more than the intended dose and/or may be chemically or microbiologically contaminated, with potentially devastating or even lethal consequences for the patients who receive them.</p>	<p>OBSERVATION, INTERVIEW AND DOCUMENT REVIEW</p> <ol style="list-style-type: none"> 1. Determine that only pharmacists or pharmacist-supervised personnel compound, package and dispense drugs or biologicals in accordance with State and federal laws and regulations and as accepted standards of practice by: <ul style="list-style-type: none"> • Interviewing pharmacy and hospital staff to determine who prepares and dispenses drugs and biologicals; • Observing on site preparation and dispensing operations (if applicable); • Inspecting drug storage areas. 2. Can the hospital demonstrate that compounded medications used and/or dispensed by the hospital are being compounded consistent with standard operating procedures and quality assurance practices equivalent to or more stringent than the standards described in USP <795> and <797>? <ol style="list-style-type: none"> a. Can the pharmacy director provide evidence that compounded medications used and/or dispensed by the hospital are being compounded consistent with standard operating procedures and quality assurance practices equivalent 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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	<p><u>USE OF REGISTERED OUTSOURCING FACILITIES</u> The Drug Quality and Security Act (DQSA), signed into law on November 27, 2013, contains provisions relating to the oversight of compounding of human drugs. The DQSA created a new section 503B in the FDCA under which a compounder may elect to become an “outsourcing facility.”</p> <p>The law defines an “outsourcing facility” as a facility at one geographic location or address that is engaged in the compounding of sterile drugs; has elected to register as an outsourcing facility; and complies with all of the requirements of section 503B of the FDCA.</p> <p><u>REGISTERED 503B OUTSOURCING FACILITIES</u> Facilities that elect to register as outsourcing facilities, per section 503B:</p> <ol style="list-style-type: none"> 1. Must comply with the FDA’s Current Good Manufacturing Practice (CGMP) requirements, which contain minimum requirements for the methods, facilities, and controls used in manufacturing, processing, and packing of a drug product. The CGMP requirements make sure that a product is safe for use, and that it has the ingredients and strength it claims to have. The FDA’s publishes the most current versions of its draft and final regulations and guidance related to compounding on its website: http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/default.htm ; 	<p>to or more stringent than the standards described in USP <795> and <797>?</p> <ol style="list-style-type: none"> b. If the hospital obtains compounded products from external compounding sources, are the external source(s) registered with the FDA as outsourcing facilities? If not, can the hospital demonstrate that it systematically evaluates and monitors whether the outside compounding pharmacy adheres to accepted standards for safe compounding? For example, does the contract include provisions ensuring that the hospital has access to quality assurance data verifying that the vendor is adhering to current USP <795> and <797> requirements, and can the hospital document that it obtains and reviews such data? 3. Can the pharmacy director explain the risk level(s) of the CSPs being produced in-house and/or obtained from external sources? Can he or she demonstrate that the assigned risk levels are consistent with USP <797> or equivalent/more stringent standards? 4. If any CSPs are produced in the hospital: <ol style="list-style-type: none"> a. Ask for one or more examples of situations in which a BUD had to be determined for a compounded sterile 	

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	<p>2. Will be inspected by FDA according to a risk-based schedule; and</p> <p>3. Must meet certain other conditions, such as reporting adverse events and providing FDA with certain information about the products they compound.</p> <p>In a January 2014 letter to purchasers of compounded medications (available at http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm380596.htm), the Commissioner of the FDA encouraged the use of registered outsourcing facilities and noted that,</p> <p><i>“[a]s a purchaser of compounded drugs, you can play an important role in improving the quality of compounded drugs by requiring compounding pharmacies that supply drugs to your facility to register as outsourcing facilities. Once they register, you and the patients you serve can be assured that FDA will inspect these facilities on a risk-based schedule, hold them to CGMP requirements, monitor the adverse event reports they are required to submit to the agency, and require appropriate labeling.”</i></p> <p>FDA has posted a list of Registered Human Drug Compounding Outsourcing Facilities, including the end date of the last FDA inspection related to compounding, whether investigators observed any significant objectionable conditions, and whether</p>	<p>medication (CSP) based on the policy. Interview pharmacy personnel assigned to carry out this function within the hospital and/or to assess how this is done by external source(s) of CSPs.</p> <p>b. Is there evidence that the BUDs are determined consistent with the hospital’s policies and procedures?</p> <p>c. Interview staff who engage in sterile and non-sterile compounding. Are they knowledgeable about applicable levels of aseptic practices?</p> <p>d. Ask the pharmacy director to demonstrate how the following are accomplished to ensure that sterile compounding practices are consistent with USP <797> or equivalent/more stringent standards for the risk level(s) of CSPs being produced for/dispensed to hospital patients:</p> <ol style="list-style-type: none"> 1) Verification of compounding accuracy and sterility. 2) Environmental quality and controls, including environmental sampling; testing and monitoring; and cleaning and disinfection; 3) Personnel training and competency assessment, including but not 	

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	<p>other FDA actions were taken based on the last inspection, at:</p> <p>http://www.fda.gov/drugs/guidancecomplianceregulatoryinformation/pharmacycompounding/ucm378645.htm</p> <ul style="list-style-type: none"> Note that these registered outsourcing facilities are also popularly referred to as “503B pharmacies.” <p>USE OF 503A COMPOUNDING PHARMACIES Compounding pharmacies, not registered as an outsourcing facility with the FDA, are popularly referred to as “503A pharmacies” and generally are subject to oversight only by their State pharmacy board.</p> <p>If a hospital obtains compounded medications from a compounding pharmacy rather than a manufacturer or a registered outsourcing facility, then the hospital must demonstrate how it assures that the compounded medications it receives under this arrangement have been prepared in accordance with accepted professional principles for compounded drugs as well as applicable State or Federal laws or regulations.</p> <p>For example, does the contract with the vendor include provisions:</p> <ol style="list-style-type: none"> Ensuring that the hospital has access to quality assurance data verifying that the vendor is 	<p>limited to accuracy/precision in identifying and measuring ingredients; cleansing and garbing; aseptic manipulation skills; environmental quality and disinfection; appropriate work practices within and adjacent to the direct compounding area; verification/calibration of equipment; sterilization; and post-production quality checks.</p> <ol style="list-style-type: none"> Review the hospital’s procedures for maintaining the quality of CSPs during storage, transport and dispensing. <ol style="list-style-type: none"> Are CSPs packaged in a manner to protect package integrity and sterility? How are CSP-specific requirements with respect to motion, light exposure, temperature and potentially hazardous contents addressed? How does the hospital ensure that such information is effectively conveyed to non-pharmacy health care personnel and/or to patients/caregivers, if applicable? Can the hospital document that it is systematically monitoring and tracking adherence to all of the quality assurance and personnel training and competency 	

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- adhering to current USP <795> and <797> requirements, and can the hospital document that it obtains and reviews such data?
2. Requiring the vendor to meet the requirements of Section 503A of the FDCA concerning pharmacy compounding of human drug products?

standards described above?

- Have any problems or risks been identified? If so, did the hospital take effective action to protect patients, if relevant, and to effectively remedy the problem/risk?

*For Information –
Not Required/Not to be Cited*

*ASHP Research and Education FoundationTM
“Outsourcing Sterile Products Preparation:
Contractor Assessment Tool”*

*The ASHP Research and Education FoundationTM
offers a tool that hospitals may find useful for
assessing vendors that provide compounded
sterile preparations. The tool can be found at:
<http://www.ashpfoundation.org/MainMenuCategories/PracticeTools/SterileProductsTool.aspx> and
click on "Start using Sterile Products Outsourcing
Tool now."*

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MEDICATIONS COMPOUNDED BY THE HOSPITAL'S PHARMACY

Only the pharmacy compounds or admixes all sterile medications, intravenous admixtures, or other drugs except in emergencies or when not feasible (for example, when there is a need for emergency or immediate patient administration of a compounded sterile preparation).

In addition, all compounding of medications used or dispensed by the hospital must be performed consistent with standards of practice equivalent to or more stringent than those described in the compounding-related chapters in the United States Pharmacopeia and the National Formulary (USP) published by the U.S. Pharmacopeial Convention, which are recognized as authoritative guidance regarding minimum standards of safe practice applicable to both sterile and non-sterile compounding.

DEFINITION

The definition of compounding as that term is used in the USP is found in USP Chapter <795> (USP <795>):
 “The preparation, mixing, assembling, altering, packaging and labeling of a drug, drug-delivery device, or device in accordance with a licensed practitioner’s prescription, medication order or initiative based on the practitioner/ patient/pharmacist/compounder relationship in the course of professional practice.

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Compounding includes the following:

1. Preparation of drug dosage forms for both human and animal patients
2. Preparation of drugs or devices in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns
3. Reconstitution or manipulation of commercial products that may require the addition of one or more ingredients
4. Preparation of drugs or devices for the purposes of, or as incident to, research (clinical or academic), teaching or chemical analysis
5. Preparation of drugs and devices for prescriber’s office use where permitted by federal and state law.”

Compounded medications, whether non-sterile or sterile, may be subject to physical and chemical contamination and unintended variations in strength. Microbial contamination and bacterial endotoxins are particularly hazardous with respect to compounded medications that are intended to be sterile.

MINIMUM STANDARDS OF PRACTICE

USP <797> outlines minimum standards of practice to be followed by all health care personnel in any setting when preparing, storing and transporting “compounded sterile preparations” (CSPs).

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Its stated objective is “to describe conditions and practices to prevent harm, including death, to patients that could result from...microbial contamination...excessive bacterial endotoxins...variability of intended strength of correct ingredients...unintended chemical and physical contaminants...and ingredients of inappropriate quality....”

Contaminated CSPs are especially hazardous if administered into body cavities, the central nervous system, vascular system, eyes, joints, and/or used as baths for live organs and tissues.

“All compounded dosage forms that must be sterile when they are administered to patients” are considered by USP <797> to be CSPs, including but not limited to:

- Aqueous bronchial and nasal inhalations;
- Baths and soaks for live organs and tissues;
- Injections [and infusions];
- Irrigations for wounds and body cavities;
- Ophthalmic drops and ointments;
- Tissue implants.”

PHYSICAL LAYOUT AND STRUCTURE

USP <797> specifies differing standards for the physical layout and structure of the locations in which compounding takes place as well as processes, precautions and quality assurance practices to be

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implemented during the preparation, transport and storage of CSPs.

The standards differ in part based on the level of risk of microbial contamination of the CSP, and the risk level has implications for whether a CSP must be terminally sterilized before being dispensed and for how long a CSP may be stored before use.

Risk Categories

The risk categories and accompanying standards are based on specific criteria, including but not limited to, factors such as:

1. The structural design, environmental controls, air quality levels (based on International Organization for Standardization (ISO) standards for particulate matter in air) and air flow patterns in and surrounding the environment to which the contents of the CSP as well as the surfaces of devices and containers for the preparation, transfer, sterilization and packaging of CSPs are exposed.
2. The sterility of the original ingredients and/or device(s) used in compounding, the number of containers that need to be entered, how many times they need to be entered, the nature and complexity of the manipulations and length of time required to prepare the CSP.
3. Whether compounding personnel are appropriately garbed and gloved.

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4. Whether multiple doses of sterile products are pooled to produce a CSP that will be administered on more than one occasion or to more than one patient.

GOAL of the USP <797> STANDARDS

The goal of the USP <797> standards is to prevent and/or minimize the risk of microbial contamination of CSPs, whether by direct contact, exposure to particles in air generated by personnel or objects, or other mechanisms.

A major concern is preventing contamination of “critical sites,” which include “any component or fluid pathway surfaces (e.g., vial septa, injection ports, beakers) or openings (e.g., opened ampules, needle hubs) exposed or at risk of direct contact with air...moisture...or touch contamination.”

USP <797> describes two basic structural designs for the physical layout and environmental controls intended to minimize airborne contamination of critical sites during preparation of CSPs.

The risk level of the CSPs a facility can produce depends, in part, on which USP <797> environmental quality and control/facility design standards the hospital (or its vendor) is able to meet (low-risk level, medium-risk level and high-risk level are discussed here; see §482.23(c) for a discussion of “immediate-use” CSPs):

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	<ol style="list-style-type: none"> 1. Some facilities may only prepare low-risk level nonhazardous and radiopharmaceutical CSPs pursuant to a physician order for a specific patient, and administration must commence within the lesser of 12 hours of preparation or as recommended in the manufacturer’s package insert. Such a facility would have a designated, demarcated room or space that is the “segregated compounding area (SCA),” which contains a device that provides unidirectional airflow of International Standards Organization (ISO) Class 5 air quality (quality class ranges from class 0, the most stringent, to class 9, the most relaxed). The SCA may not be in an area with unsealed openings/potential openings to high traffic locations, the outdoors and other proscribed environmental conditions, and the SCA area may not contain any materials or be the site of any activities unrelated to preparing low-risk CSPs. 2. If a facility is preparing high- or medium-level risk CSPs or low-risk CSPs with a beyond-use date of greater than 12 hours, it must meet additional environmental design and monitoring/testing standards in the buffer and ante-areas. 3. USP<797> contains separate standards for the safe compounding of hazardous medications (defined as “...if studies in animals or humans indicate that exposures to them have a potential for causing cancer, development or reproductive 		

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toxicity, or harm to organs...”),
radiopharmaceuticals and allergen extracts.

In addition, USP <797> includes standards for various processes, precautions and quality assurance practices required and recommended for the safe preparation of all risk levels of CSPs. These address issues such as:

1. The responsibilities of compounding personnel and their supervisors to implement and maintain proper procedures and quality assurance checks.
2. Issues specific to “immediate use” CSPs; single- and multiple-dose containers; CSPs containing hazardous drugs; radiopharmaceuticals; allergen extracts; and automated compounding devices used for parenteral nutrition compounding.
3. Methods for sterilization, depyrogenation and for verifying compounding accuracy and sterility.
4. Specifications for environmental quality and control, including but not limited to:
5. Specifications and related personnel training, including competency assessment and evaluation of skill in aseptically preparing CSPs using visual observation as well as bacterial sampling of glove fingertips and “media-fill testing” at specified intervals.

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	<p>6. Evaluation and monitoring/testing of the environment in which compounding takes place and, if applicable, the adjacent “ante-” and “buffer” areas, including facility layout, design, environmental controls, restricted access, air quality standards and testing, surface characteristics, furnishings, cleaning and disinfection procedures, and standards for personnel health, attire/cosmetics, cleansing/garbing/gloving, aseptic work practices, etc.</p> <p>7. Suggested standard operating procedures to protect the quality of the environment in which CSPs are prepared.</p> <p>8. Quality control related to ingredients, devices and equipment used in relation to CSPs.</p> <p>9. Quality checks to be performed before CSPs are dispensed or administered.</p> <p>10. Issues related to beyond-use dating and packaging, storage and transportation conditions for CSPs.</p> <p>11. Protecting dispensed and distributed CSPs.</p> <p>12. Patient education issues.</p> <p>13. Monitoring for and reporting adverse patient events related to CSPs.</p>		

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14. Requirements for a formal quality assurance program to be maintained by providers of CSPs.

**For information –
Not Required / Not to be Cited**

USP<797> Appendices I and III-V contain summaries and assessment tools that hospitals may find helpful. However, there is no requirement to use specific forms or materials as long as the hospital and/or its external sources of CSPs are implementing plans, procedures, testing and documentation consistent with applicable standards for safe compounding.

These USP<797> materials are referenced here only as examples:

- “Appendix I: Principal Competences, Conditions, Practices, and Quality Assurances That Are Required...and Recommended in USP Chapter <797>”
- “Appendix III: “Sample Form for Assessing Hand Hygiene and Garbing Related Practices of Compounding Personnel”
- “Appendix IV: “Sample Form for assessing Aseptic Technique and Related Practices of Compounding Personnel”
- “Appendix V: “Sample Form for Assessing Cleaning and Disinfection Procedures”

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PACKAGING AND LABELING OF MEDICATIONS

Safe medication use includes proper packaging and labeling to reduce the risk of error.

For individual drug containers:

1. Each floor stock drug container is expected to be labeled with the name and strength of the drug, lot and control number equivalent, and expiration date.

2. Appropriate accessory and cautionary statements are included as well as the expiration date and/or, if applicable, a beyond-use date (BUD).

3. It should be noted that, for multi-dose medication vials with antimicrobial preservatives which have been opened or entered (e.g., needle-punctured), the USP standard is that the BUD is 28 days, unless otherwise specified by the manufacturer.

4. In addition, where applicable, each patient's individual drug container is expected to be labeled with the patient's full name and quantity of the drug dispensed.

If the unit dose system is utilized, each single unit dose package is expected to be labeled with the name and strength of the drug, lot and control number equivalent, expiration date and/or, if applicable, a BUD.

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For Information Only

Certain provisions of the FDCA address the labeling of prescription drugs generally (e.g., section 503(b)(2) of the FDCA). Section 503B of the FDCA includes labeling requirements for drugs compounded by registered outsourcing facilities (see section 503B(a)(10)).

Although hospitals are expected to comply with these requirements, surveyors conducting a Medicare survey do not assess compliance with other Federal laws.

DISPENSING OF MEDICATIONS

Medications must be dispensed in a manner that is safe and meets the needs of the patient.

1. Quantities of medications are dispensed which minimize diversion and potential adverse events while meeting the needs of patients.

2. Medications are dispensed in a timely manner. The hospital must have a system that ensures that medication orders get to the pharmacy and medications get back to patients promptly.

3. Whenever possible, medications are dispensed in the most ready to administer form available from the manufacturer or, if feasible, in unit dose that

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- have been repackaged by the pharmacy.
4. The hospital consistently uses the same dose packing system, or, if a different system is used, provides education about the use of the dose packaging system.
 5. All concerns, issues or questions are clarified with the individual prescriber before dispensing; **and**
 6. **Medications dispensed by the hospital are retrieved when recalled or discontinued by the manufacturer or the Food and Drug Administration (FDA) for safety reasons.**

AVAILABILITY OF MEDICATIONS

Medications must be available for administration to patients when needed, including when the pharmacy is not open.

Methods to accomplish this when the pharmacy is not open could include, but are not limited to, one or more of the following:

1. **Automated dispensing units outside the pharmacy, night cabinets, contracted services after hours via telepharmacy contracting, on-call pharmacists, etc.**
2. **Automated Dispensing Cabinets (ADCs) for medications are a secure option for medication storage since they ensure locked storage of medications and allow for electronic tracking of**

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controlled substances and other drugs. These cabinets often have embedded security features, such as login and password or biometric identification so that they can only be accessed by authorized personnel.

3. Policies and procedures must address who can access medications during after-hours.

<p>For Information Only Not Required/Not to be Cited</p> <p>When utilizing automated dispensing cabinets (ADCs), the Institute for Safe Medication Practices recommends the following:</p> <p>http://www.ismp.org/Newsletters/acutecare/articles/20090212.asp</p> <p style="text-align: center;">And</p> <p>http://www.ismp.org/Tools/guidelines/ADC_Guidelines_Final.pdf</p> <p>Security processes are established to ensure adequate control of medications outside of the pharmacy and to reduce the potential for medication diversion from ADCs.</p> <ul style="list-style-type: none"> • Utilize biometric user identification or, at a minimum, change user passwords quarterly. • Link the ADC to the pharmacy computer to allow for patient “profiling,” so that a pharmacist can review each medication order and screen it for safety before the drug is
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dispensed or accessed by the nurse or other healthcare professional.

- Limiting the availability of overrides to the ADC system.
- Limiting access to drugs based on the patients profile so to decrease medication selection errors.
- Store each medication and strength in an individual lidded ADC compartment that opens only when the specific medication is selected.
- Document the destruction of medication waste at the time of removal of medication whenever possible. Record this waste via the ADC, and match the administered dose with ordered dose. Have a process to routinely review/ reconcile the documented medication waste.
- Return all medications to a common secure one-way bin that is maintained by pharmacy, not to an individual pocket or bin within the ADC.

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<p>25.01.03 Security of Medications. Consistent with State and Federal requirements, in the pharmacy and throughout the facility:</p> <ul style="list-style-type: none"> <i>All drugs and biologicals must be kept in a secure area, and locked when appropriate.</i> <p>§482.25(b)(2)(i)</p>	<p>A secure area means that drugs and biologicals are stored in a manner to prevent unmonitored access by unauthorized individuals.</p> <p>Drugs and biologicals must not be stored in areas that are readily accessible to unauthorized persons. For example, if medications are kept in a private office, or other area where patients and visitors are not allowed without the supervision or presence of a health care professional (for example, ambulatory infusion), they are considered secure.</p> <p>RESTRICTED AREAS Areas restricted to authorized personnel only would generally be considered “secure areas.” If there is evidence of tampering or diversion, or if medication security otherwise becomes a problem, the hospital is expected to evaluate its current medication control policies and procedures, and implement the necessary systems and processes to ensure that the problem is corrected, and that patient health and safety are maintained. (71 FR §68689)</p> <p>CONTROLLED SUBSTANCES All controlled substances must be locked. Hospitals are permitted flexibility in the storage of non-controlled drugs and biologicals when delivering care to patients, and in the safeguarding of drugs and biologicals to prevent tampering or diversion. An area in which staff are actively providing care to patients or preparing to receive patients, i.e., setting up for procedures before the arrival of a patient, would generally be considered</p>	<p><u>DOCUMENT REVIEW, INTERVIEW, AND OBSERVATION</u></p> <ol style="list-style-type: none"> Review hospital policies and procedures governing the security of drugs and biologicals to determine whether they provide for securing and locking as appropriate. Review hospital policies and procedures governing patient self-administration of drugs and biologicals. Observe whether medications in various areas of the hospital are stored in a secure area, and locked when appropriate. Are medication storage areas periodically inspected by pharmacy staff to make sure medications are properly stored? Determine that security features in automated medication distribution units are implemented and actively maintained, e.g., that access authorizations are regularly updated to reflect changes in personnel, assignments, etc. Interview staff to determine whether policies and procedures regarding patient self-administration of drugs and biologicals are implemented and effective. If patient self-administration of drugs and 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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	<p>a secure area. When a patient care area is not staffed, both controlled and non-controlled substances are expected to be locked.</p> <p>LABOR AND DELIVERY, CRITICAL CARE, AND SURGERY Generally labor and delivery suites and critical care units are staffed and actively providing patient care around the clock, and, therefore, considered secure. However, hospital policies and procedures are expected to ensure that these areas are secure, with entry and exit limited to appropriate staff, patients and visitors.</p> <p>The operating room suite is considered secure when the suite is staffed and staff are actively providing patient care.</p> <ul style="list-style-type: none"> • When the suite is not in use (e.g., weekends, holidays and after hours), it would not be considered secure. • A hospital may choose to lock the entire suite, lock non-mobile carts containing drugs and biologicals, place mobile carts in a locked room, or otherwise lock drugs and biologicals in a secure area. If an individual operating room is not in use, the hospital is expected to lock non-mobile carts, and ensure mobile carts are in a locked room. (71FR §68689) <p>This regulation gives hospitals the flexibility to integrate patient self-administration of non-controlled drugs and biologicals into their practices as</p>	<p>biologicals is permitted, interview patients and staff to determine whether policies and procedures to restrict access to authorized personnel are implemented and effective.</p>	

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appropriate.

SELF-ADMINISTRATION

When a hospital allows a patient to self-administer selected drugs and biologicals, the hospital authorizes the patient to have access to these medications. This regulation is consistent with the current practice of giving patients access at the bedside to urgently needed medications, such as nitroglycerine tablets and inhalers. It supports the current practice of placing selected nonprescription medications at the bedside for the patient’s use, such as lotions and creams, and rewetting eye drops.

Hospitals are expected to address patient self-administration of non-controlled drugs and biologicals in their policies and procedures (**see self-administration discussion at §§482.23(c)(6)(i) and 482.23(c)(6)(ii)**). This regulation supports hospital development, in collaboration with the medical staff and the nursing and pharmacy departments, of formal patient medication self-administration programs for select populations of patients, including hospital policies and procedures necessary to ensure patient safety and security of medications.

The policies and procedures are expected to include measures to ensure the security of bedside drugs and biologicals. They are also expected to address both the competence of the patient to self-administer drugs and biologicals as well as patient education regarding self-administration of drugs and biologicals. (71FR

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§68689)

MEDICATION CARTS

Due to their mobility, mobile nursing medication carts, anesthesia carts, epidural carts and other medication carts containing drugs or biologicals (hereafter, all referred to as “carts”) must be locked in a secure area when not in use. Hospital policies and procedures are expected to address the security and monitoring of carts, locked or unlocked, containing drugs and biologicals in all patient care areas to ensure their safe storage and to ensure patient safety. (71 FR §68689)

AUTOMATED DISTRIBUTION UNITS

Medication automated distribution units with security features, such as logon and password or biometric identification, are considered to be locked, since they can only be accessed by authorized personnel who are permitted access to the medications. Such units must be stored in a secure area.

25.01.04 Controlled Substances.
Drugs listed in Schedules II, III, IV, and V of the Comprehensive Drug Abuse Prevention and Control Act of 1970 must be kept locked within a secure area.

All Schedule II, III, IV, and V drugs must be kept locked within a secure area.

A secure area means the drugs and biologicals are stored in a manner to prevent unmonitored access by unauthorized individuals.

§482.25(b)(2)(ii)

Medication automated distribution units with logon and password/biometric identification are considered

DOCUMENT REVIEW, OBSERVATION, AND INTERVIEW

1. Determine whether there is a hospital policy and procedure that requires Schedule II, III, IV, and V drugs to be kept in a locked storage area.
2. Observe in various parts of the hospital whether Schedule II, III, IV and V drugs are

- 1 = Compliant
 2 = Not Compliant

This standard is not met as evidenced by:

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	<p>to be locked, since they can only be accessed by authorized personnel who are permitted access to Schedule II – V medications.</p> <p>Mobile nursing medication carts, anesthesia carts, epidural carts and other medication carts containing Schedule II, III, IV, and V drugs must be locked within a secure area.</p>	<p>locked and stored in a secure area.</p> <p>3. Determine whether security features in automated medication distribution units are implemented and actively maintained, e.g., that access authorizations are regularly updated to reflect changes in personnel, assignments, etc.</p> <p>4. Interview staff to determine whether policies and procedures to restrict access to authorized personnel are implemented and effective.</p>	
<p>25.01.05 Access To Controlled Substances <i>Only authorized personnel may have access to locked areas.</i></p> <p>§482.25(b)(2)(iii)</p>	<p>The hospital must assure that only authorized personnel may have access to locked areas where drugs and biologicals are stored.</p> <p>A hospital has the flexibility to define which personnel have access to locked areas, based on the hospital’s needs as well as State and local law. For example, a hospital could include within its definition of “authorized personnel” ancillary support personnel, such as engineering, housekeeping staff, orderlies and security personnel as necessary to perform their assigned duties.</p> <p>The hospital’s policies and procedures must specifically address how “authorized personnel” are defined for purposes of this section. It is not necessary for the policy to name specific authorized individuals, but the policy should be clear in describing the</p>	<p>DOCUMENT REVIEW AND INTERVIEW</p> <p>1. Determine whether there is a hospital policy and procedure defining authorized personnel that are permitted access to locked areas where drugs and biologicals are stored.</p> <p>2. Determine whether there is a hospital policy and procedure for limiting access to locked storage areas to authorized personnel only.</p> <p>3. Observe whether or not access to locked storage areas is limited to personnel authorized by the hospital’s policy.</p>	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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categories of personnel who have authorized access, as well as whether there are different levels of access authorized in different areas of the hospital, or at different times of day, or for different classes of drugs and biologicals, etc.

The hospital's policies and procedures must also address how it prevents unauthorized personnel from gaining access to locked areas where drugs and biologicals are stored. Whenever unauthorized personnel have access, or could gain access, to those locked areas, the hospital is not in compliance with this requirement and is expected to re-evaluate and tighten its security measures.

25.01.06 Pharmacy Security.
At a minimum, the pharmacy is equipped with locking entries.

The pharmacy is locked when not staffed. Key inventories or access codes are strictly controlled. If "unusual" risk is perceived, measures are taken to respond.

OBSERVATION & INTERVIEW

- Evaluate the security of the pharmacy.
1. The area is secure from unauthorized entry.
 2. Keys, security codes, and carts are secure.

- 1 = Compliant
 2 = Not Compliant

This standard is not met as evidenced by:

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<p>25.01.07 <u>Inventory Management System.</u> <i>Outdated, mislabeled, or otherwise unusable drugs and biologicals must not be available for patient use.</i></p> <p>§482.25(b)(3)</p>	<p>The hospital must have a pharmacy labeling, inspection, and inventory management system that ensures that outdated, mislabeled, or otherwise unusable drugs and biologicals are not available for patient use. This would include drugs that are the subject of a manufacturer’s recall.</p> <p>A drug or biological is outdated after its expiration date, which is set by the manufacturer based on stability testing under specified conditions as part of the FDA approval process. It should be noted that a drug or biological may become unusable prior to its expiration date if it has been subjected to conditions that are inconsistent with the manufacturer’s approved labeling.</p> <p><u>BEYOND-USE DATE</u> A drug or biological is also outdated after its “beyond-use date” (BUD), which may be reached before the expiration date, but never later.</p> <p>The BUD takes into account the specific conditions and potential for deterioration and microbial growth that may occur during or after the original container is opened, while preparing the medication for dispensing and administration, and/or during the compounding process if it is a compounded medication.</p> <p>The BUD is to be based on information provided by the manufacturer, whenever such information is available.</p>	<p><u>OBSERVATION AND INTERVIEW</u></p> <ol style="list-style-type: none"> 1. Spot-check the labels of individual drug containers to verify that they conform to Federal and State laws, and/or contain the following minimal information: <ol style="list-style-type: none"> a. Each patient’s individual drug container bears his/her full name, the prescriber’s name, and strength and quantity of the drug dispensed. Appropriate accessory and cautionary statements are included as well as the expiration date and/or, if applicable, a BUD. b. Each floor stock container bears the name and strength of the drug, lot and control number of equivalent, expiration date. 2. If the unit dose system is utilized, verify that each single unit dose package bears name and strength of the drug, lot and control number equivalent, and expiration date and/or, if applicable, a BUD. 3. Inspect patient-specific and floor stock medications to identify expired, mislabeled or unusable medications. 4. Review the pharmacy policies and procedures for determining BUDs (for medications compounded in-house as well 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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	<ul style="list-style-type: none"> • The hospital must maintain and implement policies and procedures that provide clear and consistent direction to pharmacy staff regarding how to determine a BUD when complete BUD information is not available from the manufacturer. • The policies and procedures must be based on accepted professional principles which are equivalent to, or more stringent than, those described in the United States Pharmacopeia-National Formulary (USP).⁴ <p>According to Chapters <795> and <797> of the USP, the BUD must be safe for patients, and determined conservatively.</p> <ol style="list-style-type: none"> 1. The section in USP <797> entitled “Determining Beyond-Use Dates,” which addresses sterile compounding, notes that “the truly valid evidence for predicting beyond-use dating can be obtained only through product-specific experimental studies.” 2. It provides an example of testing considered more appropriate for certain types of compounded sterile preparations (CSPs) such as “CSPs with a narrow therapeutic index, where close monitoring or dose titration is required to ensure therapeutic effectiveness and to avoid toxicity....” 3. It also provides examples of important issues 	<p>as from external sources).</p> <ol style="list-style-type: none"> a. Can the hospital demonstrate that the policies and procedures are consistent with or more stringent than the applicable USP standards? b. Can it demonstrate that the pharmacy personnel assigned to determining BUDs when a manufacturer’s instructions are not available have the expertise and technical support needed to properly conduct the assessments needed to make such determinations in a manner consistent with standards and hospital policies? <ol style="list-style-type: none"> 5. Ask for one or more examples of situations in which a BUD had to be determined for a compounded sterile medication (CSP) based on the policy. <ol style="list-style-type: none"> a. Interview pharmacy personnel assigned to carry out this function within the hospital and/or to assess how this is done by external source(s) of CSPs. b. Is there evidence that the BUDs are determined consistent with the hospital’s policies and procedures? 	

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that a pharmacist must be able to critically interpret and evaluate when consulting literature sources in the process of determining a BUD; and distinguishes between reviewing literature specific to a particular drug, composition, concentration of ingredients, fill volume, container, storage conditions and duration of use, etc., versus merely reviewing available publications or tables.

4. The former is the preferred approach, while the latter results in a “theoretical BUD,” which has an inherent likelihood of inaccuracy or error.

For Individual Drug Containers

1. Each floor stock drug container is expected to be labeled with the name and strength of the drug, lot and control number equivalent, and expiration date.
2. Appropriate accessory and cautionary statements are included as well as the expiration date and/or, if applicable, a BUD.
3. It should be noted that, for multi-dose medication vials with antimicrobial preservatives which have been opened or entered (e.g., needle-punctured), the USP standard is that the BUD is 28 days, unless otherwise specified by the manufacturer.

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4. In addition, where applicable, each patient’s individual drug container is expected to be labeled with the patient’s full name and quantity of the drug dispensed.

If the unit dose system is utilized, each single unit dose package is expected to be labeled with the name and strength of the drug, lot and control number equivalent, expiration date and/or, if applicable, a BUD.

⁴ All references to “USP” herein are from: United States Pharmacopeial Convention. USP on Compounding: A Guide for the Compounding Practitioner. Current with USP 37-NF32 through First Supplement. Rockville, MD: United States Pharmacopeial Convention, 2014.

25.01.08 Pharmacy Access.
When a pharmacist is not available, drugs and biologicals must be removed from the pharmacy or storage area only by personnel designated in the policies of the medical staff and pharmaceutical service, in accordance with Federal and State law.

§482.25(b)(4)

Routine after-hours access to the pharmacy by non-pharmacists for access to medication should be minimized and eliminated as much as possible.

The use of well-designed night cabinets, after-hours medication carts, and other methods may preclude the need for non-pharmacist staff to enter the pharmacy.

If an urgent or emergent patient need occurs, the hospital must be able to provide medications to the patients in its facility.

OBSERVATION & DOCUMENT REVIEW

- Determine through pharmacy records that when the pharmacist is not available, drugs are removed from the pharmacy (drug storage area) only by a designated individual (in accordance with State law if applicable) and only in amounts sufficient for immediate therapeutic needs.**
- Review policies and procedures to determine who is designated to remove drugs and biologicals from the pharmacy or storage area and the amount a non-**

1 = Compliant
 2 = Not Compliant

This standard is not met as evidenced by:

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	<p>The hospital must have a process for providing medications to meet patient needs when the pharmacy is closed.</p> <p>Policies and procedures must be consistent with federal and state law.</p> <p>When non-pharmacist healthcare professionals are allowed by law and regulation to obtain medications after the pharmacy is closed, the following safeguards are applied:</p> <ol style="list-style-type: none"> 1. Access is limited to those medications approved by the hospital. These medications can be stored in a night cabinet, automated storage and distribution device, or a limited section of the pharmacy. 2. Only trained, designated prescribers and nurses are permitted access to medications. 3. Quality control procedures (such as an independent second check by another individual or a secondary verification built into the system, such a bar coding) are in place to prevent medication retrieval errors. 4. The hospital arranges for a qualified pharmacist to be available either on-call or at another location (for example, at another organization that has 24-hour pharmacy service) to answer questions or provide medications beyond those accessible to non-pharmacy staff. 	<p>pharmacist may remove in the absence of a pharmacist.</p> <ul style="list-style-type: none"> • The individual(s) designated should be identified by name and qualifications. • The policy limits access into the Pharmacy by anyone other than RN or physician. <ol style="list-style-type: none"> 3. Determine that a system is in place that accurately documents the removal of medications (type and quantity) from either the pharmacy or the after-hours supply. 4. Determine that the pharmacist reviews all medication removal activity and correlates the removal with current medication orders in the patient medication profile. 5. Determine if the pharmacist routinely reviews the contents of the after-hours supply to determine if it is adequate to meet the after-hours needs of the hospital. <p>View the “after-hours” medication withdrawal log for at least three different nights. Is practice consistent with hospital policy?</p> <ul style="list-style-type: none"> • Entries in the “after-hours” medication withdrawal log should indicate the patient’s name <u>and not "to stock supply"</u>. • The quantity removed is not greater than that 	

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5. The process is evaluated **on an on-going basis to determine the medications accessed routinely and the causes of accessing the pharmacy after hours.**

6. Changes **are** implemented as appropriate to reduce **the amount of times non-pharmacist health care professionals are obtaining medications after the pharmacy is closed.**

Medication removals from the pharmacy or drug cabinet:

1. Are recorded.
2. Are in quantities sufficient only to dose until a pharmacist can review the order and the removal record. (This activity is to be in "preparation for immediate dosing only"; dispensing by non-pharmacists is not permitted.) Some states prohibit entry into the pharmacy proper unless a pharmacist is present thus requiring use of "night" closets or drug cupboards for after hours supply.
3. All after-hour withdrawals are logged.

needed for immediate use.

- The name of the "pharmacist on call" is readily identified.
- A retrieval accuracy validation process is in place; unit staff are able to articulate that process.

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<p>25.01.09 Automatic Stop Medication Orders. <i>Drugs and biologicals not specifically prescribed as to time and/or number of doses must automatically be stopped after a reasonable time that is predetermined by the medical staff.</i></p> <p>§482.25(b)(5)</p>	<p>In accordance with accepted standards of practice, the medical staff, in coordination and consultation with the pharmacy service, determines and establishes the reasonable time to automatically stop orders for drugs and biologicals not specifically prescribed as to time or number of doses.</p> <p>It is important to note that hospitals with an electronic health record (EHR) system may have time and dose parameters automatically built into computerized provider order entry (CPOE) screens.</p> <p>These may be part of the hospital’s plan for addressing automatic stop orders.</p>	<p><u>DOCUMENT REVIEW AND OBSERVATION</u></p> <ol style="list-style-type: none"> Review policies and procedures to determine that there is a protocol established by the medical staff to discontinue and review patients’ medical records to determine compliance with stop-order policy. Ask unit staff what happens in the case of drugs with no stop date or prescribed number of doses. <ul style="list-style-type: none"> Are they aware of the automatic stop policy? Can they describe how it is enforced? 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>
<p>25.01.10 Drug Reactions & Administration Errors & Incompatibilities. <i>Drug administration errors, adverse drug reactions and incompatibilities must be immediately reported to the attending physician and if appropriate, to the hospital’s quality assurance and performance improvement program.</i></p> <p>§482.25(b)(6)</p>	<p>Hospitals are required to ensure that the attending physician is made immediately aware of drug administration errors, adverse drug reactions, and incompatibilities.</p> <p>When the attending physician is unavailable, the covering physician must be notified. When the covering physician must be notified, the patient’s attending physician must be notified as soon as he/she is available.</p> <p>REPORT TO QAPI In addition, when appropriate, such events must also be reported to the hospital-wide Quality Assessment and Performance Improvement (QAPI) program.</p>	<p><u>DOCUMENT REVIEW, CHART REVIEW, & INTERVIEW</u></p> <ol style="list-style-type: none"> Determine that the hospital has an effective procedure that ensures drug administration errors, adverse drug reactions, and drug incompatibilities are immediately reported to the attending physician. Determine that medication error reporting includes all areas where medication is prepared and administered, e.g., pharmacy, radiology, anesthesia, respiratory therapy, and etc. Does the hospital have policies and 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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	<p>The hospital must adopt policies and procedures that identify the types of events that must be reported immediately to the attending physician, as well as those to be reported to the QAPI program.</p> <p><u>Drug Administration Error:</u> The National Coordinating Council Medication Error Reporting and Prevention definition of a medication error is: "Any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. Such events may be related to professional practice, health care products, procedures, and systems, including prescribing; order communication; product labeling, packaging, and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use."</p> <p>In the context of this regulation, however, "drug administration error" is limited to those errors in administration that actually reach the patient, i.e., a medication actually is administered to a patient when it should not be, or the wrong dose is administered, or the wrong route of administration is used, etc., or a medication that should have been administered to the patient has not been administered in a timely manner, as discussed in the medication administration standard at 42 CFR 482.23(c).</p>	<p>procedures that define medications errors, ADRs, and drug incompatibilities?</p> <ul style="list-style-type: none"> • Do they address the circumstances under which they must be reported immediately to the attending physician, as well as to the hospital's QAPI program? • Do they address how reporting is to occur? <p>4. Are all medication errors and suspected ADRs promptly recorded in the patient's medical record, including those not subject to immediate reporting?</p> <p>5. If upon review of a sample of records, a suspected ADR or medication error is identified, determine if it was reported immediately to the attending or covering physician, in accordance with the hospital's written policies and procedures.</p> <ul style="list-style-type: none"> • If it is reported to a covering physician, determine if it was also reported to the attending physician when he/she became available. <p>6. Ask hospital staff what they do when they become aware of a medication error, ADR or drug incompatibility. Are staff aware of and</p>	

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	<p><u>Adverse Drug Reaction:</u> The American Society of Health-System Pharmacists (ASHP) defines an adverse drug reaction (ADR) as "Any unexpected, unintended, undesired, or excessive response to a drug that:</p> <ol style="list-style-type: none"> 1. Requires discontinuing the drug (therapeutic or diagnostic); 2. Requires changing the drug therapy; 3. Requires modifying the dose (except for minor dosage adjustments); 4. Necessitates admission to a hospital; 5. Prolongs stay in a health care facility; 6. Necessitates supportive treatment; 7. Significantly complicates diagnosis; 8. Negatively affects prognosis; or 9. Results in temporary or permanent harm, disability, or death. <p>Consistent with the definition, an allergic reaction (an immunologic hypersensitivity occurring as the result of unusual sensitivity to a drug) and an idiosyncratic reaction (an abnormal susceptibility to a drug that is peculiar to the individual) are also considered ADRs."</p>	<p>do they follow the hospital's policy and procedures?</p> <ol style="list-style-type: none"> 7. Ask hospital staff how they manage drug incompatibilities. <ul style="list-style-type: none"> • What tools do they use in the clinical setting to minimize the risk of incompatibilities? • How is the information related to drug incompatibilities made available to the clinical staff administering IV medications (posters, online tools, etc.)? • How often is the information updated to ensure accuracy? 8. Interview hospital staff to ascertain awareness of the hospital's policy on reporting and documentation of medication errors and adverse drug reactions. 9. How does information regarding medication errors, adverse drug reactions, and incompatibilities get reported to the hospital QAPI program? Ask staff to speak to the process. 10. For QAPI reporting purposes, is the hospital's definition of an ADR and medication error based on national standards? 	

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	<p><u>Drug Incompatibilities:</u> A drug incompatibility occurs when drugs interfere with one another chemically or physiologically. Drugs known to be incompatible must not be mixed, administered together, or administered within a timeframe where they will interfere with each other.</p> <p>When IV medications are administered with known incompatibilities, an error has occurred and it needs to be reported to the attending physician immediately. Any unexpected reaction that occurs between IV medications not previously identified as incompatible also needs to be reported.</p> <p>Hospitals can minimize the risk of administering incompatible medications by making available pertinent resources, such as drug incompatibility charts and online incompatibility references. The incompatibility information needs to be readily available to staff administering medications. The information needs to be kept up-to-date as the information is frequently updated by drug manufacturers.</p> <p>The immediate reporting requirement applies to drug administration errors, adverse drug reactions or incompatibilities that have harmed or have the potential to harm the patient. If the outcome of the drug administration error is unknown, the physician must also be notified without delay.</p>	<p>Is the facility’s definition of an adverse drug reaction and medication error based on established benchmarks or studies on report rates published in peer-review journals? Is it identifying as many medication errors and adverse drug reactions as would be expected for the size and scope of services provided by the hospital?</p> <p>Review QAPI activities for medication errors and adverse reaction reports to determine if upon analyses of the reports that potential corrective actions are identified and implemented, if appropriate.</p>	

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Drug administration errors that result in no or insignificant harm to the patient must also be documented in the medical record but do not require immediate reporting to the attending physician. For example, if an analgesic dose is missed during the night shift, it can be reported first thing in the morning. Hospital staff are expected to use their clinical judgment, based on patient presentation and assessment in accordance with hospital policy and procedures, to determine whether immediate reporting is required.

On the other hand, for purposes of reporting to the hospital’s QAPI program, hospitals must, in accordance with the requirements of the QAPI CoP at 42 CFR §482.21(c)(2), track and report not only the errors that cause or risk harm to the patient, but also those which do not. Such “near misses” and suspected ADRs may reveal important information about systems vulnerabilities that the hospital should address in order to avoid events that result in harm.

Hospitals must establish policies and procedures for reporting of medication errors, ADRs, and incompatibilities, and ensure that staff are aware of the reporting process. For those events that require immediate reporting, the hospital’s policies must establish timeframes for reporting that are based on the clinical effect of the error on the patient.

To improve staff willingness to report medication error incidents, hospitals are encouraged to adopt a non-

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punitive approach that focuses on system issues rather than individual health care professionals. A non-punitive approach is likely to encourage reporting by those who otherwise may fear retribution or hospital disciplinary action.

In addition to employing broad definitions of medication errors and ADRs for QAPI tracking purposes and encouraging reporting of medication errors, ADRs and drug incompatibilities, the hospital must take additional steps to identify these events as part of its QAPI program. Reliance solely on incident reporting fails to identify the majority of errors and adverse reactions. Proactive identification includes observation of medication passes, concurrent and retrospective review of a patient’s clinical records, ADR surveillance team, implementation of medication usage evaluations for high-alert drugs, and identification of indicator drugs that, when ordered, automatically generate a drug regimen review for a potential adverse drug event.

The hospital must have a method by which to measure the effectiveness of its systems for identifying and reporting to the QAPI program medication errors and ADRs. Such methods could include use of established benchmarks for the size and scope of services provided by the hospital, or studies on reporting rates published in peer-reviewed journals. Hospitals are encouraged, and may be required by State law, to participate in statewide and national reporting of drug administration errors, adverse drug reactions, and

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incompatibilities.

National organizations include, but are not limited to, the Food and Drug Administration’s (FDA) MedWatch Reporting Program and the Institute for Safe Medication Practices (ISMP) Medication Errors Reporting Program.

25.01.11 Reporting of Controlled Drug Loss and/or Abuse.

Abuses and losses of controlled substances must be reported, in accordance with applicable Federal and State laws, to the individual responsible for the pharmaceutical service, and to the chief executive officer, as appropriate.

§482.25(b)(7)

The tracking system for Scheduled drugs is capable of detecting and reporting such abuses and losses.

DOCUMENT REVIEW, OBSERVATION, & INTERVIEW

1. Review the policy/procedure regarding abuse or loss of controlled substances.
2. Verify there is a policy that addresses the reporting of abuse and losses to the CEO, DEA (**Drug Enforcement Agency**), and appropriate State Boards.
3. Interview the pharmacists or **pharmacy employees** to determine their understanding of the controlled drug policies.
4. Review reports **of pharmaceutical services** to determine if there are reported problems with controlled drugs and what actions have been taken to correct the situation.
5. Conduct a spot check of drug use and other inventory records to ensure that drugs are properly accounted for.

- 1 = Compliant
- 2 = Not Compliant

This standard is not met as evidenced by:

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25.01.12 Informational Resources.

Information relating to drug interactions and information of drug therapy, side effects, toxicology, dosage, indications for use, and routes of administration must be available to the professional staff.

§482.25(b)(8)

The pharmacy must be a resource for medication-related information to the hospital's health-care practitioners and other health care personnel to optimize therapeutic outcomes and minimize adverse drug events. Information must be available concerning drug interactions and information of drug therapy, side effects, toxicology, dosage, indications for use, and routes of administration.

The pharmacy may also assist other health care professionals with the following medication-related functions:

6. Interview the Pharmacy Director, pharmacist and pharmacy employees to determine their understanding of the controlled drug policies.
 - Is there a policy and procedure for handling controlled drug discrepancies?
 - Problems with controlled drugs, if any, have been reported to the authorities, according to policy.
7. Determine if controlled drug losses were reported to appropriate authorities in accordance with State and Federal laws.

INTERVIEW & OBSERVATION

1. Is drug information readily available to nurses and practitioners, whether in hard copy or electronic format?
2. If drug information is built in to the hospital's EHR system, ask the pharmacy director how the hospital ensures that the information is accurate and up-to-date.
3. Ask practitioners whether needed reference information is available to them when prescribing drugs.

- 1 = Compliant
- 2 = Not Compliant

This standard is not met as evidenced by:

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	<ol style="list-style-type: none"> 1. Collection and organization of patient-specific information (height, weight, allergies); 2. Identification of the presence of medication-therapy problems, both potential and actual, such as drug-drug interactions, excessive doses; 3. Identification and specification of pharmacotherapeutic goals; 4. Implementation of a monitoring plan in collaboration with the patient, if applicable, and other health-care professionals; 5. Monitoring the effects of the pharmacotherapeutic regimen – could include adjusting doses based on lab values (i.e.: Coumadin dosing); or 6. Redesigning the regimen and monitoring plan as indicated. <p>For example, practitioners may write an order for “pharmacy to dose” an antibiotic. The pharmacist would then take patient-specific information, review the patient’s current medication therapies for any problems, and then calculate the dose required to meet therapeutic goals.</p> <p>Increasingly, as hospitals move to computerized physician-order entry (CPOE) of medication orders, much of this consultation function (e.g.; dosage, path</p>	<ol style="list-style-type: none"> 4. Ask nursing staff whether needed reference information is available to them when administering drugs or biologicals and when monitoring patients for effects of medication therapies. 	

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of administration, drug-drug interactions and other contraindications, etc.) is built in to the electronic health record (EHR) system.

- However, the pharmacy service remains responsible for the provision of accurate, up-to-date information to meet the needs of the hospital’s practitioners, nursing staff and patients.

The hospital must also have immediately available sufficient up-to-date reference material on drug therapy, whether in electronic or hard copy format.

A pharmacist also should be readily available by telephone or other means to respond to questions from practitioners and nursing personnel.

25.01.13 Formulary System.
A formulary system must be established by the medical staff to assure quality pharmaceuticals at reasonable costs.

§482.25(b)(9)

The medical staff must establish a formulary system. The formulary is reviewed at least annually to ensure the contents are current.

The formulary lists medications for dispensing or administration that the hospital maintains or that are readily available.

In accordance with accepted standards of practice, the medical staff, in consultation with the pharmacy service, should develop written criteria for determining what medications are available for

DOCUMENT REVIEW, OBSERVATION, & INTERVIEW

1. Interview the pharmacist to determine that the medical staff has established a formulary that lists drugs that actually are available in the hospital.
2. Interview the Pharmacy Director to determine the process for periodic review of the formulary.
3. **Determine that the formulary lists drugs that**

- 1 = Compliant
 2 = Not Compliant

This standard is not met as evidenced by:

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	<p>dispensing or administration.</p> <ul style="list-style-type: none"> At a minimum, the criteria include the indication for use, effectiveness, risks (including propensity for medication errors, abuse potential, and sentinel events), and costs. <p>Processes and mechanisms should be established to monitor patient responses to a newly added medication before the medication is made available for dispensing or administration within the hospital.</p> <p>Medications designated as available for dispensing or administration are reviewed periodically based on emerging safety and efficacy information. The hospital should have processes to approve and procure medications that are not on the hospital's medication list.</p> <p>The hospital should have processes to address medication shortages and outages including the following:</p> <ul style="list-style-type: none"> Communicating with appropriate prescribers and staff Developing approved substitution protocols Educating appropriate Licensed Independent Practitioners (LIPs), appropriate health care professionals, and staff about these protocols Obtaining medications in the event of a disaster. 	<p>are available.</p> <ol style="list-style-type: none"> Determine the formulary is current by reviewing the date of approval by the Medical Staff. Observe for availability of the formulary in the clinical areas. Interview clinical staff regarding the availability of the formulary. The formulary / drug list is more than a pharmacy charge - master; it includes remotely purchased / stored drugs / biological / diagnostic testing agents. 	

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Processes and mechanisms should be established to:

- Monitor patient responses to newly added medication before the medication is made available for dispensing or administration within the hospital.
- Approve and procure medications that are not on the hospital's formulary/drug list.

25.01.14 Integrity of Medication.

Drugs and biologicals are stored at proper temperatures to maintain strength / potency. Records are maintained of drug refrigerator and freezer temperatures.

Daily temperature records, from accurate thermometers, are maintained for each drug refrigerator / freezer.

Thermometer accuracy is verified against a known standard on a semiannual basis.

Recommended guidelines* for consideration are:

- A. Refrigerator temperature range:**
- **Between 2° – 8° centigrade/ (36° and 46° Fahrenheit).**
- B. Freezer temperature range:**
- **Between minus 25 degrees and minus 10 degrees centigrade (-25° and -10° centigrade) / (-13° and 14° Fahrenheit).**

*Reference **USP 797**

OBSERVATION

Verify:

1. Drugs are stored at temperatures specified by manufacturer guidelines.
2. Daily temperature logs are maintained. (Graphs are recommended but not required.)

- 1 = Compliant
 2 = Not Compliant

This standard is not met as evidenced by:

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<p>25.01.15 <u>Consultations/Resource Availability.</u> Pharmaceutical consultation is made available to prescribers of drugs, to staff administering drugs, and as appropriate to patients and families.</p>	<p>There must be sufficient pharmacist time to provide for consultations, even if there is only a part time or consulting pharmacist.</p> <p>In all instances, a pharmacist serves on the Professional Medical Staff committee(s) which discusses drug therapy.</p> <p>A pharmacist provides in-service programs for nursing staff and serves as a resource to clinical staff.</p>	<p style="text-align: center;"><u>INTERVIEW</u></p> <p>Verify:</p> <ol style="list-style-type: none"> 1. A pharmacist serves on appropriate Medical Staff committees. 2. There is sufficient staffing to provide such consultations and educational services for: <ul style="list-style-type: none"> • Clinical staff • Nursing staff • Patients and families 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>
<p>25.01.16 <u>Medication Protocols.</u> "Standing", routine or protocol orders are reviewed and revised by the prescribing practitioner and the Professional Medical Staff at least annually.</p>	<p>When protocol orders are used, the practitioner individualizes the orders for each patient.</p> <p>The order is dated, timed, and signed by the ordering practitioner.</p> <p>Annually, protocol orders are reviewed, updated as indicated, and approved by the Medical Staff. The sponsoring practitioner authenticates the "master" copy as evidenced by his/her signature.</p>	<p style="text-align: center;"><u>DOCUMENT REVIEW & INTERVIEW</u></p> <p>Interview the Director of Pharmacy. Ask if there are protocols, which have not been so reviewed.</p> <p>Verify:</p> <ol style="list-style-type: none"> 1. All standing or routine orders have been subject to annual review and/or revision. 2. Standing orders / protocols have been reviewed by the Professional Medical Staff via its committee structure. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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25.01.17 Home Medications.

The Professional Medical Staff, via Policy and / or Rules and Regulations, establishes standards regarding the use of medications brought into the facility by patients.

The facility has a process to identify medications brought into the facility from home. If such drugs are to be given to patients there shall be positive identification of the drug, including manufacturer's lot number.

Administration of drugs not supplied by the facility requires a specific policy and procedure.

INTERVIEW

Verify:

- Medical staff approved** policies and procedures and/or the Professional Medical Staff Rules/Regulations address medications obtained from sources other than the facility pharmacy service.
- The pharmacy policy applies to all areas where medication is administered.

- 1 = Compliant
 2 = Not Compliant

This standard is not met as evidenced by:

25.01.18 Labeling.

Drugs and biologicals leaving the pharmacy service, for other than "par" level storage are labeled with:

- the full name of the patient,
- the prescriber's name,
- the name - strength - quantity - expiration date of the drug, and
- appropriate accessory / cautionary statements.

State and federal requirements regarding labeling of repackaged drugs are to be enforced.

Mechanisms exist to track the manufacturer's lot number; this may be on the label or via logs for in-facility use.

Outpatient dispensing requires the lot number on the label.

OBSERVATION

Inspect unit dose drawers or patient medication cupboards for the labeling of repackaged drugs. If outpatient dispensing exists, ask to see a drug prepared to ensure the required label information is present. Verify:

- The facility has an effective system for tracking lot numbers.
- Medications are labeled with the required information including lot number and expiration date.

- 1 = Compliant
 2 = Not Compliant

This standard is not met as evidenced by:

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25.01.19 Standardization of Labeling.

The methods for labeling, packaging and storing medication have been standardized throughout the facility to reduce adverse events resulting from improper labeling, packaging and or storage of medications.

PATIENT SAFETY INITIATIVE

Improper labeling and packaging of medications are well-known causes of serious medication errors.

The evidence shows that there are effective methods for simplifying pharmacy and non-pharmacy dispensing by standardizing the labeling of medication containers and drawn-up syringes and the packaging of medications.

DOCUMENT REVIEW & OBSERVATION

Review medication administration policies. Observe medication preparation and storage areas as well as administration to validate compliance.

Review method for ensuring compliance with policies and procedures on medication labeling, packaging and storage throughout the organization.

Verify:

1. The medication administration labeling policy addresses:
 - Labeling of all medications until they are administered to the patient.
 - Validation of compliance for all areas.
 - An institution-wide approach.
 - Storage of look alike, sound alike and varied strengths of medications in physically separate locations.
2. Compliance with the medication labeling policy is evident throughout the facility.

- 1 = Compliant
- 2 = Not Compliant

This standard is not met as evidenced by:

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25.01.20 High-Alert Medications.

The safe use of “high-alert” drugs will be facilitated by implementation of the following:

1. Identification of “high-alert” drugs available to workers in the facility.
2. Implementation of a process to identify new medications for addition to the “high-alert” list.
3. Development of protocols, guidelines, dosing scales, and/or checklist for each “high-alert” drug; make these available to relevant caregivers.
4. Implementation of a process to audit compliance with the protocols and guidelines.
5. Utilization of a multidisciplinary team to identify and regularly review safeguards for all “high-alert” drugs.

PATIENT SAFETY INITIATIVE

Certain classes of medications have been repeatedly shown to cause adverse drug events and should be viewed as particularly serious threats to patient safety.

Examples of high-alert drugs are:

- Intravenous adrenergic agonists and antagonists
- Chemotherapy agents
- Anticoagulants and antithrombotics
- Concentrated parenteral electrolytes
- General anesthetics
- Neuromuscular blockers
- Insulin and oral hypoglycemics
- Narcotics and opiates

DOCUMENT REVIEW AND OBSERVATION

1. Review policies and procedures to validate that all 5 requirements are being addressed in the organization.
2. Review audit materials for ongoing compliance.
3. Observe storage and use of high alert medications on the units to validate compliance.

- 1 = Compliant
 2 = Not Compliant

This standard is not met as evidenced by:

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<p>25.01.21 <u>Dispensing Methods.</u> Medications will be dispensed in unit-dose or unit-of-use form whenever possible to reduce adverse events resulting from bulk packaging of medications. This is evidenced by:</p> <ol style="list-style-type: none"> 1. Unit-dose packaging for medications whenever possible. 2. Dispensing in ready-to-administer form. 3. Unit dose package labeling containing product name, strength, manufacturer, expiration date, and lot number produced in machine-readable code. 4. Preparation and supply of daily unit doses of medications for individual patients under the purview of pharmacists when prepackaged unit dose is not commercially available. 5. Limiting of available supply in patient areas to 24 hours or less at any one time. 6. A defined system for monitoring and improving the performance of 	<p style="text-align: center;"><u>PATIENT SAFETY INITIATIVE</u></p> <p>Hospitals purchase oral dosage medications in two forms - bulk or commercially prepared, prepackaged dosages referred to as unit-of-use or unit dose.</p> <p>When purchased in bulk, the medications must be repackaged into unit-dose aliquots.</p> <p>The evidence shows that unit-dose packaging reduces the number of medication errors and appears to be widely used in most general medical and surgical wards. However, it is not used as much as it could be in other locations such as intensive care units, operating rooms, and emergency departments.</p>	<p style="text-align: center;"><u>INTERVIEW AND OBSERVATION</u></p> <ol style="list-style-type: none"> 1. Interview the pharmacy director to validate that the process being utilized is compliant with the standard. 2. Observe medication dispensing areas to validate that the standard is being met in all locations. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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the drug distribution system.

25.01.22 Preparation of Intravenous Drugs & Fluids.

Intravenous drugs and admixed fluids are prepared in accordance with standards of pharmacy practice, congruent with State and federal regulations, in a manner to reduce the potential for bacterial or drug / drug contamination.

The expiration date of reconstituted drugs or admixed fluids is prominently printed on the solution label.

The use of horizontal and vertical flow hoods are used consistent with state and local regulations. Horizontal and vertical flow hoods are inspected and cleaned according to manufacturer instructions and state and local regulations.

Cytotoxics are not to be prepared under a horizontal hood. Some states require certification for personnel who are responsible for admixing cytotoxics and other dangerous admixtures.

Chemical/hazardous material "spill" kits are readily available to the IV preparation area. Staff is knowledgeable as to using spill kits.

Personal Protective Equipment (PPE) are used consistently and appropriately used with the preparation of IV drugs and solutions.

OBSERVATION

Verify:

1. Review the admixture procedure and quality controls for congruence with current practice.
2. The Pharmacy procedure for cleaning chemical spills, spill kits, and PPE are immediately available where cytotoxics are prepared.
3. Horizontal and vertical hoods are used for their intended purposes. Horizontal hoods are inspected and changed every six months; the external or vertical hood should be cleaned or changed by maintenance personnel quarterly, consistent with state and local regulations and manufacturer’s instructions.

- 1 = Compliant
- 2 = Not Compliant

This standard is not met as evidenced by:

PHARMACY SERVICES/MEDICATION USE

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>25.01.23 Sample Drugs. The use of "sample" drugs, if permitted, is controlled by the pharmacy director and is in conformance with federal and state laws.</p>	<p>The use of sample drugs is discouraged. The repackaging and/or resale of sample drugs is prohibited.</p> <p>If samples are allowed, hospital policy describes the use, storage, and distribution of sample drugs. Sample drugs are labeled according to hospital policy including lot number, patient name, prescriber's name, dose, and expiration date.</p> <p>If samples are allowed, the director of pharmacy has full accountability for storage, distribution, and use.</p> <p>The director of pharmacy is responsible for maintaining a log of all sample drugs in the event of a product recall. The log includes lot numbers and patient distribution information.</p>	<p style="text-align: center;"><u>INTERVIEW & OBSERVATION</u></p> <p>Review the policy regarding samples.</p> <p>Verify the practice; samples are often located in employee lounges, obstetrics and the ER. If these are the physician's personal property, sample medications should be secured.</p> <p>Verify:</p> <ol style="list-style-type: none"> 1. There is an effective, accurate recall process, consistent with the pharmacy recall process. 2. If used for patients, verify that the pharmacist has control of sample drugs. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

PHARMACY SERVICES/MEDICATION USE

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>25.01.24 Patient Medication Profile. There is a medication profile created for each inpatient and serial outpatient receiving drugs and biologicals. This profile includes data designed to assure safe and accurate administration of drugs and biologicals.</p>	<p>The profile may be manual or electronic and may be utilized as a charge document.</p> <p>The patient and drug data entered into medication profiles (or the ability to access via electronic means) includes, at least:</p> <ol style="list-style-type: none"> 1. Height, weight, diagnoses and age 2. Food and drug sensitivities 3. Allergies 4. Diet order(s) 5. History of prescribed/nonprescribed drug use including legend, over the counter, home remedy, and street drugs 6. Drugs (administered from floor stock <u>and/or</u>) dispensed for administration based upon direct review of current orders 7. Drug data indicate the route, schedule, start and stop dates including automatic stop dates, and form dispensed 	<p style="text-align: center;"><u>CHART REVIEW</u></p> <p>Review the medication profiles for five (5) active inpatient records and one (1) active serial outpatient record (such as chemo) to determine the database.</p> <p>Verify:</p> <ol style="list-style-type: none"> 1. The medication profiles consistently document each of the seven (7) required elements or that the pharmacy has access via electronic means to all required information. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

PHARMACY SERVICES/MEDICATION USE

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>25.01.25 Profile Review. The profile is reviewed with every order change by an R.Ph. The review will occur before medication is dispensed or made available for administration except in those instances when review would cause a medically unacceptable delay.</p> <p>The review includes cognitive focus for potential drug and food-drug interactions, interferences, or incompatibilities.</p> <p>The review of orders will be documented in the patient record.</p> <p>The pharmacists will maintain a log documenting interventions stemming from the profile review.</p> <p>Compliance with the medication profile review will be audited to determine compliance with the process so that ongoing improvement in medication safety will be achieved.</p>	<p><u>PATIENT SAFETY INITIATIVE</u></p> <p>Nearly half of preventable adverse drug events (ADEs) result from a problem in medication ordering. It has been demonstrated in inpatient settings that having a pharmacist review medication orders before administration is associated with a significant decrease in preventable ADEs. Similar findings have been found in ambulatory settings. Including pharmacists on clinical rounds also can reduce medication errors.</p> <p>Methods are established to assure the profile review by a Pharmacist.</p> <p>A log is maintained of pharmacist interventions resulting from the profile review.</p> <p>The pharmacist / prescriber interface, as appropriate, for notification of food service for potential food -drug interactions.</p>	<p><u>DOCUMENT REVIEW, CHART REVIEW, & INTERVIEW</u></p> <p>Review the policy that defines what would be considered a medically acceptable delay in pharmacist review of new orders. Review a minimum of 10 patient records. Interview the pharmacist and nursing staff to determine staff knowledge of the profile review process.</p> <p>Verify:</p> <ol style="list-style-type: none"> 1. A log is maintained for pharmacist interventions stemming from the review for potential interactions, interferences or incompatibilities 2. The profiles are reviewed upon order changes. The pharmacist and nursing staff are knowledgeable of the medication profile review process. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>25.01.26 Drug Administration. Mechanisms exist so that drugs and biologicals are administered in a safe, accurate, and effective manner.</p>	<p>Self-explanatory.</p>	<p>CHART REVIEW Check charts on units. Compare physician orders against the Medication Administration Records for accuracy. Verify:</p> <ul style="list-style-type: none"> Medications administered are consistent with the physician order. Medications are administered safely and accurately. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>
<p>25.01.27 Label Medications & Solutions on the Sterile Field. The facility must develop and implement policies for safe labeling of medications and solutions used on and off the sterile field in the perioperative settings.</p> <p>The facility must have policies and processes in place including, but not limited to:</p> <ol style="list-style-type: none"> The required labeling of medications and solutions, regardless of container, used on and off the sterile field throughout the perioperative experience. The methods used to differentiate and label look-alike products and solutions with similar names. The process used to verify and 	<p>PATIENT SAFETY INITIATIVE In recent years, there have been numerous reports of death or serious injury secondary to unlabeled medications and solutions on the sterile field.</p> <p>All surgery settings and procedure rooms are expected to handle chemicals, reagents, specimen preservation agents, and diluents with the same caution as medications.</p> <p>A process must be in place to label all solutions used in the surgical area including, but not limited to intravenous fluids, medications, body fluids, hydrogen peroxide, formalin, Lugol's solution, radiopaque dyes, sterile saline, sterile water, isopropyl alcohol, skin preparation solutions, chlorhexidine, glutaraldehyde, and the like. Many of the above "look alike" as they are clear/colorless solutions.</p> <p>Labels must be applied to solutions stored in all types of container used on and off the surgical field in the perioperative area including, but not limited to</p>	<p>DOCUMENT REVIEW Review policies and practices relative to medication preparation. Determine that systems are in place relating to:</p> <ol style="list-style-type: none"> Required labeling of solutions and medications on and off the sterile field. Procedure for differentiating look-alike and sound-alike medications / solutions. Procedure for individually verifying and labeling medications / solutions and respective labels. <p>*** When scoring this standard, incorporate standard compliance issues as identified in standards.</p>	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>confirm each medication/solution and the respective matching label.</p>	<p>medicine cups, solution basins, syringes, and specimen cups.</p> <p>A label is required even if only one solution is involved with the procedure.</p> <p>It would be unacceptable to write onto plastic containers such as IV bags with marking pens, as there is evidence that the ink may penetrate into the solution.</p> <p>Sterile medications/solutions that are placed onto the sterile field in the original packaging with the manufacturer’s original label on the container that indicates the name and strength of the medication do not require additional labeling.</p> <p>Use sterile markers and labels that can be opened onto the sterile field. Commercially prepared products are available for this purpose, but labels prepared by the facility are acceptable if sterilization is maintained. Labels are to clearly state the medication/solution and strength. When feasible, include these labels and markers in pre-made surgical packs.</p> <p>Many medications and solutions have similar names. A process must be identified and implemented when preparing labels to differentiate these.</p> <p>A process must be in place to verify each medication or solution and complete its preparation, labeling, and delivery to the sterile field before preparing the next</p>		

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solution. Label only one medication/solution at a time. Use two staff to verbally and visually confirm each medication / solution and respective label; one of these staff must be a licensed professional involved with the procedure.

A process must be in place to discard any unlabeled solution or medication found in the perioperative area. Unlabeled solutions should be considered a hazardous condition and reported using the facility incident reporting protocol.

At shift change or relief for breaks, required the entering and exiting staff to concurrently read container labels and verify all medications on the sterile field.

Keep original medication/solution containers in the surgical room until completion of the procedure for follow-up reference, if indicated.

References:
Medication Safety Alert, December 2, 2004,
The Institute for Safe Medication Practices.
AORN Guidance Statement: Safe Medication Practices In Perioperative Practice Settings, 2004.

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<p>25.01.28 Investigational Drugs. In order to protect the rights of patient and the Professional Medical Staff, the facility policies shall address the administration of drugs which are:</p> <ol style="list-style-type: none"> Used for other than their FDA approved use Experimental Investigational, when the primary investigator(s) is a member of the facility's Professional Medical Staff Investigational, when the facility patient brings in the drug as a prescription from a practitioner who is not a member of the facility's Professional Medical Staff. 	<p>The pharmacy director collaborates with the Professional Medical Staff in defining these circumstances. At a minimum, these policies address the following concepts:</p> <ol style="list-style-type: none"> Patient knowledge of the nonapproved use of an FDA approved drug; Patient informed consent in experimental or on-site investigational drug studies; Mechanisms for presenting study protocols and data to an Institutional Review Board or equivalent; The roles of pharmacists, nursing and other nonpractitioner staff in study protocols and data management; The acquisition and storage of investigational drugs; The need for the RN administering investigational drugs and / or planning and supervising the care of a patient receiving investigational drugs to document knowledge of the drug(s); Notification and input from any off-site investigators when their study population is admitted. 	<p align="center"><u>DOCUMENT REVIEW & CHART REVIEW</u></p> <p>Review policies related to investigational drugs. Review patient records if available.</p> <p>Verify:</p> <ol style="list-style-type: none"> The facility policy addresses non-approved, experimental and investigational uses of drugs. Each of the seven required concepts is addressed. The actual use of investigational drugs is consistent with the investigational drugs policy. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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25.01.29 Documentation.

The effects of therapy are noted in clinical records. The patient's clinical record accurately reflects all doses given as well as the effects of these agents as indicated by:

1. The prescribing practitioner, and any other medical consultants, via progress notations;
2. The nursing staff via the medication administration record in progress notation for the effects of "Pro Re Nata" (PRN) dosing and for clinical outcome dosing;
3. Clinical outcomes; or
4. The recording of testing (laboratory, imaging, cardiogram, other objective) to determine the therapeutic effect.

Self-explanatory.

CHART REVIEW

Review five recently closed inpatient records for physician progress notes, diagnostic testing data, and other clinical notations.

Verify:

1. Medical records provide evidence that all doses have been administered; appropriate observations are documented.

- 1 = Compliant
- 2 = Not Compliant

This standard is not met as evidenced by:

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25.01.30 Antithrombotic Therapy.

The facility ensures that anti-thrombotic (anticoagulation) therapy is effective and safe. The organization utilizes dedicated anti-thrombotic services that facilitate coordinated care management. Explicit organizational policies and procedures are in place regarding anti-thrombotic services.

PATIENT SAFETY INITIATIVE

Anti-thrombotic (anticoagulation) therapy is a complex and labor-intensive intervention for which success depends upon correct dosing decisions, close attention to many details, and good communication among all parties involved.

A process is in place to identify and train staff to coordinate the management of patients receiving anti-thrombotic therapy. The process addresses:

- Staff training requirements
- Dose scheduling
- Patient tracking
- Patient education

Optimal anticoagulation management occurs when a systematic and coordinated process is used. This process includes dedicated management by a qualified healthcare professional that ensures:

- Reliable patient scheduling and tracking;
- Accessible, accurate, and frequent Prothrombin Time (PT) / International Normalized Ratio (INR) testing;
- Patient-specific decision support and interaction; and
- Ongoing patient education.

DOCUMENT REVIEW & CHART REVIEW

Review facility policies and procedures in regard to antithrombotic services.

Review the medical records of patients receiving antithrombotic therapy.

Verify:

1. The policy is explicit with regards staff training requirements, dose scheduling and tracking mechanisms, and patient education materials and mechanisms for training.
2. Patient records reflect that anti-thrombotic services are being coordinated per policy and standard.

- 1 = Compliant
 2 = Not Compliant

This standard is not met as evidenced by:

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<p>25.02.01 Preparation & Administration of Drugs. Facility policies regarding medication preparation and administration are approved by the Professional Medical Staff and Pharmacy and Therapeutics Committee. Policies address at least the following:</p> <ol style="list-style-type: none"> 1. Pharmacist review of medication orders / profiles including documentation of review; defined exceptions to pharmacist review 2. Role of the pharmacist in the medication use process 3. When a full-time pharmacist is not available onsite, a pharmacist is available by telephone or accessible at another location that has 24-hour pharmacy services. 4. Order verification by the dispensing pharmacist (if the item is not stock in the patient care area); 5. Order verification by the staff administering the product; 6. Mechanisms to assure that the patient is positively identified prior 	<p align="center"><u>PATIENT SAFETY INITIATIVE</u></p> <p>Medication administration policies are based upon principles of sound nursing and pharmacy practice with a focus on patient safety.</p> <p>Policies are collaboratively developed by the pharmacy and the disciplines, e.g. nursing, respiratory, imaging, etc., administering drug products. Collaboratively developed policies are then reviewed and approved by the Professional Medical Staff for review, comment, and approval.</p> <p>All required subject areas are to be addressed by the facility in policy.</p>	<p align="center"><u>INTERVIEW</u></p> <p>Interview the pharmacy director and the nurse executive. Observe the preparation of drugs and their administration to patients. Observe at least three staff administering a drug or biological product.</p> <p>Verify:</p> <ol style="list-style-type: none"> 1. Their respective medication administration policies are congruent and have been collaboratively developed. Similarly, verify these issues with other disciplines such as, imaging, respiratory therapy, etc. 2. The collaboratively developed medication administration policies have been presented to the Professional Medical Staff for review, comment and approval. 3. Patient identification procedures are consistently followed. Patients are addressed by name and/or identification checked. The nurse remains with the patient until medication is taken. 4. If personnel other than nursing personnel administer drugs or biologicals, this is in accordance with federal and state laws and regulations. 5. The drug is identifiable up to the point of administration. The patient was positively identified. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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<p>to administering products;</p> <p>7. Mechanisms to assure that the drug, route, dose, time(s), are accurately <u>recorded</u> for the correct patient;</p> <p>8. Mechanisms for bedside supply for patient self-administration and for patient controlled dosing; (NOTE: bedside medication storage must comply with storage requirements. See 25.01.03)</p> <p>9. Mechanisms to teach the patient (or his/her family) about the medications; and</p> <p>10. Mechanisms for identifying and responding to medication variances.</p>		<p>6. If bedside patient self-administration of medication is permitted, verify:</p> <ul style="list-style-type: none"> • All storage and administration standards are in compliance (e.g. secure storage, documentation of administration) <p style="text-align: center;"><u>FILE REVIEW</u></p> <p>Verify:</p> <ul style="list-style-type: none"> • Nursing or other personnel authorized by medial staff policy to administer drugs have completed appropriate training courses, or, are licensed or authorized to do so by State law and function under supervision as necessary. 	

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<p>25.02.02 Medication Preparation Environment. The facility provides a work environment that facilitates attention to detail and promotes the accurate filling and dispensing of medication orders.</p> <p>Organizational policies and procedures are in place for the pharmacy and nursing work environments that include specific implementation guidelines that address safety in medication preparation areas, including the mechanism for ongoing monitoring of compliance.</p>	<p>PATIENT SAFETY INITIATIVE</p> <p>Although many medication errors have no or minor consequences for patients, others may cause serious morbidity or even death. Errors related to dispensing medications are common, occurring at rates ranging up to 24% of medications dispensed.</p> <p>A number of environmental factors in the medication preparation and dispensing area are known to increase the occurrence of errors. These include:</p> <ul style="list-style-type: none"> • heavy workload; • cluttered workspace; • noise; and • poor lighting. <p>Having an organized and well-lit workspace has been shown to both decrease errors and increase efficiency.</p>	<p>DOCUMENT REVIEW & OBSERVATION</p> <p>Review organizational policies. Inspect medication preparation areas in all locations where medication is prepared.</p> <p>Verify:</p> <ol style="list-style-type: none"> 1. Policy addresses the required work environment safety elements and applies to all medication preparation areas. 2. Medication preparation work areas are clean, orderly, well lit, and free of clutter, distraction, and noise 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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<p>25.02.03 Medication Reconciliation. The organization has a formal and systematic approach to the reconciliation of medications across the continuum of care. A process is in place to reconcile current medications at each key transitional point of healthcare, specifically:</p> <ol style="list-style-type: none"> 1. Upon admission, prepare a complete list of pre-admission medications the patient takes at home. 2. The patient or family member validates the list, when possible. 3. Admission orders are compared against the pre-admission medication list; any variances are reconciled. 4. The complete list of current medications is readily available to prescribers as a reference when writing medication orders. 5. The complete list of medications is provided to the next unit, service, or care setting when the patient is transferred and discharged. 6. The complete list of medications is 	<p><u>PATIENT SAFETY INITIATIVE</u></p> <p><u>Background</u> Preventable adverse drug events are associated with as many as one out of five patient injuries or deaths. The inadvertent omission of a preadmission medication or failure to order a drug upon discharge can have deleterious outcomes. Through the formal process of medication reconciliation, errors can be prevented and/or reduced throughout the continuum of care.</p> <p>According to the Institute for Healthcare Improvement (IHI), numerous studies indicate that poor communication of medical information at key transition points is responsible for up to 50% of all medication errors. A 30 – 70% disparity rate was found between medications taken at home and those listed in hospital admission orders, in one study*. The key transition points where errors with writing medication orders tend to occur are:</p> <ol style="list-style-type: none"> 1. Upon admission; 2. Upon transfer to a new unit/service/practitioner; or 3. At time of discharge. <p>The goal of medication reconciliation is to ensure that every hospitalized patient continues with the same medications taken prior to admission, unless there is a specified need for change. Admission orders should actually be considered a modification of the patient’s medication regimen.</p>	<p><u>DOCUMENT REVIEW</u></p> <p>Verify:</p> <ol style="list-style-type: none"> 1. A complete list of home medications is obtained upon admission. A process is in place to generate a list of medications in the ambulatory setting. 2. A medication reconciliation process is in place upon admission, transfer to the next level of care, and at discharge. 3. The patient/family participates with the reconciliation process, when possible. 4. The patient receives a copy of the complete medication list upon discharge. 5. A process is in place to measure the effectiveness of this initiative with reducing adverse drug events. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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given to the patient upon discharge.

The patient or family member is involved with the reconciliation process to validate the list of preadmission medications. This list includes prescribed and regularly taken over-the-counter drugs, vitamins, herbals, homeopathic, and nutritional supplements. As the intent is to develop the most accurate list of medications possible, the dose and frequency for each drug should be included in the complete list of home medications.

The list of preadmission medications is readily available for prescribers to review when writing / changing medication orders.

Policy outlines the process, responsible persons, and time frame for completing the initial reconciliation process. The initial medication reconciliation shall be completed within 24 hours of hospital admission.

Discrepancies between home medications and those ordered upon admission are discussed and reconciled with the prescriber. Preferably, a brief note is written for any medication that is not continued during the course of hospitalization.

The following practices are not acceptable:

1. "Resume previous orders"
2. "Resume preoperative orders"
3. "Resume all home medications"

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Transfer to Another Unit / Service

The list of current medications accompanies the patient when transferred to another unit or service. A process for the reconciliation of medications at this transitional point is in place. Discrepancies between the list of medications from the previous unit and those ordered following transfer are discussed and reconciled with the prescriber.

Discharge

As part of the discharge planning, there is a reconciliation process to ensure all appropriate medications (including preadmission medications) are continued following discharge. In anticipation of discharge, the list of preadmission medications should be compared against the current Medication Administration Record.

The patient/family is informed of medications that will be discontinued or changed upon discharge.

At time of discharge, a copy of the final medication list is provided to:

1. The patient / family
2. The next level of care such as home health agency, skilled nursing facility, or transfer to a higher level of care.

Monitoring Effectiveness

A process is in place to evaluate the effectiveness of this patient safety initiative with reducing adverse drug events. For example, review a random sample of

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patient records

Emergency Department

A complete list of current medications is to be obtained for Emergency Department patients.

Ambulatory Care

A complete list of current medications is to be obtained for ambulatory care patients. The list will be updated as medications are added or discontinued.

Ambulatory Services

1. A complete list of medications must be in place for those outpatient services in which medications will be administered, such as:
 - a. Ambulatory surgery
 - b. Radiological procedures requiring IV contrast and etc.

2. For those outpatient services in which no medications will be administered, such as outpatient radiology, obtaining a current list of medications is preferred, but not required.

*Cornis, PL, et al.: Unintended medication discrepancies at the time of hospital admission. *Arch Intern Med* 165: 424-429, Feb. 28, 2005.

The National Quality Forum, *National Quality Forum Updates Endorsement of Safe Practices for Better Healthcare*, October 16, 2006.

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25.03.01 Performance Improvement.

A facility-wide Quality Assessment - Performance Improvement program is in place, which incorporates Adverse Drug Response (ADR) findings and monitors the desired outcomes of medication use. This program shall be utilized to reduce risk in order to maintain and improve clinical outcome.

Annually, the facility prepares a Medication Use Review Plan.

The greatest benefit to the facility accrues when QAPI efforts give priority to reviews, which focus on high volume (cost or frequency), high risk, or problem prone areas.

The medication use review plan, or a Drug Utilization Effectiveness (DUE) plan, should indicate the rationale for selection, and actions taken to achieve improvement should be documented.

DOCUMENT REVIEW

- Review the medication use review plan. Verify:
1. The facility prepares an annual Medication Use Review or Drug Utilization Effectiveness Plan.
 2. The findings from Adverse Responses and Medication Variances have been studied and included in QAPI. Monitors are in place. Actions have been taken to achieve improvement.

- 1 = Compliant
 2 = Not Compliant

This standard is not met as evidenced by:

25.03.02 Data Collection & Monitoring.

The medication use monitoring is established to assess:

- Prescribing (appropriateness)
- Preparing/dispensing
- Administering
- Outcomes

Medication use is an interdisciplinary process in providing patient care.

Although review indicators may focus more heavily on one, all four aspects of the process are to be reviewed.

DOCUMENT REVIEW

- Verify:
1. The medication use review plan is an interdisciplinary process.
 2. Data is collected on all four (4) required functions:
 - Prescribing / appropriateness
 - Preparing / dispensing
 - Administering
 - Outcomes

- 1 = Compliant
 2 = Not Compliant

This standard is not met as evidenced by:

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<p>25.03.03 Medication Use Review. Medication use review monitors drugs used in all principal populations served by the facility.</p>	<p>Over the course of a year, the populations should include the age span (pediatric - geriatric) and service location (inpatient, outpatient, and emergency care).</p> <p>Antibiogram studies should be published and distributed to appropriate professionals at least annually.</p>	<p><u>DOCUMENT REVIEW</u></p> <p>Determine that life span and service setting populations have been incorporated in medication usage review.</p> <ol style="list-style-type: none"> The outcome of the review has been communicated to the medical staff. An annual antibiogram report been prepared and distributed. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>
<p>25.03.04 Data Reporting. Findings from medication use review are reported quarterly to appropriate Medical Staff committees and/or departments, and considered by the QAPI program, in impacting improvements in the facility service areas. Such reports are shared, as appropriate, with other disciplines to utilize in their QAPI.</p>	<p>Because medication use is interdisciplinary, the findings of medication use review are shared with various disciplines.</p>	<p><u>DOCUMENT REVIEW</u></p> <p>Review the documentation. Verify:</p> <ol style="list-style-type: none"> Medication use reviews are prepared quarterly. The medication use review information has been reported to appropriate Medical Staff committees and the QAPI program. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>
<p>25.03.05 Annual Report on Medication Use. The facility documents improvement, as a result of medication use review as reported, in an annual summary.</p>	<p>Self-explanatory.</p>	<p><u>DOCUMENT REVIEW</u></p> <p>Verify:</p> <ol style="list-style-type: none"> An annual summary of Medication Use Review is prepared and submitted to QAPI. The summary addresses actual improvements, as applicable. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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NOTE: Reviews may not always (and legitimately) result in improvements. The process of study should yield worthy results.

25.03.06 Performance Improvement in Medication Use.

The organization utilizes information obtained from review of medication processes and outcomes to continuously improve the safety of medication administration for patients.

The organization will consider technological advances available to them in improving these processes. If technological advances are not an option, the organization will implement alternatives that will resolve identified issues and reduce medication events.

PATIENT SAFETY INITIATIVE

Medication errors are common. The literature indicates that between 28-56% of adverse drug events are preventable.

Illegible handwriting, unknown or undetected allergies, drug interactions, incorrect dose, and many other factors can cause adverse drug events.

Studies have demonstrated that a significant decrease in medication errors and adverse drug events can be achieved by using computerized prescriber order entry technology. Additional technologies are continuously being developed, and it is the responsibility of the organization to examine the feasibility of implementation of these technologies to achieve a safer patient environment.

It is clear that some organizations will be unable to afford these technologies. However, that does not negate their responsibility to resolve identified issues by alternative means.

DOCUMENT REVIEW & INTERVIEW

Review medication event data. Review minutes where improvement of the medication system and processes are discussed.

Verify:

1. The organization has considered implementation of new technologies to reduce medication events.
2. If technology is not feasible, alternative strategies to reduce medication events have been implemented.

- 1 = Compliant
- 2 = Not Compliant

This standard is not met as evidenced by:

PHYSICAL REHABILITATION SERVICES: PHYSICAL THERAPY/OCCUPATIONAL THERAPY/SPEECH THERAPY AND AUDIOLOGY

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
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REHABILITATION SERVICES.

Score this section if the facility offers one or more rehabilitation services to patients who are NOT located in a PPS exempt unit.

This chapter is not applicable in this facility

26.00.00 Condition of Participation: Rehabilitation Services.

If the hospital provides rehabilitation, physical therapy, occupational therapy, audiology, or speech pathology services, the services must be organized and staffed to ensure the health and safety of patients.

This is an optional hospital service.

However, if a hospital provides any degree of rehabilitative services to its patients, the hospital must comply with the requirements of the Condition of Participation.

If rehabilitative services are provided, they must be organized and staffed in such a manner to ensure the health and safety of patients. This includes providing rehabilitative services in accordance with practitioner orders and acceptable standards of practice.

Acceptable standards of practice include compliance with any applicable Federal or State laws, regulations or guidelines, as well as standards and recommendations promoted by nationally recognized professional organizations (e.g., American Physical Therapy Association, American Speech and Hearing Association, American Occupational Therapy Association, American College of Physicians, American Medical Association, etc.).

The hospital's rehabilitation services must be integrated into its hospital-wide QAPI program.

DOCUMENT REVIEW

1. Determine if the hospital provides any degree of rehabilitation services.

If yes, scoring is based on compliance with the following standards:

- **26.00.01 through 26.00.03; and**
- **26.00.06 through 26.00.08**

2. Determine if the hospital's rehabilitation services are integrated into its hospital-wide QAPI program.

1 = Compliant
 2 = Not Compliant

This standard is not met as evidenced by:

§482.56

PHYSICAL REHABILITATION SERVICES: PHYSICAL THERAPY/OCCUPATIONAL THERAPY/SPEECH THERAPY AND AUDIOLOGY

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>26.00.01 Organization and Staffing. <i>The organization of the service must be appropriate to the scope of the services offered.</i></p> <p>§482.56(a)</p>	<p>The hospital must provide the appropriate equipment and types and numbers of qualified personnel necessary to furnish the rehabilitation services offered by the hospital in accordance with acceptable standards of practice.</p> <p>The scope of rehabilitation services offered by the hospital should be defined in written policies and procedures, and approved by the Medical staff.</p> <p>Each service, whether provided through a single discipline department or within a multi-discipline department, must function with established lines of authority and responsibility to ensure the health and safety of patients.</p> <p>There must be an adequate number of qualified staff available when needed to evaluate each patient, initiate the plan of treatment, and supervise supportive personnel when they furnish rehabilitation services. The number of qualified staff is based on the type of patients treated and the frequency, duration, and complexity of the treatment required.</p>	<p><u>DOCUMENT REVIEW, CHART REVIEW & FILE REVIEW</u></p> <p>Review organization charts and hospital policies. Verify:</p> <ol style="list-style-type: none"> The scope of rehabilitation services offered is defined in writing and approved by the medical staff. If the services are provided under an agreement, review policies and contracts to determine responsibilities and delegations of authority relative to the service provided. Responsibilities and delegations of authority relative to the service are provided. Services are provided in accordance with acceptable standards of practice. Therapy is planned and initiated by a licensed therapist. If services are provided under an arrangement, review policies and contracts. For each service, determine that adequate types and numbers of qualified staff are available to ensure safe and efficient provision of treatment. Review medical records to verify that a qualified professional evaluates the patient and initiates each treatment episode. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

PHYSICAL REHABILITATION SERVICES: PHYSICAL THERAPY/OCCUPATIONAL THERAPY/SPEECH THERAPY AND AUDIOLOGY

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>26.00.02 Leadership. <i>The director of services must have the necessary knowledge, experience and capabilities to properly supervise and administer the services.</i></p> <p>§482.56(a)(1)</p>	<p>The director must be accountable for the overall operation of the therapy services.</p> <p>An individual(s) may serve as director for more than one service either as the director of a multi-service department or single service departments.</p> <p>Each service must be accountable to an individual that directs the overall hospital-wide operation of that service.</p> <p>The service director must demonstrate through education, experience, and/or specialized training that he/she has the necessary knowledge, experience and capabilities to properly supervise and administer the service(s).</p> <p>The director may be part-time or full time. In all situations the director retains professional and administrative responsibility for personnel providing the service. If the director is part-time, the time spent directing the service should be appropriate to the scope of the services provided.</p>	<p>9. Review a sample of personnel files to verify current licensure, certifications and ongoing training, consistent with applicable State laws.</p> <p><u>DOCUMENT REVIEW, FILE REVIEW, & INTERVIEW</u></p> <ol style="list-style-type: none"> 1. Verify that each service is accountable to an individual who directs the overall operation of that service. 2. Review the service director’s position description to verify that he/she has been granted the authority and responsibility for operation of the service, consistent with hospital policies, State law, and accepted standards of practice. 3. If the directors do not work full-time, determine that the number of hours (review timesheets) spent working is appropriate to the scope of services provided. 4. Review the director’s personnel file to determine that he/she has the necessary education, experience and specialized training to properly supervise and administer the service. This includes maintaining current licensure and certifications as required by State law. 5. Interview the director to determine if he/she 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

PHYSICAL REHABILITATION SERVICES: PHYSICAL THERAPY/OCCUPATIONAL THERAPY/SPEECH THERAPY AND AUDIOLOGY

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
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26.00.03 Staff Qualifications
Physical therapy, occupational therapy, or speech-language pathology or audiology services, if provided, must be provided by qualified physical therapists, physical therapist assistants, occupational therapists, occupational therapy assistants, speech-language pathologists, or audiologists as defined in part §484 of 42 CFR 484.4.

§482.56(a)(2)

The medical staff must define in writing the required qualifications and competencies for the therapy staff, consistent with State law.

A policy describes the levels of personnel and qualifications necessary for each service provided.

A therapist is a person licensed by the State in which they are practicing and has graduated from a recognized, certified program.

has the necessary knowledge, experience and capabilities to properly supervise and administer the service.

DOCUMENT REVIEW, CHART REVIEW, & FILE REVIEW

Verify:

1. The Medical Staff have defined the qualifications and competencies for all therapy staff, consistent with State law. This document describes the services provided and various levels of personnel permitted to provide each service.
2. There is a procedure for the periodic review of the written staff qualifications to ensure these are compliant with changes in state law.
3. Therapy is planned and initiated by a licensed therapist.
4. Each employee file reflects the qualifications and competencies consistent with the written medical staff specifications.
5. Therapists have the qualifications and competencies that meet medical staff specifications.

- 1 = Compliant
 2 = Not Compliant

This standard is not met as evidenced by:

PHYSICAL REHABILITATION SERVICES: PHYSICAL THERAPY/OCCUPATIONAL THERAPY/SPEECH THERAPY AND AUDIOLOGY

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>26.00.04 <u>Minimum Staffing Requirements.</u> Therapy shall be provided by a core team that includes, but is not necessarily limited to a qualified licensed therapist.</p>	<p>This requirement depends on the mission of the facility and of the physical therapy program.</p> <p>Staff such as therapy aides, therapy assistants and other health care workers may be included as staff members as appropriate.</p>	<p align="center"><u>DOCUMENT REVIEW</u></p> <p>Review the organizational chart and staffing plan for the therapy department(s) to determine it meets the requirement.</p>	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>
<p>26.00.05 <u>Therapy Orders.</u> Policies govern who can refer / order therapy.</p> <p>Referrals / orders for therapy must indicate the reason(s) for referral / order.</p>	<p>These policies are congruent with the Medical Staff Bylaws and Rules and Regulations. They must address referrals / orders for therapy and, if verbal orders are permitted, the policy must address who is qualified to receive a verbal order.</p> <p>VERBAL ORDERS Verbal orders for the provision of treatment may be accepted and must be authenticated in accordance with the requirement in §482.56(b), consistent with Federal and State laws, the medical staff, and hospital policy.</p> <p>Verbal orders regarding treatment are acceptable if documented and signed by the person accepting the order. The time, date, and contents of the verbal order and the name of the ordering practitioner must be entered in the record at the time of the order and be countersigned by the practitioner consistent with State laws and facility policy. (See standard 10.01.04 for requirements.)</p>	<p align="center"><u>DOCUMENT REVIEW & CHART REVIEW</u></p> <p>Review policies and procedures. Examine medical records of therapy patients.</p> <p>Verify:</p> <ol style="list-style-type: none"> 1. A policy (or bylaws or rules and regulations) describing those who are allowed to refer and order therapy is in place, current, and approved by the Medical Staff. 2. Only qualified individuals, as approved by the Medical Staff, provide referrals and orders for therapy. 3. Referrals and orders for therapy include the reason for the referral. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

PHYSICAL REHABILITATION SERVICES: PHYSICAL THERAPY/OCCUPATIONAL THERAPY/SPEECH THERAPY AND AUDIOLOGY

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>26.00.06 Delivery of Services. <i>Services must only be provided under the orders of a qualified and licensed practitioner who is responsible for the care of the patient, acting within his or her scope of practice under State law, and who is authorized by the hospital's medical staff to order the services in accordance with hospital policies and procedures and State laws.</i></p> <p>§482.56(b)</p>	<p>Rehabilitation services must be ordered by a qualified and licensed practitioner who is responsible for the care of the patient.</p> <p>The practitioner must have medical staff privileges to write orders for these services or, for outpatient services, if hospital policy permits acceptance of orders from outside practitioners, the practitioner's order must meet the requirements at §482.54(c).</p> <p>For practitioners who have medical staff privileges, such privileges must be granted in a manner consistent with the State's scope of practice law, as well as with hospital policies and procedures governing rehabilitation services developed by the medical staff and approved by the governing body.</p> <p>Practitioners who may be granted privileges to order rehabilitation services include physicians, and may also, in accordance with hospital policy, include:</p> <ul style="list-style-type: none"> • Nurse Practitioners, • Physicians' Assistants, and • Clinical Nurse Specialists as long as they meet the parameters of this requirement. <p>Although the following licensed professionals are also considered "practitioners" in accordance with Section 1842(b)(18)(C) of the Social Security Act, they generally would not be considered responsible for the care of the patient or qualified to order rehabilitation services:</p>	<p align="center">CHART REVIEW</p> <ol style="list-style-type: none"> 1. Does the hospital permit acceptance of orders from outside practitioners who do not practice at the hospital? <ul style="list-style-type: none"> • If so, evaluate for compliance with §482.54(c) (standard 31.00.11). 2. Review the medical staff policies and procedures for rehabilitation services privileging. Do they identify the types of eligible practitioners and their qualification criteria? 3. Review medical records of patients receiving rehabilitation services. <ul style="list-style-type: none"> • Determine who wrote the orders for the rehabilitation services. • Determine if the practitioner is responsible for the care of the patient and privileged to write orders for rehabilitation services. • Verify the practitioner meets hospital medical staff policy criteria to order services as well as State law for ordering rehabilitation services. • Physical Therapy services are provided only in accordance with <u>practitioner orders</u> and that those orders are 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

PHYSICAL REHABILITATION SERVICES: PHYSICAL THERAPY/OCCUPATIONAL THERAPY/SPEECH THERAPY AND AUDIOLOGY

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
	<ul style="list-style-type: none"> • Certified registered nurse anesthetist (Section 1861(bb)(2) of the Act); • Certified nurse-midwife (Section 1861(gg)(2) of the Act); • Clinical social worker (Section 1861(hh)(1) of the Act); • Clinical psychologist (for purposes of Section 1861(ii) of the Act and as defined at 42 CFR 410.71); or • Registered dietitian or nutrition professional. 	<p>incorporated into the medical record.</p> <ul style="list-style-type: none"> • The treatment plan is established by the practitioner ordering the service in collaboration with an individual qualified to provide the service. 	
<p>26.00.07 Rehabilitation Orders. <i>All rehabilitation services orders must be documented in the patient's medical record in accordance with the requirements at §482.24.</i></p>	<p>The patient's medical record must contain documentation of all rehabilitation services ordered.</p> <p>The medical record entries must comply with regulations at §482.24.</p>	<p align="center">CHART REVIEW</p> <p>Review a sample of patient medical records who received rehabilitation services.</p> <p>Determine whether the rehabilitation service orders are legible, complete, dated, timed, authenticated, and meet all other medical record requirements specified at §482.24.</p>	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>
<p>§482.56(b)(1)</p>			
<p>26.00.08 Standards of Practice. <i>The provision of care and the personnel qualifications must be in accordance with national acceptable standards of practice and must also meet the requirements of §409.17 of</i></p>	<p>The provision of rehabilitation services care and development of the plan of care for rehabilitation services can be initiated only after the order is written for services by a qualified licensed practitioner responsible for the care of the patient.</p>	<p align="center">CHART REVIEW</p> <ol style="list-style-type: none"> 1. Review medical records of patients who received rehabilitation services. 2. Determine whether the required care plan was developed and implemented. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

PHYSICAL REHABILITATION SERVICES: PHYSICAL THERAPY/OCCUPATIONAL THERAPY/SPEECH THERAPY AND AUDIOLOGY

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>42 CFR 409.17. §482.56(b)(2)</p>	<p>Physical therapy, occupational therapy, or speech-language pathology must be furnished under a plan of care.</p> <p>The regulation at 42 CFR §409.17 specifies the following rehabilitation services plan of care requirements:</p> <p><u>Establishment of the Plan:</u> “The plan must be established before treatment begins by one of the following:</p> <p>(1) A physician.</p> <p>(2) A nurse practitioner, a clinical nurse specialist or a physician assistant.</p> <p>(3) The physical therapist furnishing the physical therapy services.</p> <p>(4) A speech-language pathologist furnishing the speech-language pathology services.</p> <p>(5) An occupational therapist furnishing the occupational therapy services.”</p> <p><u>Content of the Plan:</u> “The plan:</p> <p>(1) Prescribes the type, amount, frequency, and duration of the physical therapy, occupational therapy, or speech-language pathology services to be furnished to the individual; and</p> <p>(2) Indicates the diagnosis and anticipated goals.”</p>	<p>3. Review employee personnel files to verify the rehabilitation service providers (i.e., physical therapists, physical therapy assistants, occupational therapists, occupational therapy assistants, and/or speech-language pathologists) have the necessary education, experience, training, and documented competencies to provide rehabilitation services.</p> <p>4. Ask the hospital what national standards of rehabilitation practice provide the basis for its rehabilitation services. Is there supporting documentation?</p> <p>5. The plan should include:</p> <ul style="list-style-type: none"> a. Treatment goals and type; b. Amount; c. Frequency; d. Duration of services; e. Goals reflect patient and family input (as appropriate). 	

PHYSICAL REHABILITATION SERVICES: PHYSICAL THERAPY/OCCUPATIONAL THERAPY/SPEECH THERAPY AND AUDIOLOGY

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
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Changes in the Plan:
 “Any changes in the plan are implemented in accordance with hospital policies and procedures.”

Also in accordance with 42 CFR §409.17, rehabilitation services must be provided by qualified physical therapists, physical therapy assistants, occupational therapists, occupational therapy assistants, and/or speech-language pathologists who meet the personnel qualifications defined in 42 CFR §484.4.

Hospitals must have policies and procedures consistent with State law.

Rehabilitation services must be provided according to national standards of practice as established by professional organizations such as, but not limited to, the American Physical Therapy Association, the American Occupational Therapy Association, and the American Speech-Language-Hearing Association.

26.00.09 Organizational Plan.

There shall be a written description of the program which includes, at least:

1. The scope of services provided;
2. Services specific to inpatients or outpatients including:
 - a. **Admission** criteria
 - b. Assessment and evaluation process

The scope and complexity of the hospital rehabilitation service must be adequate to meet the needs of its patients.

The written scope of service document describes the inpatient and outpatient services provided, in accordance with Federal and State law, regulations, and acceptable standards of practice.

DOCUMENT REVIEW

Review department policies. Verify:

1. The scope of services for all therapies is available.
2. The scope of services includes all required components:
 - a. Services provided (e.g., inpatients and/or outpatients)
 - b. **Admission** criteria

- 1 = Compliant
 2 = Not Compliant

This standard is not met as evidenced by:

PHYSICAL REHABILITATION SERVICES: PHYSICAL THERAPY/OCCUPATIONAL THERAPY/SPEECH THERAPY AND AUDIOLOGY

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>c. A program evaluation system including outcome measures, e.g., functional index measurement (FIM), etc.</p>		<p>c. Assessment and reassessment</p> <p>d. A program evaluation of outcome measures</p>	
<p>26.00.10 Initial Assessments. Therapy patients shall have assessments completed promptly before treatment by certified/licensed staff.</p>	<p>Initial assessments must be completed prior to any treatments are initiated.</p> <p>Ordinarily, the initial assessment is completed within 24 hours of receipt of the inpatient order and on the initial visit for outpatients.</p> <p>The assessment should include an evaluation of pain as well as the effectiveness of pain management using a quantifiable tool such as:</p> <ul style="list-style-type: none"> • A visual scale of zero to ten, or • The “FACES” tool for children. 	<p align="center">CHART REVIEW</p> <p>Review a sample of closed records. Select volumes as appropriate to evaluate both inpatient and outpatient records. Verify:</p> <ol style="list-style-type: none"> 1. The initial patient assessment was made within 24 hours of receiving the physician’s order, per policy. 2. An initial assessment was completed prior to start of therapy. 3. Pain is assessed using a quantifiable tool. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>
<p>26.00.11 Treatment Plan/Plan of Care. Patient assessments shall result in the development of a plan. This treatment plan / plan of care plan identifies goals, services and interventions to assist the patient in regaining independence, reducing pain, and/or adapting to limitations in activities of daily living.</p>	<p>The patient plan of care (treatment plan) includes:</p> <ol style="list-style-type: none"> 1. Measurable short-term and long-term goals with estimated timeframes for achievement, 2. Services and interventions for achieving goals, 3. Incorporates the patient and family goals, as appropriate, and 4. Updates, as necessary, to reflect changes in the patient’s condition and response to therapy. 	<p align="center">CHART REVIEW</p> <p>Review a sample of closed records. Select volumes as appropriate to evaluate both inpatient and outpatient records. Verify:</p> <ol style="list-style-type: none"> 1. All patients have a treatment plan/plan of care in the medical record. This plan identifies goals, services, and interventions to assist the patient with regaining independence, reducing pain, and/or adapting to limitations. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

PHYSICAL REHABILITATION SERVICES: PHYSICAL THERAPY/OCCUPATIONAL THERAPY/SPEECH THERAPY AND AUDIOLOGY

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
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26.00.12 Treatment Goals.

The treatment goals shall be developed in collaboration with the patient and/or family, as appropriate. These goals include monitoring and treatment for pain management.

The patient, and/or family, assists with treatment planning to reflect their understanding of life style and activities.

2. The physician and other professional personnel participate in the establishment, review and revision of the plan of treatment. (This could be a signature, a record of a conference, or record of consultation.)

CHART REVIEW

Review a sample of closed records. Select volumes as appropriate to evaluate both inpatient and outpatient records.

Verify:

1. Patients / family (as appropriate) participate with development of treatment goals.
2. Treatment goals include pain management utilizing a visual scale from 0 – 10 or the “FACES” tool for children.

- 1 = Compliant
 2 = Not Compliant

This standard is not met as evidenced by:

26.00.13 Patient / Family Education.

The patient and/or family is informed of all aspects of the nature of the problem, injury(ies), disability, alternative treatments and devices, and methods of achieving and maintaining progress in the identified goals.

Education of patients and families is documented in the record. Such education includes, but is not limited to, methods to reduce the potential for re-injury.

CHART REVIEW

Review a sample of closed records. Select volumes as appropriate to evaluate both inpatient and outpatient records.

Verify:

- Each patient record demonstrates the delivery of patient / family education.

- 1 = Compliant
 2 = Not Compliant

This standard is not met as evidenced by:

PHYSICAL REHABILITATION SERVICES: PHYSICAL THERAPY/OCCUPATIONAL THERAPY/SPEECH THERAPY AND AUDIOLOGY

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>26.00.14 <u>Reassessment.</u> Patients are reevaluated at regular intervals. Such intervals are defined by program policy.</p>	<p>The need for therapy services is based on regular reassessment(s) of patient needs, strengths, symptoms, behaviors and goal achievement.</p> <p>Reassessment is linked to the acuity / severity of patient symptoms.</p> <p>Reassessments occur no less than:</p> <ul style="list-style-type: none"> • Every two (2) weeks for inpatients and • Monthly for outpatients. 	<p align="center"><u>CHART REVIEW</u></p> <p>Review a sample of recently closed rehabilitation records. Choose the sample based upon distribution of inpatient and outpatient volumes. Verify:</p> <ol style="list-style-type: none"> 1. Facility policy describes patient reassessment requirements. 2. Patients are regularly reevaluated per policy by all appropriate disciplines. (At least every two (2) weeks for inpatients; monthly for outpatients.) 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>
<p>26.00.15 <u>Quality Assessment Performance Improvement (QAPI).</u> Therapy services shall be integrated into the facility-wide QAPI plan.</p>	<p>Self-explanatory.</p>	<p align="center"><u>DOCUMENT REVIEW</u></p> <p>Review the QAPI plan and minutes. Verify:</p> <ol style="list-style-type: none"> 1. Therapy services are integrated into the hospital-wide QAPI program. 2. Data collected is utilized to improve the quality of patient care and patient safety. 3. Improvements are monitored to insure improvement in outcomes / results. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

PSYCHIATRIC UNITS WITHIN AN ACUTE CARE HOSPITAL / NOT PPS EXCLUDED UNITS

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
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INSTRUCTIONS

This chapter is to be used for acute care hospitals with an inpatient psychiatric unit that is reimbursed by CMS according to the Inpatient Prospective Payment System (IPPS).

For an inpatient psychiatric unit that is EXCLUDED from the Inpatient Prospective Payment System (IPPS), refer to Chapter 34.

- 1 = Compliant
- 2 = Not Compliant
- NA = Chapter Not Applicable in this Facility

Comment:

27.00.01 Clinical Focus.
Psychiatric Units within an Acute Care Hospital must:

- Be primarily engaged in providing, by or under the supervision of a doctor of medicine or osteopathic medicine, psychiatric services for the diagnosis and treatment of mentally ill persons.

The Psychiatric Services must be under the supervision of a doctor of medicine or doctor of osteopathic medicine.

OBSERVATION, INTERVIEW, AND DOCUMENT REVIEW

1. Determine the Psychiatric unit is primarily engaged in providing psychiatric services for the diagnosis and treatment of mentally ill persons.
2. Determine the Psychiatric Services are under the supervision of a doctor of medicine or osteopathic medicine

- 1 = Compliant
- 2 = Not Compliant

Comment:

27.00.02 Not Applicable.

27.00.03 Not Applicable.

27.00.04 Not Applicable.

PSYCHIATRIC UNITS WITHIN AN ACUTE CARE HOSPITAL / NOT PPS EXCLUDED UNITS

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>27.01.00 <u>Special Medical Records Requirements for Psychiatric Units.</u> The medical records maintained by a psychiatric unit must permit determination of the degree and intensity of the treatment provided to individuals who are furnished services in the institution.</p> <p>The hospital maintains clinical records on all patients, including records sufficient to permit CMS to determine the degree and intensity of treatment furnished to Medicare beneficiaries.</p>	<p>The clinical record should provide information that indicates need for admission and treatment, treatment goals, changes in status of treatment and discharge planning, and follow-up and the outcomes experienced by patients.</p> <p>The structure and content of the individual patient’s record must be an accurate functional representation of the actual experience of the individual in the facility.</p> <p>It must contain enough information to indicate that the facility knows the status of the patient, has adequate plans to intervene, and provides sufficient evidence of the effects of the intervention, and how their interventions served as a function of the outcomes experienced. You must be able to identify this through interviews with staff, and when possible with individuals being served, as well as through observations.</p>	<p align="center"><u>DOCUMENT REVIEW</u></p> <ul style="list-style-type: none"> Determine the unit has policies, procedures, and practices to ensure the requirement is met. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>Comment:</p>
<p>27.01.01 <u>Development of Assessment / Diagnostic Data.</u> Medical records must stress the psychiatric components of the record, including:</p> <ul style="list-style-type: none"> A history of findings and treatment provided for the psychiatric condition for which the patient is hospitalized. 	<p>The hospital has policies, procedures, and practices in place that ensure the psychiatric medical record contains the required elements.</p>	<p align="center"><u>CHART REVIEW</u></p> <ol style="list-style-type: none"> Determine the unit has policies, procedures, and practices that establish the medical record expectations. Review open and closed medical records to determine the requirement was met. <ul style="list-style-type: none"> The medical record includes a history of findings and treatment provided for the psychiatric condition for which the patient is hospitalized. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>Comment:</p>

PSYCHIATRIC UNITS WITHIN AN ACUTE CARE HOSPITAL / NOT PPS EXCLUDED UNITS

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>27.01.02 Patient Legal Status. Medical records must stress the psychiatric components of the record, including:</p> <ul style="list-style-type: none"> The identification data must include the patient’s legal status. 	<p>Definition: Legal status is defined in the State statutes and dictates the circumstances under which the patient was admitted and/or is being treated – i.e., voluntary, involuntary, committed by court, evaluation and recertification are in accordance with state requirements.</p> <p>The hospital has policies, procedures, and practices in place that ensure the psychiatric medical record contains the required elements.</p>	<p align="center"><u>INTERVIEW & CHART REVIEW</u></p> <ol style="list-style-type: none"> Determine through interview with hospital staff the terminology they use to define “legal status.” If evaluation and recertification is required by the State, determine that legal documentation supporting this status is present. Review open and closed medical records to determine the requirement was met. <ul style="list-style-type: none"> The medical record includes identification data regarding the patient’s legal status. Changes in legal status should also be recorded with the date of change. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>Comment:</p>
<p>27.01.03 Admitting Diagnosis. Medical records must stress the psychiatric components of the record, including:</p> <ul style="list-style-type: none"> A provisional or admitting diagnosis must be made on every patient at the time of admission, and must include the diagnosis of intercurrent diseases as well as the psychiatric diagnosis. 	<p>There is an admission or working psychiatric diagnosis (including rule-out diagnoses) written in the most current edition of the American Psychiatric Association’s Diagnostic and Statistical Manual (DSM) or the approved International Classification of Diseases (ICD) nomenclature.</p> <ul style="list-style-type: none"> This diagnosis is made and entered into the chart of each patient at the time of the admission examination. The final diagnosis may differ from the initial 	<p align="center"><u>CHART REVIEW</u></p> <ol style="list-style-type: none"> Review open and closed medical records to determine the requirement was met. The admitting diagnosis may be found on the face sheet, in the history and physical, or in the physician progress notes. Are abnormal physical examination findings and/or laboratory findings justified by further diagnostic testing and/or development of an intercurrent diagnosis? 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>Comment:</p>

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	<p>diagnosis if subsequent evaluation and observation support a change. Diagnosis should include physical illness when present.</p> <ul style="list-style-type: none"> • If a diagnosis is absent, there must be justification for its absence. For example, if a patient was psychotic on admission and was not accompanied by family or significant others. • Intercurrent (other than psychiatric) diagnoses must be documented when they are made. • Attention should be paid to physical examination notes, including known medical conditions, even allergies and recent exposure to infections, illness, or substance abuse, and to available laboratory or test reports which identify abnormal findings to see that these are reflected by appropriate diagnosis. <p>These diagnoses may be found in a variety of locations in the medical record, e.g., the identification/face sheet, the finding of admission physical examination, the psychiatric evaluation the “admission work up “ or the physician’s progress notes.</p> <p>Diagnostic categories should include physical illness when present.</p>	<ul style="list-style-type: none"> • If yes, was such done? <ol style="list-style-type: none"> 3. If an identified physical illness requires immediate treatment, is the treatment being given? 4. How will an identified physical illness be likely to impact on the patient’s eventual outcome? <ul style="list-style-type: none"> • To what extent has this potential impact been addressed by the team? 	

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<p>27.01.04 Patient Reason for Admission. Medical records must stress the psychiatric components of the record, including:</p> <ul style="list-style-type: none"> The reasons for admission must be clearly documented as stated by the patient and or others significantly involved. 	<p>The purpose of this regulation is to provide an understanding of what caused the patient to come to the hospital, and the patient’s response to admission.</p> <p>The hospital records the statements and reason for admission given by family and by others, as well as the patient (preferably verbatim), with informant identified, in a variety of locations, e.g., in transfer and admission notes from the physician, nurses and social workers.</p> <p>Records should not contain vague, ill-defined reports from unknown sources.</p> <p>Records should record “who,” “what,” “where,” “when,” and “why.”</p>	<p align="center">CHART REVIEW</p> <ol style="list-style-type: none"> Review open and closed medical records to determine the requirement was met. Can the patient describe problems, stresses, situations experienced prior to hospitalization or do they still exist? <ul style="list-style-type: none"> Who is the informant? Did the informant witness the patient’s behavior? <ul style="list-style-type: none"> If not, on what basis has the informant come to know the patient’s behavior? Has staff elicited whether the patient has exhibited similar behavior previously? <ul style="list-style-type: none"> If so, what was different this time to make hospitalization necessary? Were there other changes / events in the patient’s environment (death, separations of significant others) which contributed to the need for hospitalization? <ul style="list-style-type: none"> If so, has staff explored how these will impact in the patient’s treatment? Has this been addressed by the treatment team? 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>Comment:</p>

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27.01.05 Psychosocial History / Assessment.

Medical records must stress the psychiatric components of the record, including:

- The social service records, including reports of interviews with patients, family members, and others must provide an assessment of home plans and family attitudes, and community resource contacts as well as a social history.

The purpose of the social work assessment is to determine the current baseline social functioning (strengths and deficits) of the patient, from which treatment interventions and discharge plans are to be formulated.

Patient length of stay is a key factor influencing hospital documentation policy, i.e., establishing timeframes for completion, documentation, and filing of the psychosocial assessment, and treatment planning in the medical record.

A psychosocial history / assessment must be completed on all patients.

The three key components to be addressed include:

A. Factual and Historical Information

1. Specific reasons for the patient's admission or readmission;
2. A description of the patient's past and present bio-psychosocial functioning;
3. Family and marital history, dynamics, and patient's relationships with family and significant others;
4. Pertinent religious and cultural factors;

CHART REVIEW

Review open and closed medical records for the psychosocial history / assessment to determine that the patient participated to the extent possible.

1. Determine that family members or others provided information.
2. Determine that all three key components must be included in the assessment.
 - High-risk psychosocial issues should be included in the treatment plan.
3. Does the psychosocial history / assessment indicate:
 - a. Clear identification of the informant(s) and sources of information?
 - b. Whether information is considered reliable?
 - c. Patient participation to the extent possible in provision of data relative to treatment and discharge planning?
 - d. Integration of significant data including

- 1 = Compliant
 2 = Not Compliant

Comment:

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	<p>5. History of physical, sexual and emotional abuse;</p> <p>6. Significant aspects of psychiatric, medical, and substance abuse history and treatment as presented by family members and significant others;</p> <p>7. Educational, vocational, employment, and military service history;</p> <p>8. Identification of community resources including previously used treatment sources;</p> <p>9. Identification of present environmental and financial needs.</p> <p>B. <u>Social Evaluation</u></p> <p>1. Patient strength and deficits;</p> <p>2. High risk psychosocial issues requiring early treatment planning and intervention - i.e., unattended child(ren) in home; prior noncompliance to specific treatment and/ or discharge interventions; and potential obstacles to present treatment and discharge planning.</p> <p>C. <u>Conclusions and Recommendations</u></p> <p>Assessment of Sections A and B shall result in the development of (C) recommendations</p>	<p>identified high risk psychosocial issues (problems) into the treatment plan?</p> <p>e. How does the hospital insure the information is reliable?</p>	

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- related to the following areas:
1. Anticipated necessary steps for discharge to occur;
 2. High risk patient and/or family psychosocial issues requiring early treatment planning and immediate intervention regardless of the patient’s length of stay;
 3. Specific community resources / support systems for utilization in discharge planning - i.e., housing, living arrangements, financial aid, and aftercare treatment sources;
 4. Anticipated social work role(s) in treatment and discharge planning.

27.01.06 Neurological Examination.

Medical records must stress the psychiatric components of the record, including:

- When indicated, a complete neurological examination must be recorded at the time of the admission physical examination.

Upon admission the patient should receive a thorough history and physical examination with all indicated laboratory examinations. **These investigations must be sufficient to discover all structural, functional, systemic and metabolic disorders.**

A thorough history of the patient’s past physical disorders, head trauma, accidents, substance dependence / abuse, exposure to toxic agents,

CHART REVIEW

1. Review open and closed medical records to determine that the requirement was met.

Positive neurological symptomatology found in the systems review (history, physical, and the “neurological screening”) should result in a neurologic workup or consultation.

- 1 = Compliant
 2 = Not Compliant

Comment:

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	<p>tumors, infections, seizures or temporary loss of consciousness, and headaches, will alert the physician to look for the presence of continuing pathology or possible sequelae any of which may turn out to be significant and pertinent to the present mental illness.</p> <p>Equally important is a thorough physical examination to look for signs of any current illness since psychotic symptoms may be due to a general medical condition or substance related disorder.</p> <p>In addition to the required history and physical, when indicated, a complete neurological exam must be conducted and recorded.</p> <p><u>The Screening Neurological Examination</u> As part of the physical examination, the physician will perform a “screening” neurological examination.</p> <ul style="list-style-type: none"> • While there is no precise definition of a screening neurological examination in medical practice, such examination is expected to assess gross function of the various divisions of the central nervous system as opposite to detained, fine testing of each division. • Gross testing of Cranial Nerves II through XII should be included. • Statements such as “Cranial Nerves II to XII intact” are not acceptable. 	<ol style="list-style-type: none"> 2. Did the presence of an abnormal physical finding or laboratory finding justify the need for further diagnostic testing, or for the development of an intercurrent diagnosis? <ul style="list-style-type: none"> • If the finding justified further follow-up in either situation, was such follow-up done? 3. Is there evidence that a screening neurological examination was done and recorded at the time of the physical examination? 4. Was the screening neurological or history indicative of possible involvement (tremors, paralysis, motor weakness or muscle atrophy, severe headaches, seizures, head trauma)? 5. If indicated, was a complete, comprehensive neurological exam ordered, completed and recorded in the medical record in a timely manner? 	

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- **These areas may be found in various parts of the physical examination and not just grouped specifically under the neurological.**

In any case where a system review indicate positive neurological symptomatology, a more detailed examination would be necessary, with neurological work-up or consultation ordered as appropriate after the screening neurological examination was completed.

Complete Neurological Examination

A complete, comprehensive neurological examination includes a review of the patient’s history, physical examination and for psychiatric patients, a review of the psychiatric evaluation.

The neurologist / psychiatrist himself / herself also takes a history to obtain the necessary information not already available in the medical record or referral form.

The neurological examination is a detailed, orderly survey of the various sections of the nervous system.

- As an example, whereas a simple reading of a printed page will be sufficient to assess grossly the patient’s sight (**cranial nerve II**) in a complete neurological examination, the neurologist may test visual acuity with a snellen chart, perform a fundoscopic examination of both eyes (sometimes after dilating the pupils) and he/she will examine the patient’s visual fields.

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<p>27.01.07 Confidentiality of Information. There shall be policies and practices to protect clinical data and information, which may be described as “unusually sensitive” for psychiatric, and substance abuse patient populations.</p>	<ul style="list-style-type: none"> In the examination of the motor system, the power of muscle groups of the extremities, the neck and trunk are tested. Where an indication of diminished strength is noted, testing of smaller muscle groups and even individual muscles are tested. In a complete neurological examination all the systems are examined, but the physician will emphasize even more the areas pertinent to the problem for which the examination was requested. <p>The facility protects the clinical data and information found in the medical records of psychiatric and substance abuse patients.</p> <p>Release of information policies address specific components that may require additional patient consent.</p>	<p>DOCUMENT REVIEW AND OBSERVATION</p> <ol style="list-style-type: none"> Review the policy on security and confidentiality of patient information. Observe clinical areas for breeches in security and confidentiality of patient information. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>Comment:</p>
<p>27.01.08 Psychiatric Evaluation. Each patient must receive a psychiatric evaluation.</p>	<p>The psychiatric evaluation is done for the purpose of determining the patient’s diagnosis and treatment and, therefore, it must contain the necessary information to justify the diagnosis and planned treatment.</p> <p>The psychiatric evaluation is a total appraisal or assessment of the patient’s illness. It is the physician’s assessment of the contributing factors and forces in</p>	<p>CHART REVIEW</p> <p>Review medical records in order to satisfy the requirements of this standard, and to meet the standards of medical practice.</p> <p>Determine the psychiatric evaluation includes the following component parts:</p> <ol style="list-style-type: none"> The patient’s chief complaints and/or reaction 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>Comment:</p>

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	<p>the evolution of the patient’s illness including the patient’s perception of his or her illness. Through the psychiatric evaluation the physician seeks to secure a biographical-historical perspective of the patient’s personality, with a clear psychological picture of the patient as a specific human being with his or her individual problems.</p> <p>While performing the psychiatric evaluation, the physician reaches an understanding of the patient’s basic personality structure, of the patient’s developmental period, of his or her value systems, of his or her past medical history including surgical procedures and other treatments, his or her past psychological traumatic experiences, his or her defense mechanisms, his or her supporting systems, any precipitating factors and how all these may have impacted and interplayed with each other to result in the present illness.</p> <p>In the psychiatric evaluation the patient should emerge as a dynamic human being with a past, a present and a potential future with a thread of logical continuity.</p> <p>The psychiatric evaluation includes all the requirements described in this standard and the information necessary to justify the diagnosis and treatment.</p> <ul style="list-style-type: none"> • A physician signature is necessary. 	<p>to hospitalization, recorded in the patient’s own words when possible.</p> <ul style="list-style-type: none"> • Why is the patient in the hospital? • Was it his/her idea? (Does he/she feel ill/disturbed/frightened?) • Is the patient in the hospital against his/her will? Who decided to hospitalize? Why? <p>2. Past history of any psychiatric problems or treatment, including prior precipitating factors, diagnosis, course and treatment.</p> <ul style="list-style-type: none"> • Has the patient been chronically ill? Continuously? Repeatedly? • How severely has the past illness/treatment interfered with the patient’s development and/or adjustment/ • Are there persistent symptoms / signs/behaviors that must be addressed and treated in order to favorably impact on the future psychiatric course? • What medications or supports helped him/her improve in the past? Are the same resources available to impact on 	

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	<p>Non-Physicians In those cases where the mental status portion of the psychiatric evaluation is performed by a non-physician, there should be evidence that the person is:</p> <ol style="list-style-type: none"> 1. Credentialed by the hospital, 2. Legally authorized by the state to perform the function, and 3. A physician review and countersignature is present, where required by hospital policy or state law. 	<p>the patient’s treatment during this episode?</p> <ol style="list-style-type: none"> 3. Past family, educational, vocational, occupational and social history. <ul style="list-style-type: none"> • To what extent, if any, is there a presence or absence of familial predisposition? • What is the patient’s education level? Was he/she a good student? Is he/she still interested in learning? • What jobs has the patient held? For how long? Is he/she now employed / unemployed? For how long? Has he/she ever worked? • How does the patient get along with people? As a child, did he/she have friends? Does he/she have friends now? • Within the psychiatric evaluation does one find the specific signs and symptoms, and other factors that justify the diagnosis? 	

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<p>27.01.09 <u>Timeframe for Completion.</u> Each patient must receive a psychiatric evaluation that must:</p> <ul style="list-style-type: none"> • Be completed within 60 hours of admission; 	<p>The hospital has policies, procedures, and practices in place that ensure the psychiatric medical record complies with the required elements.</p>	<p align="center"><u>CHART REVIEW</u></p> <p>Review a sampling of open and closed medical records.</p> <ul style="list-style-type: none"> • Determine that the assessment met the requirement. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>Comment:</p>
<p>27.01.10 <u>Medical History.</u> <i>Each patient must receive a psychiatric evaluation that must:</i></p> <ul style="list-style-type: none"> • Include a medical history; 	<p>The psychiatric evaluation must include the non-psychiatric medical history including:</p> <ul style="list-style-type: none"> • Physical disabilities, • Intellectual disabilities, and • Treatment. 	<p align="center"><u>CHART REVIEW</u></p> <p>Review a sampling of open and closed medical records to determine that the psychiatric evaluation met the requirement.</p> <p>Does the psychiatric evaluation include:</p> <ol style="list-style-type: none"> 1. Relevant past surgery? Past medical conditions and disabilities especially those of a chronic nature? 2. Have these contributed to the patient's psychiatric condition? How? 3. Are any of these conditions still present to any significant degree? 4. Are they likely to impact on the patient's recovery / remission? 5. Should they be addressed immediately? 6. Does the facility have the capability to intervene? If not, how is the need to be met? 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>Comment:</p>

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<p>27.01.11 <u>Mental Status.</u> Each patient must receive a psychiatric evaluation that must:</p> <ul style="list-style-type: none"> Contain a record of mental status; 	<p>The mental status must describe the appearance and behavior, emotional response, verbalization, thought content, and cognition of the patient as reported by the patient and observed by the examiner at the time of the examination.</p> <ul style="list-style-type: none"> This description is appropriate to the patient’s condition. 	<p align="center"><u>CHART REVIEW</u></p> <p>Review a sampling of open and closed medical records.</p> <ol style="list-style-type: none"> Determine that the psychiatric evaluation met the requirement. Explore the mental status for descriptions of the patient’s presentation during the examination that are relevant to the diagnosis and treatment of the patient. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>Comment:</p>
<p>27.01.12 <u>Reason for Admission.</u> Each patient must receive a psychiatric evaluation that must:</p> <ul style="list-style-type: none"> Note the onset of illness and the circumstances leading to admission; 	<p>In a hospitalized patient, the identified problem should be related to the patient’s need for hospital admission.</p> <p>The psychiatric evaluation includes a history of present illness, including onset, precipitating factors and reason for the current admission, signs and symptoms, course, and the results of any treatment received.</p>	<p align="center"><u>CHART REVIEW</u></p> <p>Review a sampling of open and closed medical records.</p> <ol style="list-style-type: none"> Determine that the psychiatric evaluation met the requirement. How long has the patient been ill? Was it a gradual or sudden onset? <ul style="list-style-type: none"> Is this a recurrence? What were the precipitating factors? What happened? What symptoms, signs, behaviors made this hospitalization necessary? <ul style="list-style-type: none"> What treatment has the patient already received before coming to the hospital? Is any medication he received listed? 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>Comment:</p>

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<p>27.01.13 Behavioral Assessment. Each patient must receive a psychiatric evaluation that must:</p> <ul style="list-style-type: none"> Describe attitudes and behavior (those requiring change for the patient to function in a less restrictive environment); 	<p>The problem statement should describe behavior(s) which require change in order for the patient to function in a less restrictive setting.</p> <p>The identified problems may also include behavioral or relationship difficulties with significant others which require active treatment in order to facilitate a successful discharge.</p>	<p align="center"><u>CHART REVIEW</u></p> <p>Review a sampling of open and closed medical records.</p> <ol style="list-style-type: none"> Determine that the psychiatric evaluation met the requirement. The evaluation includes a problem statement that includes behavioral or relationship difficulties that require active treatment in order to facilitate a successful discharge. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>Comment:</p>
<p>27.01.14 Cognitive Assessment. Each patient must receive a psychiatric evaluation that must:</p> <ul style="list-style-type: none"> Estimate intellectual functioning, memory functioning and orientation; 	<p>The psychiatric evaluation must estimate the intellectual functioning, memory, and orientation of the patient.</p>	<p align="center"><u>CHART REVIEW</u></p> <p>Review a sampling of open and closed medical records.</p> <ol style="list-style-type: none"> Determine that the psychiatric evaluation met the requirement. The evaluation includes an estimate of intellectual functioning, memory, and orientation. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>Comment:</p>

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<p>27.01.15 <u>Inventory of Strengths.</u> Each patient must receive a psychiatric evaluation that must:</p> <ul style="list-style-type: none"> • Include an inventory of the patient’s asset (strengths) in descriptive, not interpretive fashion. 	<p>Although the term strength is often used interchangeably with assets, only the assets that describe personal factors on which to base the treatment plan or which are useful in therapy represent personal strengths.</p> <p>Strengths are personal attributes i.e., knowledge, interests, skills, aptitudes, personal experiences, education, talents and employment status, which may be useful in developing a meaningful treatment plan.</p> <ul style="list-style-type: none"> • For purposes of the regulation, words such as “youth,” “pretty,” “Social Security income,” and “has a car” do not represent assets. 	<p align="center"><u>CHART REVIEW</u></p> <p>Review a sampling of open and closed medical records.</p> <ol style="list-style-type: none"> 1. Determine that the psychiatric evaluation met the requirement. 2. The evaluation includes an inventory of the patient’s strengths (assets) in a descriptive manner. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>Comment:</p>
<p>27.01.16 <u>Not Applicable.</u></p>			
<p>27.01.17 <u>Treatment Plan: Individualized.</u> Each patient must have an individual comprehensive treatment plan.</p>	<p>The patient and treatment team collaboratively develop the patient’s treatment plan.</p> <p>The treatment plan is the outline of what the hospital has committed itself to do for the patient, based on an assessment of the patient’s needs.</p> <p>The facility selects its format for treatment plans and treatment plan updates.</p>	<p align="center"><u>INTERVIEW, DOCUMENT REVIEW, OBSERVATION, & CHART REVIEW</u></p> <p>Determination of compliance regarding treatment plans is accomplished by the surveyor using the following methods, and to the extent possible, the following order:</p> <ol style="list-style-type: none"> 1. Observation of the patient and staff at planned therapies / meetings, in various settings both on and off the patient units, in formal and informal staff-patient interactions and in a variety of daily settings; 2. Interviews with patients, families, treatment staff; 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>Comment:</p>

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27.01.18 Treatment Plan: Documentation.

There is evidence that the patient (or his/her legal surrogate) is a participant in developing and updating the individualized treatment plan.

The individualized treatment plan provides evidence of:

1. The date it was developed and the schedule for update.
2. Responsibility for implementation of each portion of the plan.
3. The treatment modalities /

The organization has policies, procedures, and practices in place to ensure the individualized treatment plan contains all required elements.

3. Reviews of scheduled treatment programs (individual, group, family meetings, therapeutic activities, therapeutic procedures);
4. Attendance at multidisciplinary treatment planning meetings, if time permits; and
5. Medical record review.
6. Has the information gained from assessing / evaluating the patient been utilized to create an individualized treatment plan?

CHART REVIEW

1. Review a sample of closed, open and outpatient records. Determine compliance to all required elements.
2. Review a random group of treatment plans to determine that an individualized treatment plan has been developed for each patient, based on the assessments and evaluations being done. The patient's response toward meeting planned goals must be reviewed periodically, and modified as necessary. The plans must reflect an integrated approach to care planning and delivery, including all disciplines caring for the patient.

- 1 = Compliant
 2 = Not Compliant

Comment:

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approaches to be used.

4. The outcome goal, mechanism, and time frame for achievement.
5. Discharge and follow up plan.
6. Reassessment per planned schedule and upon significant changes in the patient's response and progress.
7. The names of the participants in the planning process.
8. Evidence of patient (surrogate) involvement / congruence with the plan.

27.01.19 Treatment Plan: Foundation.

Each patient must have an individual comprehensive treatment plan.

- The plan must be based on an inventory of the patient's strengths and disabilities.

A disability is any psychiatric, bio-psychosocial problem requiring treatment / intervention. The term disability and problem are used interchangeably.

The treatment plan is derived from the information contained in the psychiatric evaluation and in the assessments / diagnostic data collected by the total treatment team. Based on the assessment summaries formulated by team members of various disciplines, the treatment team identifies which patient disabilities will be treated during hospitalization.

CHART REVIEW

1. Review a sample of closed, open and outpatient records. Determine compliance to all required elements.
2. The facility is expected to pursue aggressively the attendance of all relevant participants at the team meetings.
 - Question any routine and regular absences of individuals who would be expected to attend.

1 = Compliant
 2 = Not Compliant

Comment:

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	<p>Patient strengths that can be utilized in treatment must be identified.</p> <p>Treatment planning depends on several variables; whether the admission is limited to crisis intervention, short-term treatment or long-term treatment. The briefer the hospital stay, the fewer disciplines may be involved in the patient’s treatment.</p> <p>There must be evidence of periodic review of the patient’s response and progress toward meeting planned goals.</p> <p>If the patient has made progress toward meeting goals, or if there is a lack of progress, the review must justify:</p> <ol style="list-style-type: none"> 1. continuing with the current goals and approaches; or 2. revising the treatment plan to increase the possibility of a successful treatment outcome. <p>Consideration must be given to the type of psychiatric program(s) under review to determine the timeframe for treatment plan review.</p> <p>The interval within which treatment plan reviews are conducted is determined by the hospital, however, the hospital’s review system must be sufficiently responsive to ensure the treatment plan is reviewed: whenever a goal(s) has been accomplished; when a patient is regressing; when a patient is failing to</p>	<ol style="list-style-type: none"> 3. Is the treatment plan individualized, i.e., patient-specific, or is there a predictable sameness from plan to plan? 4. When packaged plans or programs are used, do staff include needed individual adaptations in the plan? 5. Are the patient’s observed behaviors consistent with the problems and strengths identified in the plan or update? 6. Have the views which the patient communicated to the surveyor regarding problems which require treatment during hospitalization and plans for discharge, been incorporated in the plan or update? 	

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progress; or when a patient requires a new treatment goal.

**27.01.20 Treatment Plan Contents:
Diagnosis.**

The written plan must include:

- A substantiated diagnosis;

The substantiated diagnosis serves as the basis for treatment interventions. A substantiated diagnosis is the diagnosis identified by the treatment team to be the primary focus upon which treatment planning will be based. It evolves from the synthesis of data from various disciplines.

At the time of admission, the patient may have been given an initial diagnosis or a rule-out diagnosis.

- At the time of treatment planning, a substantiated diagnosis must be recorded.
- It may be the same as the initial diagnosis, or, based on new information and assessment, it may differ.
- Rule-out diagnoses, by themselves are not acceptable as a substantiated diagnosis.

Data to substantiate the diagnosis may be found in, but is not limited to, the psychiatric evaluation, the medical history and physical examination, laboratory tests, medical and other psychological consults, assessments done by disciplines involved in patient evaluations and information supplied from other sources such as community agencies and significant others.

CHART REVIEW

Review a sample of closed, open and outpatient records. Determine compliance to all required elements

1. What specific problems will be treated during the patient’s hospitalization?
2. Does the treatment plan identify and precisely describe problem behaviors rather than generalized statements i.e., “paranoid,” “aggressive,” “depressed?” or generic terminology i.e., “alteration in thought process,” “ineffective coping,” “alteration in mood?”
3. Are physical problems identified and included in the treatment plan if they require treatment, or interfere with treatment, during the patient’s hospitalization?

- 1 = Compliant
- 2 = Not Compliant

Comment:

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STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>27.01.21 <u>Treatment Plan Contents: Goals.</u> The written plan must include:</p> <ul style="list-style-type: none"> • Short-term and long range goals; 	<p>Based on the problems identified for treatment, short-term and long-range goals are developed. Whether the use of short-term or a combination of short-term and long-range goals is appropriate is dependent on the length of hospital stay.</p> <p>Short-term and long-range goals include specific dates for expected achievement.</p> <ul style="list-style-type: none"> • As goals are achieved, the treatment plan should be revised. When a goal is modified, changed or discontinued without achievement, the plan should be reviewed for relevancy, and updated as needed. <p>In crisis intervention and short-term treatment there may be only one timeframe for treatment goals. As the length of hospital stay increases (often because of the long-term chronic nature of the patient’s illness), both long-range and short-term goals are needed.</p> <p>The long-range goal is achieved through the development of a series of short-term goals, i.e., smaller, logical sequential steps which will result in reaching the long-range goal.</p> <ul style="list-style-type: none"> • Both the short-term and long-range goals must be stated as expected behavioral outcomes for the patient. • Goals must be related to the problems identified for treatment. Goals must be written as 	<p align="center"><u>CHART REVIEW</u></p> <p>Review a sample of closed, open and outpatient records. Determine compliance to all required elements.</p> <ol style="list-style-type: none"> 1. How do treatment plan goals relate to the problems being treated? 2. Do goals indicate the outcomes to be achieved by the patient? 3. Are the goals written in a way that allows changes in the patient’s behavior to be measured? 4. If not apparent, what criteria do staff use to measure success? 5. How relevant are the treatment plan goals to the patient’s condition? 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>Comment:</p>

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observable, measurable patient behaviors to be achieved.

- Discharge criteria may be included as long-range goals.

27.01.22 Treatment Plan Contents: Treatment Modalities.

The written plan must include:

- The specific treatment modalities utilized;

This requirement refers to all of the planned treatment modalities used to treat the patient during hospitalization. Having identified the problems requiring treatment, and defining outcome goals to be achieved, appropriate treatment approaches must be identified.

Modalities include all of the active treatment measures provided to the patient. It describes the treatment that will be provided to the patient. It describes the treatment that will be provided by various staff.

A daily schedule of unit activities does not, in itself, constitute planned modalities of treatment. It is expected that when a patient attends various treatment modalities/activities, it is a part of individualized planning with a specific purpose and focus for that patient.

Simply “naming” modalities (i.e., individual therapy, group therapy, occupational therapy, medication education) is not acceptable. The focus of the treatment must be included.

CHART REVIEW

Review a sample of closed, open and outpatient records. Determine compliance to all required elements.

1. Are qualified staff observed following the methods, approaches and staff intervention as stated?
2. Can staff explain the focus of the modality they have provided?
3. Are observed treatment methods, approaches and interventions from all disciplines included in the plan?
4. Do the pieces of the treatment plan work together to achieve the greatest possible gain for the patient?
5. Does the hospital integrate its activities, therapies, treatments, and patient routines to work for the patient’s therapeutic interest first, and its own convenience second?

- 1 = Compliant
- 2 = Not Compliant

Comment:

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STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
	<p>Simply “stating” modality approaches (i.e., “set limits,” “encourage socialization,” “discharge planning as needed”) is not acceptable. Modality approaches must be specifically described in order to assure consistency of approach.</p> <p>Observation of staff implementing treatment, both in structured and non-structured settings, is a major criterion to determine whether active treatment is being provided in accordance with planned treatment.</p> <p>It must be clear to you that the active treatment received by the patient is internally consistent and not simply a series of disconnected specific modalities delivered within certain scheduled intervals.</p>	<ol style="list-style-type: none"> 6. Do the disciplines present at observed treatment planning meetings represent all of the patient’s needs? 7. If the patient attends treatment planning, how does the staff prepare the patient to participate? 8. If the patient does not attend, what reasons does staff give to explain the absence? 9. Is there a process to enable staff to reach a consensus regarding how treatment will be carried out? 10. Is the patient included in the decision-making, whenever possible? 11. Are the final decisions regarding treatment approaches defined clearly by the end of the discussion? 12. How does the patient get to know his/her treatment regime? 13. How does the treatment team encourage the patient to accept responsibility for engaging in the treatment regime, rather than accepting it passively? 	

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STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>27.01.23 Treatment Plan Contents: Individual Staff Responsibilities. The written plan must include:</p> <ul style="list-style-type: none"> The responsibilities of each member of the treatment team; 	<p>There are no “correct” numbers of staff who comprise the treatment team.</p> <p>The disciplines involved in the patient’s treatment depend upon the problems to be treated, the short-term and long-range goals and the treatment approaches and modalities used to achieve the goals.</p> <p>The intent of the regulation is to insure that each individual on the treatment team who is primarily responsible for ensuring compliance with particular aspects of the patient’s individualized treatment program is identified. Identification of the staff should be recorded in a manner that includes the name and discipline of the individual. If other professionals or paraprofessionals provide care, the facility has the latitude to decide the manner with which it will identify them on the treatment plan.</p> <p>The patient, as well as family / significant others, should be aware of the staff responsible for various aspects of treatment.</p>	<p align="center">CHART REVIEW</p> <p>Review a sample of closed, open and outpatient records. Determine compliance to all required elements.</p> <ol style="list-style-type: none"> Are staff who are designated in the treatment plan observed carrying out treatment activities and therapies? <ul style="list-style-type: none"> Is the information in the plan consistent with surveyor observations? Are the patients able to name the staff responsible for implementing their treatment? Is this information consistent with the treatment plan? 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>Comment:</p>

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STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>27.01.24 <u>Treatment Plan Contents:</u> <u>Justification of Diagnosis.</u> The written plan must include:</p> <ul style="list-style-type: none"> Adequate documentation to justify the diagnosis and the treatment and rehabilitation activities carried out. 	<p>When the progress and treatment notes are reviewed, the content of the notes must relate to the treatment plan.</p> <p>The notes must indicate what the hospital staff is doing to carry out the treatment plan and the patient’s response to the interventions.</p>	<p align="center"><u>CHART REVIEW</u></p> <p>Review a sample of closed, open and outpatient records. Determine compliance to all required elements</p> <ol style="list-style-type: none"> Are the treatment notes relative to the identified problems? Are the treatment notes indicative of the patient’s response to treatment? Do the progress notes relate to specific patient problems or progress? 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>Comment:</p>

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STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>27.01.25 <u>Documentation of Active Treatment.</u> Treatment received by the patient must be documented in such a way to assure that all active therapeutic efforts are included.</p>	<p>Active treatment is an essential requirement for inpatient psychiatric care. Active treatment is a clinical process involving ongoing assessment, diagnosis, intervention, evaluation of care and treatment, and planning for discharge and aftercare, under the direction of a psychiatrist.</p> <p>The patient is in the hospital because it has been determined that the patient requires intensive, 24-hour, specialized psychiatric intervention that cannot be provided outside the psychiatric unit or hospital. The medical record must indicate that the hospital adheres to the patient’s right to be counseled about medication, its intended effects, and the potential side effects. If the patient requires, because of danger to self or others, a more restrictive environment, the hospital must indicate that the staff attempted to care for the patient in the least restrictive setting before progressing to a more restrictive setting.</p> <p>Through observation, look for evidence that each patient is receiving all the aspects of treatment to which the hospital has committed itself based upon his/her assessment, evaluation and plan of care. It is the hospital’s responsibility to provide those treatment modalities with sufficient frequency and intensity to assure that the patient achieves his/her optimal level of functioning.</p> <p>Through observation and interviews, look for evidence that each patient’s rights are being addressed and protected.</p>	<p><u>CHART REVIEW, DOCUMENT REVIEW, OBSERVATION AND INTERVIEW</u></p> <ol style="list-style-type: none"> Review policies and procedures on therapeutic use of restrictions, such as visitors, mail, and phone calls to validate patient rights are being protected. Through observation, look for evidence that each patient is receiving all aspects of treatment to which the hospital has committed itself based upon his/her assessment, evaluation and plan of care. It is the hospital’s responsibility to provide those treatment modalities with sufficient frequency and intensity to assure that the patient achieves his/her optimal level of functioning. Through observation and interviews, look for evidence that each patient’s rights are being addressed and protected. There should be policies and procedures in place to address the following areas: <ul style="list-style-type: none"> Informed consent Confidentiality Privacy and security Expect to see detailed policies and procedures regarding the therapeutic use of restrictions, such as visitors, mail and phone calls. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>Comment:</p>

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STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
	<p><u>Policies and Procedures</u> There should be policies and procedures in place to address the following areas:</p> <ul style="list-style-type: none"> • informed consent, • confidentiality, • privacy, and • security <p>Expect to see detailed policies and procedures regarding the therapeutic use of restrictions, such as visitors, mail, and phone calls.</p> <p>Seclusion and restraint policies and procedures must address patient protection and safety while in a restricted setting.</p> <p><u>Clarification of the types of notes found in the medical record.</u></p> <p>A. <u>TREATMENT NOTES</u> Treatment notes are recordings in the medical record that indicate provision of, and a patient’s response to, a specific modality. This modality may be drug therapy, individual, family, marital, or group therapy, art therapy, recreational therapy, and any specialized therapy ordered by the physician or anyone credentialed by the facility, in accordance with the State law, to write orders in the medical record.</p> <p>A combined treatment and progress note may be written.</p>	<p>6. Seclusion and restraint policies and procedures must address patient protection and safety while in a restricted setting.</p> <p><u>Patient Interviews and Chart Review</u></p> <ol style="list-style-type: none"> 1. Review open and closed medical records to determine that treatment modalities were provided with sufficient frequency and intensity to assure that the patient achieves an optimal level of functioning. 2. Does the patient know his/her diagnosis? 3. What did the patient contribute to the formulation of the treatment plan? Goals of treatment? 4. If the patient receives medication, does the patient understand the reason for the medication? The name of the medication? The dose prescribed? The time of administration? The desired effects? The potential side effects? 5. If medication is changed, is there a rationale for the change? 6. Are staff members recording their observations relative to the patient’s response to the treatment modalities, including medication? 	

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	<p>B. <u>PROGRESS NOTES</u> Progress notes are recordings in the medical record that are written by persons directly responsible for the care and active treatment of the patient. Progress notes give a chronological picture of how the patient is progressing toward the accomplishment of the individual goals in the treatment plan. These are frequently shift notes, weekly notes, or monthly notes.</p>	<ol style="list-style-type: none"> 7. Is there evidence that the patient was afforded the opportunity to participate in his/her plan of care? 8. What progress has the patient made? 9. Has the patient achieved his/her optimal level of functioning? If not, why? Are these reasons / barriers reflected in the current treatment plan? 10. Do treatment and progress notes support these insights? 11. Does the observed status of the patient in the various treatment modalities correspond to the progress note reports of status? 12. Do all treatment team members document their observations and interventions so that the information is available to the entire team? 13. If a restrictive procedure is used (e.g., restraint and/or seclusion), is there evidence that attempts were made systematically to treat the patient in the least restrictive manner? 14. Is there evidence that the rights of the patient were protected while in the restrictive setting in accordance with Federal 	

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27.01.26 Progress Notes.

Progress notes must be recorded by:

- The doctor of medicine or osteopathic medicine responsible for the care of the patient
- Nurse
- Social worker
- When appropriate, others significantly involved in active treatment modalities.

Refer to **standard 27.01.25** for clarification between treatment notes and progress notes.

- The recording of progress is evidence of individual patient performance.
- Specifically, the progress notes recorded by the professional staff, or others responsible for the patient’s treatment, must give a chronological picture of the patient’s progress or lack of progress towards attaining short and long-range goals outlined in the individual treatment plan.
 - Progress notes should relate to the goals of the treatment plan.
 - Notes that state, “patient slept well” or “no complaints” constitute observations and do not indicate how the patient is responding to treatment and progressing towards set goals.

Frequency alone does not determine the adequacy of progress notes. Expect to see greater frequency when patients are more acutely ill and/or in a crisis of some kind. Notes should be dated and signed (signature and title or discipline).

and State law and accepted standards of practice?

CHART REVIEW

1. Review open and closed patient records. Review progress notations for patient progress.
 - Select two or more identified problems and goal statements to trace the documentation of progress.
 - Entries must be dated and signed with the discipline identified.
 - The progress notes recorded by the professional staff, or others responsible for the patient’s treatment, must give a chronological picture of the patient’s progress or lack of progress towards attaining short and long-range goals of the treatment plan.
 - Expect to see greater frequency when patients are more acutely ill and/or in a crisis of some kind.
2. Are the physicians, nurses, social workers and other disciplines, i.e., rehabilitative therapy and psychology who are significantly involved in active treatment modalities / interventions actually documenting progress?

- 1 = Compliant
 2 = Not Compliant

Comment:

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3. Do the progress notes relate to the goals of the treatment plan? Do they include precise statements of progress?
4. Is there a correlation between what is observed by the surveyor and what is described in the notes?
5. Do the notes give a clear picture of the patient's progress or lack thereof, during the course of hospitalization?
6. In reviewing the patient's progress, are aftercare / discharge plans being evaluated?

SURVEYOR NOTE:

If progress notes are determined to be inadequate, you must specify which discipline's notes did not meet requirements.

27.01.27 Frequency of Progress Notes.

The frequency of progress notes is determined by hospital policy and the condition of the patient, but, must be recorded:

1. At least weekly for the first two months and at least once a month thereafter; and

Expect to see greater frequency when patients are more acutely ill and/or in a crisis of some kind.

Notes should be dated and signed (signature and title or discipline).

CHART REVIEW

1. Review open and closed medical records to determine if the frequency of progress notes meets the bylaws requirements and address the needs related to the condition of the patient.
 - Scoring must address frequency, recommendations for revisions of the treatment plan and assessment of progress in relationship to the plan.

- 1 = Compliant
 2 = Not Compliant

Comment:

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<p>2. Must contain recommendations for revisions in the treatment plan as indicated; and</p> <p>3. Must contain a precise assessment of the patient’s progress in accordance with the original or revised treatment plan.</p>		<p>2. What is the frequency of progress notes in relation to the condition of the patient?</p> <p>3. Do the progress notes contain documentation substantiating changes / revisions in the treatment plan and subsequent assessment of the patient’s responses and progress</p> <p>4. Do the notes give a clear picture of the patient’s progress, or lack thereof, during the course of hospitalization?</p> <p>5. Are the progress notes related to the goals of the treatment plan?</p>	
<p>27.01.28 Discharge Planning & Summary. The record of each patient who has been discharged must have a discharge summary that includes:</p> <ul style="list-style-type: none"> • A recapitulation of the patient's hospitalization and • Recommendations from appropriate services concerning 	<p>The record of each patient who has been discharged should indicate the extent to which goals established in the patient’s treatment plan have been met.</p> <p>As part of discharge planning, staff consider the discharge alternatives addressed in the psychosocial assessment and the extent to which the goals in the treatment plan have been met.</p> <p>The surveyor should refer to hospital policy for discharge timeframes.</p>	<p align="center">CHART REVIEW</p> <p>1. Verify that closed patient records have a discharge plan and summary per standard included in the record.</p> <p>These elements are considered when reviewing closed in and out patient records:</p> <ul style="list-style-type: none"> • The patients’ behavioral condition in relation to short and long term goals in the treatment plan. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>Comment:</p>

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<p>follow up or aftercare and</p> <ul style="list-style-type: none"> A brief summary of the patient’s condition on discharge. 	<p>The discharge summary should contain a recapitulation of the patient’s hospitalization, which is a summary of the circumstances and rationale for admission, and a synopsis of accomplishments achieved as reflected through the treatment plan.</p> <p><u>Recommendations for Follow-up or Aftercare</u> The patient’s discharge summary should describe the services and supports that are appropriate to the patient’s needs and that will be effective on the day of discharge.</p> <p>Examples include:</p> <ul style="list-style-type: none"> A complete description of arrangements with treatment and other community resources for the provision of follow-up services. Reference should be made to prior verbal and written communication and exchange of information; A plan outlining psychiatric, medical/physical treatment and the medication regimen as applicable; Specific appointment date(s) and names and addresses of the service provider(s); Description of community housing/living arrangement; Economic/financial status or plan, i.e., supplemental security income benefits; 	<ul style="list-style-type: none"> Concurrent physical problems identified with treatment and outcomes. Relevant facts about the aftercare plan and community resources. Documentation of psych-education of patients and families on signs and symptoms of illness to prevent re-hospitalization and improve their disease management skills. <ol style="list-style-type: none"> How does the discharge planning process verify appointment source(s), dates and addresses? How was the patient involved in the discharge and aftercare planning process? Were discharge related documents made available to the patient, family, community treatment source and/or any other appropriate sources? Is there indication that the discharge planning process included the participation of multidisciplinary staff and the patient? Have the results been communicated to the post-hospital treatment entity? Is there evidence that contact with the post-hospital treatment entity included 	

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	<ul style="list-style-type: none"> • Recreational and leisure resources; and • A complete description of the involvement of family and significant others with the patient after discharge. <p><u>Summary of Patient’s Condition at Discharge</u> The patient’s discharge planning process should address anticipated problems after discharge and suggested means for intervention, i.e., accessibility and availability of community resources and support systems including transportation, special problems related to the patient’s functional ability to participate in aftercare planning.</p> <p>The discharge summary and/or plan should contain information about the status of the patient on the day of discharge, including psychiatric, physical and functional condition.</p>	<p>communication of treatment recommendations (including information regarding the patient’s medications)?</p> <p>7. Is a contact person named, and does the patient have a specific appointment date and time for the initial follow-up visit?</p>	

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STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>27.02.00 <u>Special Staffing Requirements for Psychiatric Units in Acute Care Hospitals.</u> The psychiatric unit must have adequate numbers of qualified professional and supportive staff to evaluate patients, formulate written individualized comprehensive treatment plans, provide active treatment measures and engage in discharge planning.</p>	<p>The purpose of this standard is to ensure that the psychiatric hospital is adequately staffed with qualified mental health professionals and supportive staff to carry out an intensive and comprehensive active treatment program and to protect and promote the physical and mental health of the patients.</p>	<p><u>OBSERVATION, INTERVIEW, & RECORD REVIEW</u> Through observation, interview and record review determine if numbers and/or deployment of qualified staff is a concern. Review incident reports, medication error reports, patient and staff injury reports for indications that staffing is an issue.</p> <p>Adequate numbers are defined to mean the numbers, and deployment of staff with qualifications to evaluate, plan, implement and document active treatment.</p> <p>Do not look at numbers alone. The hospital is responsible for organizing its available staff and administrative duties along with patient appointments, treatment plan meetings, treatment sessions, activities, materials, equipment, and patient assignments to wards and groups in such a way that results in patients achieving the maximum therapeutic benefit.</p> <p>Assess the adequacy of the Special Staffing Condition by:</p> <ol style="list-style-type: none"> 1. Observing sampled patients and others during structured sessions and in unstructured settings. You should be able to observe behavioral evidence of a rational organization of resources. 2. Next, interview patients and staff to 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>Comment:</p>

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determine whether or not necessary treatment modalities and other services are being provided in a timely manner.

3. Next review the medical records of patients in the sample to ascertain if necessary active treatment assessments, treatments, evaluations and activities have been conducted and documented.
4. Also, review other records such as restraint and seclusion records, incident reports, medication error reports, reports of patient / staff injuries, etc., to determine the extent to which staffing levels or deployment contributed to negative patient outcomes.
5. Evaluate all outcome data in light of the success or failure observed during the survey relevant to each patient receiving active treatment, and achieving desired outcomes of care. This is the primary basis for evaluating the adequacy of the hospital's staffing under this Special Condition.

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<p>27.02.01 Staffing Requirements. The psychiatric unit must employ or undertake to provide adequate numbers of qualified professional, technical and consultative personnel to:</p> <ul style="list-style-type: none"> Evaluate patients 	<p>The facility should be adequately staffed with qualified mental health professionals to carry out an intensive and comprehensive active treatment program and to protect and promote the physical and mental health of its patients.</p>	<p align="center"><u>OBSERVATION & INTERVIEW</u></p> <p>Through observation, interview and record review determine if numbers and/or deployment of qualified staff is a concern. Review incident reports, medication error reports, and patient and staff injury reports for indications that staffing is an issue. Review the planned and actual staffing patterns.</p> <p>Review the treatment calendar. Review admission and discharge logs to determine patterns. Correlate these findings with open and closed patient record review, looking at documentation for assessments and treatments as well as restraint and seclusion utilization to determine if staffing was having a negative impact on outcomes.</p> <p align="center"><u>CHART REVIEW</u></p> <p>Review open and closed medical records to determine if documentation adequately reflects assessments, evaluations and progress.</p> <ol style="list-style-type: none"> Is there adequate staff to assure that the admission work-ups (assessment, diagnostic data gathering) are completed in a timely manner? Is there evidence that there is continuing evaluation of the patient's progress and response to treatment? Are evaluations delayed or absent? 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>Comment:</p>

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<p>27.02.02 <u>Staffing Requirements.</u> The psychiatric unit must employ or undertake to provide adequate numbers of qualified professional, technical and consultative personnel to:</p> <ul style="list-style-type: none"> Formulate written individualized comprehensive treatment plans. 	<p>Staffing must be sufficient so that members of the patient’s treatment team and others responsible for evaluation and assessment can contribute their respective data for consideration in the formulation of the treatment plan.</p>	<p align="center"><u>CHART REVIEW</u></p> <p>Review open and closed medical records to determine if documentation adequately reflects comprehensive treatment plans.</p> <ol style="list-style-type: none"> Was there sufficient discipline participation at the treatment team meeting to assure formulation of a treatment plan that meets the patient’s individualized needs? What problems prevent staff members from attending treatment meetings? Do they relate to staffing? Are the assessments / evaluations absent or delayed to the extent that they are not useful to the treatment team for the purpose of planning individualized treatment? 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>Comment:</p>
<p>27.02.03 <u>Staffing Requirements.</u> The psychiatric unit must employ or undertake to provide adequate numbers of qualified professional, technical and consultative personnel to:</p> <ul style="list-style-type: none"> Provide active treatment measures. 	<p>Active treatment occurs when the patient receives treatment interventions that are delivered under the direction of a physician, and which are specific to patient strengths, disabilities, and problems identified in the treatment plan. Treatment interventions and other services are furnished in accordance with accepted standards of professional practice. Although the active treatment process must be identifiable in documentation, it must be first and foremost observable and evident in daily practice.</p> <p>Treatment interventions need to be individualized, in</p>	<p align="center"><u>CHART REVIEW</u></p> <p>Review open and closed medical records to determine if documentation adequately reflects active, continuous treatment.</p> <ol style="list-style-type: none"> Through observation, interviews and record reviews, can you determine that patients receive active treatment? Is the distribution of staff consistent with particular patient needs? Is appropriate staffing sufficient to carry out treatment 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>Comment:</p>

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	<p>that the patient receives assistance with resolving or ameliorating the problems / circumstances that led to hospitalization.</p> <p>Expect to see treatment focused on the unique needs of individual patients. For example, several patients may be referred to “Anger Management Group,” but the focus of discussion and therapeutic intervention may differ depending on the individual patient’s particular issue regarding managing anger. Whether structure must be imposed by staff or whether the patient can direct his or her own activities for periods of time (without staff supervision), is based on the patient’s ability to engage in constructive, appropriate behavior (without engaging in harm to self or others). Be certain that the patient’s time on the unit is maximized toward the further development of appropriate desired outcomes, including but not limited to leisure and recreation.</p>	<p>plans?</p> <ol style="list-style-type: none"> 3. Does the patient attend therapies that are relevant to the identified problems that brought the patient to the hospital? 4. Are staff absences and/or vacancies preventing the patient from receiving active treatment? Are patients not attending therapeutic activities off the unit because there is no staff to escort them? 5. Are therapeutic groups not available on the unit for patients who are not able to go off the unit? 6. Are patients observed not engaged in activities while staff attend to administrative tasks? 7. Are active treatment sessions or activities carried out at discrete time intervals exclusively? Or is active treatment implemented as the patient’s needs emerge during the course of the day, as well? 8. Does a review of quality assurance data reveal a pattern of serious incidents occurring on particular shifts and/or days of the week? 9. What do patients report to the surveyor are their treatment modalities? 	

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10. Do patient interviews indicate that patients believe the treatment being provided is helpful?
11. Does the scheduling of activities and their content relate directly to the patient's treatment objectives or are the activities/content generalized, non-therapeutic "time-fillers"?
12. Can staff describe how their activities relate to the patient's treatment objectives?
13. At any point in time, in any of the patient's experiences in the hospital is the thrust of the patient's treatment plan observable during the staff and/or patient interactions?
14. Is there a consistent, observable pattern of evidence that hospital staff provide, reinforce and otherwise implement measures to achieve active treatment objectives?

27.02.04 Staffing Requirements.

The psychiatric unit must employ or undertake to provide adequate numbers of qualified professional, technical and consultative personnel to:

- Engage in discharge planning

The patient together with all relevant professionals caring for the patient should be expected to participate in the discharge planning process.

Staffing should be sufficient to facilitate this outcome, to the maximum extent possible.

CHART REVIEW

Review open and closed medical records to determine if documentation adequately reflects an appropriate, thorough discharge plan.

1. Do patients participate in their discharge planning process? If not, why?
2. Do staff interviews elicit information that

- 1 = Compliant
 2 = Not Compliant

Comment:

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27.02.05 Medical Director of Inpatient Psychiatric Services.

Inpatient Psychiatric Services must be under the supervision of a clinical director, service chief or equivalent who is qualified to provide the leadership required for an intensive treatment program.

Of the members of the organized Medical Staff, one is named as Clinical Director (**Medical Director**).

- The clinical director is ultimately responsible for the medical and psychiatric care that is provided to patients.
- The clinical director should ascertain that quality improvement programs are in place to monitor all areas of patient care, and should implement educational programs for all levels of staff.

Inpatient psychiatric services include the following functions:

1. admission interviews, assessments and evaluations;
2. psychiatric and medical work-ups;
3. treatment team leadership;
4. medication management;
5. on-call provision of emergency psychiatric and

staff working with patients are aware of the discharge plans for those patients?

3. Do record review and interviews indicate that all relevant staff have participated in discharge planning?

DOCUMENT REVIEW AND INTERVIEW

1. Determine that there is a **member of the medical staff named as the Clinical Director**.
 - Review the job description to determine that quality improvement program development is a responsibility of the clinical director, as well as implementation of educational programs for all levels of staff.
2. Just prior to the end of the survey, schedule a meeting with the clinical director. By the time of this meeting, you should already have conducted required observation, interviews and record reviews for at least a majority of the patients in the sample.

Collect any additional information that is necessary to consider in light of outcomes observed for patients, including:

 - the qualifications of the clinical director;
 - the leadership exhibited for the scope of

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 2 = Not Compliant

Comment:

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	medical treatment; 6. provision of individual, group and family therapies; 7. provision of clinical supervision to other professionals and paraprofessionals; 8. provision of medical and psychiatric educational workshops and conferences for all staff; and 9. provision of consultation to staff for clinical and/or administrative matters.	psychiatric / medical treatment programs needed by patients; and • the rationale for medical staffing coverage. If necessary, follow-up on letters of complaint previously reported serious problems, discrepancies with Data Collection Medical Staff Coverage	
<p>27.02.06 Medical Staff. The number and qualifications of doctors of medicine and osteopathic medicine must be adequate to provide essential psychiatric services.</p>	<p>There are sufficient Medical Staff members to provide services; the number depends upon the size of the facility or unit and the scope of services provided.</p> <p>The number of full-time, part-time and consulting staff, who are board certified within each category and their availability to the hospital must be adequate to provide psychiatric services, as described above.</p> <p>Adequacy is considered in light of the following:</p> <ol style="list-style-type: none"> Number of admissions, discharges and current patients by treatment units; Size of the hospital; Geographic proximity of the wards and units; 	<p><u>OBSERVATION, INTERVIEW, & CHART REVIEW</u></p> <ol style="list-style-type: none"> Determine that there are enough qualified Medical Staff to provide the services offered. The services must be provided in a timely manner. Determine if coverage is adequate to meet the needs of the patients. <ul style="list-style-type: none"> There should be at least one qualified physician to provide back-up / relief services for the Clinical Director. <ol style="list-style-type: none"> How many medical staff are board certified? Fully trained? How many full-time/part-time specialties are represented? 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>Comment:</p>

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	<ol style="list-style-type: none"> 4. Organization and kinds of treatment services rendered to the patients; 5. Availability of the physician coverage on evening, nights and weekends; 6. Availability of physicians to participate in treatment planning; 7. Availability of psychiatrists to consult with non-psychiatric physicians about psychotropic medication regimens; and 8. Availability of physicians to consult with multidisciplinary staff about treatment issues. 	<ol style="list-style-type: none"> 4. How are medical staff deployed? To what programs/units are they assigned? Why? 5. How much time do physicians spend on the units? Based on observations, interviews, and medical record reviews is coverage adequate to meet the needs of sampled patients? To meet the needs of other patients observed during the survey? 	
<p>27.02.07 Medical Director Qualifications. The Clinical Director, service chief or equivalent must meet the training and experience requirements for examination by the American Osteopathic Board of Neurology and Psychiatry or the American Board of Psychiatry and Neurology.</p>	<p>The Clinical Director is a physician who has completed an approved residency program and has been certified, or is eligible for examination to become certified by the American Board of Psychiatry and Neurology, or the American Osteopathic Board of Neurology and Psychiatry.</p> <p>To be admitted to the American Board Examinations the following conditions must be met:</p> <ol style="list-style-type: none"> 1. License without restrictions 2. Graduation from a medical school approved by either the Medical Osteopathic Association or the American Medical Association. 	<p align="center">FILE REVIEW</p> <ol style="list-style-type: none"> 1. Determine that the Clinical Director meets the residency requirements of a psychiatry/neurology program, approved by the American Board of Psychiatry and Neurology (ABPN) or the American Osteopathic Board of Neurology and Psychiatry (AOBNP). <ul style="list-style-type: none"> • Determine his/her Board status. 2. Review the clinical director’s personnel folder or ask the clinical director if he/she has one of the following: <ol style="list-style-type: none"> a. Certification of the American Board of 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>Comment:</p>

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	<p>3. A successful completion of an approved residency-training program for at least 3 years before 1988 that the America Council on Graduate Medical Education (ACGME) approves. After 1988, it has to be a four year accredited program.</p>	<p>Psychiatry and Neurology and/or certification of the American Osteopathic Board of Neurology and Psychiatry.</p> <p>b. If no certification, evidence that the person took the Boards would satisfy that the person had the training and equivalency to be admitted to the board examination.</p> <p>c. If indicated, medical school and residency training.</p> <p>d. Length of time he/she has been employed at the facility; length of time he has been at his position</p>	
<p>27.02.08 Medical Director Responsibilities. The Medical Director must monitor and evaluate the quality and appropriateness of services and treatment provided by the medical staff.</p>	<p>The Medical Director is accountable for the oversight of the QAPI program of services provided by the Professional Staff.</p> <p>Services and treatment prescribed to patients must be in accordance with appropriate and acceptable standards of practice.</p> <p>In states that allow psychologists to have admitting privileges, it is still the responsibility of the clinical director to oversee the quality of the patient’s treatment.</p>	<p align="center"><u>DOCUMENT REVIEW</u></p> <p>1. Determine that the Clinical Director is knowledgeable of and accountable for the Professional Staff QAPI program. Verify that the medical director is fulfilling these responsibilities.</p> <p>2. What mechanisms does the director use to monitor and evaluate the work of the medical staff? (Personal interviews? Quality Improvement reports? Incident reports?)</p> <p>3. When problems are discovered by the clinical director, how are they corrected?</p>	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>Comment:</p>

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27.02.09 Availability of Medical Personnel.

Doctors of medicine and osteopathic medicine and other appropriate professional personnel must be available to provide necessary medical and surgical diagnostic and treatment services.

If medical and surgical diagnostic services and treatment are not available within the institution, the institution must have an agreement with an outside source of these services to ensure that they are immediately available or a satisfactory agreement must be established for transferring patients to a general hospital that participates in the Medicare program.

Psychiatric patients are to have available general facility diagnostic and medical / surgical services.

- Services may be provided directly, by contractual arrangement, or by referral to another facility. In a specialty facility there shall be provision for basic diagnostics and clinical intervention, including cardiopulmonary.

Contracts or other arrangements with individuals and/or providers assure that medical and surgical services are available to meet the needs of the patients.

Review the medical and surgical services provided by the hospital during the interview with the clinical director.

- Discuss contract or arrangements with the clinical director for services provided off grounds.

4. Are services, notes, and reports timely?
5. Are medications used appropriately for the patient's diagnosis?

DOCUMENT REVIEW, INTERVIEW, & OBSERVATION

1. Review the array of services available. If necessary, review contracts or other agreements for the provision of services, which may be required to meet identified needs of the patient population.
 - Verify that all services are available 24/7. Note that all services provided (direct or contract) are included in the QAPI monitoring program.
2. How did the hospital meet the medical / surgical / diagnostic needs represented by each patient in the sample?
 - Were these done timely?
 - Appropriately?
3. If contracts are not current or available, how are these services provided for the patient, if needed? Is there evidence of negative outcomes as a result of these arrangements?

- 1 = Compliant
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27.02.10 Nursing Services.

The hospital, or unit, must have a qualified Director/Manager of Psychiatric Nursing Services.

In addition to the Director/Manager of Psychiatric Nursing Services, there must be adequate numbers of registered nurses, licensed practical / vocational nurses, and mental health workers to provide nursing care necessary under each patient's active treatment program and to maintain progress notes on each patient.

Of the members of the organized Nursing Staff one is named as director.

Psychiatric nursing functions may include the following:

- supervision of paraprofessional staff;
- assessment, planning, provision, and evaluation of psychiatric nursing care to patients;
- medication teaching;
- management of the therapeutic milieu;
- provision of mandatory and voluntary in-service training to all staff; and
- provision of specialized treatments and therapies, such as individual, group and family therapies, that require the clinical expertise of a professional psychiatric nurse.

4. Are reports from other services such as pharmacy, radiology, and clinical laboratory timely? Appropriate?

FILE REVIEW

- Determine that there is a qualified Director/Manager of Psychiatric Nursing Services providing the required leadership and supervision for the psychiatric nursing department.

- 1 = Compliant
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Expect to see evidence of orientation programs as well as ongoing continuing education programs for Licensed Practical Nurses and mental health workers that stress individualized treatment interventions.

27.02.11 Director of Nursing Qualifications.

The Director / **Manager** of Psychiatric Nursing Services must be a registered nurse who has a master’s degree in psychiatric or mental health nursing or its equivalent from a school of nursing accredited by the National League for Nursing, or be qualified by education and experience in the care of the mentally ill.

The director must demonstrate competence:

- to participate in interdisciplinary formulation of individual treatment plans;
- to give skilled nursing care and therapy; and
- to direct, monitor, and evaluate the nursing care furnished.

During the interview with the **Director / Manager of Psychiatric Nursing Services**, assess his/her educational background and psychiatric nursing and leadership skills.

- If the **Director / Manager of Psychiatric Nursing Services** has less than a Master’s Degree in Psychiatric Nursing, expect to see evidence of experience and on-going training in psychiatric nursing. Documented consultation from a nurse with a Master’s in Psychiatric Nursing constitutes on-going training.

INTERVIEW

1. Based on structured observations of the patients in the psychiatric unit, patient and staff interviews and medical record review, ascertain that nursing services are provided in accordance with safe, acceptable standards of nursing practice under the leadership of the Director/Manager of psychiatric services.
2. Information obtained during interview with the **Director / Manager of Psychiatric Nursing Services** should verify the following.
 - a. implementation of continuous quality improvement programs;
 - b. provision of orientation, in-service and continuing education programs for nursing personnel especially in the areas of psychiatric nursing, nursing process, prevention and management of violence,
 - c. CPR training and
 - d. Universal Precautions training for staff.

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Comment:

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		<ol style="list-style-type: none"> 3. Verify the Director/ Manager of Psychiatric Nursing Services has the required education / experience in the care of the mentally ill as evidenced by either: <ol style="list-style-type: none"> a. A master's degree in psychiatric/mental health nursing; OR b. A RN with a related master's, such as psychology or nursing education, with 2 years of psychiatric inpatient nursing care; OR c. A BSN, ADN, or diploma in nursing with at least 2 years of psychiatric inpatient nursing care and documented educational programs (ANA Psychiatric Nurse certification, psychiatric specific CEU's e.g., American Psychiatric Nurses Association) focused on psychiatric nursing, occurring at sufficient intervals to keep the Director of Psychiatric Nursing current; d. Documented clinical consultation / supervision from a master's-prepared psychiatric nurse. 4. Are nursing assessments completed on all patients? 5. Do the multidisciplinary treatment plans 	

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		<p>reflect nursing input which include specific nursing interventions for nursing problems (e.g. violence toward self / others, physical / medical crises)?</p> <p>6. Is nursing care evaluated by an R.N., with changes in the care based on the patient's progress or lack thereof?</p> <p>7. Are intrusive techniques (e.g. seclusion, restraint, electroconvulsive therapy (ECT), and/or medical procedures) and patient incidents (e.g. medication errors, patient falls, patient-to-patient and patient-to-staff injuries) monitored in accordance with hospital policy, State statutes and safe nursing practice?</p> <p>8. Are nursing personnel observed relating to patients in a therapeutic manner?</p>	
<p>27.02.12 Staffing. The staffing pattern must ensure the availability of a Registered Nurse 24 hours each day.</p> <p>There must be adequate numbers of registered professional nurses, licensed practical nurses, and mental</p>	<p>There is at least one RN for each distinct (program) unit in the facility for each shift of operation.</p> <ul style="list-style-type: none"> "On call" RNs do not constitute coverage. <p>Additional professional and supportive nursing staff is provided to adequately implement the philosophy of care and to meet identified needs of the patient</p>	<p align="center"><u>DOCUMENT REVIEW, INTERVIEW, AND OBSERVATION</u></p> <p>1. Review planned and actual staffing for mix and coverage for appropriateness. Considerations include "locked" and open units, the use of seclusion / restraints, the numbers of patients requiring close observation for suicidal, elopement or</p>	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>Comment:</p>

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<p>health workers to provide the nursing care necessary under each patient's active treatment program.</p>	<p>populations.</p> <p>There are sufficient staff members to provide services; the number depends upon the size of the facility or unit and the scope of services provided.</p> <p>Psychiatric nursing functions may include the following:</p> <ul style="list-style-type: none"> • Supervision of paraprofessional staff • Assessment, planning of psychiatric nursing care of patients • Medical teaching • Management of therapeutic milieus • Provision of mandatory and voluntary in-service training of specialized treatments and therapies, such as individual group and family therapies, that require the expertise of the professional psychiatric nurse <p>The evaluation of sufficient numbers and level of RNs, LPNs and mental health workers is based on the patient characteristics as seen in structured observations of patients in the sample and other patients in the psychiatric unit, patient interviews, and as evidenced in medical records and other data related to patients (e.g. incident reports, seclusion/restraint reports).</p> <p>Patient care assignments should be appropriate to the skills and qualifications of the nursing personnel providing patient care.</p> <ul style="list-style-type: none"> • There should be evidence that all nursing 	<p>assaultive precautions, and other measures of patient acuity.</p> <ul style="list-style-type: none"> • Verify the availability of at least one RN per shift for each facility unit. Request calculations regarding planned and actual staffing in raw numbers and full time equivalencies. • Determine if nurse staffing is diluted by their performance of non-nursing activities such as housekeeping and escort services. Determine the program uses of nurses such as group facilitation, 1:1 interventions, etc. <p>2. Staffing patterns should be reviewed on a sample of 25% of the wards.</p> <ul style="list-style-type: none"> • The staffing, including levels of nursing personnel, should be reviewed for the days of the survey and evaluated based on the level of needs presented by the patients. Additional staffing patterns shall be reviewed if a problem or concern is evidence. Patient need / assessment / acuity shall be reviewed for any wards as deemed necessary based on problems / concerns found in sampling review. <p>If your observations and/or interviews indicate a staffing problem, you may want to consider the following variables in assessing adequacy of</p>	

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	<p>personnel have education, experience and/or training in psychiatric care.</p> <p>Mental health workers spend the majority of their workday interacting with patients.</p> <ul style="list-style-type: none"> • Expect to see evidence that they are receiving on-going supervision and training. • Mental health workers should be assigned patient care duties and therapeutic modalities that reflect their educational level, psychiatric training, and experience. 	<p>nursing personnel coverage:</p> <ol style="list-style-type: none"> 1. Organization and types of services provided to patients by the nursing department; 2. Number and levels of nursing care needs of patients, including average length of stay, acuity of patients and nursing care requirements; 3. Number and levels of nursing personnel based on the roles and functions required of nursing; 4. Number of suicidal / assaultive patients; 5. Seclusion / restraint incidents; 6. Number of admissions and discharges; 7. Number and type of accidents and/or injuries; 8. Amount and complexity of medication regimens; 9. Medication errors; 10. Use of P.R.N. (as needed) medications; 11. Medical (physical) procedures; 12. Assignment and utilization of “pool” nursing 	

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		<p>personnel (those staff who are hired through a contract service and are not employees of the hospital). Contractual staff should receive orientation and training necessary for assigned functions, and should be supervised by employees of the hospital;</p> <p>13. Availability of RNs to supervise/consult with nursing / non-nursing personnel about patient care;</p> <p>14. Availability of RNs to assess and implement care in crisis situations;</p> <p>15. Availability of RNs to interact with patients in structured activities; and</p> <p>16. Involvement of patients with personnel.</p> <p>17. Are personnel interacting with patients? Are patients involved in structured activities? Are patients lying in beds / on floors, sitting alone, fighting and arguing?</p> <p>18. When interviewing / observing staff, do they interact therapeutically with patients? If unclear, request rationale from staff.</p> <p>19. Why have nursing staff been deployed in the manner that they have?</p>	

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<p>27.02.13 Psychological Services. The facility must provide or have available psychological services to meet the needs of the patients.</p>	<p>Psychology services may include the following:</p> <ul style="list-style-type: none"> • Diagnostic testing and diagnostic formulations on request from physicians • Provision of individual, group and family therapies • Participation in multidisciplinary treatment conferences • Program development and evaluation. <p>Psychologist personnel are available to provide essential diagnostic formulations upon request. Psychologist personnel are available to provide program development, interdisciplinary planning and intervention, and evaluate program effectiveness as needed to implement the program philosophy.</p> <p>The number of full-time, part-time and consulting psychologists must be adequate to provide necessary services to patients. Arrangements with outside resources must assure that necessary patient services will be provided.</p>	<p align="center"><u>DOCUMENT REVIEW, CHART REVIEW, & OBSERVATION</u></p> <ol style="list-style-type: none"> 1. Determine the number of full time, part time, and consulting psychologists. If contractual services are utilized, determine their availability to provide needed services to patients. 2. Determine the extent that psychological testing is requested, the response time and the availability of the results. 3. Did the patients in the sample have a need for psychological services or testing? <ul style="list-style-type: none"> • Were they provided in a timely manner and with sufficient intensity? 4. Did any of the patients in the sample indicate a need for psychological services, but none were requested? 5. What types of psychological services are offered? (e.g., assessments, therapy) 6. Do certain groups of patients receive testing routinely? Dementia? Children? Adolescents? Why? 7. Once tests are performed, are results reported in sufficient time to be integrated in the patient's active treatment and treatment 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>Comment:</p>

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27.02.14 Social Services.

There must be a Director of Social Services who monitors and evaluates the quality and appropriateness of social services furnished.

Social work functions may include the following functions:

- Intake or admission screening
- Psychosocial assessment of the newly admitted patient
- Developing an update or detailed reassessment of the patient
- High-social risk case finding
- Contact with family and others significant in the patient's life

Such functions may include:

- patient and family education, support, and advocacy;

plan?

8. How does the hospital or Psychological Service Department determine whether or not:
 - it meets the needs of patients?
 - Its services are underutilized or over-utilized?
9. Why have psychological services staff been deployed in the manner that they have?

INTERVIEW

1. Just prior to the end of the survey, schedule a meeting with the Director of Social Work. By the time of the meeting, you should already have conducted required observations, interviews and record reviews for at least a majority of the patients in the sample.

Collect any additional information that is necessary to consider in light of outcomes observed for patients, including: the qualifications of the director; the leadership exhibited for the scope of services needed by the patient; and the rationale for social work staffing coverage.

2. How does the director periodically audit the quality of social work services furnished?

- 1 = Compliant
 2 = Not Compliant

Comment:

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	<ul style="list-style-type: none"> • providing coordination / liaison with community-based social and mental health agency(ies) regarding the pre-admission status of the patient; • participating as a member of the treatment team in development of treatment planning and • subsequent planned interventions (modalities). Such modalities may include supportive, individual, couple, family, or group therapy, aimed at meeting specified goals identified in the treatment plan. <p>Continuity of care is an important social work principle and may be demonstrated through case management and a major role in discharge planning. Activities, in conjunction with the patient wishes, may include contact with patient’s family, identifying and assisting in referral of the patient to community-based agency(ies) at the time of discharge.</p> <p>Finally, post-discharge follow-up may be done to assure that linkage of the patient with community resources has occurred to reduce re-hospitalization.</p> <p>Determine who completed the assessment and initiated preliminary discharge planning.</p> <ul style="list-style-type: none"> • When staff other than a Social Worker perform these duties, the Director of Social Work or a Master’s level social worker (MSW) qualified supervisory staff member should be 	<ol style="list-style-type: none"> 3. What are the outcomes of audits conducted? 4. What percentage of psychosocial assessments was completed and available in written form at the time of the interdisciplinary treatment plan? 5. How does the patient’s social needs as addressed by the social worker in the psychosocial assessment compare against the goals developed in the interdisciplinary treatment plan? 6. Has social work staff provided active treatment in accordance with the patient’s treatment plan? 	

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<p>27.02.15 Social Service Staff Standards of Practice. Social services must be furnished in accordance with accepted standards of practice and established policies and procedures.</p>	<p>involved to oversee the quality and appropriateness of service provided.</p> <p>Patient and staff interviews, structured observations and review of selected medical records yield the information necessary to determine how well social work has met the needs of the patients. The surveyor should evaluate these data to determine adequacy of qualified and support staff deployed to patient areas and their duties.</p> <p>The social work policies for service provision to the patient should describe:</p> <ul style="list-style-type: none"> • the organizational structure of the department (program) and • the range of services performed by the department. <p>Social work staff is sufficient to participate in assessments, treatment planning, and discharge planning to include arranging for follow up care and the provision of transfer information.</p> <p>The role of the social worker must reflect psycho-education of patients and families on signs and symptoms of illness to prevent re-hospitalization and improve their disease management skills.</p> <p>Accepted standards of practice are based on policy statements adopted by the National Association of Social Workers and a definition of social work practice</p>	<p><u>DOCUMENT REVIEW & CHART REVIEW</u></p> <ol style="list-style-type: none"> 1. Determine the number of full time, part time and consulting social work staff. Determine their roles and responsibilities in accomplishing the philosophy of the program(s). 2. Determine the adequacy of social work in the characteristics listed with emphasis on discharge planning / liaison, and their role in psycho-education to prevent re-hospitalization. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>Comment:</p>

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STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
	<p>in health care adapted by the Consortium of Health Care Social Work Organizations.</p> <p>Staff should adhere to the facility's personnel requirements.</p>		
<p>27.02.16 Social Services Director Qualifications. The director of the social work department or service must have a master's degree from an accredited school of social work or must be qualified by education and experience in the social service needs of the mentally ill.</p> <p>If the director does not hold a master's degree in social work, at least one staff member must have this qualification.</p>	<p>The duties, functions, and responsibilities of the director of social services / social work should be clearly delineated and documented in the facility's policies and procedures.</p> <p>If the director is not MSW qualified and at least one staff member is MSW qualified, verify the duties, functions, and responsibilities of the MSW.</p>	<p align="center"><u>FILE REVIEW & INTERVIEW</u></p> <ol style="list-style-type: none"> 1. Review the job description and qualifications of the director of social work to determine the requirement was met. 2. Verify the Director of Social Work Services holds a Masters in Social Work, or is a BSW with a MSW staff available on at least a part time basis. 3. Verify the director has documented experience in providing services to mental health populations. 4. What are the director's qualifications, experience and scope of duties within this position? 5. If a MSW staff member, other than the director, is performing any of these duties, what are this staff member's experience and scope of duties performed? Why were these duties delegated? 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>Comment:</p>

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<p>27.02.17 Social Service Staff Responsibilities. Social service staff responsibilities must include but are not limited to participating in discharge, planning, arranging for follow-up care, and developing mechanisms for exchange of appropriate information with sources outside the hospital.</p>	<p>Social work contact with the patient, family, and significant others should occur during, or as soon as possible, after the admission.</p> <p>High-risk case finding should result in significant data being available for early integration into the treatment plan and subsequent social work action as indicated.</p> <p>The treatment plan should consider the anticipated social work role and expected interventions as recommended in the psychosocial assessment.</p> <p>Treatment and discharge planning activities, liaison / follow-up efforts should be based upon the goals and staff responsibilities specified in the treatment plan.</p>	<p>6. To what extent is the director’s knowledge of the social work needs of the various wards?</p> <p>7. Why has the social work staff and services provided throughout the hospital been deployed in the manner it has?</p> <p align="center">INTERVIEW AND CHART REVIEW</p> <p>1. Interview the social worker to verify services are provided consistent with the needs of patients.</p> <p>2. Review a select group of medical records to determine the requirement was met.</p> <p>3. Are social work staff routinely involved in providing services to the patient that are identified in the treatment plan?</p> <p>4. To what extent do social work staff provide discharge planning services to the patient in the way of: supportive individual, couple, family, or group therapy focused on discharge goals of the patient?</p> <ul style="list-style-type: none"> • Carrying out a liaison role with community resource providers? <p>5. Have social work staff assured that adequate information is provided to post-hospital patient service providers?</p>	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>Comment:</p>

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<p>27.02.18 <u>Therapeutic Activities Program.</u> The psychiatric unit must provide a therapeutic activities program.</p>	<p>There are sufficient resources to provide physical and psychosocial therapeutic activities to meet the needs of the patient populations.</p> <p>Therapeutic activities are provided within the program schedule on the day and evening shifts each day of the week, including weekends. Activities do not present undue hazard to the therapeutic milieu.</p> <p>Activities may be planned / directed by:</p> <ul style="list-style-type: none"> • An Occupational Therapist • Recreational Therapist with a Bachelor’s of Science Degree • A Music Therapist with a Bachelor’s of Science degree or Bachelor’s of Art degree, or • Other related therapist. <p>A variety of therapeutic and rehabilitative activities are selectively used as therapeutic tools in providing active treatment to the psychiatric patients.</p> <p>Therapeutic activities focus upon the development and maintenance of adaptive skills that will improve the patient’s functioning. In contrast, leisure activities provide the patient with individualized opportunities to acquire knowledge, skills and attitudes about meaningful leisure involvement and experiences.</p> <p>A patient may need treatment and/or remediation of functional behavior(s) prior to leisure involvement. However, for some psychiatric patients the priority need may be for leisure education and activities.</p>	<p align="center"><u>DOCUMENT REVIEW, CHART REVIEW, AND OBSERVATION</u></p> <p>Determine the adequacy of activities in providing safe and meaningful outlets that correlate to the identified needs of the patient population.</p>	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>Comment:</p>

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27.02.19 Focus of the Activities Program.

The program must be appropriate to the needs and interests of the patients and be directed toward restoring and maintaining optimal levels of physical and psychosocial functioning.

The hospital is responsible for ensuring consistent availability and provision of individualized therapeutic activities and rehabilitative services based on patient needs.

The selection of individualized therapeutic and rehabilitative staff modalities should be based on patient need and goals set in the patient’s treatment plan.

Rehabilitative services may include educational, occupational, recreational, physical, art, dance, music, and speech therapies and vocational rehabilitation evaluation and counseling.

There are other disciplines that also serve patients. Consultants include but are not limited to the following: educational instructors, registered occupational therapist / certified occupational therapy assistant, certified therapeutic recreation specialist, certified therapeutic recreation assistant, speech-language pathologist has certificate of clinical competence, registered and certified music therapist, registered art therapist, and registered physical therapist.

The qualified vocational specialist may perform duties of a rehabilitation counselor, vocational evaluator, or the work adjustment specialist.

DOCUMENT REVIEW, INTERVIEW, AND CHART REVIEW

Verify that the program provides adequate variety and availability of activities that are focused on restoring and maintaining physical and psychosocial function.

- 1 = Compliant
- 2 = Not Compliant

Comment:

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<p>27.02.20 <u>Activities Program Staffing.</u> The number of qualified therapists, support personnel, and consultants must be adequate to provide comprehensive therapeutic activities consistent with each patient's active treatment program.</p>	<p>Qualified staff should complete their respective discipline assessments for use in multidisciplinary treatment planning. Specific role(s) and modalities to be implemented by rehabilitative staff must be determined by goals set in the patient's treatment plan.</p> <p>Qualified therapists who provide clinical services and administrative staff should utilize established monitoring and evaluation mechanisms to conduct consistent timely review of the quality and appropriateness of therapeutic and rehabilitative services delivered to patients.</p>	<p align="center"><u>DOCUMENT REVIEW, CHART REVIEW, AND OBSERVATION</u></p> <ol style="list-style-type: none"> 1. Determine the number of full time, part time and consulting therapeutic activity staff. Determine their roles and responsibilities in accomplishing the philosophy of the program(s). 2. Verify the number of staff available provides a comprehensive program consistent with treatment plans. 3. Is there evidence that sampled patients and staff are familiar with the goals and staff interventions described in the patient's treatment plan? <ul style="list-style-type: none"> • Are these observed interventions being carried out? • What is the patient's response? • Are these interventions and activities of sufficient frequency and intensity to achieve maximum therapeutic benefit? 4. What are the qualifications, experience, duties and responsibilities of the Therapeutic Activities Director and discipline supervisor(s)? 5. How is the program organized? 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>Comment:</p>

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6. Did the patients in the sample have a need for any therapeutic activities?
 - Were their needs met?
7. Did any of the patients in the sample indicate a need for therapeutic activities, but none were considered?
8. What kinds of services are provided to the patient population?
9. Are activity areas/sites accessible and available to meet the patient's individual needs? Are the facilities and resources adequate to enable implementation of goals set in the patient's treatment plan?
10. Does the program utilize available community resources to provide opportunities for socialization, leisure, and therapeutic and/or rehabilitation activities for patients who can participate outside the hospital setting?
11. Are current activity schedules clearly posted for patient and staff reference and use? Are the scheduled activities related to the particular patient area and specific treatment needs of patients?
12. Are patient needs met consistently at all

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27.02.21 Scope & Description of Available Services.
 There is a written program description which includes, but is not limited to:

- A. The scope of services provided specific to inpatient, partial day, residential and outpatient and aftercare programs
- B. How these programs relate to each other
- C. Admission criteria, including limitations
- D. Assessment / evaluation processes
- E. Treatment planning processes
- F. Therapeutic modalities utilized

The plan for the provision of psychiatric care and services is a component of the facility-wide written plan.

times including evenings and weekends?

- 13. If a large number of patients are assigned to the same therapeutic activity, do patients have individualized goals within their treatment plans?
- 14. Why have therapeutic activities staff been deployed in the manner they have?

DOCUMENT REVIEW

Verify that the plan for the provision of services effectively outlines the areas listed. Verify that the plan addresses the ages of patients and the conditions accepted for service.

- 1 = Compliant
- 2 = Not Compliant

Comment:

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G. Provisions for children, adolescents, young adults, adults, geriatric, and mentally / developmentally disabled patients

H. Staffing, including the roles, responsibilities and supervisory relationships of professional staff as part of the treatment team

I. The quality assessment performance improvement processes

27.03.01 Not Applicable.

27.03.02 Not Applicable.

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<p>27.03.03 Patient Bedrooms: Safety & Security. Patient bedrooms have closable doors; door locks and other structural restraints are kept to a minimum.</p> <p>Doors are constructed to prevent barricading and allow staff to enter patient rooms, baths, toilet, and shower rooms. Mirrors are as distortion free as possible.</p>	<p>Privacy for sleeping and personal activities is afforded to the extent possible while maintaining access by staff to protect patients who may accidentally or intentionally be involved in harmful behaviors.</p>	<p align="center"><u>OBSERVATION</u></p> <ol style="list-style-type: none"> 1. Observe doors in the unit to determine staff access. 2. Doors for rooms where patients at high risk for self-harm are housed may be specially fitted (piano hinge or other devices) to reduce risk of suicidal hanging gestures. 3. Are barricading possibilities considered and mechanisms to reduce or deal with such behavior in place? 4. Are mirrors shatter resistant? 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>Comment:</p>
<p>27.03.04 Sleeping Accommodations. Sleeping areas meet the program goals and the (age, developmental and clinical) needs of the patients.</p> <ul style="list-style-type: none"> • Multi-person bedrooms are restricted to same sex patients and do not exceed State requirements for maximum number of patients per room. 	<p>Bedrooms Programs often utilize "dormitory" style beds. Provisions for "Gatch" facility beds exist for those patients who may require elevations of the upper or lower body such as for hiatal hernia, etc., and for the attachment of side rails. Some beds may be specially equipped for restraint application. All mattresses and pillows meet facility requirements for fluid barrier resistance and fire resistance.</p> <p>Personal Property Lockers may be provided; access to property is not unreasonably restricted. Closets are provided to hang garments; breakaway devices may be utilized in closets. Patient personal property which does not represent a unit safety or fire hazard may be kept by the patient for use or display in his / her bedroom.</p>	<p align="center"><u>INTERVIEW AND OBSERVATION</u></p> <p>Interview program staff to determine the variations in needs of patients who are typically served.</p> <ol style="list-style-type: none"> 1. Are some clinical needs not met due to non-availability of equipment / furnishings? 2. When "Gatch" beds are utilized are they non-electric or has the lock out mechanism been placed to prevent accidental injury? 3. Do coverings for mattresses and pillows adequately provide fluid barrier and fire protection? 4. Are safe provisions made for hanging of garments? 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>Comment:</p>

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Privacy and Security

Privacy for sleeping and personal activities is afforded to the extent possible while maintaining access by staff to protect patients who may accidentally or intentionally be involved in harmful behaviors. Provision of a lockable door protects vulnerable patients from unwanted/ harmful contact with other patients.

5. Is there a locker for each available bed?
6. Are potentially hazardous belongings secured?
7. Do sleeping areas reflect "personalization" by patients?
8. Observe doors in the unit to determine staff accesses.

27.04.01 Performance Improvement.
The unit based performance improvement measures include the Core Measures for inpatient psychiatric units (HBIPS).

See the IPFQR Program requirements at <https://www.qualitynet.org>, Inpatient Psychiatric Facilities, for current criteria.

2016 MEASURES

1. Hours of Physical Restraint Use
2. Hours of Seclusion Use
3. Patients Discharged on Multiple Antipsychotic Medications
4. Patients Discharged on Multiple Antipsychotic Medications with Appropriate Justification.
5. Post Discharge Continuing Care Plan Created
6. Past Discharge Continuing Care Plan Transmitted

INTERVIEW, DOCUMENT REVIEW
Review the facility quality data reporting to determine that HBIPS quality measures are being utilized in the quality monitoring system. Identify if improved compliance has been achieved

- 1 = Compliant
 2 = Not Compliant

Comment:

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to Next Level of Care Provider Upon Discharge

- 7. Alcohol Use Screening
- 8. Follow-up After Hospitalization for Mental Illness
- 9. Assessment of Patient Experience of Care
- 10. Use of an Electronic Health Record (HER)
- 11. Measures added for 2017
- 12. Influenza Immunization
- 13. Influenza Vaccination Coverage Among Healthcare Personnel
- 14. Tobacco Use Screening
- 15. Tobacco Use Treatment Provided or Offered and the subset, Tobacco Use Treatment (during the hospital stay)

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Note: A Substance Abuse treatment program is an optional service.

If Substance Abuse treatment services are not provided at this facility, Chapter 28 is not included with the accreditation survey.

Many services and treatments formerly provided at the inpatient level are now more appropriate in an outpatient setting. Clinical assessments are the basis for making objective decisions relative to patient placement.

A method/clinical guide is needed to match individuals to the most appropriate treatment based on the needs of the client and severity of illness. One such guide is the 2001 *“ASAM Patient Placement Criteria for the Treatment of Substance-Related Disorders – Second Edition, Revised.”* The American Society of Addiction Medicine (ASAM) identifies five (5) levels of care that provide the continuum of addiction services:

Level of Care	Services Provided
Level 0.5	Early Intervention
Level I	Outpatient Services
Level II	Intensive Outpatient or Partial Hospitalization
Level III	Residential or Inpatient Services
Level IV	Medically Managed Intensive Inpatient Services

According to the 2001 ASAM PPC-2R, Opioid Maintenance Therapy (OMT), a service that goes beyond methadone maintenance, can be provided at any level of care; however, OMT is most often

Healthcare facilities that provide either an inpatient or outpatient Substance Abuse program must demonstrate compliance with:

1. All HFAP standards for acute care hospitals,
2. All CMS hospital conditions of participation (CoPs),
3. The Confidentiality of Alcohol and Drug Abuse Patient Records Regulations (42 CFR Part 2), (2002)
4. HIPAA Privacy Rules, and
5. All CMS psychiatric hospital conditions of participation (CoPs) that are applicable to Substance Abuse programs.

NA = Substance Abuse treatment services are not provided at this facility; Chapter 28 is not applicable.

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provided in an outpatient setting.

28.00.01 Organization Chart.

The organizational chart of the facility reflects the reporting relationships of the Substance Abuse program.

The Substance Abuse program is included on the facility organizational chart; generally, this program falls within the Department of Psychiatric Services.

DOCUMENT REVIEW

Review the organizational chart for the facility. Determine that the reporting relationships of the Substance Abuse program are addressed.

- 1 =Compliant
- 2 = Not Compliant

This standard is not met as evidenced by:

28.00.02 Scope & Description of Services.

A written Substance Abuse program description is in place describing the services provided and the methods for referring clients to services not provided.

Substance abuse treatment programs are a comprehensive continuum of services designed to promote recovery and enable the substance abuser to fully integrate into society as a healthy, substance-free individual. These programs assist the client with setting goals, maintaining long-term sobriety, accessing needed social services, transition to the next level of care, avoiding gaps in service, and rapid response to threats of relapse.

DOCUMENT REVIEW

Examine Substance Abuse program policies and procedures. Verify:

- 1 =Compliant
- 2 = Not Compliant

This standard is not met as evidenced by:

The program description includes, but is not limited to:

- A. The scope of services provided and how these programs relate to each other.
- B. Admission criteria, including limitations
- C. Assessment / evaluation processes
- D. Treatment planning processes

Facilities may offer one or more of the five levels of Substance Abuse care as described previously. Substance Abuse programs may be provided in a variety of settings such as inpatient, partial day, residential, or outpatient.

Substance Abuse affects a wide spectrum of populations including all races, genders, sexual orientation, and age groups. While it is not required to treat each population, a process is in place to refer clients, as necessary, for appropriate services.

1. The program description addresses all required elements including:
 - a. Reporting relationships
 - b. Delegation of authority
 - c. Accountability and responsibility
 - d. Policies, procedures, protocols and/or clinical pathways
 - e. The monitoring of each level of care provided is integrated into the facility-wide QAPI program
2. An administrative policy and memorandum of agreement are in place for the transfer of substance abuse clients requiring services not provided at the facility.

CHART REVIEW

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E. Therapeutic modalities utilized		Review medical records.	
F. Provisions for children, adolescents, young adults, adults, geriatric, and mentally / developmentally disabled patients.	<p><u>Special Needs Populations:</u> The Substance Abuse program is sensitive to clients with special needs and has a plan to address these needs. Special needs clients include:</p> <ul style="list-style-type: none"> • Cultural and language differences. (translators are available, as needed) • Gender. • Disability, physical or mental. • Sexual orientation. • Pregnancy. • Infectious diseases. • Life stage. • Those involved with the criminal justice program. 	<p>Verify:</p> <ol style="list-style-type: none"> 1. The client screening process documents an assessment of the special needs of clients. 2. Appropriate admission placements and discharge referrals are made for special needs patients. 	
G. Staffing, including the roles, responsibilities and supervisory relationships of professional staff as part of the treatment team			
H. Quality Assessment Performance Improvement (QAPI) processes are integrated into the facility-wide QAPI program.	<p>An effective substance abuse treatment program offers a variety of services to assist the client with meeting goals and the successful transition into society. Critical elements of a comprehensive program include:</p> <ol style="list-style-type: none"> 1. Screening 2. Assessment 3. Comprehensive, client-oriented treatment plan 4. Therapeutic relapse prevention techniques 5. Case / care management of the client’s progress consistent with the individualized treatment plan <p><u>Special Services</u> Individuals with Substance Abuse issues may require special services. A process is in place to provide the following services. If a special service is not provided</p>		

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onsite, a process is in place for client referrals, most often through a Memorandum of Agreement (MOA).

- Anger Management / Domestic Violence.
- Alcohol Addiction.
- Illicit Drug Addiction.
- Individuals with Infectious Diseases including HIV and AIDS.
- Vocational rehabilitation.

Quality Assessment Performance Improvement (QAPI)

A process is in place to measure the quality of services for each level of care provided (Level I, II, III, or IV). Each level of care provided must be integrated into the facility-wide QAPI program.

28.00.03 The Continuum of Substance Abuse Services.

The Substance Abuse program has an active affiliation with other community programs to ensure clients have access to the full continuum of Substance Abuse treatments.

As treatment may include inpatient and outpatient programs, the Substance Abuse program has a plan for coordinating clients through each of the three phases of treatment. The plan includes the assessment and referral of individuals to the most

Treatments focus upon activities that assist the substance abuse client to recognize the extent of their substance abuse problem, acquire the motivation and tools to remain sober, and to use the tools.

Phases of Substance Abuse Treatment

The Substance Abuse program must provide at least one of the three phases of care. The three (3) phases of Substance Abuse treatment are:

- Motivational Interviewing
- Primary Treatment
- Relapse Prevention

Motivational Interviewing

The initial phase of substance abuse treatment is one

DOCUMENT REVIEW

Review the Substance Abuse treatment program scope of service document.

Verify:

- At least one of the three (3) phases of Substance Abuse treatment is provided by the facility:
 - Motivational Interviewing
 - Primary Treatment
 - Relapse Prevention
- The program has access to each phase of treatment not provided.
- The program has a plan for coordinating

- 1 =Compliant
 2 = Not Compliant

This standard is not met as evidenced by:

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<p>appropriate level of care based upon need and severity of illness.</p>	<p>in which case-finding activities take place. These activities may include formal relationships with potential referral sources, as well as with management care organizations. This phase of care usually occurs with ASAM Level 0.5.</p> <p><u>Primary Treatment</u> With this phase of treatment the client begins to examine the impact that substance abuse has played in various areas of his/her life.</p> <p>An extensive “biopsychosocial” assessment is collected during this phase to determine the most appropriate treatment modality and level of care. Upon completion of this phase of the program, supervision and treatment activities should be coordinated to promote gradual movement to independences. Primary treatment encompasses patient placements of ASAM Levels I, II, III, and IV.</p> <p><u>Relapse Prevention</u> Relapse prevention is incorporated into all phases of Primary Treatment that is ASAM Levels I, II, III, and IV. The client has a self-directed plan for relapse prevention and has minimal interaction with a counselor to monitor activities to prevent relapse. Relapse prevention activities may include self-help activities, group sessions, and faith-based groups.</p>	<p>clients through:</p> <ol style="list-style-type: none"> a. Motivational Interviewing b. Primary Treatment c. Relapse Prevention 	

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<p>28.00.04 <u>Criteria for Client Placement.</u> The medical staff has approved a set of patient placement criteria which determines the most appropriate level of treatment for Substance Abuse clients.</p>	<p>The facility should adopt nationally accepted patient placement criteria, such as those prepared by the American Society for Addiction Medicine (ASAM).</p> <p>These criteria are used consistently to determine the care needs of clients and to ensure placement into the most appropriate level of care, e.g., Level I, II, III, or IV.</p>	<p style="text-align: center;"><u>DOCUMENT REVIEW AND CHART REVIEW</u></p> <p>Review the policies and procedures for the Substance Abuse program.</p> <ul style="list-style-type: none"> • Verify the Medical Staff have approved nationally accepted patient placement criteria. <p>Review the medical records of Substance Abuse program clients.</p> <ul style="list-style-type: none"> • Verify the medical staff approved criteria are consistently used to place patients into the most appropriate level of care. 	<p style="text-align: right;"> <input type="checkbox"/> 1 =Compliant <input type="checkbox"/> 2 = Not Compliant </p> <p style="text-align: right;">This standard is not met as evidenced by:</p>
<p>28.00.05 <u>Patient Placement Criteria for Level 0.5 – Early Intervention.</u> Early intervention services are either provided by the facility or available in the community for individuals at risk for developing substance-related problems.</p>	<p>Early intervention services are generally provided in the ambulatory setting. This phase of treatment uses motivational interviewing techniques to focus on prevention and early intervention.</p> <p>A Level 0.5 service, for example, could be a DUI or DWI program. For some clients, completion of the program may be required by the legal system to have driving privileges re-instated.</p> <p>Qualified personnel of sufficient numbers provide Level 0.5 services.</p> <p>The Level 0.5 Substance Abuse program has protocols in place that describe:</p> <ol style="list-style-type: none"> 1. Where in the community this level of service is provided. 	<p style="text-align: center;"><u>DOCUMENT REVIEW</u></p> <p>Review policies relative to Level 0.5 Early Intervention services.</p> <p>Verify:</p> <ol style="list-style-type: none"> 1. This level of service is either provided by the facility or available in the community. 2. The role and responsibilities of the Substance Abuse program are described relative to this level of care. 3. Patient assessments are in place to determine imminent danger and the need for transfer / referral to an appropriate level of care. 4. Level 0.5 services are provided by qualified Substance Abuse professionals. 	<p style="text-align: right;"> <input type="checkbox"/> 1 =Compliant <input type="checkbox"/> 2 = Not Compliant </p> <p style="text-align: right;">This standard is not met as evidenced by:</p>

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2. Role and responsibilities of the facility with regard to patient assessment, referrals, and transfers.
3. Use of Medical Staff approved patient placement criteria.
4. Assessment of clients to determine:
 - a. Imminent danger;
 - b. Need for transfer to an appropriate level of care;
 - c. Appropriate referrals.
5. Development and implementation of an individualized treatment plan.

28.00.06 Patient Placement Criteria for Level I – Outpatient Treatment.

Level I services are either provided by the facility or available in the community.

Level I Outpatient Treatment services may be delivered in a variety of settings.

Services provided in Level I Outpatient Treatment assist the individual with achieving permanent changes in his/her substance abuse behavior and mental functioning. These services must address the major lifestyle, attitudinal, and behavioral issues that undermine treatment goals and impact coping abilities.

Regardless of the setting, qualified addiction or mental health treatment personnel provide professionally directed evaluation, treatment, and recovery services. These services may include regularly scheduled sessions.

DOCUMENT REVIEW

Review policies relative to Level I Outpatient Treatment services.

Verify:

1. This level of service is either provided by the facility or available in the community.
2. The role and responsibilities of the Substance Abuse program are described relative to this level of care.
3. Policies/protocols, approved by the Medical Staff, describe the evaluation, treatment, and recovery services provided.
4. Level I services are provided by qualified

- 1 =Compliant
 2 = Not Compliant

This standard is not met as evidenced by:

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Substance Abuse professionals.

The services provided follow a defined set of policies / protocols approved by the Medical Staff. The program has protocols in place that describe:

1. Where in the community other levels of Substance Abuse services are provided
2. Role and responsibilities of the facility with regard to patient assessment, referrals, and transfers
3. Use of Medical Staff approved patient placement criteria
4. Development and implementation of an individualized treatment plan

28.00.07 Patient Placement Criteria for Level II – Intensive Outpatient Treatment / Partial Hospitalization.

Level II services are either provided by the facility or available in the community. These services provide essential education and treatment while patients apply these skills within “real world” environments.

Level II Intensive Outpatient Treatment/Partial Hospitalization services provide treatment before or after work / school during the day, evening, or weekends.

Level II Substance Abuse treatment services may provide comprehensive biopsychosocial assessments.

Level II services are affiliated with other levels of care. Qualified personnel assist clients with accessing community resources such as childcare, transportation, and vocational training.

The program has protocols in place that describe:

1. Where in the community other levels of

DOCUMENT REVIEW

Review policies / protocols relative to Level II Intensive Outpatient / Partial Hospitalization services.

Verify:

1. This level of service is either provided by the facility or available in the community.
2. The role and responsibilities of the Substance Abuse program are described relative to this level of care.
3. Policies / protocols, approved by the Medical Staff, describe the evaluation, treatment, and recovery services provided.

- 1 =Compliant
- 2 = Not Compliant

This standard is not met as evidenced by:

SUBSTANCE ABUSE SERVICES

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
	<p>Substance Abuse services are provided</p> <ol style="list-style-type: none"> 2. Role and responsibilities of the facility with regard to patient assessment, referrals, and transfers 3. Use of Medical Staff approved patient placement criteria 4. Development and implementation of an individualized treatment plan <p>Memorandum of Agreement: When the facility does not provide this level of care, an agreement, such as a Memorandum of Agreement, is in place with a program in the community. Through the agreement, the community program agrees to comply with all applicable standards listed HFAP Chapter 28 - Substance Abuse Services.</p>	<ol style="list-style-type: none"> 4. Level II services are provided by qualified Substance Abuse professionals. 5. Memorandum of Agreement: When this level of care is not provided by the facility, review the Memorandum of Agreement. Verify, the agency agrees to comply with applicable HFAP Substance Abuse standards. 	
<p>28.00.08 Patient Placement Criteria for Level III – Residential / Inpatient Treatment. Level III services are either provided by the facility or available in the community for those individuals who need a safe and stable living environment while developing recovery skills.</p>	<p>Level III Residential / Inpatient Treatment services provide a planned regimen of care in a 24-hour live-in setting in which the client can safely reside. These living environments may be in the same treatment facility or in a separate facility affiliated with the treatment center. These are staffed 24-hours a day.</p> <p>Level III Substance Abuse services are staffed by qualified addiction treatment and mental health personnel who provide a planned regimen of care.</p>	<p style="text-align: center;">DOCUMENT REVIEW</p> <p>Review policies relative to Level III Residential / Inpatient Treatment services. Verify:</p> <ol style="list-style-type: none"> 1. This level of service is either provided by the facility or available in the community. 2. The role and responsibilities of the Substance Abuse program are described relative to this level of care. 	<p><input type="checkbox"/> 1 =Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

SUBSTANCE ABUSE SERVICES

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
	<p>Services are provided according to a defined set of policies approved by the Medical Staff. Mutual and self-help group meetings may be provided onsite.</p> <p>Following assessment using the Medical Staff approved criteria for patient placement, the Substance Abuse client has an individualized treatment plan developed and appropriate treatment initiated. The program has protocols in place that describe:</p> <ol style="list-style-type: none"> 1. Where in the community other levels of Substance Abuse services are provided. 2. Role and responsibilities of the facility with regard to patient assessment, referrals, and transfers. 3. Use of Medical Staff approved patient placement criteria. 4. Development and implementation of an individualized treatment plan. <p><u>Memorandum of Agreement:</u> When the facility does not provide this level of care, an agreement, such as a Memorandum of Agreement, is in place with a program in the community. Through the agreement, the community program agrees to comply with all applicable standards listed HFAP Chapter 28 - Substance Abuse Services.</p>	<ol style="list-style-type: none"> 3. Patient assessments are in place to determine imminent danger and the need for transfer to an appropriate level of care. 4. Level III services are provided by qualified Substance Abuse professionals. 5. <u>Memorandum of Agreement:</u> When this level of care is not provided by the facility, review the Memorandum of Agreement. Verify, the agency agrees to comply with applicable HFAP Substance Abuse standards. 	

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STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>28.00.09 Patient Placement Criteria for Level IV – Medically Managed Intensive Inpatient Treatment.</p> <p>Level IV services are either provided by the facility or available in the community for those individuals requiring 24-hour acute inpatient care.</p>	<p>Level IV programs provide a planned regimen of 24-hour medically directed evaluation, care, and treatment of substance abuse and mental health disorders in the acute care inpatient setting. Level IV clients have mental and substance-related problems that are so severe that they require primary biomedical, psychiatric, and nursing care.</p> <p>Level IV Substance Abuse programs are staffed by qualified clinicians including addiction-credentialed physicians, psychiatrists, mental health and other addiction-credentialed professionals.</p> <p>Services are provided in a permanent facility that has inpatient beds and the full array of services of a general acute care hospital or psychiatric hospital.</p> <p>Treatment, specific to mental health and substance-related disorders, is available 24-hours a day.</p> <p>An interdisciplinary team and other support services allow for the conjoint treatment of any co-occurring biomedical condition.</p> <p>Services are provided according to a defined set of policies approved by the Medical Staff. The program has protocols in place that describe:</p> <ol style="list-style-type: none"> 1. Where in the community other levels of Substance Abuse services are provided 2. Role and responsibilities of the facility with regard to patient 3. Assessment, referrals, and transfers 	<p style="text-align: center;"><u>DOCUMENT REVIEW</u></p> <p>Review policies relative to Level IV Medically Managed Intensive Inpatient Treatment services. Verify:</p> <ol style="list-style-type: none"> 1. This level of service is either provided by the facility or available in the community. 2. The role and responsibilities of the Substance Abuse program are described relative to this level of care. 3. Patient assessments are in place to determine imminent danger and the need for transfer to an appropriate level of care. 4. Level IV services are provided by qualified Substance Abuse professionals. 5. <u>Memorandum of Agreement:</u> When this level of care is not provided by the facility, review the Memorandum of Agreement. Verify, the agency agrees to comply with applicable HFAP Substance Abuse standards. 	<p><input type="checkbox"/> 1 =Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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- 4. Use of Medical Staff approved patient placement criteria
- 5. Development and implementation of an individualized treatment plan

Memorandum of Agreement:

When the facility does not provide this level of care, an agreement, such as a Memorandum of Agreement, is in place with a program in the community. Through the agreement, the community program agrees to comply with all applicable standards listed HFAP Chapter 28 - Substance Abuse Services.

28.00.10 Opioid Maintenance Therapy.

Opioid Maintenance Therapy (OMT) services are either provided by the facility or available in the community for those individuals requiring this level of care.

Opioid Maintenance Therapy (OMT) is a treatment program that may be indicated for individuals addicted to heroin, cocaine, methadone, and other opioids.

Detoxification services may be appropriately provided at a Level I, II, III, or IV program. Inpatient services are usually not indicated for opioid detoxification unless medically necessary for coexisting comorbidities.

Both inpatient and outpatient detoxification and maintenance services are provided in accordance with Medical Staff approved protocols.

Clients are assessed, using medical staff approved criteria, to determine appropriate patient placement. These patient placement criteria should be based on current, nationally accepted guidelines, such as those

DOCUMENT REVIEW

Review policies / protocols / practices relative to Opioid Maintenance Therapy (OMT) services.
Verify:

- 1. This level of service is either provided by the facility or available in the community.
- 2. The role and responsibilities of the Substance Abuse program are described relative to this level of care.
- 3. Patient assessments are in place to determine imminent danger and the need for transfer to an appropriate level of care.
- 4. **For Methadone clinics and Office Based Opioid Maintenance Therapy (OBOT):** The facility must have a current:

- 1 =Compliant
- 2 = Not Compliant

This standard is not met as evidenced by:

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	<p>published by ASAM.</p> <p><u>Methodone Detoxification:</u></p> <ol style="list-style-type: none"> 1. Detoxification and maintenance treatment may be appropriately provided at a methadone clinic. Clients should be informed that methadone detoxification may also be provided through “office based opioid maintenance therapy” (OBOT). 2. Methadone clinics and OMT offices must have in place a current: <ol style="list-style-type: none"> a. Federal license and registration. b. DEA suffix for dispensing drugs. 3. Practitioners working in the methadone detoxification clinic/OBOT are not required to be credentialed in methadone treatment. Nor are these clinicians required to have a separate DEA. <p>The OMT program has policies / protocols in place that describe:</p> <ol style="list-style-type: none"> 1. The referral process to other levels of Substance Abuse services in the community. 2. Location and telephone number of other Substance Abuse services in the community. 3. The role and responsibilities of the facility with regard to patient assessment, referrals, and transfers. 	<ol style="list-style-type: none"> a. Federal license and registration. b. DEA suffix for dispensing drugs. <p>5. <u>Memorandum of Agreement:</u> When this level of care is not provided by the facility, review the Memorandum of Agreement. Verify, the agency agrees to comply with applicable HFAP Substance Abuse standards.</p>	

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4. The use of medical staff approved patient placement criteria.
5. The development and implementation of individualized treatment plans.

Memorandum of Agreement:

When the facility does not provide this level of care, an agreement, such as a Memorandum of Agreement, is in place with a program in the community. Through the agreement, the community program agrees to comply with all applicable standards listed HFAP Chapter 28 - Substance Abuse Services.

28.00.11 Treatment Modalities.

The facility provides a variety of treatment modalities for the Substance Abuse client.

Substance abuse and addictive disorders have origins that are psychological, biological, and social. An array of treatment modalities should be available to serve the individual client with achieving individual goals.

The treatment modalities, in varying levels of intensity, assist the client to:

1. Develop insight regarding the factors related to the onset of the substance abuse disorder;
2. Promote responsibility for changing behaviors relating to the abuse of drugs and alcohol;
3. Promote awareness of the recovery process;
4. Provide exposure to the supportive, motivating influences of other recovering individuals; and

DOCUMENT REVIEW

Review policies relative to treatments provided. Verify:

1. A variety of group activities are scheduled to assist the client with meeting individual goals as identified by the psychosocial assessment. These activities are available throughout the day to meet the needs of the client.
2. A list of self-help groups is available to the client.

- 1 =Compliant
 2 = Not Compliant

This standard is not met as evidenced by:

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5. Foster motivation for treatment.

28.00.12 Treatment of Co-Occurring Substance Abuse & Mental Health Disorders.

Resources are available for the evaluation and treatment of substance abuse clients with co-occurring substance abuse and mental health disorders.

Substance Abuse Treatment Programs should anticipate the admission of clients with co-occurring substance abuse and mental health disorders.

DOCUMENT REVIEW

Review policies / protocols / practices relative to treatments provided.

Verify:

1. Resources are available for the evaluation and treatment of substance abuse clients with co-occurring disorders including:
 - Mood disorders
 - Anxiety
 - Thought disorders

- 1 =Compliant
 2 = Not Compliant

This standard is not met as evidenced by:

28.00.13 Treatment Protocols – Alcohol Withdrawal.

The facility has adopted protocols to assist the alcohol dependent client through a safe and effective withdrawal from alcohol.

For the alcohol dependent client, alcohol withdrawal can be life threatening. The abrupt cessation of alcohol exposure results in brain hyperexcitability, which manifests clinically as anxiety, irritability, agitation, and tremors. Severe manifestations include alcohol withdrawal seizures and delirium tremens. Delirium tremens have a mortality rate of 1 to 5 percent.

Medical staff approved protocols are in place to provide safe and effective alcohol withdrawal. Practitioners adhere to the established protocols of the facility. Practitioners, e.g. nurses and counselors, providing alcohol withdrawal care are trained on these facility protocols.

DOCUMENT REVIEW AND CHART REVIEW

Review facility protocols. Review the medical records of clients receiving alcohol withdrawal treatments.

Verify:

1. Protocols are in place to ensure the safe and effective withdrawal from alcohol.
2. The alcohol withdrawal protocol is consistently implemented.
3. Clients are not routinely admitted to the ICU for alcohol withdrawal.
4. Clients are managed without the adverse event of seizures or delirium tremens.

- 1 =Compliant
 2 = Not Compliant

This standard is not met as evidenced by:

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Minimally, protocols address:

1. **Treatment Setting:** Alcohol withdrawal treatment may be performed in either the inpatient or outpatient setting. Admission criteria based on the needs of the client is outlined. Management of alcohol withdrawal typically does not require an Intensive Care Unit admission unless there are other medical conditions requiring this resource.

2. **Medication Therapy:** Typically, treatment includes the use of benzodiazepines, thiamine, multivitamins, folic acid, anticonvulsants, and fluids. Use of benzodiazepines in the outpatient setting requires special precautions due to potential use with alcohol resulting in patient safety issues such as injuries, coma, or apnea. More effective medication therapies have received FDA approval for detoxification, e.g., Naltrexone and Campral.

3. **Patient Monitoring:** Patients are assessed and monitored per internal or external developed protocols. Monitoring during alcohol withdrawal minimally includes frequent heart rate, respiratory rate, blood pressure, and temperature checks. A low-grade fever during withdrawal, for example, can be significant for pending delirium tremens. One example of a patient assessment tool is the “Clinical Institute Withdrawal Assessment for Alcohol (CIWA-Ar) scale.”

5. Adverse events such as seizures or delirium tremens are investigated and patient care protocols reviewed.

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	<ol style="list-style-type: none"> 4. Identification and treatment of: <ol style="list-style-type: none"> a. Minor withdrawal symptoms. b. Alcoholic hallucinations. c. Alcohol withdrawal delirium (delirium tremens). 1. Due to the availability of newer FDA approved medications, clients should experience alcohol withdrawal without seizures or delirium tremens. 2. Delirium tremens and seizures that occur during alcohol withdrawal should be considered an adverse event, investigated, and reported as such according to facility policy. During the investigation, determine the use of medical staff approved protocols; revise protocols, as necessary. 		
<p>28.00.14 Treatment Protocols – Use of FDA Approved Medications in Treatment of Alcohol Abuse Disorders.</p> <p>For optimal results, facilities using any FDA approved medication for treatment of alcohol dependency, have written protocols in place to provide direction in client care. These protocols should minimally address:</p> <ol style="list-style-type: none"> 1. Eligibility criteria 	<p>Practitioners adhere to medical staff approved protocols when FDA approved medications are used in the treatment of alcohol abuse.</p> <p>The Food and Drug Administration (FDA) has approved medications for treatment of alcohol abuse disorders including the following:</p> <ol style="list-style-type: none"> 1. Antabuse™ (Disulfiram), an aversive medication, does not reduce cravings or normalize brain functioning. 2. ReVia® (Naltrexone), an opioid antagonist, blocks 	<p><u>DOCUMENT REVIEW AND CHART REVIEW</u></p> <p>Review facility policies / protocols.</p> <ul style="list-style-type: none"> • Verify when these FDA approved medications are used in the treatment of alcohol abuse, medical staff approved treatment protocols are in place. <p>Review medical records of clients receiving this treatment.</p> <ul style="list-style-type: none"> • Verify the client treatment is provided consistent with the medical staff approved protocols. 	<p><input type="checkbox"/> 1 =Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

SUBSTANCE ABUSE SERVICES

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2. Contraindications	opioid receptors to reduce alcohol cravings. It is not a cure for alcohol dependency. While Naltrexone may not be effective for everyone with alcohol abuse disorder, when used as an adjunct to psychosocial therapy it can greatly improve outcomes for some individuals.		
3. Medical work-up and testing for medical appropriateness, e.g., liver and kidney function tests.	Naltrexone is contraindicated for individuals with impaired liver function. Vivitrol™, a once-monthly, intramuscular (IM) form of Naltrexone, received FDA approval for the treatment of alcohol abuse in April 2006.		
4. Dosing, administration, and tolerance			
5. Monitoring			
6. Adverse drug reactions			
7. Patient education including, but not limited to: <ul style="list-style-type: none"> a. Medication compliance b. Benefits and limits of medication c. Side effects 	3. Acamprosate (calcium acetylhomotaurinate) and delayed release tablets Campral® (acamprosate calcium) have received FDA approval for the postwithdrawal maintenance of alcohol abstinence. Acamprosate, to be considered as one component of a comprehensive management program, should not be prescribed for individuals with severe renal impairment.		
8. Concurrent counseling treatments and/or group therapy			
9. Successful termination of medication therapy.			

SUBSTANCE ABUSE SERVICES

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<p>28.00.15 Treatment Protocols – Use of FDA Approved Medications in Treatment of Opiate Addiction.</p> <p>For optimal results, facilities using Buprenorphine or other FDA approved medications for treating addiction, have written protocols in place that provide guidelines for client care.</p> <p>These protocols should minimally address:</p> <ol style="list-style-type: none"> 1. Each of the three phases of buprenorphine and buprenorphine – naloxone therapy. 2. Eligibility criteria 3. Medical work-up and testing 4. Dosing, administration, and tolerance 5. Safe packaging and storage 6. Monitoring 7. Adverse drug reactions 8. Patient education 	<p>Practitioners adhere to the established protocols of the facility.</p> <p>Nearly 1 million Americans are dependent on opiates; yet only 200,000 receive treatment in a licensed methadone clinic. In October 2002, the Food and Drug Administration (FDA) approved the use of Subutex® (buprenorphine hydrochloride) as a treatment for treatment of opiate addiction. Buprenorphine reduces or eliminates the withdrawal symptoms that are associated with opioid dependence.</p> <p>Subutex® (buprenorphine hydrochloride) and Suboxone® (the combination of buprenorphine with naloxone) are the first medications approved under the Drug Abuse Treatment Act of 2000 (DATA) that allows office-based treatment of opiate addiction. Buprenorphine is classified as the less restrictive, Schedule III Controlled Substance. This will permit physicians to treat individuals that are dependent on heroin or prescription painkillers such as OxyContin in their offices rather than the daily visits to a methadone clinic. Patients entering or continuing treatment in clinic settings are eligible to receive the new medications.</p> <p>Subutex® (Buprenorphine) is prescribed for early stages of treatment. Suboxone® (buprenorphine with naloxone) is prescribed for long-term maintenance therapy and will allow patients to resume and maintain more normal and productive lives.</p>	<p><u>DOCUMENT REVIEW AND CHART REVIEW</u></p> <ol style="list-style-type: none"> 1. Review facility policies. <ul style="list-style-type: none"> • Verify if Buprenorphine or other FDA approved medications are used in the treatment of opiate addiction, medical staff approved treatment protocols relating to these medications are in place. 2. Review medical records of clients receiving opiate addiction treatment. <ul style="list-style-type: none"> • Verify the client treatment is provided consistent with the medical staff approved opioid addiction protocols. 	<p><input type="checkbox"/> 1 =Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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9. Successful termination of medication therapy

The three phases of the buprenorphine maintenance treatment are addressed by facility protocol:

1. **The Induction Phase:**
In this phase, buprenorphine is administered when the opioid depending individual has abstained from opioids for 12-24 hours and is in early stages of opioid withdrawal. Induction is typically started in the physician’s office as an observed therapy. It should be noted that if the individual is not in the early stages of withdrawal, the buprenorphine could precipitate acute withdrawal if he/she has opioids in the bloodstream.
2. **The Stabilization Phase:**
In this phase, the individual has discontinued or reduced their drug abuse and no longer has cravings.
3. **The Maintenance Phase:**
In this phase the individual is doing well with a steady dose of the buprenorphine.

28.00.16 Medical Staff Qualifications for Administration of Buprenorphine. Buprenorphine is prescribed only by qualified physicians.

Under the terms of Drug Abuse Treatment Act of 2000 (DATA), physicians providing Buprenorphine treatment MUST:

1. Receive a special DEA waiver registration for use of this drug.
2. Complete special training to dispense these

FILE REVIEW

Review the files of physicians that provide Buprenorphine to treat opiate addiction.

Verify:

1. These physicians have been credentialed and privileged to provide this treatment.

- 1 = Compliant
- 2 = Not Compliant

This standard is not met as evidenced by:

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	<p>medications.</p> <p>3. Agree to treat no more than 100 patients at one time in an office setting.</p> <p>4. Agree to provide 24-hour coverage including coverage during times of absence.</p> <p>5. Refer patients to appropriate counseling and support services to enhance pharmacological treatment.</p>	<p>2. These physicians meet the Drug Abuse Treatment Act of 2000 (DATA) requirements for providing these treatments including special training, 24-hour coverage, and a limit of 100 patient receiving Buprenorphine.</p>	
<p>28.00.17 Informed Consent. The risk involved with drug use and substance abuse treatments shall be thoroughly explained to the patient.</p> <p>Written consent shall be obtained from the patient prior to the use of hazardous drugs and procedures.</p>	<p>Clients must provide consent prior to receiving substance abuse withdrawal therapy as withdrawal has the potential for dangerous side effects. The drug Antibuse, for example, is associated with seizure activity and Lorazepam may cause delirium.</p> <p>Providing informed consent should be viewed as an interactive process between healthcare providers and patients.</p> <p>Practitioners shall show evidence that risks of continued substance use, benefits of withdrawal, potential complications of withdrawal, benefits, and alternatives of all detoxification treatments have been discussed with the patient prior to initiation of the treatment.</p> <p>As part of therapy, client are instructed:</p> <p>a. To avoid use of substances and</p>	<p style="text-align: center;">CHART REVIEW</p> <p>Review patient records. Verify:</p> <p>1. The client has provided informed consent prior to procedures / administration of hazardous drugs.</p> <p>2. The risks of drug use and therapy have been explained to the patient or the patient’s family prior to consent.</p>	<p><input type="checkbox"/> 1 =Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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b. To avoid anesthesia to prevent relapse

When the patient lacks decision -making capacity, the family or designated decision - maker provides informed consent, prior to the use of hazardous drugs and procedures.

28.00.18 Activities Programs.

Programs are planned and provided to meet the needs of the clients. These social, educational, and recreational activities are scheduled during daytime, evening, and weekends consistent with the level of care provided.

Activity programs provided will vary depending upon the service setting, e.g., Level I, II, III, or IV, and hours of operation.

While socialization, education, and recreational activities should be available in Level IV settings, these activities may not be appropriate in the outpatient setting.

DOCUMENT REVIEW

Verify:

1. Availability of planned programs on days, evenings and weekends.
2. Programs that meet the needs of the Substance Abuse client are scheduled. Social, educational, recreational activities, as appropriate to the level of care provided, are available during daytime, evenings, and weekends.

- 1 =Compliant
 2 = Not Compliant

This standard is not met as evidenced by:

28.00.19 Referral & Access to Special Services.

Substance Abuse clients shall have access to special services when medically indicated.

The Substance Abuse program shall have written protocols that identify criteria and processes relative to client referral and/or transfer.

There is an Administrative Policy that defines:

1. The special services and medical conditions that necessitate transfer to a higher level of care and
2. The arrangements for transferring clients to the next level of care.

There is a memorandum of agreement (MOA) in place for emergency medical services and transport per the local Emergency Medical System (EMS).

Situations that require patient transfer may include:

DOCUMENT REVIEW AND CHART REVIEW

Examine Substance Abuse program policies and procedures.

- Verify that an administrative policy and memorandum of agreement are in place for the transfer of substance abuse clients requiring special services and a higher level of care.

- 1 =Compliant
 2 = Not Compliant

This standard is not met as evidenced by:

Examine the medical records of clients that have

SUBSTANCE ABUSE SERVICES

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	<ol style="list-style-type: none"> 1. Those examinations, assessments and consultations that are not within the professional domain or expertise of the staff. 2. Special treatment services 3. Other resources that may contribute to the patient's well-being. 	<p>been referred or transferred to another facility for special services.</p> <p>Verify:</p> <ol style="list-style-type: none"> 1. Appropriateness of referrals 2. Compliance with the administrative policy with regards to initiation of referral/transfer. 	
<p>28.00.20 <u>Family Psychosocial Assessment.</u> A family psychosocial assessment shall be part of the process leading to the development of the individual treatment plan.</p>	Self-explanatory.	<p style="text-align: center;"><u>CHART REVIEW</u></p> <p>Review medical records.</p> <p>Verify:</p> <ul style="list-style-type: none"> • A family psychosocial assessment is a part of the individual treatment plan of the inpatient and/or outpatient. 	<p><input type="checkbox"/> 1 =Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>
<p>28.00.21 <u>Personal Belongings.</u> Provision shall be made to secure and protect the personal property of clients.</p>	Self-explanatory.	<p style="text-align: center;"><u>OBSERVATION</u></p> <p>Verify personal property is secured and protected.</p>	<p><input type="checkbox"/> 1 =Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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<p>28.00.22 Policies & Procedures. The Substance Abuse program shall have a policy manual describing the regulations, policies, and guidelines for patient care. The policies will be reviewed minimally every three (3) years and revised as necessary.</p>	<p>Self-explanatory.</p>	<p style="text-align: center;"><u>DOCUMENT REVIEW</u></p> <p>Review the departmental policy manual. Verify:</p> <ul style="list-style-type: none"> • Policies have been reviewed within the past three (3) years. 	<p><input type="checkbox"/> 1 =Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>
<p>28.00.23 Common Areas & Space Requirements. Space shall be provided for client therapies, activities, and social interaction, including:</p> <ol style="list-style-type: none"> 1. Client workspace 2. A library or access to library services. 3. Space for public socialization as well as private visits with other patients, family, and friends. 4. Space for physical exercise or access to the outdoors, unless therapeutically contraindicated. 5. Dining room facilities, if appropriate. 	<p>Space provided is consistent with the care provided, e.g., Level I, II, III, and IV, as well as the setting (inpatient or outpatient).</p> <p>Regardless of the setting and level of care, library materials shall be available to the client.</p>	<p style="text-align: center;"><u>OBSERVATION</u></p> <p>Tour the facility. Determine that appropriate space is provided for clients regarding:</p> <ol style="list-style-type: none"> 1. Access to library services. 2. Socialization as well as private visits with other patients, family and friends. 3. Outside physical exercise. 4. Dining room facilities, if appropriate. 	<p><input type="checkbox"/> 1 =Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

SUBSTANCE ABUSE SERVICES

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28.00.24 Work Space & Therapeutic Equipment Requirements.

Adequate work space and equipment to accommodate the needs of the professional staff shall be provided. The following shall be available to the staff:

1. Office space
2. A group meeting or conference room
3. Space to house various therapeutic and activity functions
4. Audiovisual equipment such as television, educational tapes, and projector.

Self-explanatory.

OBSERVATION

Tour the facility.

Verify that the professional staff have available:

1. Office space
2. A group meeting or conference room
3. Space for various therapeutic and activity functions of the program
4. Therapeutic equipment

- 1 =Compliant
 2 = Not Compliant

This standard is not met as evidenced by:

28.00.25 Client Access to Staff.

The substance abuse client has access to the staff.

Staff are available and accessible to their clients at all levels of care, regardless of the setting or level of care provided.

OBSERVATION

Verify:

- Nursing personnel and other therapeutic staff are in view for free interchanges with clients.

- 1 =Compliant
 2 = Not Compliant

This standard is not met as evidenced by:

SUBSTANCE ABUSE SERVICES

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<p>28.00.26 <u>After-Hours Resources.</u> The facility provides the Substance Abuse client and/or family with information regarding availability of twenty-four (24) hour emergency services.</p>	<p>All levels of care must provide instructions for current and perspective clients who seek emergency services. These instructions direct clients to another practitioner or to the nearest emergency department.</p> <p>An outpatient facility should provide this emergency services information in the following manner:</p> <ol style="list-style-type: none"> 1. A descriptive telephone / answering machine message 2. A sign on the clinic / office door 3. As part of the client handbook <p>A Level IV facility may be the recipient of clients requiring transfer for a higher level of care.</p>	<p style="text-align: center;"><u>DOCUMENT REVIEW</u></p> <p>Verify:</p> <ul style="list-style-type: none"> • The facility provides information regarding availability of 24-hour emergency services. 	<p><input type="checkbox"/> 1 =Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>
<p>28.00.27 <u>Patient Rights.</u> Dignity, as well as the human and legal rights of the client shall be maintained. Each substance abuse service shall support and protect basic human, civil, constitutional and statutory rights of patients.</p> <p>In addition to the Patient Rights listed under in standard #15.01.02, specific rights complying with state laws are delineated for psychiatric / substance abuse populations. These include, at least, the right of the patient, or his</p>	<p>Patients receiving substance abuse treatment may be vulnerable to exploitation or coercion. Efforts to provide protection of rights are paramount to effective treatment as well as to demonstrate congruence with equity in access to and the provision of care and services.</p> <p>There is to be evidence that staff actively promote and protect patient rights.</p> <p>Patient's Rights documents are posted. Any additional rights mandated by State or local jurisdictions are included with the document.</p>	<p style="text-align: center;"><u>DOCUMENT REVIEW, OBSERVATION, & INTERVIEW</u></p> <p>Determine that facility policies and practices identify and promote the rights of the substance abuse populations served.</p> <p>Verify that in addition to statements within policy manuals, Patient Rights statements are:</p> <ol style="list-style-type: none"> 1. Prominently posted 2. Provided to each patient in language he/she can understand 3. Utilized in the program quality assessment – 	<p><input type="checkbox"/> 1 =Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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<p>legal surrogate decision maker, to be fully informed of:</p> <p>A. The current and future use and disposition of products of special observation and audiovisual techniques such as one way vision mirrors, tape recorders, closed circuit video or audio monitors, movies, photographs or video recordings.</p> <p>B. The responsibility of the treatment team (facility), when the patient refuses treatments, to seek appropriate legal alternatives or orders of involuntary treatment, or in accordance with professional standards, to terminate the relationship with the patient upon reasonable notice.</p> <p>C. The right to withdraw informed consent at any time.</p> <p>D. The rules and regulations of the facility applicable to his/her conduct.</p> <p>E. The discharge plan designed to meet his/her needs for follow-up care / services.</p>	<p>Policies and procedures relating to patient's rights are reviewed at least annually, approved by the governing body, and provide for:</p> <p>A. Education of staff regarding their role in upholding these rights.</p> <p>B. The posting of patient's rights in conspicuous areas in the hospital.</p> <p>C. Mechanisms to inform each patient of his or her rights in a language the patient readily understands - at a minimum this is via written text.</p> <p>D. Mechanisms to resolve potential, or actual, issues arising in supporting patient's rights.</p> <p>Patient rights identified in 15.01.02 through 15.01.10 also apply and are to be scored there.</p>	<p>improvement monitoring program;</p> <p>4. Congruent with federal, state, and local laws and regulations.</p> <p style="text-align: center;"><u>CHART REVIEW</u></p> <p>Verify:</p> <ul style="list-style-type: none"> • The medical record reflects that the patient rights have been explained to the client; the client has been provided a document with describing patient rights and information about legal rights. 	

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F.	The right to send or receive mail provided there are no violations of federal, state, or local laws (Inpatients ONLY).		
G.	The right to conduct personal telephone conversations unless clinically contraindicated in the individualized treatment plan (INPATIENTS ONLY).		
H.	The right to request, at his/her own expense, the opinion of a consultant (INPATIENTS ONLY).		
I.	The right to request a review of his/her individualized treatment plan.		
J.	The right of access to legal or religious counsel without regard to visiting schedules (INPATIENTS ONLY).		
K.	The right to reasonable time and space for visiting by family or other social supports unless such visits are clinically contraindicated. The age of visitors may be a limiting factor but not absolute if provisions for visiting are possible (INPATIENTS ONLY).		

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- L. The right to request limitations in who may visit or inquire as to his/her status as a patient (INPATIENTS ONLY).
- M. The right to have staff knock / announce themselves appropriately when entering his/her private area.
- N. The right to initiate a complaint or grievance procedure and the appropriate means of requesting a hearing or review of the complaint.

28.00.28 Written Consent.

Consent in writing shall be obtained from the patients or, if they are unable to make this judgment, from family members having the legal right to consent, prior to the use of hazardous drugs and procedures.

Self-explanatory.

CHART REVIEW

Examine records for documentation of consent in writing for use of hazardous drugs or procedures.

- 1 =Compliant
- 2 = Not Compliant

This standard is not met as evidenced by:

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<p>28.00.29 Referral & Access to Special Services. The drug abuse / alcoholism program shall have written referral policies and procedures that delineate the conditions under which referrals are made, including the need for the following:</p> <ul style="list-style-type: none"> A. Examinations, assessments, and consultations that are not within the professional domain or expertise of the staff. B. Special treatment services C. The assistance of other resources that can contribute to the patient's well being. 	<p>Some facilities are not able to provide the level of treatment appropriate for the patient and other resources may need to be accessed. Many states have a range of services offered by the department of health.</p> <p>Examples may include community based agencies that partner with mental health centers, outpatient residential services, specialized programs for children and adolescents, forensic services, and services for the blind and hard of hearing.</p>	<p>CHART REVIEW Examine written referral policies and procedures to determine that appropriateness of referrals is maintained and there is compliance with the referral policy in regards to initiation of referrals.</p>	<p><input type="checkbox"/> 1 =Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>
<p>28.00.30 Required Emergency Services. Twenty-four hour emergency service shall be available to all patient and their families with drug abuse/alcohol problems. This service shall include:</p> <ul style="list-style-type: none"> A. Counseling and evaluations on treatment of patient B. Counseling of family C. Determination of recovery from 	<p>Self-explanatory.</p>	<p>INTERVIEW Verify 24-hour emergency service is available.</p>	<p><input type="checkbox"/> 1 =Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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acute drug and alcohol abuse

- D. Referral of patient to appropriate type of care (inpatient, intermediate or outpatient) for additional evaluation and extended care.
- E. Discharge planning, including a program for the continuing care and support of the patient.

28.00.31 Intermediate Plan of Care.

An intermediate care component shall be provided as a formal organizational plan for the patient's continued treatment and shall include but not be limited to the following:

- A. A plan including job descriptions of all personnel providing this care.
- B. Continued counseling
- C. Vocational rehabilitation
- D. Recreational therapy
- E. Individualized treatment plan for the patient and his/her family
- F. Intermediate care plan should

CHART REVIEW

Verify an intermediate care component for the patient's continued treatment exists.

- 1 =Compliant
- 2 = Not Compliant

This standard is not met as evidenced by:

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provide facilities for outside community services, e.g. Alcoholics Anonymous, AL-ANON, etc.

28.00.32 Outpatient Follow-Up Care.

An outpatient and/or follow-up program component shall be provided as a formal organizational plan for the patient's continued treatment and shall include but not be limited to the following:

- A. A plan including job descriptions of all personnel providing this care.
- B. A description of services the program will provide should be outlined for outpatient treatment.
- C. Providing a relationship with required community services, e.g. Alcoholic Anonymous, AL-ANON, etc.
- D. Updating of the program plan to reflect changing needs. This is suggested quarterly.

CHART REVIEW

Verify there is an outpatient and/or follow-up plan for the patient's continued treatment.

- 1 =Compliant
- 2 = Not Compliant

This standard is not met as evidenced by:

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<p>28.01.01 Medical Staff. The Medical Staff of the Substance Abuse program shall be a recognized department of the facility with responsibilities and participation in Medical Staff activities equivalent to other clinical services as provided in the Medical Staff Bylaws and Rules and Regulations.</p>	<p>The Medical Staff Bylaws / Rules and Regulations recognize inpatient and outpatient substance abuse programs, as applicable.</p> <p>It is understood that care will be provided by a qualified Substance Abuse counselor or a physician qualified by education, experience and/or certification by an appropriately recognized certifying organization, e.g., the American Society of Addiction Medicine, ABMS board, or appropriate AOA certifying board.</p>	<p style="text-align: center;"><u>DOCUMENT REVIEW</u></p> <p>Review the Medical Staff Bylaws and Rules and Regulations. Verify:</p> <ul style="list-style-type: none"> • The Medical Staff Bylaws / Rules and Regulations demonstrate compliance. 	<p><input type="checkbox"/> 1 =Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>
<p>28.01.02 Availability of Medical Personnel. <i>Doctors of medicine and osteopathic medicine and other appropriate professional personnel must be available to provide necessary medical and surgical diagnostic and treatment services. If medical and surgical diagnostic services and treatment are not available within the institution, the institution must have an agreement with an outside source of these services to ensure that they are immediately available or a satisfactory agreement must be established for transferring patients to a general hospital that participates in the Medicare program.</i> §482.62(c)</p>	<p>Patients in the Substance Abuse program shall have general diagnostic and medical / surgical services available. Services may be provided directly, by contractual arrangement, or by referral to another facility.</p> <p>In a specialty facility there shall be provision for basic diagnostics and clinical intervention, including cardio-pulmonary.</p> <p>For services that are not provided onsite, a process is in place for client referrals, most often through a Memorandum of Agreement (MOA).</p> <p>Contracts or other arrangements with individuals and/or providers assure that medical and surgical services are available to meet the needs of the patients.</p> <p>Review the medical and surgical services provided by</p>	<p style="text-align: center;"><u>DOCUMENT REVIEW</u></p> <p>Verify:</p> <ol style="list-style-type: none"> 1. General diagnostic and medical/surgical services are available onsite, through contract, or through memorandum of agreement. 2. How did the hospital meet the medical/surgical/diagnostic needs represented by each patient in the sample? Were these done timely? Appropriately? 3. If contracts are not current or available, how are these services provided for the patient, if needed? Is there evidence of negative outcomes as a result of these arrangements? 4. Are reports from other services such as pharmacy, radiology, and clinical laboratory 	<p><input type="checkbox"/> 1 =Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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the hospital during the interview with the clinical director. Discuss contract or arrangements with the clinical director for services provided off grounds.

timely? Appropriate?

28.01.03 Staff Knowledge of Client Legal Rights & the Criminal Judicial System.

Staff of Substance Abuse programs should be thoroughly familiar with the federal, state, and local legal issues associated with a Substance Abuse treatment program.

Client Legal Rights:

The Substance Abuse treatment program staff have access to current Federal Regulations, as well as state and local laws relative to substance abuse clients.

Staff demonstrate knowledge of:

1. Medicare regulations – Section 42 Code of Federal Regulations, Part 2, “Confidentiality of Alcohol and Drug Abuse Patient Records.”
2. HIPAA requirements relating to client privacy and confidentiality.
3. Confidentiality issues relating to documentation and release of medical records.

Criminal Justice System

Substance Abuse treatment programs should establish a working relationship with the criminal justice system.

The Substance Abuse treatment program staff should be knowledgeable and have access to current Federal Regulations, as well as state and local laws relating to substance abuse treatment programs, especially:

1. Civil protection and restraining orders
2. Reporting child abuse

DOCUMENT REVIEW, FILE REVIEW & OBSERVATION

Verify:

1. Required protocols are in place.
2. Staff have access to the required federal, state, and local laws.

Review training records of the substance abuse personnel.

- Verify the staff have received all required training.

- 1 =Compliant
 2 = Not Compliant

This standard is not met as evidenced by:

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<p>28.01.04 Staffing Qualifications. <i>The hospital must have adequate numbers of qualified professional and supportive staff to evaluate patients, formulate written individualized comprehensive treatment plans, provide active treatment measures and engage in discharge planning.</i> §482.62</p> <p><i>The facility must employ or undertake</i></p>	<p>3. Reporting domestic violence</p> <p>Protocols are in place that guide personnel with the following:</p> <ol style="list-style-type: none"> 1. Response to legal inquiries 2. Response to onsite law enforcement agents 3. Response to subpoenas 4. Response to warrants for arrest 5. Search warrants 6. Clients that are the survivors of violence and/or abuse 7. Clients that are the perpetrators of domestic or other types of violence and abuse. <p>The Substance Abuse program is adequately staffed with qualified substance abuse and mental health professionals and supportive staff to provide appropriate services and meet the needs of the client within the scope of the program.</p> <p>The higher the level of care provided, the higher the qualification required of the staff. That is, staff providing Level IV care are required to have higher qualifications than staff working in a Level I, II, or III setting.</p>	<p>DOCUMENT REVIEW</p> <p>Review staffing records and personnel folders. Verify:</p> <ol style="list-style-type: none"> 1. Ample numbers of staff are assigned consistent with the level of care provided. 2. Staff are qualified to provide this level of care. 	<p><input type="checkbox"/> 1 =Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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to provide adequate numbers of qualified professional, technical and consultative personnel to:

- *Evaluate patients*
- *Formulate written individualized comprehensive treatment plans*
- *Provide active treatment measures*
- *Engage in discharge planning*

§482.62(a)
 §482.62(a)(1)
 §482.62(a)(2)
 §482.62(a)(3)
 §482.62(a)(4)

28.01.05 Competencies of Addiction Counselors & Specialists.

Counselors and addiction-focused disciplines must demonstrate competency in the professional treatment of substance abuse disorders and possess related knowledge, skills, and attitudes.

The facility has identified the required competencies of Addiction Counselors, such as the *“Addiction Counseling Competencies: The Knowledge, Skills, and Attitudes of Professional Practice,”* written by the *National Curriculum Committee of the Addiction Technology Transfer Center Program (ATTC)*. The ATTC recommends these dimensions of competency for counselors and addiction-focused disciplines:

1. Clinical Evaluation (Screening and Assessment)
2. Treatment Planning

DOCUMENT REVIEW

Review the position descriptions for Addiction Counselors and Specialists.

Verify:

- Competencies are defined, preferably based upon national guidelines.

1 =Compliant
 2 = Not Compliant

This standard is not met as evidenced by:

FILE REVIEW

Verify:

- Staff have received required training; competencies are measured.

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- 3. Referrals
 - 4. Service Coordination
 - 5. Counseling
 - 6. Client, Family, and Community Education
 - 7. Documentation
 - 8. Professional and Ethical Responsibilities
- All addiction-focused disciplines demonstrate knowledge in:
- 1. Understanding addiction
 - 2. Treatment models
 - 3. Effects of psychoactive drugs
 - 4. Continuum of care
 - 5. Social contexts of treatment and the recovery process

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28.01.06 Coordination of Social Services.

The facility provides a mechanism, such as a case / care manager to coordinate the support services that will enable the individual to maintain long-term sobriety while fully integrating into society.

Substance abuse clients need access to social services. Studies support that these individuals have better treatment outcomes if other problems, such as occupational, family issues, and mental health issues, are concurrently addressed.

Substance abuse programs that provide Levels I, II, III, and IV services have an individual responsible to link the client to long term recovering community resources, such as residences with counseling or faith based agencies. The case / care manager works with the client to identify and fill immediate needs and to reduce barriers with accessing needed care.

Generally, there are five (5) central functions of the substance abuse case / care manager:

1. Engagement
2. Assessment
3. Planning, goal setting, and implementation
4. Linkage, monitoring, and advocacy
5. Disengagement

DOCUMENT REVIEW

Review the organizational chart for the Substance Abuse program.

Determine that the program has in place:

- An individual that serves to coordinate the support services for the substance abuse client.

- 1 =Compliant
 2 = Not Compliant

This standard is not met as evidenced by:

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<p>28.01.07 Case/Care Manager – Qualifications. The case / care manager has the knowledge, skills, and attitudes required to effectively coordinate referrals and community services required for the Substance Abuse client, particularly clients with dual-diagnoses.</p>	<p>Linking the substance abuse client with community resources can be a challenge.</p> <p>The competent case / care manager of substance abuse clients has the ability to coordinate referrals for clients with dual-diagnoses, such as schizophrenia, and those that are impoverished or with limited financial resources.</p> <p>The facility has identified the knowledge, skills, and attitudes necessary for the case/care manager of this program.</p> <p>General competencies the incumbent should possess to be effective in this role include:</p> <ol style="list-style-type: none"> 1. Referrals 2. Service Coordination 3. Cultural Competence 	<p><u>FILE REVIEW</u></p> <p>Review the personnel file of the case/care manager.</p> <p>Verify:</p> <ul style="list-style-type: none"> • The case / care manager has the qualifications and experience to coordinate the support services needed by the substance abuse client. 	<p><input type="checkbox"/> 1 =Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>
<p>28.02.01 Medical Record Requirements. The clinical record shall provide information that indicates need for admission and treatment, treatment goals, changes in status of treatment, discharge planning, follow-up, and client outcomes.</p>	<p>All medical record entries must be legible and complete. The progress notes recorded by the professional staff, or others responsible for the patient’s treatment, must give a chronological picture of the patient’s progress or lack of progress towards attaining short and long-range goals of the treatment plan.</p> <p>Expect to see greater frequency when patients are more acutely ill and/or in a crisis of some kind.</p> <p>The clinical record shall provide information that</p>	<p><u>CHART REVIEW</u></p> <p>Review medical records. Select two or more identified problems and goal statements to trace the documentation of progress.</p> <p>Verify:</p> <ol style="list-style-type: none"> 1. Treatment goals are identified. 2. Notes reflect the needs and progress of the patient 3. Entries must be dated, timed, and signed 	<p>Scoring deferred to Standard 10.01.05.</p>

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- indicates:
1. Need for admission and treatment
 2. Treatment goals
 3. Changes in status of treatment and discharge planning, and follow-up
 4. Client progress / outcomes with achieving goals

with the discipline identified.

28.02.02 History Assessment Requirements.

A pertinent medical history shall be obtained and documented in the medical record.

The Substance Abuse practitioner must have a client history in order to select the most appropriate treatment plan for the client.

The pertinent medical history is obtained by a physician or other qualified healthcare practitioner as allowed by State or local law and per facility policy.

Inpatients:

For inpatients a pertinent medical history shall be documented and in the medical record within 24 hours of admission.

Outpatient Programs:

1. For outpatient clients, a pertinent medical history or medical history screening shall be documented and placed in the medical record within three (3) visits.
2. The content of the pertinent medical history or

DOCUMENT REVIEW AND CHART REVIEW

Review program policies / protocols / practices.

1. Determine that expectations for completing a patient history are in place.
 - Verify the medical staff has approved the content of the pertinent medical history/medical history screening tool.
2. Review medical records.
 - Verify that a pertinent medical history / medical history screening is documented in the medical record.

- 1 =Compliant
 2 = Not Compliant

This standard is not met as evidenced by:

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medical history screening tool is approved by the medical staff at least every three (3) years.

28.02.03 Physical Assessment Requirements.

A pertinent physical assessment shall be completed and documented in the medical record.

It is understood that a physical examination may be threatening to certain substance abuse clients, especially, in the outpatient setting. And yet, a pertinent physical examination is needed to assist the practitioner with selection of the most appropriate treatment plan for the client.

The pertinent physical assessment is conducted by a physician or other qualified healthcare practitioner as allowed by state or local law and per facility policy.

Inpatients:

For the inpatient, a pertinent physical assessment shall be documented and placed in the medical record within 24 hours of admission.

Outpatient Programs:

For programs that provide Level I or II services, a process is in place to refer clients for a complete / pertinent physical assessment, as indicated, based upon the findings of the pertinent medical history / screening.

DOCUMENT REVIEW

Review program policies / protocols / practices. Verify:

- A process is in place to refer clients for a physical assessment when identified by the medical history screening.

- 1 =Compliant
 2 = Not Compliant

This standard is not met as evidenced by:

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<p>28.02.04 Individualized Treatment Plan. An individualized treatment plan will be developed for each Substance Abuse client receiving Level I, II, III, or IV services.</p>	<p>Individualized treatment plans, developed in collaboration with the client, include:</p> <ol style="list-style-type: none"> 1. Problem statements. 2. Treatment goals. 3. Measurable objectives. <p>Goals must be identified and treatment activities planned for each phase of care consistent with the level of treatment provided at the facility:</p> <ol style="list-style-type: none"> 1. Motivational Interviewing; 2. Primary Treatment; and 3. Relapse Prevention. <p>The individualized treatment plan is developed based upon an assessment of the client and includes, as appropriate:</p> <ol style="list-style-type: none"> 1. Individual and/or group counseling 2. Vocational rehabilitation 3. Recreational therapy 4. Patient and family therapy 5. Relapse prevention to provide follow-up monitoring and referrals for continuing support with outside community services to prevent relapse, e.g. Alcoholics Anonymous, AL-ANON, etc. 	<p align="center">CHART REVIEW</p> <p>Review medical records. Verify each patient has:</p> <ol style="list-style-type: none"> 1. An individualized treatment plan developed in collaboration with the client and includes: <ol style="list-style-type: none"> a. Treatment goals b. Objectives to achieve the identified goals. 2. An individualized treatment plan for each of the three (3) phases of care: <ol style="list-style-type: none"> a. Motivational Interviewing b. Primary Treatment c. Relapse Prevention 	<p><input type="checkbox"/> 1 =Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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<p>28.02.05 Documentation of Active Treatment. <i>Treatment received by the patient must be documented in such a way to assure that all active therapeutic efforts are included.</i></p> <p>§482.61(c)(2)</p>	<p>Active treatment is implemented based upon the therapeutic goals identified and the individualized treatment plan.</p> <p>Active treatment is a clinical process under the direction of a qualified substance abuse professional. Documentation of the treatment plan address:</p> <ul style="list-style-type: none"> • Assessment • Diagnosis • Interventions • Evaluation of care and treatment • Transition planning • Relapse prevention 	<p style="text-align: center;"><u>CHART REVIEW</u></p> <p>Review medical records. Verify:</p> <ul style="list-style-type: none"> • A progress note is documented for each treatment session provided in Level I, II, III, or IV program. 	<p><input type="checkbox"/> 1 =Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>
<p>28.02.06 Discharge Summary. <i>All records must document the following as appropriate: Discharge summary with outcome of hospitalization, disposition of case, and provisions for follow-up care.</i></p> <p>§482.24(c)(4)(vii)</p> <p>(See standard 10.01.18)</p>	<p>The discharge summary or final progress note addresses:</p> <ol style="list-style-type: none"> 1. The final evaluation regarding the progress of the client with meeting the goals and objectives set forth in the initial treatment plan. 2. A transition plan. 	<p style="text-align: center;"><u>CHART REVIEW</u></p> <p>Review medical records. Verify:</p> <ol style="list-style-type: none"> 1. A discharge summary or final progress report is in place for each discharged client. 2. The discharge summary / final progress report includes: <ol style="list-style-type: none"> a. The final evaluation regarding the progress of the patient toward meeting goals and b. A transition plan 	<p>Scoring deferred to standard #10.01.18</p>

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<p>28.02.07 <u>Statement of Ability.</u> The medical record includes a written statement of abilities for each client.</p>	<p>An assessment is obtained and documented indicating the client’s ability to function and evacuate himself / herself in the event of a fire or other life-threatening emergency.</p>	<p style="text-align: center;"><u>CHART REVIEW</u></p> <p>Review medical records. Verify:</p> <ul style="list-style-type: none"> Each record includes documentation of the patient’s ability to function in the event of a life-threatening situation. 	<p><input type="checkbox"/> 1 =Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>
<p>28.02.08 <u>Not Applicable.</u></p>			
<p>28.03.01 <u>Confidentiality of Substance Abuse Patient Records.</u> Substance abuse treatment programs maintain client and medical record confidentiality.</p>	<p>The Substance Abuse program has policies / protocols that outline patient rights, the release of information, and patient confidentiality. The facility is responsible for all federal and state laws and regulations, including those beyond the scope of this accreditation manual.</p> <p>The federal government has published two sets of regulations regarding patient confidentiality; while there are commonalities, there are also differences. Substance abuse treatment programs must comply with both sets of regulations.</p>	<p style="text-align: center;"><u>DOCUMENT REVIEW</u></p> <p>Review facility policies. Verify the following are in place:</p> <ol style="list-style-type: none"> Processes for maintaining patient confidentiality. Procedure for obtaining client consent prior to release of information. For inpatients, the release of medical records does not include the substance abuse episode of care without the client’s signed consent. A process is in place restricting unauthorized personnel from viewing substance abuse treatment records 	<p><input type="checkbox"/> 1 =Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>
	<p><u>Overview of Federal Requirements for Substance Abuse Programs:</u></p> <ol style="list-style-type: none"> 42 CFR Part 2 (commonly referred to as “<u>Part 2</u>”): The Code of Federal Regulations relative to confidentiality are described in the 2002 update of “The Confidentiality of Alcohol and Drug Abuse Patient Record regulations (42 CFR Part 2). These regulations apply to any program that provides 	<p style="text-align: center;"><u>INTERVIEW</u></p> <p>Interview staff members. Inquire of the processes for maintaining confidentiality and for</p>	

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	<p>alcohol or drug abuse diagnosis, treatment, and which is federally assisted, directly or indirectly.</p> <p>Substance abuse treatment programs must follow the Part 2 “general rule” which means that they cannot disclose information unless they obtain consent or point to an exception to that rule that specifically permits the disclosure.</p> <p>The “Part 2” regulation:</p> <ul style="list-style-type: none"> a. Protects any and all information that could reasonably be used to identify an individual b. Requires that disclosures be limited to the information necessary to carry out the purpose of the disclosure c. Protects all information about any person who has applied for or been given diagnosis or treatment for alcohol or drug abuse at a federally assisted program. <p>For more information, go to http://www.tie.samhsa.gov/Taps/Tap11/tap11fedregister.html</p> <p>2. Health Insurance Portability and Accountability Act (HIPAA): “The Confidentiality of Alcohol and Drug Abuse Patient Records Regulation and the HIPAA Privacy Rule: Implications for Alcohol and Substance Abuse Programs (June 2004) identifies those substance abuse treatment programs that</p>	<p>obtaining patient consent prior to release of information.</p>	

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are subject to the HIPAA confidentiality requirements. Substance abuse treatment programs that are subject to HIPAA must comply with the HIPAA Privacy Rule (known as the “Privacy Rule”).

HIPAA regulations apply to substance abuse treatment program transactions, such as the following:

- a. Submission of claims to health plans
- b. Coordination of benefits with health plans
- c. Inquiries to health plans regarding eligibility, coverage or benefits or status of health care claims
- d. Transmission of enrollment and other information related to payment to health plans
- e. Referral certification and authorization (i.e., requests for review of health care to obtain an authorization for providing health care or requests to obtain authorization for referring an individual to another health provider)
- f. Electronic transmission of health information

The Privacy Rule permits programs to assign a code or

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other means of record identification to allow information that has been de-identified to be re-identified, as provided in 45 CFR §164.514 (c).

For more information about the HIPAA “Privacy Rule,” go to:
[http://www.hipaa.samhsa.gov/download2/SAMHSA's Part2-HIPAAComparisonClearedWordVersion.doc](http://www.hipaa.samhsa.gov/download2/SAMHSA's%20Part2-HIPAAComparisonClearedWordVersion.doc)

28.03.02 Consent for Disclosure of Information.

Substance abuse treatment programs obtain the client’s written consent prior to disclosing identifiable health information or sending insurance reimbursement claims.

Definitions:

Source: 42 CFR Part 2 - Code of Federal Regulations.

- Disclosure:** “A communication of patient identifying information, the affirmative verification of another person’s communication of patient identifying information, or the communication of any information from the record of a patient who has been identified.”
- Patient Identifying Information:** The name, address, social security number, fingerprints, photograph, or similar information by which the identity of a patient can be determined with reasonable accuracy and speed either directly or by reference to other publicly available information.

The term does not include a number assigned to a patient by a program, if that number does not consist of, or contain numbers (such as a social

DOCUMENT REVIEW AND CHART REVIEW

Verify:

- The consent form complies with the nine (9) elements required by Medicare Part 2.

Review medical records to determine:

- The facility obtains consent prior to any release of information.
- Patients are provided with a copy of the signed consent form.
- For clients with medical emergencies: Immediately following the disclosure of confidential client information, the required three (3) elements are documented in the medical record.

- 1 =Compliant
- 2 = Not Compliant

This standard is not met as evidenced by:

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security, or driver’s license number) which could be used to identify a patient with reasonable accuracy and speed from sources external to the program.”

Client Education – Insurance Implications:

As a condition for reimbursement, traditional health insurance programs require patients to sign consents for the release of information about their care. While HMOs do not require patients to submit claim forms, the HMO can review clinical records at any time. For this reason, providers should discuss with the client:

1. The information that will be disclosed;
2. The alternatives available (refusal to disclose) and
3. The consequences of those alternatives, e.g., non-payment.

The provider should explain that if the client does not comply with the release of information, it is likely that:

1. Some of the services may not be reimbursed,
2. The client could lose some or all insurance coverage, and
3. The client may be unable to obtain future coverage.

Providers need to be sensitive about the amount and kind of information disclosed in the medical record. To protect patient privacy, keep documentation neutral and within professionally accepted standards.

The Part 2 Consent Form:

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The acknowledgment that a client has applied to or is enrolled in the program is only permitted if the patient has signed a consent form (or another of the regulations' narrow exceptions applies.) Medicare 42 CFR Part 2 is explicit with the information that must be included in the client consent form (see box below.)

<p><u>Consent for Disclosure of Information (form)</u></p> <p>Medicare Part 2 requires <u>each</u> of the following elements to be included with the client consent form:</p> <ol style="list-style-type: none"> 1. Name or general designation of the program or person permitted to make the disclosure 2. Name or title of the individual or name of the organization to which disclosure is to be made 3. Name of the patient 4. Purpose of the disclosure 5. How much and what kind of information is to be disclosed 6. Signature of patient (and, in some States, a parent or guardian) 7. Date on which consent is signed 8. Statement that the consent is subject to revocation at any time except to the extent that the program has already acted on it 9. Date, event, or condition upon which consent will expire if not previously
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revoked.

When programs operating under Part 2 disclose information pursuant to a consent form:

- They must include a written statement that the information cannot be re-disclosed (42 CFR 2.32).

The Privacy Rule Consent

The Privacy Rule imposes three (3) additional steps the substance abuse programs must take when disclosing information pursuant to a patient’s written consent:

1. Program must ensure that the consent complies with the applicable requirements of 45 CFR §164.508.
2. Programs must give patients a copy of the signed form 45 CFR §164.508.
3. Programs must keep a copy of each signed form for six (6) years from its expiration date 45 CFR §164.508(b)(6).

Revoke Consent

1. Part 2 permits a patient to revoke consent orally.
 - Substance abuse treatment programs must continue to honor verbal revocations but may want to obtain written revocation when possible or at a minimum document the revocation in the patient’s record.

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- The Privacy Rule requires written revocation of a consent authorization.

Medical Emergencies

Part 2 allows patient-identifying information to be disclosed to medical personnel who have a need for the information about a patient for the purpose of treating a condition which poses an immediate threat of any individual and requires immediate medical intervention.

Immediately following the disclosure, the program must document the following in the medical record:

- Name and affiliation of the medical personnel to whom disclosure was made.
- Name of the individual making the disclosure.
- Date and time of the disclosure.
- Nature of the emergency.

28.03.03 Notice of Privacy Practices.

The facility provides patients with a summary of the federal regulations that protect the confidentiality of substance abuse medical records.

(42 CFR 2.22; Part 2.) Substance Abuse treatment programs must notify patients that by Federal law and regulations the confidentiality of alcohol and drug abuse patient records is protected.

- A written summary of the regulations' requirements must be given to each client at the time of admission or as soon thereafter as the patient is capable of rational communications.

The HIPAA Privacy Rule requires that patients be given:

DOCUMENT REVIEW AND OBSERVATION

Verify:

- The Notice of Privacy is posted in the facility in prominent location. The Notice is available on the facility's website.
- A process is in place to provide clients with the Notice of Privacy upon admission or as soon thereafter as possible.

- 1 =Compliant
 2 = Not Compliant

This standard is not met as evidenced by:

CHART REVIEW

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	<ul style="list-style-type: none"> • A notice of the program’s privacy practices as well as their rights under the Privacy Rule. • The notice on the date of the first service delivery, including service delivered electronically. <p>Programs subject to <u>both</u> Part 2 and HIPAA rules may “combine” the requirements into a single notice (see box below).</p> <p>The program must also have the notice available on site for patients to take with them and posted in a clear and prominent location where it is reasonable to expect patients to be able to read it. Whenever there is a material change to the notice, the notice must be promptly revised, made available upon request, and re-posted as previously referenced.</p> <p>The program must make a good faith effort to obtain the client’s written acknowledgement of receipt of the notice, except in an emergency treatment situation, on the date of the first service delivery. If written acknowledgment is not obtained, the program must document its efforts and the reason it was not able to obtain the acknowledgment.</p> <p>A program that maintains a web site that provides information about its services must prominently post its notice on the site and make it available electronically on the site. When clients agree, the program can provide the notice by e-mail.</p> <div data-bbox="541 1321 1131 1356" style="border: 1px solid black; padding: 2px; margin-top: 10px;"> <p><u>Notice of Privacy Practices:</u></p> </div>	<p>Review medical records.</p> <p>Verify:</p> <ol style="list-style-type: none"> 1. Clients have received a summary of the federal regulations to protect confidentiality, as required by Part 2 of federal regulation 42 CFR 2.22. 2. Clients have received the program’s privacy practices, as required by HIPAA. 3. Clients receive the Notice of Privacy Practices at the time of admission or as soon as client is rationale. 	

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Facilities subject to both Part 2 and HIPAA may use a combined notice of privacy to inform clients of federal regulations. The combined notice must contain all elements required by 42 CFR 2.22 as well as the following:

- a. Statement prominently displayed stating, “This notice describes how medical information about you may be used and disclosed and how you can get access to this information. Please review it carefully”
- b. A description in sufficient detail of the types of uses and disclosures that the program may take without the patient’s consent or authorization. For substance abuse treatment programs, these would include uses and disclosures:
 - a. In connection with treatment, payment or health care operations (include at least one example of each)
 - b. To qualified service organizations or business associates who provide services to the program’s treatment, payment or health care operations
 - c. In medical emergencies
 - d. Authorized by court order
 - e. To auditors and evaluators
 - f. To researches if the information will be protected as required by Federal regulations
 - g. To report suspected child abuse or neglect
 - h. To report a crime or a threat to commit a

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<p>crime on program premises or against program personnel</p> <p>c. A statement that other disclosures will be made only with the patient’s written consent or authorization which can be revoked, unless the program has taken action in reliance on the consent or authorization</p> <p>d. A statement that the program may contact the patient to provide appointment reminders or information about treatment alternatives or other health-related benefits and services that may be of interest to the patient.</p> <p>e. A statement that it is required by law to maintain the privacy of PHI and to notify patients of its legal duties and privacy practices, including any changes to its policies</p> <p>f. A statement that the program must abide by the terms of the notice currently in effect; a statement that the program reserves the right to change the terms of its notice and to make the new notice provisions effective for all information it maintains; and a statement describing how it will provide patients with a revised notice of its practices</p> <p>g. The name or title and telephone number of a person or office the patient can contact for further information</p> <p>h. A statement of the patient’s rights with respect to PHI and a brief description of how the patient may exercise those rights, including:</p> <p> a. The right to request restrictions on</p>
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- certain uses and disclosures of PHI, including the statement that the program is not required to agree with requested restriction
- b. The right to receive confidential communications of PHI (such as having mail and telephone calls be limited to home or office location)
 - c. The right to access and amend PHI
 - d. The right to receive an accounting of the program’s disclosures of PHI
 - e. The right to complain – free from retaliation – to the program and to the Secretary of Health and Human Services (HHS) about violations of privacy rights, and information on how to file a complaint with the program
 - f. The right to obtain a paper copy of the notice upon request.
 - g. The effective date of the notice.

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28.04.01 Quality Assessment Performance Improvement (QAPI).
 To measure the effectiveness of the Substance Abuse program, indicators of success must be defined and reported to the facility-wide QAPI program.

The effectiveness of each program provided within the substance abuse program is measured, analyzed, and reported.

Quality indicators the substance abuse program might consider:

1. #Attendance at treatment sessions / month
2. #Clients that stop use of illicit substances / month
3. #Clients with improved family functioning / month
4. #Clients with fewer encounters with the criminal justice system / month
5. #Clients that have become employed / month
6. #Clients that experience relapse while in treatment / month
7. #Adverse events, e.g., # delirium tremens

DOCUMENT REVIEW

Verify:

- Each level of care provided (Level I, II, III, or IV) of the Substance Abuse program is integrated into the facility wide QAPI program.

- 1 =Compliant
- 2 = Not Compliant

This standard is not met as evidenced by:

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All applicable acute care standards and CMS Conditions of Participation (CoP) apply to special care units and must be considered in evaluation of compliance in addition to the Special Care Unit standards identified below.

29.00.01 Special Care Units.

Special Care Units (SCU) exist to provide the focused use of intensive staff and technologic resources for patients. Such services, when offered, are organized to support the facility mission and scope statements and reflect the special needs of the facility service area.

Special Care Unit services may include:

- Medical and coronary care
- Surgical care
- Pulmonary care
- Neurological care
- Pediatric care
- Trauma care
- Burn care
- Neonatal care, and etc.

**DOCUMENT REVIEW, INTERVIEW,
& OBSERVATION**

Review the facility, and service, statements of scope and mission.

- Determine the services provided are consistent with the scope and mission statements.

- 1 =Compliant
 2 = Not Compliant

This standard is not met as evidenced by:

29.00.02 Medical Care.

Each patient in a Special Care Unit has a physician member of the Medical Staff responsible for his/her medical condition. This physician has been granted privileges to admit and care for patients in the unit.

All physician privilege delineations, appropriate to the SCU, are copied and made available to the SCU nursing staff.

Specific procedural delineations typically include, but are not limited to:

- Admission to the unit,
- Insertion of lines,
- Endoscopic, endotracheal, trocar invasions,
- Ventilator management,
- Cardioversion,
- Thrombolytic therapy, etc.

CHART REVIEW & OBSERVATION

Verify:

1. A current list of physician privilege delineations are readily accessible to the SCU staff.
2. A physician member of the Professional Medical Staff is responsible for the medical care of each patient.

- 1 =Compliant
 2 = Not Compliant

This standard is not met as evidenced by:

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<p>29.00.03 <u>Nursing Care.</u> The Special Care Unit nursing staff has competencies (educational and experience) unique to the patient population(s) of the unit.</p>	<p>There is at least one (1) registered nurse, with appropriate special care unit training and experience, on duty at all times that the unit is open. Additional staff is provided to assure that identified nursing needs of the patient population are met.</p>	<p><u>DOCUMENT REVIEW</u> Review unit staffing plans, practices, and patient census for six of the last twelve weeks. Verify: 1. The availability of an appropriate number of qualified registered nurses to meet the needs of patients. 2. Nursing personnel have demonstrated competence for the unique patient population of the unit.</p>	<p><input type="checkbox"/> 1 =Compliant <input type="checkbox"/> 2 = Not Compliant This standard is not met as evidenced by:</p>
<p>29.00.04 <u>Admission Criteria.</u> The SCU medical and nursing staff have developed a Standard of Practice identifying the types of patients, with their acuity needs, who are eligible for care in the unit.</p>	<p>The diagnoses / conditions requiring SCU resources have been identified. The needs are described in physiologic and / or behavioral (quantifiable) terms.</p>	<p><u>DOCUMENT REVIEW, CHART REVIEW, & INTERVIEW</u> Review policies. Review patient records. Verify: 1. The Special Care Unit has a patient admission eligibility policy that includes the types of patients and unique acuity needs. This policy has been approved by the medical staff within the last three years. 2. Patient records demonstrate that practice is consistent with the criteria. 3. Staff verifies the criteria is utilized.</p>	<p><input type="checkbox"/> 1 =Compliant <input type="checkbox"/> 2 = Not Compliant This standard is not met as evidenced by:</p>

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<p>29.00.05 <u>Discharge Criteria</u> The SCU medical and nursing staff have developed a policy identifying the types of patients, with their special needs, who are eligible for discharge from the unit.</p>	<p>The diagnoses / conditions no longer requiring SCU resources have been identified. The needs are described in physiologic and/or behavioral (quantifiable) terms.</p>	<p style="text-align: center;"><u>DOCUMENT REVIEW, CHART REVIEW & INTERVIEW</u></p> <p>Review policies. Review patient records. Verify:</p> <ol style="list-style-type: none"> 1. The Special Care Unit has a discharge eligibility policy approved by the medical staff within the last three years. 2. Compliance with the criteria. 3. Staff verify the criteria is utilized. 	<p> <input type="checkbox"/> 1 =Compliant <input type="checkbox"/> 2 = Not Compliant </p> <p>This standard is not met as evidenced by:</p>
<p>29.00.06 <u>Prioritization of Care.</u> Admission Criteria (standard #29.00.04) and Discharge Criteria (standard #29.00.05) indicate mechanisms for establishing priority in applying the admission and discharge criteria.</p>	<p>The Standards of Practice criteria are applied using priority levels to establish levels of expected benefit from the intensive use of resources.</p>	<p style="text-align: center;"><u>DOCUMENT REVIEW AND INTERVIEW</u></p> <ol style="list-style-type: none"> 1. Review the Standards of Practice criteria to determine that levels of priority are documented. 2. Verify with staff that the prioritization process is utilized and is effective. 	<p> <input type="checkbox"/> 1 =Compliant <input type="checkbox"/> 2 = Not Compliant </p> <p>This standard is not met as evidenced by:</p>
<p>29.00.07 <u>Staff Orientation.</u> Staff orientation to the Special Care Unit(s) assesses current knowledge and identifies learning needs to care for the anticipated patient population(s) of the unit.</p>	<p>The orientation program will vary in length dependent upon previous skills of the staff; in all cases the program provides for basic orientation in the four identified parameters of ICU practice.</p>	<p style="text-align: center;"><u>FILE REVIEW</u></p> <p>Review the overall curriculum and the records of the last two staff oriented to the unit. All four areas are addressed.</p> <ul style="list-style-type: none"> • Determine the four (4) required orientation topics have been addressed for each staff. 	<p> <input type="checkbox"/> 1 =Compliant <input type="checkbox"/> 2 = Not Compliant </p> <p>This standard is not met as evidenced by:</p>

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There is a document describing the required training needed to be effective in the unit, including, but not limited to:

- Physical
- Emotional
- Rehabilitative
- Technological skills

29.00.08 Physical Environment.
 Adequate space exists to provide for use of necessary equipment, while providing for as much physical and auditory privacy as can occur, during the application of special care unit clinical procedures.

The Special Care Unit staff have access to current state codes regarding square footage, outside and artificial lighting, and the ability to provide for contagious disease isolation.

The facility is in compliance with such codes, or has a state approved plan, for managing the variance.

OBSERVATION & INTERVIEW

Verify:

1. The Special Care Unit has adequate space for care delivery as well as support services.
2. The Special Care Unit provides for auditory and physical privacy.
3. Staff has access to the current state codes. There is a plan to achieve code compliance; the plan is on schedule, if applicable.

- 1 =Compliant
 2 = Not Compliant

This standard is not met as evidenced by:

29.00.09 For Future Use.

29.00.10 For Future Use.

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<p>29.00.11 <u>Equipment: Training.</u> Staff receive training on the use of all equipment available in the Special Care Unit, as appropriate.</p>	<p>Staff education (initial and annual) is documented relating to the use of electrical equipment.</p> <p>Staff receive training on electrical equipment prior to use and periodically thereafter. Training includes:</p> <ul style="list-style-type: none"> • Setup and operation of new, rarely used, or complex equipment • Electrical safety • Patient safety • Equipment malfunctions and emergency situations 	<p style="text-align: center;"><u>DOCUMENT REVIEW, FILE REVIEW, & INTERVIEW</u></p> <p>Verify:</p> <ol style="list-style-type: none"> 1. Initial and annual education includes electrical equipment safety, with emphasis on this patient population. 2. Education is provided for new, complex, or rarely used equipment. 	<p><input type="checkbox"/> 1 =Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>
<p>29.00.12 <u>Equipment: Required.</u> Each Special Care Unit maintains an adequate inventory of equipment.</p> <p>At a minimum, equipment to be readily available includes:</p> <ol style="list-style-type: none"> 1. Suction at each bedside 2. Oxygen and compressed air at each bedside 3. Mechanical ventilation 4. Physiologic monitoring, at each bedside, either hard wire or telemetric 	<p>Equipment and supplies are maintained in sizes and quantities sufficient to meet the anticipated needs of patients.</p> <p>Pediatric defibrillation paddles are maintained in the unit if a small child <u>may</u> be a patient and/or for use with small/frail adults.</p> <p>Oxygen masks and intubations tubes are available in a sufficient number and a variety of sizes.</p>	<p style="text-align: center;"><u>OBSERVATION</u></p> <p>Assess the availability of the equipment listed within this standard.</p>	<p><input type="checkbox"/> 1 =Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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5. Crash cart(s) with endotracheal tubes, breathing masks, and drugs, appropriate to the sizes of potential patients			
6. Cardiac defibrillation, with paddles appropriate to the sizes of potential patients			
7. Sterile procedure trays: Cutdown, tracheostomy, vascular cutdown, lumbar puncture, etc.			
8. Patient weighing device			
9. Thermal controlling devices (cooling and warming, such as K-thermia, Bears, bassinets, etc.)			
10. Portable radiographic unit(s)			
11. Communication system from each bedside to the central (SCU) nursing station.			

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<p>29.00.13 Supply Storage. Sterile trays are stored in a manner so as to protect them from surface or airborne contamination. Staff who routinely work in the area know the location of these supplies.</p>	<p>Self-explanatory.</p>	<p><u>OBSERVATION</u> Assess the logistics of storing and protecting sterile trays.</p>	<p><input type="checkbox"/> 1 =Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>
<p>29.00.14 Required Policies & Procedures. Policies and procedures are developed by the SCU medical and nursing staffs relating to, at least:</p> <ol style="list-style-type: none"> 1. The circumstances leading to required consultations for SCU patients. 2. Determining the acuity of patient care to adjust from core nursing staffing. 3. Management of specific patient care emergencies via protocol until the physician can be notified. 4. Circumstances (examples of) requiring immediate notification of the physician. 5. Management of patients during a facility disaster (equipment or utility failure, plus natural 	<p>Self-explanatory.</p>	<p><u>DOCUMENT REVIEW, OBSERVATION, & INTERVIEW</u> Review the SCU policy and procedure manual. Verify:</p> <ol style="list-style-type: none"> 1. All required policies are in place and are readily available for staff use. 2. Policies reflect current literature. 3. Practice is consistent with established policy. 	<p><input type="checkbox"/> 1 =Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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disaster{s}).

6. Infection control measures unique to the physical layout of the units, the equipment used, and potential patients served.
7. Mechanisms relating to unit specific quality control and quality improvement monitors.
8. Traffic control in the unit, including visiting hours for patient support persons.
9. Maintenance of par levels of supplies and drugs for anticipated needs.
10. Elements of assessment and reassessment and frequencies.
11. Collaborative practice principles including conflict resolution (medicine / nursing and other support providers).

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29.00.15 Policies: Collaborative Development.

The SCU Policy and Procedure manual is collaboratively prepared and reviewed on at least a triennial basis.

Although the medical and nursing staff have primary responsibility for this document, other staff are consulted to provide input or co-authorship as appropriate. This may include, for example, persons with expertise in pharmacy, nutrition, social service, or cardiopulmonary services.

Self-explanatory.

DOCUMENT REVIEW

Review the SCU Policy and Procedure manual. Verify:

1. Policies are collaboratively prepared with appropriate disciplines.
2. Policies have been approved by the medical staff within the past three years.

- 1 =Compliant
 2 = Not Compliant

This standard is not met as evidenced by:

29.00.16 Policies: Subspecialty Policies Address Unique Patient Needs.

Policies and procedures are developed by the SCU medical and nursing staff relating to any focused areas of concern for subspecialty special care needs.

The manual is not limited to the listed topics, but shall address this core group of practice standards.

If the unit predominantly serves adult patients but will occasionally accept pediatric patients, the manual addresses how their unique developmental needs of children will be addressed within the integrated plan of care. For example, burn unit policies will have increased emphasis on infection control, pain management, emotional supports, etc.

Policies and procedures will be modeled upon current literature and may stem from specialty organizations.

DOCUMENT REVIEW

If subspecialty needs do exist, review SCU policies and list of references. Verify:

1. Guidelines are current, appropriate for the unit, and based on current literature.
2. Policies reflect specialty needs, as appropriate to the unit.

- 1 =Compliant
 2 = Not Compliant

This standard is not met as evidenced by:

SURGICAL SERVICES

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<p>30.00.00 Condition of Participation: Surgical Services. <i>If the hospital provides surgical services, the services must be well organized and provided in accordance with acceptable Standards of Practice.</i></p> <p><i>If outpatient surgical services are offered, the services must be consistent in quality with inpatient care in accordance with the complexity of services offered.</i></p> <p>§482.51</p>	<p>The provision of surgical services is an optional hospital service. However, if a hospital provides any degree of surgical services to its patients, the hospital must comply with all the requirements of this Condition of Participation (CoP).</p> <p>What constitutes “surgery”? For the purposes of determining compliance with the hospital surgical services CoP, CMS relies, with minor modification, upon the definition of surgery developed by the American College of Surgeons.</p> <p>Definition Accordingly, the following definition is used to determine whether or not a procedure constitutes surgery and is subject to this CoP:</p> <p style="padding-left: 40px;">“Surgery is performed for the purpose of structurally altering the human body by the incision or destruction of tissues and is part of the practice of medicine. Surgery also is the diagnostic or therapeutic treatment of conditions or disease processes by any instruments causing localized alteration or transposition of live human tissue which include lasers, ultrasound, ionizing radiation, scalpels, probes, and needles. The tissue can be cut, burned, vaporized, frozen, sutured, probed, or manipulated by closed reductions for major dislocations or fractures, or otherwise altered by mechanical, thermal, light-based, electromagnetic, or chemical means.</p>	<p style="text-align: center;"><u>OBSERVATION</u></p> <p>Inspect all operative rooms and suites. Request the use of proper attire for inspection. Observe the practices to determine if the services are provided in accordance with acceptable standards of practice.</p> <p>Verify:</p> <ol style="list-style-type: none"> 1. That access to the operative and recovery area is limited to authorized personnel and that the traffic flow pattern adheres to accepted standards of practice. 2. The conformance to aseptic and sterile technique by all individuals in the surgical area. 3. That there is appropriate cleaning between surgical cases and appropriate terminal cleaning applied. 4. That operating room attire is suitable for the kind of surgical case performed, that persons working in the operating suite must wear only clean surgical costumes, that surgical costumes are designed for maximum skin and hair coverage. 5. That equipment is available for rapid and routine sterilization of operating room materials. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant <input type="checkbox"/> NA = Chapter Not Applicable in this facility.</p> <p>Comment:</p>

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	<p>Injection of diagnostic or therapeutic substances into body cavities, internal organs, joints, sensory organs, and the central nervous system also is considered to be surgery (this does not include the administration by nursing personnel of some injections, subcutaneous, intramuscular, and intravenous, when ordered by a physician). All of these surgical procedures are invasive, including those that are performed with lasers, and the risks of any surgical procedure are not eliminated by using a light knife or laser in place of a metal knife, or scalpel. Patient safety and quality of care are paramount and, therefore, patients should be assured that individuals who perform these types of surgery are licensed physicians (physicians as defined in 482.12(c)(1)) who are working within their scope of practice, hospital privileges, and who meet appropriate professional standards.”</p> <p>If surgical services are provided, they must be organized and staffed in such a manner to ensure the health and safety of patients.</p> <p>Acceptable standards of practice include maintaining compliance with applicable Federal and State laws, regulations and guidelines governing surgical services or surgical service locations, as well as, any standards and recommendations promoted by or established by nationally recognized professional organizations (e.g., the American Medical Association, American College of Surgeons, Association of Operating Room Nurses, Association for Professionals in Infection Control and</p>	<p>6. That equipment is monitored, inspected, tested, and maintained by the hospital’s biomedical equipment program and in accordance with Federal and State law, regulations and guidelines and following manufacturer’s recommendations.</p> <p>7. That sterilized materials are packaged, handled, labeled, and stored in a manner that ensures sterility e.g., in a moisture and dust controlled environment and policies and procedures for expiration dates have been developed and are followed in accordance with accepted standards of practice.</p> <p>8. That temperature and humidity are monitored and maintained within accepted standards of practice.</p> <p>9. That medical / surgical devices and equipment are checked and maintained routinely by clinical / biomedical engineers.</p> <p style="text-align: center;"><u>INTERVIEW & DOCUMENT REVIEW</u></p> <p>Verify:</p> <ul style="list-style-type: none"> • All surgical service activities and in all locations are integrated into the hospital-wide QAPI program. 	

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Epidemiology, etc.).

OUTPATIENT SURGICAL SERVICES

Outpatient surgical services must be in compliance with all hospital CoPs including the surgical services CoP. Outpatient surgical services must be provided in accordance with acceptable standards of practice. Additionally, the hospital’s outpatient surgical services must be consistent in quality with the hospital’s inpatient surgical services. Post-operative care planning, coordination for the provision of needed post-operative care and appropriate provisions for follow-up care of outpatient surgery patients must be consistent in quality with inpatient care in accordance with the complexity of the services offered and the needs of the patient.

The hospital’s inpatient and outpatient surgical services must be integrated into its hospital-wide QAPI program.

A process is in place for Surgery, Anesthesia, and Post-Anesthesia Recovery Services to collect and analyze data. Data is collected from all surgical / invasive procedure areas of the facility, including remote locations. These data are integrated with the hospital-wide QAPI program.

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<p>30.00.01 <u>Organizational Structure.</u> <i>The organization of the surgical services must be appropriate to the scope of the services offered.</i></p> <p>§482.51(a)</p>	<p>When the hospital offers surgical services, the hospital must provide the appropriate equipment and the appropriate types and numbers of qualified personnel necessary to furnish the surgical services offered by the hospital in accordance with acceptable standards of practice.</p> <p>The scope of surgical services provided by the hospital should be defined in writing and approved by the medical staff.</p>	<p style="text-align: center;"><u>DOCUMENT REVIEW</u></p> <ol style="list-style-type: none"> 1. Review the hospital’s organizational chart displaying the relationship of the operating room service to other services. 2. Confirm that the operating room’s organization chart indicates lines of authority and delegation of responsibility within the department or service. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>
<p>30.00.02 <u>Leadership.</u> <i>The operating rooms must be supervised by an experienced registered nurse or a Doctor of Medicine or Doctor of Osteopathic Medicine.</i></p> <p>§482.51(a)(1)</p>	<p>The operating room (inpatient and outpatient) must be supervised by an experienced RN or Doctor of Medicine / Doctor of Osteopathic Medicine.</p> <p>The RN or MD/DO supervising the operating room must demonstrate appropriate education, background working in surgical services, and specialized training in the provision of surgical services/management of surgical service operations.</p> <p>The hospital should address its required qualifications for the supervisor of the hospital’s operating rooms in its policies and the supervisor’s personnel file should contain information demonstrating compliance with the hospital’s established qualifications.</p>	<p style="text-align: center;"><u>DOCUMENT REVIEW & FILE REVIEW</u></p> <ol style="list-style-type: none"> 1. Verify that an RN or a doctor of medicine or osteopathic medicine is assigned responsibility for supervision of the operating rooms. 2. Request a copy of the supervisor’s position description to determine that it specifies qualifications, duties and responsibilities of the position. 3. Verify that the supervisor is experienced and competent in the management of surgical services. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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30.00.03 Scrub Nurses.

A Registered Nurse plans and supervises the care of each operative patient.

Licensed Practical Nurses (LPNs) and surgical technologists (operating room technicians) may serve as "scrub" nurses under the supervision of a registered nurse.

§482.51(a)(2)

If the hospital utilizes LPNs or operating room technicians (ORTs) as "scrub nurses", those personnel must be under the supervision of a RN who is immediately available to physically intervene and provide care.

Operative records will indicate which RN assessed and planned the perioperative care for each surgical / invasive procedure patient.

Assisting staff, including private employees of surgeons, will be identified in the medical record.

CHART REVIEW, OBSERVATION & INTERVIEW

Review patient charts. Verify:

1. The perioperative / invasive procedure documents provide space for identification of personnel present.
2. A RN planned and supervised the perioperative care.
3. An RN is immediately available to all LPN and ORT scrub nurses.
4. Determine that an RN is available for supervision in the department or service.
5. Validate the availability by requesting and reviewing a staffing schedule for the OR.
6. Review staffing schedules to determine adequacy of staff and RN supervision.

- 1 = Compliant
- 2 = Not Compliant

This standard is not met as evidenced by:

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<p>30.00.04 Circulating Nurse. <i>Qualified registered nurses may perform circulating duties in the operating room. In accordance with applicable State laws and approved medical staff policies and procedures, LPNs and surgical technologists may assist in circulatory duties under the supervision of a qualified registered nurse who is immediately available to respond to emergencies.</i></p> <p>§482.51(a)(3)</p>	<p>The circulating nurse must be a registered nurse (RN).</p> <p>An LPN or surgical technologist may assist an RN with carrying out circulatory duties (in accordance with applicable state laws and medical-staff approved hospital policy) but the LPN or surgical technologist must be under the supervision of the circulating RN who is in the operating suite and who is available to immediately and physically respond/intervene to provide necessary interventions in emergencies.</p> <p>The supervising RN would not be considered immediately available if the RN was located outside the operating suite or engaged in other activities / duties which prevent the RN from immediately intervening and assuming whatever circulating activities/duties that were being provided by the LPN or surgical technologist.</p> <p>The hospital, in accordance with State law and acceptable standards of practice, must establish the qualifications required for RNs who perform circulating duties and LPNs and surgical technologists who assist with circulating duties.</p> <p>If a case is circulated by other than an RN, the operative record will be co-authored by the RN who was immediately available. The term “Immediate availability” precludes simultaneous primary circulating duties.</p>	<p style="text-align: center;"><u>INTERVIEW & DOCUMENT REVIEW</u></p> <ol style="list-style-type: none"> 1. If LPNs and surgical technologists (STs) are assisting with circulating duties, verify that they do so in accordance with applicable State laws and medical-staff approved policies and procedures. 2. Verify in situations where LPNs and STs are permitted to assist with circulating duties that a qualified RN supervisor is immediately available to respond to emergencies. 3. Verify that RNs working as circulating nurses are working in accordance with applicable State laws and medical-staff approved policies and procedures. 4. If a case is circulated by other than an RN, an appropriate mechanism is in place for the immediate supervision and availability of an RN (within the suite); the medical record is co-authored by the supervising RN. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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<p>30.00.05 Surgical Privileges. <i>Surgical privileges must be delineated for all practitioners performing surgery in accordance with the competencies of each practitioner.</i></p> <p><i>The surgical service must maintain a roster of practitioners specifying the surgical privileges of each practitioner.</i></p> <p>§482.51(a)(4)</p>	<p>Surgical privileges must be reviewed and updated at least every 2 years.</p> <p>A current roster listing each practitioner’s specific surgical privileges must be available in the surgical suite and area/location where the scheduling of surgical procedures is done.</p> <p>A current list of surgeons suspended from surgical privileges or whose surgical privileges have been restricted must also be retained in these areas / locations.</p> <p><u>Surgical Privileges</u></p> <ol style="list-style-type: none"> 1. The hospital must delineate the surgical privileges of all practitioners performing surgery and surgical procedures. 2. The medical staff is accountable to the governing body for the quality of care provided to patients. 3. The medical staff bylaws must include criteria for determining the privileges to be granted to an individual practitioner in all categories utilized and a procedure for applying the criteria to individuals requesting privileges. 4. Surgical privileges are granted in accordance with the competencies of each practitioner. 5. The medical staff appraisal procedures must evaluate each individual practitioner’s training, 	<p style="text-align: center;"><u>DOCUMENT REVIEW</u></p> <ol style="list-style-type: none"> 1. Review the hospital’s method for reviewing the surgical privileges of practitioners. This method should require a written assessment of the practitioner’s training, experience, health status, and performance. 2. Determine that a current roster listing each practitioner’s specific surgical privileges is current and complete and available in the surgical suite and the area where the scheduling of surgical procedures is done. 3. Determine that a current list of surgeons suspended from surgical privileges or who have restricted surgical privileges is retained in these areas/locations. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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	<p>education experience, and demonstrated competence as established by the hospital's QAPI program, credentialing process, the practitioner's adherence to hospital policies and procedures and in accordance with scope of practice and other State laws and regulations.</p> <p>6. The hospital must specify the surgical privileges for each practitioner that performs surgical tasks. This would include practitioners such as:</p> <ul style="list-style-type: none"> • Doctor of Medicine / Doctor of Osteopathic Medicine • Dentists • Oral surgeons • Podiatrists • RN first assistants • Nurse practitioners • Surgical physician assistants • Surgical technicians, etc. <p>7. When a practitioner may perform certain surgical procedures under supervision, the specific tasks / procedures and the degree of supervision (to include whether or not the supervising practitioner must be physically present in the same OR, in line of sight of the practitioner being supervised) are delineated in that practitioner's surgical privileges and included on the surgical roster.</p> <p>8. Credentialing and privileging criteria requirements apply to all categories of practitioners utilized in</p>		

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the facility. The granting of surgical privileges is a function of governance upon the recommendation of the Professional Medical Staff. Initial and revised / renewed privileges are copied to the surgical services.

9. **If the hospital utilizes RN First Assistants, surgical PA, or other non-MD/DO surgical assistants, the hospital must establish criteria, qualifications and a credentialing process to grant specific privileges to individual practitioners based on each individual practitioner’s compliance with the privileging/credentialing criteria and in accordance with Federal and State laws and regulations. This would include surgical services tasks conducted by these practitioners while under the supervision of an MD/DO.**

10. **When practitioners whose scope of practice for conducting surgical procedures requires the direct supervision of an MD/DO surgeon, the term “supervision” would mean the supervising MD/DO surgeon is present in the same room, working with the same patient.**

11. **Surgery and all surgical procedures must be conducted by a practitioner who meets the medical staff criteria and procedures for the privileges granted, who has been granted specific surgical privileges by the governing body in accordance with those criteria, and who is working within the scope of those granted and**

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documented privileges.

30.00.06 Not Applicable.

30.00.07 First Assistants.

The Medical Staff Rules and Regulations and/or policies identify:

1. Hazardous cases which require a physician first assistant to be scrubbed.
2. The types of cases wherein a qualified non-physician first assistant may be scrubbed.

The facility has a policy that:

1. Defines the hazardous procedures performed at the facility. The definition of "hazardous" procedures may vary from one facility to another. As an example, open cranial and thoracic procedures are noted as those requiring a physician first assistant.
2. The Medical Staff Rules should delineate the "qualification" process for non-physician first assistants.
3. Defines cases that require:
 - a. A scrubbed physician first assistant
 - b. A scrubbed non-physician first assistant

DOCUMENT REVIEW

Verify:

1. The Rules and Regulations or policy lists the hazardous cases that require a physician first assistant.
2. The policy regarding use of first assistants is available; practice is compliant with policy.

- 1 = Compliant
 2 = Not Compliant

This standard is not met as evidenced by:

30.00.08 Physician Availability.

The Medical Staff Rules and Regulations and/or policies require that when the entire surgical team is non-physician that a physician be immediately available to the procedure.

When the surgeon is a dental or podiatric (non-physician) practitioner, and the anesthesia provider is non-physician:

- There shall be evidence that a physician responsible for management of medical crises has been notified of the case start and is immediately available to provide intervention (three to five minutes).

DOCUMENT REVIEW & INTERVIEW

Verify:

1. If a case is entirely non-physician, the medical record reflects that a physician is notified, accepts accountability, and is immediately available.
2. The Rules and Regulations describe this

- 1 = Compliant
 2 = Not Compliant

This standard is not met as evidenced by:

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30.00.09 Standards of Practice.
Surgical services must be consistent with needs and resources.

Policies governing surgical care must be designed to assure the achievement and maintenance of high standards of medical practice and patient care.

§482.51(b)

- Policies governing surgical care should contain:**
1. Aseptic and sterile surveillance and practice, including scrub techniques.
 2. Identification of infected and non-infected cases.
 3. Housekeeping requirements / procedures.
 4. Patient care requirements, **including:**
 - a. preoperative work-up,
 - b. patient consents and releases,
 - c. clinical procedures,
 - d. safety practices,
 - e. patient identification procedures.
 5. Duties of scrub and circulating nurse.
 6. Safety practices, including patient identification, site identification, procedure verification, and surgical counts.

scenario for ensuring physician availability.

3. Staff is knowledgeable of this process.

DOCUMENT REVIEW

Review the Surgical Services policy manual.
 Verify:

1. All required policies are in place and enforced. Policies reflect current practice.
2. The Surgical Services policy manual reflects current practice and has been reviewed and approved within the last three **(3)** years by all appropriate individuals / groups.
3. Practices in remote locations are consistent with the Surgical Service Standards for Practice, (i.e., draping, setting up "back table, etc.)
4. **Review policies and procedures to determine whether they address the elements specified in the interpretive guidelines. If the hospital uses alcohol-based skin preparations in anesthetizing locations,**

- 1 = Compliant
 2 = Not Compliant

This standard is not met as evidenced by:

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	<p>7. The requirement to conduct surgical counts in accordance with accepted standards of practice.</p> <p>8. Scheduling of patients for surgery.</p> <p>9. Personnel policies unique to the OR.</p> <p>10. Resuscitative techniques.</p> <p>11. DNR status.</p> <p>12. Care of surgical specimens, including collection, labeling, handling, and processing methods.</p> <p>13. Malignant hyperthermia.</p> <p>14. Appropriate protocols for all surgical procedures performed. These may be procedure-specific or general in nature and will include a list of equipment, materials, and supplies necessary to properly carry out job assignment.</p> <p>15. Sterilization and disinfection procedures.</p> <p>16. Acceptable operating room attire.</p> <p>17. Handling infectious, biomedical, and medical waste.</p> <p>18. Outpatient surgery postoperative care planning and coordination, and provisions for follow-up care.</p>	<p>determine whether it has adopted policies and procedures to minimize the risk of surgical fires.</p> <p style="text-align: center;"><u>OBSERVATION & INTERVIEW</u></p> <p>Verify that all of the required policies are being enforced. Practice is consistent with policy.</p> <p>1. Interview surgical services staff to determine whether they are aware of and follow hospital policies and procedures.</p>	

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There is a policy manual governing activities in all operative/invasive procedure locations.

- This includes the "main" operating room and all remote surgical suites, including cesarean and general delivery rooms, endoscopy and invasive vascular labs.

POLICY APPROVAL

Principles of care are consistent in all locations.

The policies are developed, or are approved, by the Surgical Services Supervisor, Chief of Surgery, administration, Infection Control committee, and the Pharmacy Therapeutics Committees, as appropriate, and the Professional Medical Staff.

Policies and procedures must be written, implemented, and enforced. Surgical services' policies must be in accordance with acceptable standards of medical practice and surgical patient care.

Policies and procedures are developed relating to changes or new technology and procedures. Policies are reviewed and revised as necessary, consistent with state regulations and facility policy, but no less often than triennially.

NOTE: Use of Alcohol-based Skin Preparations in Anesthetizing Locations.

Alcohol-based skin preparations are considered the

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most effective and rapid-acting skin antiseptic, but they are also flammable and contribute to the risk of fire.

It is estimated that approximately 100 surgical fires occur each year in the United States, resulting in roughly 20 serious patient injuries, including one to two deaths annually. (ECRI, "Surgical Fire Safety," *Health Devices* 35 no 2 (February, 2006) 45-66) Fires occur when an ignition source, a fuel source, and an oxidizer come together. Heat-producing devices are potential ignition sources, while alcohol-based skin preparations provide fuel. Procedures involving electro-surgery or the use of cautery or lasers involve heat-producing devices. There is concern that an alcohol-based skin preparation, combined with the oxygen-rich environment of an anesthetizing location could ignite when exposed to a heat-producing device in an operating room. Specifically, if the alcohol-based skin preparation is improperly applied, the solution may wick into the patient's hair and linens or pool on the patient's skin, resulting in prolonged drying time. Then, if the patient is draped before the solution is completely dry, the alcohol vapors can become trapped under the surgical drapes and channeled to the surgical site. (ECRI for Pennsylvania Patient Safety Advisory 2, No. 2 (June, 2005) 13)

On the other hand, surgical site infections (SSI) also pose significant risks to patients; according to the Centers for Disease Control and Prevention (CDC), such infections are the third most commonly reported

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hospital-acquired infections. Although the CDC has stated that there are no definitive studies comparing the effectiveness of the different types of skin antiseptics in preventing SSI, it also states that “Alcohol is readily available, inexpensive, and remains the most effective and rapid-acting skin antiseptic.” (CDC Hospital Infection Control Practices Advisory Committee, “Guideline for Prevention of Surgical Site Infection, 1999,” Infection Control and Hospital Epidemiology April 1999 (Vol 20 No. 4) 251, 257) Hence, in light of alcohol’s effectiveness as a skin antiseptic, there is a need to balance the risks of fire related to use of alcohol-based skin preparations with the risk of surgical site infection.

The use of an alcohol-based skin preparation in inpatient or outpatient anesthetizing locations is not considered safe, unless appropriate fire risk-reduction measures are taken, preferably as part of a systematic approach by the hospital to preventing surgery-related fires.

A review of recommendations produced by various expert organizations concerning use of alcohol-based skin preparations in anesthetizing locations indicates there is general consensus that the following risk reduction measures are appropriate:

- Using skin prep solutions that are:
 - 1) packaged to ensure controlled delivery to the patient in unit dose applicators, swabs, or other similar applicators; and
 - 2) provide clear and explicit manufacturer /

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supplier instructions and warnings. These instructions for use should be carefully followed.

- Ensuring that the alcohol-based skin prep solution does not soak into the patient’s hair or linens. Sterile towels should be placed to absorb drips and runs during application and should then be removed from the anesthetizing location prior to draping the patient.
- Ensuring that the alcohol-based skin prep solution is completely dry prior to draping. This may take a few minutes or more, depending on the amount and location of the solution. The prepped area should be inspected to confirm it is dry prior to draping.
- Verifying that all of the above has occurred prior to initiating the surgical procedure. This can be done, for example, as part of a standardized pre-operative “time out” used to verify other essential information to minimize the risk of medical errors during the procedure.

Hospitals that employ alcohol-based skin preparations in anesthetizing locations should establish appropriate policies and procedures to reduce the associated risk of fire. They should also document the implementation of these policies and procedures in the patient’s medical record.

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Failure by a hospital to develop and implement appropriate measures to reduce the risk of fires associated with the use of alcohol-based skin preparations in anesthetizing locations should be cited as **condition-level noncompliance**.

30.00.10 History & Physical.

Prior to surgery or a procedure requiring anesthesia services and except in the case of emergencies:
 (i) *A medical history and physical examination must be completed and documented no more than 30 days before or 24 hours after admission or registration.*
 (ii) *An updated examination of the patient, including any changes in the patient's condition, must be completed and documented within 24 hours after admission or registration when the medical history and physical examination are completed within 30 days before admission or registration.*

§482.51(b)(1)

There must be a complete history and physical examination (**H&P**), and an **update, if applicable**, in the medical record of every patient prior to surgery, or a procedure requiring anesthesia services, except in emergencies.

1. **The H&P must be conducted in accordance with the requirements of 42 CFR 482.22(c)(5).**
2. The history and physical must be **completed and documented** no more than 30 days **before** or 24 hours after hospital admission or registration. **In all cases, except for emergencies, the H&P must be completed and documented before the surgery or procedure takes place, even if that surgery or procedure occurs less than 24 hours after admission or registration.**
3. If the H&P was completed within 30 days **before** of admission **or registration, then** an updated examination **must be completed and documented** within 24 hours **after** admission or registration. **In all cases, except for emergencies, the update must be completed and documented before the surgery or procedure takes place,**

CHART REVIEW

Review a **sample of open and closed medical records of patients (both inpatient and outpatient) who have had surgery or a procedure requiring anesthesia.**

1. **Determine whether an H&P was conducted and documented in a timely manner.**

- A history and physical has been completed according to the required timeline and is placed in the medical record within 24 hours of admission or registration and in all cases prior to surgery or a procedure requiring anesthesia services. (In emergent cases a brief admission note with the critical patient information and vital signs is documented in the medical record.)
- A history and physical completed within 30 days of admission is acceptable if an updated medical history and physical examination is completed including any changes; the update is documented and

- 1 = Compliant
- 2 = Not Compliant

This standard is not met as evidenced by:

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	<p>even if that surgery or procedure occurs less than 24 hours after admission or registration.</p> <p>The documented history and physical is placed in the patient’s medical record within 24 hours of admission or registration and prior to any surgery or procedure requiring anesthesia services.</p> <p>Any history and physical conducted more than 30 days prior to admission is not acceptable and must be repeated.</p> <ol style="list-style-type: none"> 1. A physician, oromaxillofacial surgeon, or other qualified individual is expected to review the history and physical that was completed prior to admission and conduct an assessment and include any changes since the initial examination. 2. If there are no changes to the history and physical: The practitioner is expected to prepare a medical record entry update indicating that the history and physical was reviewed, the patient examined, and that the physician concurs with the findings of the history and physical completed on the specified date. 3. The updated medical history and physical is attached to the original history and physical within 24 hours of admission or registration and prior to any surgery or a procedure requiring anesthesia services. 	<p>placed in the medical record within 24 hours of admission or registration and before surgery or a procedure requiring anesthesia services. This update must be attached to the original history and physical.</p> <ol style="list-style-type: none"> 2. Determine whether the H&P was conducted in accordance with the requirements of 42 CFR 482.22(c)(5). 3. Determine whether the records of patients who did not have a timely H&P or update indicate that the surgery or procedure was conducted on an emergency basis. 	

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<p>4. If patient changes are identified during the updated evaluation, the practitioner documents the changes in the updated note.</p> <p>30.00.11 Informed Consent. <i>A properly executed Informed Consent Form for the operative procedure must be in the patient's chart prior to the procedure, except in emergencies.</i></p> <p>§482.51(b)(2)</p> <p><i>The medical record must contain properly executed informed consent forms for procedures and treatments specified by the medical staff, or by federal or state law if applicable, to require written patient consent.</i></p> <p>§482.24(c)(2)(v)</p>	<p>PATIENT SAFETY INITIATIVE</p> <p>The medical record contains a properly executed informed consent form for procedures and treatments in accordance with standard 10.01.06 (§482.24(c)(4)(v)).</p> <p>Informed consents will be written in simple sentences (4th grade comprehension level) and in the primary language of the patient.</p> <p>Interpreter services will be provided as need is identified.</p> <p>After the informed consent discussion has occurred, the patient or legal representative will be asked to recount what he or she has been told.</p> <p>Informed consent is addressed in two other portions of the CMS Hospital CoPs and the SOMI. Surveyors should review the guidelines for §482.13(b)(2) under Patients' Rights and the guidelines for §482.24(c)(2)(v) under Medical Records to understand all requirements related to informed consent.</p>	<p><u>DOCUMENT REVIEW, CHART REVIEW, AND INTERVIEW</u></p> <p>Review the medical records of post-surgical inpatients and outpatients. Review surgery department policies.</p> <p>Verify:</p> <ol style="list-style-type: none"> 1. The medical staff has specified which procedures are considered surgery and, thus, are those that require a properly executed informed consent form. 2. The medical record contains a properly executed informed consent form for each procedure or treatment performed, per hospital policy. 3. The facility provides a properly executed Informed Consent form in the language that the patient can understand. The informed consent contains the twelve required components. Determine that the informed consent contains the information in the explanation is a way that a layperson can understand. 	<p>Scoring deferred to Standard #10.01.16</p>

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	<p>The primary purpose of the informed consent process for surgical services is to ensure that the patient, or the patient’s representative, is provided information necessary to enable him/her to evaluate a proposed surgery before agreeing to the surgery. Typically, this information would include potential short- and longer-term risks and benefits to the patient of the proposed intervention, including the likelihood of each, based on the available clinical evidence, as informed by the responsible practitioner’s professional judgment. Informed consent must be obtained, and the informed consent form must be placed in the patient’s medical record, prior to surgery, except in the case of emergency surgery.</p> <p>Hospitals must assure that the practitioner(s) responsible for the surgery obtain informed consent from patients in a manner consistent with the hospital’s policies governing the informed consent process.</p> <p>It should be noted that there is no specific requirement for informed consent within the regulation at §482.52 governing anesthesia services. However, given that surgical procedures generally entail use of anesthesia, hospitals may wish to consider specifically extending their informed consent policies to include obtaining informed consent for the anesthesia component of the surgical procedure.</p>	<p style="text-align: center;"><u>INTERVIEW</u></p> <p>Interview the staff and medical staff regarding the process for patient verbalization of understanding.</p> <p>Interview patients, if possible regarding the informed consent process.</p> <ol style="list-style-type: none"> 1. Verify that the hospital’s informed consent policies address the circumstances when a surgery would be considered an emergency and thus not require an informed consent form be placed in the medical record prior to surgery. 2. Review a minimum of six medical records of surgical patients and verify that they did not involve emergency surgery and that they contain informed consent forms that were executed prior to the surgery. When possible, review medical records of patients who are about to undergo surgery, or who are located in a surgical recovery area. 3. Interview two or three post-surgical patients, as appropriate based on their ability to provide a cogent response, or the patients’ representatives to see how satisfied they are with the informed consent discussion prior to their surgery. 	

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PATIENT SAFETY INITIATIVE

In recent years, informed consent forms have largely become legal documents that protect institutions rather than provide information for shared decision-making. Because an estimated 40 million people in the United States are marginally or functionally illiterate and a much larger number are medically illiterate, policies should be implemented to ensure the use of clear informed consent forms that most patients and their families can readily understand. Similarly, providing informed consent should be viewed as an interactive process between healthcare providers and patients, not merely a form for which a signature must be obtained.

Medical staff bylaws should address which procedures and treatments require written informed consent. There may also be applicable federal or state regulations regarding informed consent. The informed consent form should provide evidence that it was properly executed.

Medicare requires an Informed Consent form.

Surgical Informed Consent Policy

Hospitals must assure that the practitioner(s) responsible for the surgery obtains informed consent from patients in a manner consistent with hospital policy.

The hospital’s **surgical informed consent** policy **should describe the following:**

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1. Who may obtain the patient’s informed consent
2. Which procedures require informed consent
3. The circumstances under which surgery is considered an emergency, and may be undertaken without an informed consent.
4. The circumstances when a patient’s representative, rather than the patient, may give informed consent for the surgery.
5. The content of the informed consent form and instructions for completing the form.
6. The process used to obtain informed consent, including how informed consent is to be documented in the medical record.
7. Mechanisms that ensure the informed consent form is properly executed and is in the patient’s medical record prior to the surgery (except in the case of emergency surgery).
8. If the informed consent process and informed consent form are obtained outside the hospital, how the properly executed informed consent form is incorporated into the patient’s medical record prior to surgery.

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If there are additional requirements under State law for informed consent, the hospital must comply with those requirements.

A Well Designed Informed Consent Process:

A well-designed informed consent process would include discussion of the following:

1. Description of the proposed surgery, including the anesthesia to be used;
2. Indications for the proposed surgery;
3. Material risks and benefits for the patient related to the surgery and anesthesia, including the likelihood of each, based on the available clinical evidence, as informed by the responsible practitioner’s clinical judgment. Material risks could include risks with a high degree of likelihood but a low degree of severity, as well as those with a very low degree of likelihood but a high degree of severity;
4. Treatment alternatives, including the attendant material risks and benefits;
5. The probable consequences of declining recommended or alternative therapies;
6. Who will conduct the surgical intervention and administer anesthesia;

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7. Whether physicians other than the operating practitioner, including but not limited to residents, will be performing important tasks related to the surgery, in accordance with the hospital’s policies. Important tasks include:
 - a. opening and closing
 - b. dissecting tissue
 - c. removing tissue
 - d. harvesting grafts
 - e. transplanting tissue
 - f. administering anesthesia
 - g. implanting devices
 - h. placing invasive lines

Informed Consent Forms

See the guidelines for §482.24(c)(2)(v) under Medical Records for discussion of the content of a properly executed informed consent form.

A properly executed consent form must contain at least the following:

1. Name of patient
2. Name of hospital
3. Name of procedure or other type of medical treatment for which consent is being given.
4. Name of The responsible practitioner performing the procedure or administering the medical treatment

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5. Statement that the procedure or treatment, including the anticipated benefits, material risks, and alternative therapies, was explained to the patient or the patient’s legal representative. (Material risks could include risks with a high degree of likelihood but a low degree of severity, as well as those with a very low degree of likelihood but a high degree of severity. Hospitals are free to delegate to the responsible practitioner, who uses the available clinical evidence as informed by the practitioner’s professional judgment, the determination of which material risks, benefits and alternatives will be discussed with the patient.)
6. Alternative procedures and treatments
7. Signature of patient or the patient’s legal representative
8. Date and time the informed consent from is signed by the patient or patient’s legal representative
9. Statement that procedure was explained to patient or guardian
10. Signature and professional designation of person witnessing the consent.
11. Name/signature of person who explained the procedure to the patient or guardian

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12. Additional content of the informed consent form, as required by applicable State law.

The operating surgeon shall show evidence that all risks, benefits, and alternatives of all procedures / surgeries have been discussed with the patient prior to performance of the procedure / surgery.

Situations may arise such that at the time of surgery the actual practitioners who conduct surgical tasks may change.

Prior to surgery and when time and circumstances permit, the patient must be informed of changes in practitioners who will be conducting their surgery.

After surgery, each practitioner’s name, category and specific surgical task conducted will be documented in the operative report.

Use of Surgical Residents

For surgeries in which residents will perform important parts of the surgery, discussion is encouraged to include the following:

1. That it is anticipated that physicians who are in approved post-graduate residency training programs will perform portions of the surgery, based on their availability and level of competence;
2. That it is decided at the time of the surgery which residents will participate and their manner or

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participation, and that this will depend on the availability of the residents with the necessary competence; the knowledge the operating practitioner / teaching surgeon has of the resident’s skill set; and the patient’s condition;

3. That residents performing surgical tasks will be under the supervision of the operating practitioner / teaching surgeon.
4. Whether, based on the resident’s level of competence, the operating practitioner / teaching surgeon will not be physically present in the same operating room for some or all of the surgical tasks performed by residents.

Note: A “moonlighting” resident or fellow is a post-graduate medical trainee who is practicing independently, outside the scope of his/ her residency training program and would be treated as a physician within the scope of the privileges granted by the hospital.

5. Whether, as permitted by State law, qualified medical practitioners who are not physicians will perform important parts of the surgery or administer the anesthesia, and if so, the types of tasks each type of practitioner will carry out; and that such practitioners will be performing only tasks within their scope of practice for which they have been granted privileges by the hospital.

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<p>30.00.12 Required Equipment. The Surgical Services maintains an adequate inventory of instrumentation, supplies and equipment. <i>The following equipment must be available to the operating room suites:</i></p> <ul style="list-style-type: none"> • <i>Call-in-system (intercom or equivalent)</i> • <i>Cardiac monitor</i> • <i>Defibrillator</i> • <i>Aspirator (suction equipment /vacuum)</i> • <i>Resuscitator (ventilator)</i> • <i>Tracheotomy set</i> <p>§482.51(b)(3)</p>	<p>Systems and processes shall be in working order and available for emergency communication and for patient care crises. The availability of oxygen is essential. The use of pulse oximetry and immediate availability of blood gas analysis should be considered as "standard."</p> <p>A cryothyroidotomy set is not a substitute for a tracheotomy set. The term "resuscitator" refers to a hand-held bag type of device; a mechanical ventilator is not required.</p> <p>Adequate equipment must be available to respond to emergencies in more than one location simultaneously. The call-in system must have the capability of summoning help internally as well as externally to the department, as needed.</p> <p>Age-specific resuscitation equipment is required to meet the emergency needs of the patient. If the facility treats pediatric patients, pediatric sized resuscitation equipment is immediately available.</p>	<p style="text-align: center;"><u>OBSERVATION</u></p> <p>Tour the surgical and invasive procedure rooms.</p> <ol style="list-style-type: none"> 1. Verify all required systems are working. 2. Verify all required equipment is readily available with adequate inventory for patient care. 3. Verify that all equipment is working and, as applicable, in compliance with the hospital's biomedical inspection, testing, and maintenance program. 4. Age-specific resuscitation equipment is readily available. If the facility treats pediatric patients, ensure pediatric size endotracheal tubes / tracheostomy set are immediately available. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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<p>30.00.13 <u>Supply and Instrumentation Availability & Sterilization.</u> Instrumentation, supplies, and equipment are sufficient in quantity so that movement in and out of the area is minimized during cases.</p> <p>Processed instruments are protected from surface / airborne contamination.</p> <p>“IUSS” (Immediate Use Steam Sterilization formerly known as "Flash" sterilization) is limited to rare circumstances.</p> <p>The facility follows IUSS criteria and guidelines for sterilization.</p> <p>Shipping cartons are not permitted in the "clean" environment.</p>	<p>The design of Operating Room and Invasive Procedure Rooms is such that personnel and supply movement provides for the protection of "clean" supplies. Signage, or "red" lines, may be utilized to denote "clean" from general traffic areas.</p> <p>Clean linen and sterile packages are not subject to dust accumulation, moisture, or other potential sources of contamination.</p> <p>“IUSS” (flash sterilization) is not to be used in lieu of adequate instrument inventories.</p> <p>The facility adopts criteria and practices in accordance with manufacturer’s instructions and national guidelines such as CDC, CDC-HICPAC, AORN, AAMI, and etc.</p>	<p style="text-align: center;"><u>OBSERVATION & DOCUMENT REVIEW</u></p> <ol style="list-style-type: none"> 1. Determine that general and "clean" areas are clearly identified. 2. Determine that staff adheres to traffic rules. Movement in and out of the area is minimized. 3. Determine that shipping cartons are neither stored in the clean storage area nor on the floor. 4. Determine that sterile packages are intact and protected from dust, moisture, and other sources of contamination. 5. Determine that the sterilization log demonstrates that IUSS (flash sterilization) is only used for emergency purposes. 6. Determine the facility utilizes IUSS guidelines. 7. Determine the staff utilizes safety measures with the chemicals disinfectants / cold sterilant products. These products are labeled and reflect current dates. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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<p>30.00.14 Operative Site Verification. The facility shall have a policy and procedure that requires documented verification of the operative site before surgery occurs. The operative site verification policy and procedure must define the following:</p> <ol style="list-style-type: none"> 1. Patient involvement in the process. 2. Types of cases requiring marking, but at minimum, cases involving laterality, multiple structures (fingers/toes) or multiple levels (spine) and the process to support completion. 3. Documents/information required in the verification process (i.e., patient interview, consent, H&P, surgery schedule, X-Rays/test results). 4. How discrepancies are handled. 5. Use of a procedural “time out” prior to the start of the procedure which includes verification of: <ul style="list-style-type: none"> • Patient identity • Correct side and site • Agreement on procedure • Availability of implants/special 	<p style="text-align: center;"><u>PATIENT SAFETY INITIATIVE</u></p> <p>The surgeon shall clearly document the <u>intended</u> intervention site in the patient’s records; these records should accompany the patient to the operating room.</p> <p>The operative site must be identified prior to surgery.</p> <p>The non-surgical site must never be marked.</p> <p>Standardization is necessary, in that often medical staff perform procedures in more than one location. Lack of standardization has caused confusion and surgical errors as a result.</p>	<p style="text-align: center;"><u>DOCUMENT REVIEW & FILE REVIEW</u></p> <p>Review the policy and procedure as well as closed medical records to determine that the requirement was met.</p>	<p> <input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant </p> <p>This standard is not met as evidenced by:</p>

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equipment/requirements

- Required documentation for each element

30.00.15 Not Applicable.

30.00.16 Pneumatic Tourniquets.

Whenever a pneumatic tourniquet is used, the patient is evaluated for risk of an ischemic and/or thrombotic complication. Prophylactic measures are instituted, as appropriate.

The requirements to demonstrate standards compliance are as follows:

1. Explicit organizational policies and procedures for the proper use and maintenance of pneumatic tourniquets, including a risk assessment protocol and the plan to prevent complications.
2. Documentation in the patient record of the risk assessment and the complication prevention plan.

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Pneumatic tourniquets are sometimes used to create a bloodless surgical field (e.g., to improve visualization for orthopedic and plastic surgery on the extremities) or for the instillation of regional anesthesia to the limb.

Ischemic neuromuscular injury may occur if the tourniquet remains inflated too long. Direct pressure injury to nerves may also occur. Additionally, tourniquet inflation and deflation may depress cardio-respiratory function in the perioperative period, including causing “showers” of embolic debris to the heart, which may in turn cause a pulmonary embolism.

Examples of approaches for implementation are as follows:

1. Provide training in the proper use of the pneumatic tourniquet device for all perioperative staff.
2. Perform regular inspection and maintenance of

DOCUMENT REVIEW & CHART REVIEW

Review organizational policy on use of the pneumatic tourniquet. Review patient records. Verify:

1. A policy on the use of the pneumatic tourniquet is in place; all required content is included
2. The medical record provides evidence of care consistent with the pneumatic tourniquet policy, including a risk assessment and plan for prevention of complications.

- 1 = Compliant
- 2 = Not Compliant

This standard is not met as evidenced by:

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the device according to the manufacturer’s written instructions.

3. Ensure proper fit of the device by selecting the proper size and appropriate positioning of the tourniquet cuff.
4. Keep tourniquet inflation time to a minimum.
5. Keep tourniquet inflation pressure to a minimum.
6. Follow inflation and deflation procedures as recommended by the manufacturer.
7. Perform continuous monitoring of the tourniquet inflation time and pressure display.

30.00.17 Postoperative Care.

There must be adequate provisions for immediate postoperative care.

§482.51(b)(4)

Adequate provisions for immediate post-operative care includes:

1. Post-operative care must be **provided to all surgical patients, including same-day surgery patients**, in accordance with acceptable standards of practice.
2. A post-operative care area, **usually referred to as the post-anesthesia care unit (PACU)**, is a separate area of the hospital. Access is limited to authorized personnel.
3. Policies and procedures specify transfer requirements to and from the **PACU**.

DOCUMENT REVIEW & OBSERVATION

Verify:

1. The hospital has provisions for postoperative care. Patient assessments are consistent with policy.
2. There are policies and procedures that govern the recovery room area and consistently used throughout the organization.
3. Observe care provided to patients in a PACU to determine whether patients are monitored and assessed appropriately prior to transfer or discharge (in the case of same-day surgery

- 1 = Compliant
 2 = Not Compliant

This standard is not met as evidenced by:

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	<p>4. Depending on the type of anesthesia and length of surgery, the post-operative check before transferring the patient from the PACU includes, but is not limited to:</p> <ul style="list-style-type: none"> a. Level of activity b. Respirations c. Blood pressure d. Level of consciousness e. Level of pain f. Patient color g. Cardiac status <p>5. If a patient is not transferred to the PACU, determine that provisions are made for close observation until the patient has regained consciousness, e.g., direct observation by a qualified RN in the patient's room.</p>	<p>patients) from the PACU.</p> <p>4. Does the hospital have a system for identifying and addressing the monitoring needs of post-operative patients transferred from the PACU to other areas of the hospital?</p> <p>5. Ask staff in the PACU and in units who receive patients from the PACU how the needs of post-operative patients for vigilant monitoring is addressed when the patients are transferred from the PACU to other areas of the hospital.</p>	

POST-OPERATIVE MONITORING

Hospitals are expected to develop and implement policies and procedures addressing the minimum scope and frequency of patient monitoring in post-PACU care settings, consistent with accepted standards of practice.

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Patients receiving post-operative intravenous (IV) opioid medications are of particular concern, due to the higher risk for over-sedation and respiratory depression¹⁰.

Once out of the PACU, patients receiving IV opioid medication may be placed on units where vital signs and other monitoring traditionally has not been done as frequently as in the PACU or intensive care units, increasing the risk that patients may develop respiratory compromise that is not immediately recognized and treated. (See the interpretive guidelines at §482.23(c)(4)).

When post-surgical patients are transferred out of the PACU to another area of the hospital but continued on IV opioid medications, they need vigilant monitoring, even if post-PACU care is not typically referred to as “immediate” post-operative care.

Opioid- induced respiratory compromise has resulted in inpatient deaths that might have been prevented with appropriate assessment and vigilant monitoring of respiration and sedation levels.¹¹

¹⁰ *Institute for Safe Medication Practices (ISMP), Medication Safety Alert- High Alert Medication Feature Reducing Patient Harm from Opiates. February 22, 2007.*

¹¹ *Institute for Safe Medication Practices (ISMP), Medication Safety Alert – Fatal PCA Adverse Events*

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Continue to Happen...Better Patient Monitoring is Essential to Prevent Harm. May 30, 2013

30.00.18 Operating Room Register.
The operating room register(s) must be complete and up-to-date.

§482.51(b)(5)

Registers may separately exist for operative/invasive procedures accomplished in remote locations such as cesarean delivery rooms, endoscopy, cardiac catheterization labs, etc. Whether these are manual journals, or electronic logs, the data are consistent.

The Register includes at least the following information:

1. Patient's name
2. Patient's hospital identification number
3. Date of the operation
4. Inclusive or total time of the operation
5. Identity of the surgeon and any assistant(s)
6. Name of nursing personnel (scrub and circulating)
7. Type of anesthesia used and name of person administering it
8. Operation performed
9. Pre and post-op diagnosis
10. Age of patient.

DOCUMENT REVIEW

Examine the OR register or equivalent record which lists all **surgery performed by the surgery service.**

Determine:

1. The register includes all items **specified in the interpretative guidelines.**
2. **The register is current.**
3. The register is used in all operative / invasive procedure areas.

- 1 = Compliant
 2 = Not Compliant

This standard is not met as evidenced by:

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<p>30.00.19 Operative Report. <i>An operative report describing-</i></p> <ul style="list-style-type: none"> • <i>Techniques,</i> • <i>Findings, and</i> • <i>Tissues removed or altered must be written or dictated immediately following surgery and signed by the surgeon.</i> <p>§482.51(b)(6)</p>	<p>The operative/procedure report is made <u>immediately</u> available so that care of the patient is "transferable" if the surgeon is unable to attend to the immediate needs of the patient.</p> <p>If handwritten, the Operative Report is legible.</p> <p>If dictated, the Operative Report is printed and in the medical record no more than 24 hours after the procedure.</p> <p>The operative report includes at least :</p> <ol style="list-style-type: none"> 1. Name and hospital identification number of the patient. 2. Date and times of the surgery. 3. Name(s) of the surgeon(s) and assistants or other practitioners who performed surgical tasks. 4. Pre-operative and post-operative diagnosis. 5. Name of the specific surgical procedure(s) performed. 6. Type of anesthesia administered. 7. Complications, if any. 8. A description of techniques, findings, and tissues removed or altered. 	<p style="text-align: center;"><u>CHART REVIEW</u></p> <ol style="list-style-type: none"> 1. Review a minimum of six medical records of patients who had a surgical encounter. Verify an operative / procedure report is immediately available in the medical record. 2. Verify that they contain a surgical report that is dated and signed by the responsible surgeon and includes the information specified in the interpretive guidelines. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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9. Prosthetic devices, grafts, tissues, transplants, or devices implanted, if any.
10. Surgeon(s) or practitioner’s names and a description of specific significant surgical tasks that were conducted by practitioners other than the primary surgeon/practitioner (**significant surgical procedures include: Opening and closing, harvesting grafts, dissecting tissue, removing tissue, implanting devices, altering tissues**).

30.00.20 Pathology Review Exemptions.

All tissues and foreign bodies not submitted for pathologic review shall be described and recorded in the medical record by the operating surgeon or physician removing the tissue or foreign body.

The facility has a policy, approved by the medical staff, that specifies the required documentation and description relative to removal of tissues/foreign bodies. At a minimum, the policy addresses:

1. The detailed descriptions and photographs that are to be included in the medical record for all foreign bodies of potential medico legal significance.
2. The recording of the model number or serial numbers of orthopedic appliances,
3. An accurate count of teeth from partial or full mouth extractions.
4. The process to ensure strict chain-of-custody to be maintained on all foreign bodies or other specimens of potential medico-legal importance.

CHART REVIEW

Review five (5) medical records of patients who have had foreign bodies removed or foreign bodies implanted (e.g., orthopedic appliances).

Verify:

1. The required policy, approved by the Medical Staff, is in place.
2. Medical record documentation includes a description and model numbers of tissue or foreign bodies removed.

- 1 = Compliant
- 2 = Not Compliant

This standard is not met as evidenced by:

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<p>30.00.21 <u>Label Medications & Solutions on and off the Sterile Field.</u> The facility must develop and implement policies for safe labeling of medications and solutions used on and off the sterile field in the perioperative settings.</p> <p>The facility must have policies and processes in place including, but not limited to:</p> <ol style="list-style-type: none"> 1. The required labeling of medications and solutions, regardless of container, used on and off the sterile field throughout the perioperative experience. 2. The methods used to differentiate and label look-alike products and solutions with similar names. 3. The process used to verify and confirm each medication / solution and the respective matching label. 	<p style="text-align: center;"><u>PATIENT SAFETY INITIATIVE</u></p> <p>In recent years, there have been numerous reports of death or serious injury secondary to unlabeled medications and solutions on the sterile field.</p> <p>All surgery settings and procedure rooms are expected to handle chemicals, reagents, specimen preservation agents, and diluents with the same caution as medications.</p> <p>A process must be in place to label all solutions used in the surgical area including, but not limited to intravenous fluids, medications, body fluids, hydrogen peroxide, formalin, Lugol’s solution, radiopaque dyes, sterile saline, sterile water, isopropyl alcohol, skin preparation solutions, chlorhexidine, glutaraldehyde, and the like. Many of the above “look alike” as they are clear / colorless solutions.</p> <p>Labels must be applied to solutions stored in all types of containers used on and off the surgical field in the perioperative area including, but not limited to medicine cups, solution basins, syringes, and specimen cups.</p> <p>A label is required even if only one solution is involved with the procedure.</p> <p>It would be unacceptable to write onto plastic containers such as IV bags with marking pens, as there is evidence that the ink may penetrate into the solution.</p>	<p style="text-align: center;"><u>DOCUMENT REVIEW</u></p> <p>Review policies and practices relative to medication preparation. Determine that systems are in place relating to:</p> <ol style="list-style-type: none"> 1. Required labeling of solutions and medications on and off the sterile field. 2. Procedure for differentiating look-alike and sound-alike medications / solutions. 3. Procedure for individually verifying medications / solutions and respective labels. 	<p>Scoring deferred to 25.01.27</p>

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Sterile medications / solutions that are placed onto the sterile field in the original packaging with the manufacturer’s original label on the container that indicates the name and strength of the medication do not require additional labeling.

Use sterile markers and labels that can be opened onto the sterile field. Commercially prepared products are available for this purpose, but labels prepared by the facility are acceptable if sterilization is maintained. Labels are to clearly state the medication / solution and strength. When feasible, include these labels and markers in pre-made surgical packs.

Many medications and solutions have similar names. A process must be identified and implemented when preparing labels to differentiate these.

A process must be in place to verify each medication or solution and complete its preparation, labeling, and delivery to the sterile field before preparing the next solution. Label only one medication / solution at a time. Use two staff to verbally and visually confirm each medication / solution and respective label; one of these staff must be a licensed professional involved with the procedure.

A process must be in place to discard any unlabeled solution or medication found in the perioperative area. Unlabeled solutions should be considered a hazardous condition and reported using the facility incident reporting protocol.

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At shift change or relief for breaks, require the entering and exiting staff to concurrently read container labels and verify all medications on the sterile field.

Keep original medication / solution containers in the surgical room until completion of the procedure for follow-up reference, if indicated.

References:

1. Medication Safety Alert, December 2, 2004, *The Institute for Safe Medication Practices*.
2. *AORN Guidance Statement: Safe Medication Practices in Perioperative Practice Settings, 2004*.

30.00.22 Not Applicable.

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<p>30.01.00 Condition of Participation: Medical Leadership for Anesthesia Services. <i>If the hospital furnishes anesthesia services, they must be provided in a well-organized manner under the direction of a qualified Doctor of Medicine or Doctor of Osteopathic Medicine.</i></p> <p><i>The service is responsible for all anesthesia administered in the hospital.</i></p> <p>§482.52</p>	<p>A qualified physician is identified as the Medical Director of anesthesia services.</p> <p>A single anesthesia director must be responsible for the single hospital-wide anesthesia service.</p> <p>The provision of anesthesia services is an optional hospital service. However, if a hospital provides any degree of anesthesia service to its patients, the hospital must comply with all the requirements of this Condition of Participation (CoP).</p> <p>If a facility offers surgical or obstetric services there shall be the provision for anesthesia services.</p> <p>“Anesthesia” involves the administration of a medication to produce a blunting or loss of:</p> <ul style="list-style-type: none"> • pain perception (analgesia); • voluntary and involuntary movements; • autonomic function; and • memory and/or consciousness, <p>depending on where along the central neuraxial (brain and spinal cord) the medication is delivered.</p> <p>In contrast, “analgesia” involves the use of a medication to provide relief of pain through the blocking of pain receptors in the peripheral and/or central nervous system. The patient does not lose consciousness, but does not perceive pain to the extent that may otherwise prevail.</p>	<p style="text-align: center;"><u>DOCUMENT REVIEW, FILE REVIEW & INTERVIEW</u></p> <p>Request a copy of the organizational chart for anesthesia services. Review the position description.</p> <ol style="list-style-type: none"> 1. Determine that a Doctor of Medicine or Doctor of Osteopathic Medicine has the authority and responsibility for directing all anesthesia services throughout the hospital. 2. Look for evidence in the director’s file of the director’s appointment privileges and qualifications, consistent with the criteria adopted by the hospital’s governing body. Review the position description. 3. Confirm that the director’s responsibilities include at least the following: <ul style="list-style-type: none"> • Planning, directing, and supervising all activities of the service; • Establishing staffing schedules for coverage when the service is normally closed; • Evaluating the quality and appropriateness of anesthesia services provided to patients as part of the hospital’s QAPI program; and • Anesthesia services in all areas of the 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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	<p>Anesthesia exists along a continuum. For some medications there is no bright line that distinguishes when their pharmacological properties bring about the physiologic transition from the analgesic to the anesthetic effects. Furthermore, each individual patient may respond differently to different types of medications. The additional definitions below illustrate distinctions among the various types of “anesthesia services” that may be offered by a hospital. These definitions are generally based on American Society of Anesthesiologists definitions found in its most recent set of practice guidelines (Anesthesiology 2002; 96:1004-17).</p> <ul style="list-style-type: none"> • General Anesthesia: a drug-induced loss of consciousness during which patients are not arousable, even by painful stimulation. The ability to independently maintain ventilatory support is often impaired. Patients often require assistance in maintaining a patent airway, and positive pressure ventilation may be required because of depressed spontaneous ventilation or drug-induced depression of neuromuscular function. Cardiovascular function may be impaired. For example, a patient undergoing major abdominal surgery involving the removal of a portion or all of an organ would require general anesthesia in order to tolerate such an extensive surgical procedure. General anesthesia is used for those procedures when loss of consciousness is required for the safe and effective delivery of surgical services; 	<p>hospital.</p> <ol style="list-style-type: none"> 4. The director of anesthesia is responsible for anesthesia services delivered in all areas of the hospital where applicable including operating room suites, both inpatient and outpatient, obstetrical suites, the radiology department, clinics and outpatient surgery areas. 5. Anesthesia services are integrated into the hospital-wide QAPI program. 6. Request a copy of and review the hospital’s anesthesia services policies and procedures. <ul style="list-style-type: none"> • Do they apply in all hospital locations where anesthesia services are provided? • Do they indicate the necessary qualifications that each clinical practitioner must possess in order to administer anesthesia as well as moderate sedation or other forms of analgesia? • Do they address what clinical applications are considered to involve analgesia, in particular moderate sedation, rather than anesthesia, based on identifiable national guidelines? What are the national guidelines that they are 	

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	<ul style="list-style-type: none"> • Regional Anesthesia: the delivery of anesthetic medication at a specific level of the spinal cord and/or to peripheral nerves, including epidurals and spinals and other central neuraxial nerve blocks, is used when loss of consciousness is not desired but sufficient analgesia and loss of voluntary and involuntary movement is required. Given the potential for the conversion and extension of regional to general anesthesia in certain procedures, it is necessary that the administration of regional and general anesthesia be delivered or supervised by a practitioner as specified in 42 CFR §482.52(a). • Monitored Anesthesia Care (MAC): anesthesia care that includes the monitoring of the patient by a practitioner who is qualified to administer anesthesia as defined by the regulations at §482.52(a). Indications for MAC depend on the nature of the procedure, the patient’s clinical condition, and/or the potential need to convert to a general or regional anesthetic. Deep sedation/analgesia is included in MAC. <ul style="list-style-type: none"> ○ Deep Sedation / Analgesia: a drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully following repeated or painful stimulation. The ability to independently maintain ventilatory function may be 	<p style="text-align: right;">following and how is that documented?</p> <p>7. Does the hospital have a system by which adverse events related to the administration of anesthesia and analgesia, including moderate sedation, are tracked and acted upon?</p>	

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impaired. Patients may require assistance in maintaining a patent airway, and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained. Because of the potential for the inadvertent progression to general anesthesia in certain procedures, it is necessary that the administration of deep sedation/analgesia be delivered or supervised by a practitioner as specified in 42 CFR §482.52(a).

- **Moderate Sedation/Analgesia: (Conscious Sedation):** a drug-induced depression of consciousness during which patients respond purposefully to verbal commands, either alone or accompanied by light tactile stimulation. No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is usually maintained. CMS, consistent with ASA guidelines, does not define moderate or conscious sedation as anesthesia (71 FR 68690-1).
- **Minimal Sedation:** a drug-induced state during which patients respond normally to verbal commands. Although cognitive function and coordination may be impaired, ventilator and cardiovascular functions are unaffected. This is also not anesthesia.

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- Topical or Local Anesthesia:** the application or injection of a drug or combination of drugs to stop or prevent a painful sensation to a circumscribed area of the body where a painful procedure is to be performed. There are generally no systemic effects of these medications, which also are not anesthesia, despite the name.

Rescue Capacity: As stated above, because the level of sedation of a patient receiving anesthesia services is a continuum, it is not always possible to predict how an individual patient will respond. Further, no clear boundary exists between some of these services. Hence, hospitals must ensure that procedures are in place to rescue patients whose level of sedation becomes deeper than initially intended, for example, patients who inadvertently enter a state of Deep Sedation/Analgesia when Moderate Sedation was intended.

- “**Rescue**” from a deeper level of sedation than intended requires an intervention by a practitioner with expertise in airway management and advanced life support. The qualified practitioner corrects adverse physiologic consequences of the deeper-than-intended level of sedation and returns the patient to the originally intended level of sedation. (Rescue capacity is not only required as an essential component of anesthesia services, but is also consistent with the requirements under the Patients’ Rights standard at §482.13(c)(2),

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guaranteeing patients care in a safe setting.)

Anesthesia services throughout the hospital (including all departments in all campuses and off-site locations where anesthesia services are provided) must be organized into one anesthesia service.

Areas where anesthesia services are furnished may include (but are not limited to):

- Operating room suite(s), both inpatient and outpatient;
- Obstetrical suite(s);
- Radiology department;
- Clinics;
- Emergency department;
- Psychiatry department;
- Outpatient surgery areas;
- Special procedures areas (e.g., endoscopy suite, pain management clinic, etc.)

The anesthesia services must be under the direction of one individual who is a qualified Doctor of Medicine (MD) or Doctor of Osteopathic Medicine (DO).

Consistent with the requirement at §482.12(a)(4) for it to approve medical staff bylaws, rules and regulations, the hospital’s governing body approves, after considering the medical staff’s recommendations, medical staff rules and regulations establishing criteria for the qualifications for the director of the anesthesia services. Such criteria must be consistent with State laws and acceptable standards of practice.

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As previously mentioned, there is often no bright line, i.e., no clear boundary, between anesthesia and analgesia. This is particularly the case with moderate versus deep sedation, but also with respect to labor epidurals. However, the anesthesia services CoP establishes certain requirements that apply only when anesthesia is administered. Consequently, each hospital that provides anesthesia services must establish policies and procedures, based on nationally recognized guidelines that address whether specific clinical situations involve anesthesia versus analgesia. (It is important to note that anesthesia services are usually an integral part of “surgery”, as we have defined that term in our guidance. Because the surgical services CoP at §482.51 requires provision of surgical services in accordance with acceptable standards of practice, this provides additional support for the expectation that anesthesia services policies and procedures concerning anesthesia are based on nationally recognized guidelines.)

We encourage hospitals to address whether the sedation typically provided in the emergency department or procedure rooms involves anesthesia or analgesia. In establishing such policies, the hospital is expected to take into account the characteristics of the patients served, the skill set of the clinical staff in providing the services, as well as the characteristics of the sedation medications used in the various clinical settings.

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The regulation at 42 CFR 482.52(a) establishes the qualifications and, where applicable, supervision requirements for personnel who administer anesthesia. However, hospital anesthesia services policies and procedures are expected to also address the minimum qualifications and supervision requirements for each category of practitioner who is permitted to provide analgesia services, particularly moderate sedation. This expectation is consistent not only with the requirement under this CoP to provide anesthesia services in a well-organized manner, but also with various provisions of the Medical Staff CoP at §482.22 and the Nursing Services CoP at §482.23 related to qualifications of personnel providing care to patients. Taken together, these regulations require the hospital to assure that any staff administering drugs for analgesia must be appropriately qualified, and that the drugs are administered in accordance with accepted standards of practice. Specifically:

- The Medical Staff CoP at §482.22(c)(6) requires the medical staff bylaws, “Include criteria for determining the privileges to be granted to individual practitioners and a procedure for applying the criteria to individuals requesting privileges.”
- The Nursing Services CoP requires at:
 - §482.23(b)(5) that nursing personnel be assigned to provide care based on “the specialized qualifications and competence of the nursing staff

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available.”

- §482.23(c) that, “Drugs and biologicals must be prepared and administered in accordance with Federal and State laws, ...and accepted standards of practice.”

And

- §482.23(c)(3) , “... If ... intravenous medications are administered by personnel other than doctors of medicine or osteopathic medicine, the personnel must have special training for this duty.”

Finally, it is expected that the anesthesia services policies and procedures will undergo periodic re-evaluation that includes analysis of adverse events, medication errors and other quality or safety indicators related not only to anesthesia, but also to the administration of medications in clinical applications that the hospital has determined involve analgesia rather than anesthesia. This expectation is also supported by the provisions of the Quality Assessment and Performance Improvement (QAPI) CoP at §482.21, which requires the hospital to ensure its QAPI program, “...involves all hospital departments and services...”; “...focuses on indicators related to improved health outcomes and the prevention and reduction of medical errors...”; “...track[s] quality indicators, including adverse patient events...”; “...

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use[s] the data collected to monitor the effectiveness and safety of the services and quality of care...”; and “...take[s] actions aimed at performance improvement...”

Hospitals are free to develop their own specific organizational arrangements in order to deliver all anesthesia services in a well-organized manner.

Although not required under the regulation to do so, a well-organized anesthesia service would develop the hospital’s anesthesia policies and procedures in collaboration with several other hospital disciplines (e.g., surgery, pharmacy, nursing, safety experts, material management, etc.) that are involved in delivering these services to patients in the various areas in the hospital.

A well-organized anesthesia service must be integrated into the hospital’s required Quality Assessment/Performance Improvement program, in order to assure the provision of safe care to patients.

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<p>30.01.01 <u>Scope of Service:</u> <u>Anesthesia.</u> <i>The organization of anesthesia services must be appropriate to the scope of the services offered.</i></p> <p>§482.52(a)</p>	<p>A written scope of services describes the anesthesia services provided throughout the organization at all locations, including outpatient services.</p>	<p style="text-align: center;"><u>DOCUMENT REVIEW & OBSERVATION</u></p> <p>Review the anesthesia service policy manual, the organizational chart and the service description. Verify:</p> <ol style="list-style-type: none"> 1. All locations in which anesthesia is administered are included. 2. All techniques used to administer anesthesia are addressed. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>
<p>30.01.02 <u>Anesthesia Providers.</u> <i>Anesthesia must be administered only by:</i></p> <ol style="list-style-type: none"> (1) <i>A qualified anesthesiologist;</i> (2) <i>A Doctor of Medicine or Doctor of Osteopathic Medicine (other than an anesthesiologist);</i> (3) <i>A dentist, oral surgeon, or podiatrist who is qualified to administer anesthesia under State law;</i> (4) <i>A certified registered nurse anesthetist (CRNA), as defined by §410.69 (b) of 42 CFR 410.69, who, unless exempted in accordance with paragraph (c) of 42 CFR 482.52, is under the supervision of the operating practitioner or of an</i> 	<p style="text-align: center;"><u>WHO MAY ADMINISTER ANESTHESIA</u></p> <p><u>Topical/Local Anesthetics, Minimal Sedation, Moderate Sedation:</u> The requirements at §482.52(a) concerning who may administer anesthesia do not apply to the administration of topical or local anesthetics, minimal sedation, or moderate sedation. However, the hospital must have policies and procedures, consistent with State scope of practice law, governing the provision of these types of anesthesia services.</p> <p>Further, hospitals must assure that all anesthesia services are provided in a safe, well-organized manner by qualified personnel.</p> <p><u>General Anesthesia, Regional Anesthesia And Monitored Anesthesia, Including Deep Sedation/Analgesia, may only be administered by:</u></p> <ul style="list-style-type: none"> • A qualified anesthesiologist; 	<p style="text-align: center;"><u>DOCUMENT REVIEW & FILE REVIEW</u></p> <ol style="list-style-type: none"> 1. Examine the medical staff bylaws / policies. 2. Review the qualifications of individuals authorized to administer general anesthesia, regional anesthesia and monitored anesthesia, including deep sedation/analgesia to determine if they satisfy the requirements at 482.52(a) and (c). 3. Review at least three anesthesia provider files. <ul style="list-style-type: none"> • Determine that there is documentation of current licensure and, as applicable, current certification for all persons administering anesthesia. • Each has received privileges to administer anesthesia. 4. Determine if the state is an “opt-out 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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<p><i>anesthesiologist who is immediately available if needed; or</i></p> <p>(5) <i>An anesthesiologist's assistant, as defined in Sec. 410.69 (b) of 42 CFR 410.69, who is under the supervision of an anesthesiologist who is immediately available if needed.</i></p> <p>§482.52(a); §482.52(a)(2); §482.52(a)(3); §482.52(a)(4); §482.52(a)(5)</p> <p>State exemption:</p> <p>(1) <i>A hospital may be exempted from the requirement for Doctor of Medicine/Doctor of Osteopathic Medicine supervision of CRNAs as described in paragraph (a)(4) of 42 CFR 482.52, if the State in which the hospital is located submits a letter to CMS signed by the Governor, following consultation with the State's Boards of Medicine and Nursing, requesting exemption from MD/DO supervision for CRNAs. The letter from the Governor must attest that he or she has consulted with the State Boards of Medicine and</i></p>	<ul style="list-style-type: none"> • A Doctor of Medicine or Doctor of Osteopathic Medicine (other than an anesthesiologist); • A dentist, oral surgeon or podiatrist who is qualified to administer anesthesia under State law; • A CRNA who is supervised by the operating practitioner or by an anesthesiologist who is immediately available if needed; or • An anesthesiologist's assistant under the supervision of an anesthesiologist who is immediately available if needed. <p><u>Administration by an Doctor of Medicine/Doctor of Osteopathic Medicine/Dentist/Oral Surgeon/Podiatrist:</u></p> <p>The hospital's anesthesia services policies must address the circumstances under which a Doctor of Medicine or Doctor of Osteopathic Medicine who is not an anesthesiologist, a dentist, oral surgeon or podiatrist is permitted to administer anesthesia. In the case of a dentist, oral surgeon or podiatrist, administration of anesthesia must be permissible under State law and comply with all State requirements concerning qualifications.</p> <p>Hospitals should conform to generally accepted standards of anesthesia care when establishing policies governing anesthesia administration by these types of practitioners as well as Doctors of Medicine</p>	<p>state" and therefore permits CRNA's to administer anesthesia without supervision in accordance with 482.52(c).</p> <p>5. Review the hospital's policies and procedures governing supervision of CRNAs and anesthesiologist's assistants, and determine whether they comply with the regulatory requirements.</p> <p>6. Review the qualifications of individuals authorized to furnish other anesthesia services, to determine if they are consistent with the hospital's anesthesia service policies.</p> <p>Verify:</p> <ol style="list-style-type: none"> 1. The Bylaws / policies identify the qualifications of individuals authorized to deliver anesthesia. 2. The privilege delineation process describes the scope of practice for each provider. In the case of non-physician providers there is indication of the accountability to the organized medical staff as deemed appropriate by the facility. 3. For States with CRNA Exemption: Request to view the letter of exemption from the state governor. It is the facility's responsibility to 	

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<p><i>Nursing about issues related to access to and the quality of anesthesia services in the State and has concluded that it is in the best interests of the State’s citizens to opt-out of the current MD/DO supervision requirement, and that the opt-out is consistent with State law.</i></p> <p>(2) <i>The request for exemption and recognition of State laws, and the withdrawal of the request may be submitted at any time, and are effective upon submission.</i></p> <p>§482.52(c)(1); §482.52(c)(2)</p>	<p>or Doctors of Osteopathic Medicine who are not anesthesiologists.</p> <p><u>Administration by a CRNA</u> Unless the hospital is located in a State that has chosen to opt out of the CRNA supervision requirements, a CRNA administering general, regional and monitored anesthesia must be supervised either by the operating practitioner who is performing the procedure, or by an anesthesiologist who is immediately available.</p> <p>Hospitals should conform to generally accepted standards of anesthesia care when establishing policies for supervision by the operating practitioner.</p> <p>An anesthesiologist is considered “immediately available” when needed by a CRNA under the anesthesiologist’s supervision only if he/she is physically located within the same area as the CRNA, e.g., in the same operative / procedural suite, or in the same labor and delivery unit, and not otherwise occupied in a way that prevents him/her from immediately conducting hands-on intervention, if needed.</p> <p>If the hospital is located in a State where the Governor has submitted a letter to CMS attesting that he or she has consulted with State Boards of Medicine and Nursing about issues related to access to and the quality of anesthesia services in the State and has concluded that it is in the best interests of the State’s</p>	<p>obtain information that the hospital is exempt from the requirement for physician supervision of CRNAs based on a letter submitted to the CMS by the Governor of the State.</p> <p>4.</p>	

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citizens to opt-out of the current physician supervision requirement, and that the opt-out is consistent with State law, then a hospital may permit a CRNA to administer anesthesia without operating practitioner or anesthesiologist supervision. (A list of States that have opted out of the CRNA supervision requirement may be found at http://www.cms.hhs.gov/CFCsAndCoPs/02_Spotlight.asp)

A CRNA is defined in §410.69(b) as a “registered nurse who:

- 1) Is licensed as a registered professional nurse by the State in which the nurse practices;
- 2) Meets any licensure requirements the State imposes with respect to non-physician anesthetists;
- 3) Has graduated from a nurse anesthesia educational program that meets the standards of the Council on Accreditation of Nurse Anesthesia Programs, or such other accreditation organization as may be designated by the Secretary; and
- 4) Meets the following criteria:
 - i. Has passed a certification examination of the Council on Certification of Nurse Anesthetists, the Council on Recertification of Nurse Anesthetists, or any other certification organization that may be designated by the

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Secretary; or

- ii. Is a graduate of a program described in paragraph (3) of this definition and within 24 months after that graduation meets the requirements of paragraph (4)(i) of this definition.”

Administration by an Anesthesiologist’s Assistant

An anesthesiologist’s assistant may administer anesthesia when under the supervision of an anesthesiologist.

The anesthesiologist must be immediately available if needed. An anesthesiologist is considered “**immediately available**” to assist the anesthesiologist’s assistant under the anesthesiologist’s supervision only if he/she is physically located within the same area as the anesthesiologist’s assistant, e.g., in the same operative/procedural suite, or in the same labor and delivery unit, and not otherwise occupied in a way that prevents him/her from immediately conducting hands-on intervention, if needed.

An anesthesiologist’s assistant is defined at §410.69(b) as a “person who-

- 1) Works under the direction of an anesthesiologist;
- 2) Is in compliance with all applicable requirements of State law, including any licensure requirements the State imposes on nonphysician

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anesthetists; and

- 3) Is a graduate of a medical school-based anesthesiologist’s assistant education program that –
 - a. Is accredited by the Committee on Allied Health Education and Accreditation; and
 - b. Includes approximately two years of specialized basic science and clinical education in anesthesia at a level that builds on a premedical undergraduate science background.”

Anesthesia Services Policies

The medical staff bylaws or rules and regulations must include criteria for determining the anesthesia service privileges to be granted to an individual practitioner and a procedure for applying the criteria to individuals requesting privileges, as required by the regulations at §482. 22(c)(6) for any type of anesthesia services, including those not subject to the anesthesia administration requirements at §482.52(a).

The hospital’s governing body must approve the specific anesthesia service privileges for each practitioner who furnishes anesthesia services, addressing the type of supervision, if any, required. The privileges granted must be in accordance with State law and hospital policy. The type and complexity of procedures for which the practitioner may administer anesthesia must be specified in the

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privileges granted to the individual practitioner. Deficiencies related to these requirements should be cited under §482. 22(c)(6).

When a hospital permits operating practitioners to supervise a CRNA administering anesthesia, the medical staff bylaws or rules and regulations must specify for each category of operating practitioner, the type and complexity of procedures that category of practitioner may supervise.

However, individual operating practitioners do not need to be granted specific privileges to supervise a CRNA.

30.01.03 Moderate Sedation (Conscious Sedation).

The use of moderate sedation (Conscious Sedation) is limited to qualified individuals.

Moderate sedation (conscious sedation) is the responsibility of the ordering practitioner; thus there is to be evidence that this technique is included in the privilege delineation for those practitioners.

There may be requirements, within Anesthesia policies, to document the advanced training and competencies of the Registered Nurses who give the medications and/or monitor patients having moderate sedation (conscious sedation).

FILE REVIEW

Review at least three anesthesia provider files. Verify:

1. The qualifications including current certification with verifications are present in the files of the reviewed practitioners.
2. Non-anesthesia practitioners who are using moderate sedation (conscious sedation) have requested and have been granted privileges.

- 1 = Compliant
- 2 = Not Compliant

This standard is not met as evidenced by:

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<p>30.01.04 Required Policies. <i>Anesthesia services must be consistent with needs and resources.</i></p> <p><i>Policies on anesthesia procedures must include the delineation of preanesthesia and postanesthesia responsibilities. §482.52(b)</i></p>	<p>The Anesthesia Standards of Practice (policy manual) addresses these issues consistent with Federal, State, and other regulations.</p> <p>This manual reflects review and/or update so that it conforms with any regulatory or practice changes. Policies are reviewed at least triennially.</p> <p>Anesthesia services must be delivered in a manner that is consistent with the needs and the resources of the hospital. Anesthesia policies at a minimum must address:</p> <ol style="list-style-type: none"> 1. How the hospital’s anesthesia services needs will be met. 2. The delineation of pre- and post-anesthesia staff responsibilities including qualifications, supervision required of all personnel who administer anesthesia. 3. Delivery of anesthesia services consistent with recognized standards for anesthesia care. A well-designed anesthesia services policy would address issues such as: <ol style="list-style-type: none"> a) Patient consent b) Infection control measures c) Safety practices in all anesthetizing areas d) Protocol for supportive life functions, e.g., cardiac and respiratory emergencies e) Reporting requirements f) Documentation requirements g) Equipment requirements, as well as the 	<p style="text-align: center;"><u>DOCUMENT REVIEW</u></p> <p>Review the policies developed on anesthesia procedures.</p> <p>Determine whether the anesthesia service policies for delivery of care address the issues identified in interpretative guidelines.</p> <p>Verify:</p> <ul style="list-style-type: none"> • The Anesthesia Services manual addresses all required policies. • Policies are current. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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<p>30.01.05 Pre-anesthesia Evaluation. <i>The policies must ensure that the following are provided for each patient:</i></p> <ul style="list-style-type: none"> • <i>A pre-anesthesia evaluation completed and documented by an individual qualified to administer anesthesia, as specified in paragraph (a) of 42 CFR 482.52, performed within 48 hours prior to surgery or a procedure requiring anesthesia services.</i> <p>§482.52(b)(1)</p>	<p style="text-align: center;">monitoring, inspection, testing and maintenance of anesthesia equipment in the hospital’s biomedical equipment program.</p> <p>A pre-anesthesia evaluation must be performed for each patient who receives general, regional or monitored anesthesia.</p> <p>While current practice dictates that the patient receiving moderate sedation be monitored and evaluated before, during, and after the procedure by trained practitioners, a pre-anesthesia evaluation performed by someone qualified to administer anesthesia as specified in §482.52(a) is not required because moderate sedation is not considered to be “anesthesia”, and thus is not subject to that requirement under this regulation.</p> <p>The evaluation must be performed by someone qualified to administer anesthesia as specified in §482.52(a), i.e., only by:</p> <ul style="list-style-type: none"> • A qualified anesthesiologist; • A Doctor of Medicine or Doctor of Osteopathic Medicine (other than an anesthesiologist); • A dentist, oral surgeon, or podiatrist who is qualified to administer anesthesia under State law; 	<p style="text-align: center;"><u>DOCUMENT REVIEW & CHART REVIEW</u></p> <ol style="list-style-type: none"> 1. Review documents (collaborative statements / agreements, pre-operative records, medical staff bylaws, rules and regulations). 2. Review recently closed patient medical records, include at least: <ul style="list-style-type: none"> • One general anesthesia and one other technique, and • At least one Moderate Sedation (Conscious Sedation) record for two practitioners using this technique. 3. Determine if there is a State exemption for supervision of CRNAs. If a state exemption does not apply, determine that appropriate CRNA supervision was provided as required. 4. Review a sample of inpatient and outpatient medical records for patients who had surgery or a procedure requiring administration of anesthesia. <ul style="list-style-type: none"> • Determine whether each patient had a pre-anesthesia evaluation by a practitioner qualified to administer 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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	<ul style="list-style-type: none"> • A certified registered nurse anesthetist (CRNA), who, unless exempted in accordance with paragraph (c) of this section, is under the supervision of the operating practitioner or of an anesthesiologist who is immediately available if needed; or • An anesthesiologist’s assistant who is under the supervision of an anesthesiologist who is immediately available if needed. <p>Although §482.12 (c)(1)(i) generally provides broad authority to physicians to delegate tasks to other qualified medical personnel, the more stringent requirements at §482.52(b)(1) do not permit delegation of the pre-anesthesia evaluation to practitioners who are not qualified to administer anesthesia.</p> <p>The pre-anesthesia evaluation must be completed and documented within 48 hours immediately prior to any inpatient or outpatient surgery or procedure requiring anesthesia services. The delivery of the first dose of medication(s) for the purpose of inducing anesthesia, as defined above, marks the end of the 48 hour time frame.</p> <p>In accordance with current standards of anesthesia care, some of the individual elements contributing to the pre-anesthesia evaluation may be performed prior to the 48-hour timeframe. However, under no circumstances may these elements be performed</p>	<p>anesthesia.</p> <ul style="list-style-type: none"> • Determine whether each patient’s pre-anesthesia evaluation included at least the elements described above. • Determine that the pre-anesthesia evaluation was updated, completed and documented within 48 hours prior to the delivery of the first dose of medication(s) given for the purpose of inducing anesthesia for the surgery or a procedure requiring anesthesia services. 	

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more than 30 days prior to surgery or a procedure requiring anesthesia services. Review of these elements must be conducted, and any appropriate updates documented, within the 48-hour timeframe.

The pre-anesthesia evaluation of the patient includes, at a minimum:

1. Elements that must be performed within the 48-hour timeframe:
 - Review of the medical history, including anesthesia, drug and allergy history; and
 - Interview, if possible given the patient’s condition, and examination of the patient.

2. Elements that must be reviewed and updated as necessary within 48 hours, but which may also have been performed during or within 30 days prior to the 48-hour time period, in preparation for the procedure:
 - Notation of anesthesia risk according to established standards of practice (e.g., ASA classification of risk);
 - Identification of potential anesthesia problems, particularly those that may suggest potential complications or contraindications to the planned procedure (e.g., difficult airway, ongoing infection, limited intravascular access);
 - Additional pre-anesthesia data or information, if applicable and as required in

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accordance with standard practice prior to administering anesthesia (e.g., stress tests, additional specialist consultation);

- Development of the plan for the patient’s anesthesia care, including the type of medications for induction, maintenance and post-operative care and discussion with the patient (or patient’s representative) of the risks and benefits of the delivery of anesthesia.

30.01.06 Intraoperative Anesthesia Record.

The policies must ensure that the following are provided for each patient:

- *An Intra-operative Anesthesia record.*

§482.52(b)(2)

There must be an intra-operative anesthesia record or report for each patient who receives general, regional or monitored anesthesia.

While current practice dictates that the patient receiving moderate sedation be monitored and evaluated before, during, and after the procedure by trained practitioners, an intra-operative anesthesia report is not required because, as explained above, moderate sedation is not “anesthesia”.

Current standard of care stipulates that an intra-operative anesthesia record, at a minimum, includes:

- Name and hospital identification number of the patient;
- Name(s) of practitioner(s) who administered anesthesia, and as applicable, the name and profession of the supervising anesthesiologist or

CHART REVIEW

Review records to determine that each patient has an intraoperative anesthesia record that includes the required elements.

- 1 = Compliant
- 2 = Not Compliant

This standard is not met as evidenced by:

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operating practitioner;

- Name, dosage, route and time of administration of drugs and anesthesia agents;
- Techniques(s) used and patient position(s), including the insertion/use of any intravascular or airway devices;
- Name and amounts of IV fluids, including blood or blood products if applicable;
- Timed-based documentation of vital signs as well as oxygenation and ventilation parameters; and
- Any complications, adverse reactions, or problems occurring during anesthesia, including time and description of symptoms, vital signs, treatments rendered, and patient’s response to treatment.

30.01.07 Post-anesthesia Assessment.
The policies must ensure that the following are provided for each patient:

- *A post-anesthesia evaluation completed and documented by an individual qualified to administer anesthesia, as specified in*

A postanesthesia evaluation must be completed and documented no later than 48 hours after surgery or a procedure requiring anesthesia services.

The evaluation is required any time general, regional, or monitored anesthesia has been administered to the patient. While current practice dictates that the patient receiving moderate sedation be monitored and evaluated before, during, and after the procedure

DOCUMENT REVIEW AND CHART REVIEW

1. Review facility policies that describe expectations for post-anesthesia assessments. Verify:
 - There is one standard of care throughout the facility for the timeliness of completing the post-anesthesia assessment.

1 = Compliant
 2 = Not Compliant

This standard is not met as evidenced by:

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<p><i>paragraph (a) of 42 CFR 482.52, no later than 48 hours after surgery or a procedure requiring anesthesia services. The postanesthesia evaluation for anesthesia recovery must be completed in accordance with State law and with hospital policies and procedures that have been approved by the medical staff and that reflect current standards of anesthesia care.</i></p> <p>§482.52(b)(3)</p>	<p>by trained practitioners, a post-anesthesia evaluation performed by someone qualified to administer anesthesia as specified in §482.52(a) is not required under this regulation. (71 FR 68691)</p> <p>The postanesthesia evaluation must be completed and documented by any practitioner who is qualified to administer anesthesia; this need not be the same practitioner who administered the anesthesia to the patient. In accordance with §482.52(a), anesthesia must be administered only by:</p> <ul style="list-style-type: none"> • A qualified anesthesiologist; • A Doctor of Medicine or Doctor of Osteopathic Medicine (other than an anesthesiologist); • A dentist, oral surgeon, or podiatrist who is qualified to administer anesthesia under State law; • A certified registered nurse anesthetist (CRNA), who, unless exempted in accordance with paragraph (c) of this section, is under the supervision of the operating practitioner or of an anesthesiologist who is immediately available if needed; or • An anesthesiologist’s assistant who is under the supervision of an anesthesiologist who is immediately available if needed. 	<p>2. Review a sample of medical records for patients who had surgery or a procedure requiring general, regional or monitored anesthesia to determine whether a post anesthesia evaluation was written for each patient.</p> <ul style="list-style-type: none"> • Determine whether the evaluation was conducted by a practitioner who is qualified to administer anesthesia. • Determine whether the evaluation was completed and documented within 48 hours after the surgery or procedure. • Determine whether the appropriate elements of a post-anesthesia evaluation are documented in the medical record. 	

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Although §482.12(c)(1)(i) provides broad authority to physicians to delegate tasks to other qualified medical personnel, the more stringent requirements of §482.52(b)(3) do not permit delegation of the post-anesthesia evaluation to practitioners who are not qualified to administer anesthesia.

The calculation of the 48-hour timeframe begins at the point the patient is moved into the designated recovery area.

The evaluation generally should not be performed immediately at the point of movement from the operative area to the designated recovery area. Rather, accepted standards of anesthesia care indicate that the evaluation should not begin until the patient is sufficiently recovered from the acute administration of the anesthesia so as to participate in the evaluation, e.g., answer questions appropriately, perform simple tasks, etc.

While the evaluation should begin in the PACU/ICU or other designated recovery location, it may be completed after the patient is moved to another inpatient location or, for same day surgeries, if State law and hospital policy permits, after the patient is discharged, so long as it is completed within 48 hours.

The 48 hour timeframe for completion and documentation of the post-anesthesia evaluation is an outside parameter. Individual patient risk factors may dictate that the evaluation be completed and

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documented sooner than 48 hours. This should be addressed by hospital policies and procedures (71 FR 68690).

For those patients who are unable to participate in the postanesthesia evaluation (e.g., post-operative sedation, mechanical ventilation, etc.), a postanesthesia evaluation should be completed and documented within 48 hours with notation that the patient was unable to participate.

DOCUMENTATION

This documentation should include the reason for the patient’s inability to participate as well as expectations for recovery time, if applicable.

For those patients who require long-acting regional anesthesia to ensure optimum medical care of the patient, whose acute effects will last beyond the 48-hour timeframe, a post-anesthesia evaluation must still be completed and documented within 48 hours. However, there should be a notation that the patient is otherwise able to participate in the evaluation, but full recovery from regional anesthesia has not occurred and is not expected within the stipulated timeframe for the completion of the evaluation.

The elements of an adequate post-anesthesia evaluation should be clearly documented and conform to current standards of anesthesia care, including:

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1. Respiratory function, including respiratory rate, airway patency, and oxygen saturation;
2. Cardiovascular function, including pulse rate and blood pressure;
3. Mental status;
4. Temperature;
5. Pain;
6. Nausea and vomiting; and
7. Postoperative hydration.

Depending on the specific surgery or procedure performed, additional types of monitoring and assessment may be necessary.

The medical staff is responsible to establish one standard of care throughout the facility for the assessment of patients following anesthesia.

One standard of care is required for all locations including, but not limited to the main operating room, outpatient surgery, ambulatory surgery centers, interventional radiology, nuclear medicine, obstetrics, cardiac catheterization lab, endoscopic services, and other procedure rooms in which general anesthesia, spinal anesthesia, regional anesthesia, epidural, or moderate sedation is administered.

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<p>30.01.08 <u>Equipment Safety.</u> All anesthetizing equipment utilized is maintained to conform to Safe Medical Devices/Food Drug Administration requirements.</p> <p>30.02.01 <u>Not Applicable.</u></p> <p>30.02.02 <u>Not Applicable.</u></p>	<p>Regardless of the location of the anesthesia, the post-anesthesia assessment must be completed within 48 hours. The facility will establish a process for ensuring the post-anesthesia assessment is completed for patients who are discharged within 48 hours of the procedure.</p> <p>Self-explanatory.</p>	<p><u>DOCUMENT REVIEW & FILE REVIEW</u></p> <p>Verify:</p> <ol style="list-style-type: none"> The anesthesia event record should document the anesthesia machine "number" and that it was "checked" prior to use. Request evidence of preventive maintenance consistent with manufacturer's recommendations, semi-annual gas waste, gas testing, and electrical safety testing. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>
<p>30.02.03 <u>Nursing Care: Postanesthesia.</u> A Registered Nurse plans and supervises the care of each post-anesthesia patient.</p>	<p>PACU records will indicate which RN assessed and planned the post-anesthesia care for each surgical/invasive procedure patient.</p> <p>Assisting staff are identified in the medical record.</p>	<p><u>CHART REVIEW</u></p> <p>Review patient records. Verify:</p> <ol style="list-style-type: none"> The post-anesthesia care (PACU) documents provide space for identification of personnel that provided patient care. An RN planned and supervised the PACU care. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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<p>30.02.04 Registered Nurse Supervision: Postanesthesia Recovery. Licensed practical / vocational nurses and technologists may provide services under the supervision of a Registered Nurse.</p>	<p>A qualified RN provides immediate post-anesthesia care for any surgical or invasive procedure patient.</p> <p>If permitted by state law, Medical Staff policies may be formulated to permit LPN's/LVN's/or technologists to assist in these duties, under the supervision of a qualified RN who is immediately available to respond to emergencies.</p>	<p style="text-align: center;"><u>CHART REVIEW & INTERVIEW</u></p> <p>Review policies and medical records. Verify:</p> <ol style="list-style-type: none"> 1. A process is in place describing the supervision of LPNs/LVNs, if permitted by state law and hospital policy. 2. If care is provided by staff other than a RN, both staff names are identified on the medical record as evidence of the immediate supervision and availability of a RN (within the suite). 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>
<p>30.02.05 Staff Orientation & Training: Postanesthesia Recovery. In addition to licensure verification, there is evidence that staff have completed an orientation program designed for the types of post-anesthesia care provided appropriate to the types of cases being accomplished.</p>	<p>Facilities may require certifications and other evidence of competence. A mechanism exists to assess acuity of patient needs so that the most complex patient has a RN immediately available. Immediate availability precludes simultaneous primary duties for other non-postanesthesia patients.</p>	<p style="text-align: center;"><u>FILE REVIEW</u></p> <p>Review the files of post-anesthesia staff. Verify:</p> <ol style="list-style-type: none"> 1. Staff received an orientation to post-anesthesia patient care. 2. Staff competencies regarding post-anesthesia patient care are assessed. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>
<p>30.02.06 Required Equipment. The Post-anesthesia Recovery Services maintains an adequate inventory of instrumentation, supplies and equipment. At a minimum the following equipment must be</p>	<p>Systems and processes shall be in working order and available for emergency communication and for patient care crises. The availability of oxygen is essential.</p> <p>A cricothyroidotomy set is not a substitute for a</p>	<p style="text-align: center;"><u>OBSERVATION & DOCUMENT REVIEW</u></p> <p>Verify:</p> <ol style="list-style-type: none"> 1. Surgical and invasive procedure postanesthesia recovery rooms have these working systems and an adequate inventory of equipment available for 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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<p>available:</p> <ul style="list-style-type: none"> • Call-in-system (intercom or equivalent) • Cardiac monitor • Defibrillator • Aspirator (suction equipment / vacuum) • Resuscitator (ventilator) • Tracheotomy set <p>§482.51(b)(3)</p>	<p>tracheotomy set. The term “resuscitator” refers to a hand-held bag type of device; a mechanical ventilator is not required.</p> <p>Adequate equipment must be available to respond to emergencies in more than one location simultaneously.</p> <p>The call-in system must have the capability of summoning help internally as well as externally to the department, as needed.</p> <p>The following should be available to meet the assessed needs of patients:</p> <ol style="list-style-type: none"> 1. Oxygen, humidified 2. Pulse oximetry and immediate availability of blood gas analysis 3. Patient temperature monitoring 4. Re-warming mechanisms 5. Immediate access to supplies to manage a malignant hyperthermia crisis. <p>Age-specific resuscitation equipment is required to meet the emergency needs of the patient. If the facility treats pediatric patients, pediatric sized resuscitation equipment is immediately available.</p>	<p>patient care.</p> <ul style="list-style-type: none"> • Verify all required systems are working. • Verify all required equipment is readily available with adequate inventory for patient care. <ol style="list-style-type: none"> 2. Verify that all equipment is working and, as applicable, in compliance with the hospital’s biomedical inspection, testing, and maintenance program. 3. Age-specific resuscitation equipment is readily available. 4. If the facility treats pediatric patients, ensure pediatric size endotracheal tubes / tracheostomy set are immediately available. 	

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<p>30.02.07 <u>Supply & Equipment Availability.</u> Supplies and equipment are sufficient in quantity so that movement in and out of the area is minimized during peak care times.</p> <p>Processed and clean supplies are protected from surface / airborne contamination. Provisions are made for the care of patients with respiratory or wound contamination and those requiring isolation.</p>	<p>The design of Postanesthesia Care (Recovery) Areas is such that personnel and supply movement provides for the protection of "clean" supplies.</p> <p>Clean linen and/or sterile packages are not subjected to dust accumulation, moisture or other potential sources of contamination. Shipping cartons are not permitted in the "clean" area.</p> <p>Processes are in place for handling and disposal of contaminated / infectious / hazardous waste.</p> <p>The post-anesthesia care unit meets current isolation requirements relating to patient care, air exchange / flow, and etc., as defined by the Centers for Disease Control and Prevention (CDC).</p>	<p style="text-align: center;"><u>OBSERVATION</u></p> <p>Verify:</p> <ol style="list-style-type: none"> General and "clean" areas are clearly identified; staff adhere to traffic rules regarding such. The soiled utility and "hopper" areas do not have storage of clean supplies. Provisions are in place for the recovery of patients requiring isolation. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>
<p>30.02.08 <u>Not Applicable.</u></p>			
<p>30.02.09 <u>Not Applicable.</u></p>			
<p>30.02.10 <u>Required Policies.</u> Post-anesthesia Care Service Standards of Practice (policies) provide for the achievement and maintenance of high standards of medical practice and patient care.</p> <p>Minimally, the following standards are</p>	<p>There is a policy manual governing activities available in all PACU locations. This includes:</p> <ul style="list-style-type: none"> The "main" PACU and All remote surgical suites, cesarean and general delivery rooms, endoscopy and invasive vascular labs. 	<p style="text-align: center;"><u>DOCUMENT REVIEW & OBSERVATION</u></p> <p>Review the PACU Service Policy Manual.</p> <p>Verify:</p> <ol style="list-style-type: none"> All required policies are in place. The PACU policy manual reflects current practice and has been reviewed and approved within the last three years by all 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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<p>in place:</p> <p>1. Infection control – environment</p> <p>2. Infection control – contaminated cases</p> <p>3. Disinfection / sterilization of reusable equipment</p> <p>4. Traffic control</p> <p>5. Staff ratios and duties</p> <p>6. Nursing assessment, planning, implementation and evaluation of care</p> <p>7. Medical Staff responsibilities including assessments, progress notes, discharge of patients, emergency management, etc.</p> <p>8. General and specific PACU safety</p> <p>9. Housekeeping</p> <p>10. Control of pharmaceuticals</p> <p>11. Procedure protocols to include equipment, supplies and materials necessary to carry out job assignments</p>	<p>Standards of Care are consistent in all locations.</p> <p>The policies are developed or approved by the PACU services supervisor, Chief of Anesthesia, administration, the Infection Control Committee, and the Pharmacy Therapeutics Committees, as appropriate, and the Professional Medical Staff.</p> <p>Policies are developed relating to changes or new technology and procedures. Policies are reviewed and revised as necessary in accordance with State regulation and facility policy but no less often than triennially.</p>	<p>appropriate individuals / groups.</p> <p>3. Practice is consistent with policy. Practices in remote locations are consistent with the PACU Services policy manual.</p> <p>4. If separate PACU service policies exist in remote locations (i.e., modifications to determining acuity, etc.) these have been authored or co-authored and approved by the PACU services supervisor prior to other approvals.</p>	

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- 12. Human resource policies unique to the PACU services
- 13. Patient’s rights in a PACU setting; and
- 14. Management of pain including assessment and treatment utilizing a visual scale of zero to ten or the “FACES” tool for children.

30.02.11 Policy: Bypass of Postanesthesia Recovery Service.

There is a system to determine which patients require the PACU services and which patients may "bypass" this service.

If a patient is transferred directly to an ICU following anesthesia, there is a post anesthesia recovery period in that ICU. All post anesthesia patients (exception: local / topical) shall be considered as PACU candidates.

The facility has a policy, approved by the Medical Staff, which lists patients that may bypass the PACU following anesthesia. Patients that might be excluded from PACU include those who received:

- Local/topical anesthesia
- Acupuncture or hypnosis
- Anxiolytic drugs therapy used as "anesthesia."

The medical record shall contain an assessment of the patient’s condition at the conclusion of the surgical/invasive procedure that justifies bypassing PACU care, consistent with hospital policy criteria.

CHART REVIEW

Review medical records for patients that bypassed the PACU.

Verify:

1. A PACU “bypass” policy in place.
2. The PACU bypass criteria were consistently met.
3. The medical records contain documentation of an appropriate post- procedure assessment. Upon conclusion of the procedure and upon arrival in the ICU.

- 1 = Compliant
- 2 = Not Compliant

This standard is not met as evidenced by:

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<p>30.02.12 <u>Recovery in Non-PACU Locations.</u> Provisions are made to provide patients with the same standard of post anesthesia care when the regular PACU mechanism is not available.</p>	<p>There shall be one level of care provided to patients recovering from anesthesia regardless of whether the recovery is in the PACU, the ICU, or another location. This requirement also applies to patients that require post-anesthesia recovery after usual business hours.</p> <p>Qualified personnel of ample numbers shall provide post-anesthesia care. When patients are recovered in a location other than the PACU or after usual business hours, these personnel have received an orientation and ongoing training relative to the care of patients following all types of anesthesia provided at the facility. Staff training includes the PACU related policies and Standards of Practice.</p> <p>There is evidence that the staff who provide after hours care meet the orientation / competency requirements for regular PACU staff.</p>	<p style="text-align: center;"><u>FILE REVIEW & INTERVIEW</u></p> <p>Verify:</p> <ul style="list-style-type: none"> Processes are in place to provide orientation and ongoing training to ensure competent staff care for patients that are recovered in locations other than PACU or after-hours. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>
<p>30.02.13 <u>Discharge Criteria.</u> The Medical Staff Rules and Regulations define the PACU discharge criteria. These criteria, if used in lieu of a practitioner assessment / order, are consistently applied whenever post anesthesia recovery occurs.</p>	<p>The post-anesthesia criteria provide consistent and quantifiable data to make the discharge decisions.</p>	<p style="text-align: center;"><u>CHART REVIEW</u></p> <p>Review of charts of patients discharged from PACU. Verify:</p> <ul style="list-style-type: none"> The medical record reflects the consistent and appropriate use of approved discharge criteria when determining discharge readiness from the PACU. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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<p>30.02.14 Documentation Requirements. A Postanesthesia Care record is prepared for each patient and documents the following:</p> <ol style="list-style-type: none"> 1. Nature of surgical / invasive / manipulative procedure. 2. Date / time of arrival, and transported by whom. 3. Level of consciousness and vital signs at time of arrival. 4. Name of anesthesia provider and anesthesia technique employed. 5. Condition of patient on arrival to the PACU as jointly assessed by the anesthesia provider and PACU RN. 6. "Key" observations at intervals specified in the PACU standards of practice to include vital signs, reactivity, sensorium, fluid intake / output / balance, pain management, medications given with appropriate observations, and according to patient need, EKG, SAO2 and other monitoring results. 	<p>Post-anesthesia Care records document the required information regardless of location where the care is provided.</p> <p>These are made a permanent part of the patient's medical record.</p> <p>Close observation of the patient is essential during transportation and the period of emergence from anesthesia.</p> <p>Emotional and physiological responses to surgery, manipulation or invasion are to be monitored to the point that a patient can be determined to be safely transferred to another level of care. Transfer / discharge from the PACU is only by physician order or Medical Staff approved criteria.</p>	<p style="text-align: center;"><u>CHART REVIEW</u></p> <p>Review medical records of patients that received Post-anesthesia Care.</p> <p>Verify:</p> <ol style="list-style-type: none"> 1. The medical record contains a Post-anesthesia Care report. 2. The required information is consistently documented. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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<p>7. Name of the nurse receiving the patient from PACU.</p> <p>8. Name of the licensed independent practitioner discharging the patient from PACU care.</p>			
<p>30.02.15 Staffing Requirements. There are adequate provisions for staffing the post-anesthesia care unit.</p>	<p>PACU staffing patterns reflect consistent assignments of oriented / competent staff.</p> <p>Staffing ratios take into consideration the standards promulgated by the American Society of Post Anesthesia Nurses.</p> <p>Staff ratios should be based on patient acuity and the scope and mix of anesthesia and surgical practices provided.</p>	<p style="text-align: center;">DOCUMENT REVIEW</p> <p>Review staffing plans and work schedules for the two-week period exactly eight weeks prior. Consider the needs of the patients when reviewing “remote” PACU locations. If timing permits, observe the admission of a patient to PACU setting.</p> <p>Verify:</p> <ul style="list-style-type: none"> • The staffing ratio is appropriate to patient needs. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>
<p>30.03.01 Outpatient Discharge Requirement. Outpatient surgical / invasive procedure patients, who have had other than local or topical anesthesia, shall have a responsible person to provide transportation following the procedure, except those exempted by the practitioner who performed the surgical procedure.</p>	<p>The outpatient who has had anesthesia may have delayed responses to these agents which impact judgment and personal safety. For patient safety, it is essential that provisions for the patient’s discharge are made prior to the procedure.</p> <p>Transportation may be provided by someone known to the patient or through other arrangements, as deemed appropriate by the facility. These arrangements are documented in the medical record.</p>	<p style="text-align: center;">INTERVIEW & CHART REVIEW</p> <ol style="list-style-type: none"> 1. Determine that staff can articulate the facility’s discharge practices. 2. Review medical records for patients discharged following outpatient surgery / procedure. <ul style="list-style-type: none"> • Determine there is documentation that a responsible person transported the patient following the procedure, or the 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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Arrangements for **transportation** by a responsible **person** shall be **clarified by** staff, prior to initiation of the procedure.

exemption to this requirement is documented by the physician performing the procedure.

30.03.02 Outpatient Discharge

Instructions.

Outpatient surgical / invasive procedure patients, and their families – companions as appropriate, are provided with instructions regarding post procedure management in language that the patient or accompanying responsible person can understand.

Post procedure instructions include, at least:

1. Signs / symptoms of post-procedure feelings that are "normal"
2. Signs / symptoms of post-procedure problems that require immediate attention and/or notification of the physician
3. The mechanism to utilize in the event of post-procedure problems when the physician cannot be notified
4. The date and time to next see a health care provider for follow-up care
5. Changes in diet / medication
6. Pain management and treatment utilizing a visual scale of zero to ten or the "FACES" tool for children
7. Alterations in activity
8. Management of wounds or devices

CHART REVIEW

Review medical records for patients discharged following outpatient surgery / procedure.

- **Determine that the medical record contains documentation that** post procedure care instructions were provided to the patient / responsible adult.

- 1 = Compliant
 2 = Not Compliant

This standard is not met as evidenced by:

SURGICAL SERVICES

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>30.03.03 <u>Post-Procedure Follow-Up Call.</u> Outpatient surgical / invasive procedure patients are contacted by the facility within 24 to 72 hours post procedure, when possible, to determine their status.</p>	<p>The hospital policy identifies patients to be “at risk” that should receive a follow-up call to assess the clinical well-being post-surgery.</p> <p>Mechanisms are established to determine patient status following discharge.</p> <ol style="list-style-type: none"> 1. A process is in place to document these follow-up calls. The clinical evaluation information obtained from post-discharge follow-up telephone calls is recorded in the medical record. 2. Information obtained from these calls is tracked and reported to the QAPI program in order to identify opportunities for improving the outpatient program. Adverse events may include, but are not limited to: <ul style="list-style-type: none"> • Pain management issues • Bleeding • Returns to the Emergency Department 3. Patient satisfaction with the facilities and the service can also be assessed; however, this information is not ordinarily recorded in the medical record. <p>Facilities may determine the time frame, which is "best" for their population. (Some patients return to school or work so rapidly that contact may not be possible.)</p>	<p><u>DOCUMENT REVIEW & CHART REVIEW</u></p> <ol style="list-style-type: none"> 1. Interview staff to determine what process is implemented. 2. Determine the medical records contain documentation of these follow-up calls. 3. Determine that there is a mechanism to review and trend outcome or process issues as a result of the follow-up calls. Determine if the findings are reported to the QAPI Committee. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

OUTPATIENT SERVICES

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>31.00.00 Condition of Participation: Outpatient Services. <i>If the hospital provides outpatient services, the services must meet the needs of the patients in accordance with acceptable standards of practice.</i></p> <p>§482.54</p>	<p>This is an optional hospital service; however, if a hospital provides any degree of outpatient care to its patients, the hospital must comply with the requirements of this Condition of Participation (CoP).</p> <p>The Medicare Hospital CoP applies to both inpatient and outpatient services of the hospital. The hospital must be in compliance with the CoP in 42 CFR §482 in all on-campus and off-campus outpatient service locations.</p> <p>The hospital's outpatient services must be integrated into its hospital-wide QAPI program.</p> <p>Tag 1080 provides more detailed guidance on the overall requirements for outpatient services and permits standard-level citations for identified deficiencies.</p> <p>The manner and degree of noncompliance identified in relation to Tags 1077 – 1080 may result in substantial noncompliance with this CoP, requiring citation at the condition level. (31.00.01; 31.00.02; 31.00.12)</p> <p>All outpatient services provided by the hospital, both on campus and at any provider-based clinics, must meet the needs of the patients, in accordance with acceptable standards of practice.</p> <p>The hospital must ensure that the services, equipment, staff and facilities are adequate to provide</p>	<p><u>DOCUMENT REVIEW, OBSERVATION, CHART REVIEW, & FILE REVIEW</u></p> <p>Determine locations and type(s) of outpatient services provided.</p> <p>Verify:</p> <ol style="list-style-type: none"> 1. All outpatient services at all locations are in compliance with the hospital CoP. 2. Equipment, staff and facilities are adequate to provide the outpatient services offered at each location are in accordance with acceptable standards of practice. 3. The hospital's outpatient services are integrated into its hospital-wide QAPI program. 4. Ask the individual(s) directing outpatient services whether the hospital orders for that type of outpatient service from referring physicians who are not members of the hospital's medical staff. If yes: <ul style="list-style-type: none"> • Ask for evidence that the medical staff has approved the policy. 5. Ask how the hospital verifies that the order comes from a referring practitioner who is appropriately licensed in the jurisdiction where he/she sees the patient to prescribe such orders. Ask for documentation of such 	<p><input type="checkbox"/> 1 =Compliant <input type="checkbox"/> 2 = Not Compliant <input type="checkbox"/> NA = Chapter Not Applicable in this facility.</p> <p>This standard is not met as evidenced by:</p>

OUTPATIENT SERVICES

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>31.00.01 <u>Integration of Services.</u> <i>Outpatient services must be appropriately organized and integrated with inpatient services.</i></p> <p>§482.54(a)</p>	<p>the outpatient services offered at each location in accordance with acceptable standards of practice.</p> <p>If the hospital offers outpatient surgical services, the surgical services Condition of Participation requires that the offered services must be consistent in quality with inpatient care in accordance with the services offered.</p> <p>Acceptable standards of practice include standards that are set forth in Federal or State laws, regulations or guidelines, as well as standards and recommendations promoted by nationally recognized professional organizations (e.g., the American Medical Association, American College of Radiology, American College of Surgeons, etc.).</p> <p>The facility has a written plan for outpatient services.</p> <p>The hospital’s outpatient services, at all locations, must be integrated with inpatient services (e.g., radiology, laboratory, surgical services, anesthesia (including pain management) services, other diagnostic services, etc.) as appropriate to the outpatient services offered.</p> <p>The hospital must have written policies in place to assure the integration of outpatient services, including an established method of communication between outpatient service departments to corresponding inpatient services.</p>	<p>verification efforts.</p> <ul style="list-style-type: none"> Score compliance with this Condition of Participation based on the scoring throughout the requirements cited in this chapter. If non-compliance does not rise to the Condition Level, score at standard 31.00.12. <p><u>DOCUMENT REVIEW, CHART REVIEW, AND INTERVIEW</u></p> <p>Review the outpatient organization plan.</p> <p>Verify:</p> <ol style="list-style-type: none"> The outpatient organization plan is integrated with the inpatient services in accordance with the needs of the patient care provided at each of those locations. That the hospital has an established method of communication and established procedures to assure integration with inpatient services to provide continuity of care. 	<p><input type="checkbox"/> 1 =Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

OUTPATIENT SERVICES

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
	<p>The hospital must coordinate the care, treatment and services to a patient. In order to provide continuity of care, it should have an established method of communication between inpatient services and outpatient care in order to provide continuity of care to its patients.</p>	<ol style="list-style-type: none"> 3. Review medical records of outpatients who were later admitted to the hospital in order to determine that pertinent information from the outpatient record has been included in the inpatient record. 4. Verify that the outpatient services are organized in a manner appropriate to the scope and complexity of services offered. 	
<p>31.00.02 Personnel.</p> <ol style="list-style-type: none"> 1. <i>The hospital must assign one or more individuals to be responsible for outpatient services.</i> 2. <i>The hospital must have appropriate professional and nonprofessional personnel available at each location where outpatient services are offered, based on the scope and complexity of outpatient services.</i> <p>§482.54(b)(1) §482.54(b)(2)</p>	<p>The hospital's outpatient services may be directed by one or more individuals.</p> <p>Hospitals have the flexibility to determine how best to organize their outpatient services, including how direction will be provided. As services offered in outpatient departments become more varied, complex and technologically advanced, hospitals may find it better to have individuals with more specialized expertise providing direction for a specific type of outpatient services.</p> <p>Hospitals should define in writing the qualifications and competencies necessary for their outpatient services department leader(s). These qualifications should include items such as education, experience, and specialized training consistent with State law and acceptable standards of practice.</p> <p>The hospital should define in writing the qualifications</p>	<p><u>DOCUMENT REVIEW AND FILE REVIEW</u></p> <ol style="list-style-type: none"> 1. Ask the hospital how it has organized its outpatient services and to identify the individual(s) responsible for providing direction for outpatient services. 2. Review the organizations policies and procedures to determine the person's responsibility. 3. Review the position description and personnel file of the individual(s) responsible for a selection of outpatient services to ensure they are qualified, in accordance with State law, acceptable standards of practice and hospital policy to direct the service for which they are responsible. 4. Visit several on- and off-campus locations where hospital outpatient services are 	<p><input type="checkbox"/> 1 =Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

OUTPATIENT SERVICES

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
	<p>and competencies necessary to direct each outpatient service for which there is a separate director. Qualifications include necessary education, experience and specialized training consistent with state law and acceptable standards of practice.</p> <p>Adequate types and numbers of qualified licensed healthcare professionals and other personnel must be available to provide patients with the appropriate level of care for the outpatient services offered by the hospital. The types and number of qualified personnel required for each area of the hospital's main campus or for each provider-based off-site location must be based on the scope and complexity of outpatient services offered and the number and types of patients treated as outpatients at each.</p>	<p>provided. Given the scope and complexity of the services being offered, are there sufficient personnel with the appropriate education, experience, certifications, current licensure where appropriate, and competencies for assigned responsibilities?</p> <ol style="list-style-type: none"> 5. Verify: <ul style="list-style-type: none"> • All outpatient services are assigned to one (1) or more persons to manage the overall operation of hospital outpatient services. 6. Review policies and contracts, if services are provided under an arrangement. 7. Review the staffing plan and the weekly / monthly schedule. Verify: <ul style="list-style-type: none"> • There is sufficient staff available by classification and volume to care for the patients served. • The staff qualifications including education, experience, certifications, current licensure where appropriate and competencies are appropriate for assigned responsibilities. 8. Review personnel files to verify that the staff qualifications including education, experience, certifications, current licensure where appropriate and competencies are 	

OUTPATIENT SERVICES

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
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31.00.03 Documentation in Patient Records.

All consultation reports, laboratory reports, radiology reports, etc., shall be reviewed with appropriate follow-up action noted in the outpatient record.

Appropriate follow up shall be defined in the outpatient services policies and procedures.

appropriate for assigned responsibilities.

9. Compare duty rosters to patient log to verify that sufficient MD/DO, nurses and other staff are available to provide care to verify that the types and number of qualified personnel are appropriate for the types and numbers of patients receiving care, and the frequency, duration, and complexity of services offered.

CHART REVIEW & DOCUMENT REVIEW

Review policy and procedures.

Review medical records for determination of appropriate follow-up action. Verify:

1. Follow-up expectations are defined in facility policy.
2. Outpatient medical records demonstrate appropriate follow-up action, consistent with policy.

- 1 =Compliant
- 2 = Not Compliant

This standard is not met as evidenced by:

OUTPATIENT SERVICES

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>31.00.04 <u>Patient Satisfaction.</u> Patient satisfaction questionnaires / comment cards shall be available for patients.</p>	<p>Self-explanatory.</p>	<p style="text-align: center;"><u>DOCUMENT REVIEW</u></p> <p>Verify:</p> <ol style="list-style-type: none"> 1. Patient satisfaction is measured for outpatient services. 2. Review data. 	<p><input type="checkbox"/> 1 =Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>
<p>31.00.05 <u>Activity Logs.</u> The facility shall have appointment / encounter / recall and phone logs in use that are up to date.</p>	<p>Self-explanatory.</p>	<p style="text-align: center;"><u>DOCUMENT REVIEW</u></p> <p>Review the appointment / recall and phone logs.</p> <p>Verify:</p> <ul style="list-style-type: none"> • Documentation is current and consistent with policy. 	<p><input type="checkbox"/> 1 =Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>
<p>31.00.06 <u>After-Hours Resources.</u> The facility shall have after-hours care arrangements in place with call schedules available for the patients.</p>	<p>Self-explanatory.</p>	<p style="text-align: center;"><u>DOCUMENT, REVIEW, & INTERVIEW</u></p> <p>Review after-hours arrangements. If possible, interview a patient. Verify:</p> <ol style="list-style-type: none"> 1. Processes are in place to meet this requirement. 2. The after-hours care arrangements are clearly communicated to patients. 	<p><input type="checkbox"/> 1 =Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

OUTPATIENT SERVICES

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
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31.00.07 Referrals.

The facility shall have arrangements in place for referring patients that require higher level of appropriate care (i.e. hospitalizations, consults, procedures, and diagnostics).

Self-explanatory.

INTERVIEW

Interview the person responsible for outpatient service. Verify:

- Arrangements for these levels of care are in place.

- 1 =Compliant
 2 = Not Compliant

This standard is not met as evidenced by:

31.00.08 Not Applicable.

31.00.09 Not Applicable.

31.00.10 Storage.

The commodities supplied to patient care and support services are stored in such a manner so as to protect them from damage, or loss, such as from moisture, thermal change, rodents, vermin, or theft.

Self-explanatory.

OBSERVATION

Observe supply carts, cabinets, and storeroom(s). Verify:

- Supplies are appropriately stored and protected from damage due to moisture, temperature changes, theft, and etc.

- 1 =Compliant
 2 = Not Compliant

This standard is not met as evidenced by:

OUTPATIENT SERVICES

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>31.00.11 <u>Orders for Outpatient Services.</u> <i>Outpatient services must be ordered by a practitioner who meets the following conditions:</i></p> <p>(1) <i>Is responsible for the care of the patient.</i></p> <p>(2) <i>Is licensed in the State where he or she provides care to the patient.</i></p> <p>(3) <i>Is acting within his or her scope of practice under State law.</i></p> <p>(4) <i>Is authorized in accordance with State law and policies adopted by the medical staff, and approved by the governing body, to order the applicable outpatient services. This applies to the following:</i></p> <p>(i) <i>All practitioners who are appointed to the hospital's medical staff and who have been granted privileges to order the applicable outpatient services.</i></p> <p>(ii) <i>All practitioners not appointed to the medical staff, but who satisfy the</i></p>	<p>Orders for outpatient services may be made by any practitioner who is:</p> <ol style="list-style-type: none"> 1. Responsible for the care of the patient; 2. Licensed in, or holds a license recognized in, the jurisdiction where he/she provides care to the patient; 3. Acting within his/her scope of practice under State law; and 4. Authorized by the medical staff to order the applicable outpatient services under a written hospital policy that is approved by the governing body. This includes both practitioners who are on the hospital medical staff and who hold medical staff privileges that include ordering the services, as well as other practitioners who are not on the hospital medical staff, but who satisfy the hospital's policies for ordering applicable outpatient services. <p>This regulation allows hospitals to accept orders for outpatient services both from practitioners who hold hospital privileges as well as practitioners who do not, including those who are not located in the hospital's close geographic area.</p> <ul style="list-style-type: none"> • It is not uncommon for individuals to obtain health care services in a variety of locations from a variety of practitioners. Sometimes an individual elects to seek services from a specialist in a tertiary setting removed from the 	<p style="text-align: center;"><u>DOCUMENT REVIEW</u></p> <ol style="list-style-type: none"> 1. Determine whether the facility allows outpatient services to be ordered by non-physician practitioners or physicians who are not members of the medical staff. 2. Determine that the facility has medical staff approved policies that address the professionals that are eligible to order outpatient services. <p>Survey a variety of settings that offer outpatient services. Ask department staff whether orders or referrals for that type of outpatient service are accepted from practitioners who do not hold hospital privileges. If yes:</p> <ol style="list-style-type: none"> 1. Ask for evidence that the medical staff has adopted the policy. 2. Ask how the hospital verifies that the order or referral comes from a referring practitioner who is appropriately licensed in the jurisdiction where he/she provides care to the patient and is practicing within his/her scope of practice under State law to prescribe such orders. Ask for documentation of such verification efforts. 3. Ensure the same verification process is followed consistently in all outpatient settings. 	<p> <input type="checkbox"/> Compliant <input type="checkbox"/> Not Compliant <input type="checkbox"/> Not Applicable </p> <p>This standard is not met as evidenced by:</p>

OUTPATIENT SERVICES

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p><i>above criteria for authorization by the medical staff and the hospital for ordering the applicable outpatient services for their patients.</i></p> <p>§482.54(c) §482.54(c)(1) §482.54(c)(2) §482.54(c)(3) §482.54(c)(4) §482.54(c)(4)(i) §482.54(c)(4)(ii)</p>	<p>area where the individual lives, but prefers to get follow-up care, such as physical therapy after a surgery, closer to home. Sometimes an individual may have multiple residences in different areas and may need to continue care locally when moving between residences. Sometimes individuals receive urgent or even emergent care while traveling.</p> <ul style="list-style-type: none"> • Accepting orders and referrals for outpatient services from practitioners not on the medical staff or not holding privileges enables a hospital to promote ready access to care for patients in the area it serves. • Finally, sometimes a practitioner who does not practice in a local hospital may nevertheless refer patients to that hospital for outpatient services, such as diagnostic imaging, physical and occupational therapy, etc. <p><u>AUTHORITY</u> The authority to write orders for outpatient services is covered under the hospital’s medical staff privileging process for members of the hospital’s medical staff and for practitioners who have been granted privileges by the hospital without being appointment to the medical staff.</p> <p>For practitioners who do not hold hospital privileges the hospital’s medical staff policy may permit them to refer patients to the hospital with orders for specific outpatient services so long as all of the above</p>		

OUTPATIENT SERVICES

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criteria are met.

- (1) The policy must address how the hospital verifies the referring/ordering practitioner is appropriately licensed and acting within his/her scope of practice. The regulation does not prescribe the details of the licensure and scope of practice verification process but instead provides a hospital the flexibility to accomplish this in the manner it finds efficient and effective.

- (2) The hospital is expected to ensure the verification process is followed for all outpatient services in all hospital locations.

- (3) The policy must also make clear whether the policy applies to all hospital outpatient services, or whether there are specific services for which orders may only be accepted from practitioners with medical staff privileges. For example, a hospital may prefer not to accept orders for a regimen of outpatient chemotherapy or outpatient therapeutic nuclear medicine services from a referring physician who does not hold medical staff privileges. In such cases, the hospital's policy must make these exceptions clear to the general authorization for accepting orders from referring practitioners.

A hospital is required to comply with this requirement only if it chooses to allow practitioners who are not members of the medical staff to order outpatient services.

OUTPATIENT SERVICES

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Hospitals have the flexibility to determine whether or not they will allow a practitioner who is not a member of the medical staff to order outpatient services as well as the ability to establish through medical staff bylaws and hospital policy other parameters for who will and who will not be authorized to order outpatient services.

If a hospital is unable or unwilling to verify the respective State scope of practice, licensure, etc., for a practitioner, the hospital is not required to authorize the practitioner to order outpatient services in its facility.

If a hospital allows practitioners who are not on the hospital's medical staff to order hospital outpatient services, the hospital must be able to demonstrate compliance with the regulatory requirement.

If the facility chooses to allow outpatient services to be ordered by non-physician practitioners or physicians that are not members of the medical staff, the hospital has medical staff approved policies and procedures that establish:

1. Whether to allow non-physician practitioners, such as Physical Therapists, Occupational Therapists, Speech Language Pathologists, qualified Dietitians, and qualified nutrition professionals to write orders, consistent with State law and regulations.
2. Whether to allow practitioners with a

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professional license from another State to write outpatient orders, consistent with State law and regulations.

3. When presented with a referral or order for outpatient services from a practitioner who does not have privileges at the hospital, prior to performing the test or procedure, staff perform verification that practitioner who does not have privileges at the hospital:
 - a) Is licensed in the State where he or she provides care to the patient.
 - b) Is acting within his or her scope of practice under State law.
 - c) Is authorized in accordance with State law and policies adopted by the medical staff, and approved by the governing body, to order the applicable outpatient services.

The above medical staff policies are approved by the governing body at least every three (3) years and more often as changes are implemented.

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31.00.12 STANDARD:
Outpatient Services.
 If the hospital provides outpatient services, the services must meet the needs of the patients in accordance with acceptable standards of practice.

§482.54

Self-explanatory.

DOCUMENT REVIEW

Surveyor: After reviewing all CMS requirements:

- Identification of CMS standard-level deficiencies within the Condition of Participation should be cited here if non-compliance does not rise to the Condition level.
- Do NOT include HFAP standard deficiencies.

- 1 =Compliant
- 2 = Not Compliant

This standard is not met as evidenced by:

SWING BEDS

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CLARIFICATION OF TERMS RELATING TO ‘SPOUSAL’ RELATIONSHIPS.

Section 3 of the Defense of Marriage Act (DOMA), enacted in 1996 (codified at 1 U.S.C. §7), defined “marriage” and “spouse” as follows:

- “The word ‘marriage’ means only a legal union between one man and one woman as husband and wife, and
- The word ‘spouse’ refers only to a person of the opposite sex who is a husband or a wife.”

However, in June 2013, the United States Supreme Court ruled that Section 3 of DOMA is unconstitutional, because it violates equal protection (*United States v. Windsor*, 570 U.S. 12, 133 S. Ct. 2675 (2013) (“*Windsor*”). After the Supreme Court’s opinion in *Windsor*, section 3 of DOMA is no longer a barrier to the Federal government recognizing same-sex marriages when administering Federal statutes and programs.

CMS is clarifying in our guidance for provider and supplier types subject to certification the following terms: “spouse,” “marriage,” “family,” and “relative” consistently with the *Windsor* decision. Specifically:

- “Spouse” means an individual who is married to another individual as a result of marriage lawful where it was entered into, including a lawful same-sex marriage, regardless of whether the jurisdiction where the provider or supplier providing health care services to the individual is located, or in which the spouse lives, permits such marriages to occur or recognizes such marriages.
- “Marriage” means a marriage lawful where it was entered into, including a lawful same-sex marriage, regardless of whether the jurisdiction where the provider or supplier providing health care services to the individual is located, or in which the spouse lives, permits such marriages to occur or recognizes such marriages;
- “Family” includes, but is not limited to, an individual’s “spouse” (see above); and
- “Relative,” when used as a noun, includes, but is not limited to, an individual’s “spouse” (see above)

Further, we are clarifying that, except where CMS regulations explicitly require an interpretation in accordance with State law, wherever the text of a regulation or associated guidance uses the above terms or includes a reference to a patient’s or resident’s “representative,” “surrogate,” “support person,” “next-of-kin,” or similar term in such a manner as would normally implicitly or explicitly include a spouse, the terms are to be interpreted consistent with the guidance above.

SWING BEDS

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>32.00.00 <u>Special Requirement for Hospital Providers of Long-Term Care Services (“Swing-Beds”).</u> A hospital that has a Medicare provider agreement must meet the following requirements in order to be granted an approval from CMS to provide post-hospital extended care services, as specified in <u>§409.30</u> of 42 CFR 409.30, and be reimbursed as a swing-bed hospital, as specified in <u>§413.114</u> of 42 CFR 413.114.</p> <p>§482.58</p>	<p>Surveyors assess the manner and degree of non-compliance with the swing bed standards in determining whether there is condition-level compliance or non-compliance.</p>	<p><u>Score this standard based on the results of scoring from standards 32.00.01-32.05.05</u></p>	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant <input type="checkbox"/> NA = Chapter Not Applicable in this facility.</p> <p>Comment:</p>
<p>32.00.01 <u>Eligibility.</u> A hospital must meet the following eligibility requirements:</p> <p>(1) <i>The facility has fewer than 100 hospital beds, excluding beds for newborns and beds in intensive care type inpatient units (for eligibility of hospitals with distinct parts electing the optional reimbursement method, see §413.24(d)(5) of 42 CFR 413.24).</i></p> <p>(2) <i>The hospital is located in a rural area. This includes all areas not</i></p>	<p>The swing-bed concept allows a hospital to use their beds interchangeably for either acute-care or post-acute care. A “swing-bed” is a change in reimbursement status. The patient swings from receiving acute-care services and reimbursement to receiving skilled nursing (SNF) services and reimbursement.</p> <p>Allowing a hospital to operate swing-beds is done by issuing a “swing-bed approval.”</p> <ul style="list-style-type: none"> If the facility fails to meet the swing-bed “requirements” (not the same as the provider CoPs), and the facility chooses not to initiate a plan of correction, they lose the approval to operate swing-beds and receive swing-bed reimbursement. 	<p><u>DOCUMENT REVIEW AND INTERVIEW</u></p> <ol style="list-style-type: none"> Verify total number of beds meets eligibility requirements. Verify the facility meets criteria as a rural facility. Verify the facility does NOT have a nursing waiver in place. Verify the facility has not had a termination of swing bed approval within the 2 years prior to application. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>Comments:</p>

SWING BEDS

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p><i>delineated as “urbanized” areas by the Census Bureau, based on the most recent census.</i></p> <p>(3) The hospital does not have in effect a 24-hour nursing waiver granted under §488.54(c) of 42 CFR 488.54.</p> <p>(4) The hospital has not had a swing-bed approval terminated within the two years previous to application.</p> <p>§482.58(a) §482.58(a)(1) §482.58(a)(2) §482.58(a)(3) §482.58(a)(4)</p>	<ul style="list-style-type: none"> The facility does not go on a termination track. If the hospital continues to meet the CoPs for the provider type, it continues to participate in Medicare, but loses swing-bed approval. <p>Swing beds do not have to be located in a special section of the hospital. The patient does not have to change locations in the hospital merely because their status changes unless the hospital requires it.</p> <ul style="list-style-type: none"> The change in status from acute care to swing-bed status can occur within the same part of the hospital for swing-bed admission Likewise, a patient may be discharged from one hospital and admitted in swing bed status to another hospital that has swing bed approval. <p>There must be discharge orders changing status from acute care services, appropriate progress notes, discharge summary, and subsequent admission orders to swing-bed status regardless of whether the patient stays in the same hospital or transfers to another hospital with swing bed approval.</p> <p>If the patient remains within the hospital, the same chart can be utilized but the swing-bed section of the chart must be separate, with appropriate admission orders, progress notes, and supporting documents.</p> <p>There is no length of stay restriction for any hospital swing-bed patient. There is no Medicare requirement to place a swing-bed patient in a nursing home and</p>		

SWING BEDS

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
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there are no requirements for transfer agreements between hospitals and nursing homes.

The statute governing Medicare payment requires a 3-day qualifying stay in any hospital or CAH prior to admission to a swing bed in any hospital or CAH, or **admission to a skilled nursing facility (SNF)**. The **Medicare beneficiary's** swing-bed stay must fall within the same spell of illness as the qualifying stay.

- **This requirement applies only to patients who are Medicare beneficiaries who seek Medicare coverage of their SNF services. It is not enforced through the survey and certification process, since it is a payment requirement.**

In accordance with SOM Section 2037 hospitals seeking swing bed approval are screened prior to survey for their eligibility for swing beds. However, the CMS Regional Office makes the determination whether the hospital has satisfied the eligibility criteria, regardless of whether the State Survey Agency or Accrediting Organization, as applicable, recommends approval of swing bed status.

This requirement does not apply to patients who are not receiving Medicare reimbursement.

32.00.02 Not Applicable.

32.00.03 Not Applicable.

SWING BEDS

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32.00.04 Not Applicable.

32.00.05 Not Applicable.

32.00.06 Skilled Nursing Facility Services.

The facility must be in substantial compliance with the following skilled nursing facility requirements which are scored individually.

- (1) Resident rights (§483.10(b)(3), (b)(4), (b)(5), (b)(6), (d), (e), (h), (i), (j)(1)(vii), (j)(1)(viii), (l), and (m)),
- (2) Admission, transfer, and discharge rights (§483.12(a)(1), (a)(2), (a)(3), (a)(4), (a)(5), (a)(6) and (a)(7),
- (3) Resident behavior and facility practices (§483.13),
- (4) Patient activities (§483.15 (f)),
- (5) Social services (§483.15(g)),
- (6) Discharge Planning. (§483.20(l)),
- (7) Specialized rehabilitative services (§483.45),

Self-explanatory.

Swing-bed standards within this chapter are applicable to **only those** acute care hospitals and critical access hospitals (CAH) **that have a Medicare provider agreement for Swing-beds**

Scoring deferred.

This standard is scored, as applicable, individually throughout the chapter.

SWING BEDS

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
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(8) Dental services (§483.55),

§482.58(b)

32.01.01 Resident Rights.

The resident has the right to a dignified existence, self-determination and communication with and access to persons and services inside and outside the facility.

A facility must protect and promote the rights of each resident, including each of the following rights.

§483.10

Long-term residents have rights guaranteed to them under federal and state law.

OBSERVATION, CHART REVIEW, & INTERVIEW

Review the document listing patient rights to determine it includes required rights as identified in 32.01.02 through 32.02.02.

Review the policy on the communication services/mechanisms available to patients who face problems with communication, hearing and cognition limits.

Verify:

1. The policy addresses all impairments.
2. The written rights materials are produced in an alternative language as needed by the population served, or resources are available for interpretation.

- 1 = Compliant
 2 = Not Compliant

This standard is not met as evidenced by:

SWING BEDS

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>32.01.02 <u>Notice of Rights and Services.</u> <i>The resident has the right to be fully informed in language that he or she can understand of his or her total health status, including but not limited to, his or her medical condition;</i></p> <p>§483.10(b)(3)</p>	<p>The intent of this requirement is to assure that each resident knows his or her rights and responsibilities and that the facility communicates this information prior to or upon admission, during the resident’s stay, and when the facility’s rules changes.</p> <p>A facility must promote the exercise of rights for all residents, including those who face barriers such as communication problems, hearing problems and cognition limits.</p> <p>These rights include the resident’s right to:</p> <ul style="list-style-type: none"> • Be informed about what rights and responsibilities the resident has (<u>§483.10(b)(3 through 6)</u>); • Choose a physician (<u>§483.10(d)</u>); • Participate in decisions about treatment and care planning (<u>§483.10(d)</u>); • Have privacy and confidentiality (<u>§483.10(e)</u>); • Work or not work (<u>§483.10(h)</u>); • Have privacy in sending and receiving mail (<u>§483.10(i)</u>); • Visit and be visited by others from outside the facility (<u>§483.10(j)(1)(vii and viii)</u>); • Retain and use personal possessions (<u>§483.10(l)</u>); 	<p><u>OBSERVATION AND CHART REVIEW</u></p> <ol style="list-style-type: none"> 1. Look for on-going efforts on the part of facility staff to keep residents informed. 2. Look for evidence that information is communicated in a manner that is understandable to residents. 3. Is information available when it is most useful to the residents such as when they are expressing concerns, raising questions, and on an on-going basis? 4. Is there evidence in the medical record that the patient was informed of his rights, including the right to accept or refuse medical or surgical treatment? 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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- Share a room with a spouse (§483.10(m)).

“Total health status” includes;

- functional status,
- medical care,
- nursing care,
- nutritional status,
- rehabilitation and restorative potential,
- activities potential,
- cognitive status,
- oral health status,
- psychosocial status, and
- sensory and physical impairments.

Information on health status must be presented in language that the resident can understand. Communicating with the resident in language that the resident can understand includes minimizing the use of technical words, providing interpreters for non-English speaking residents, using sign language when needed, or other interventions, as appropriate.

SWING BEDS

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>32.01.03 <u>Right to Refuse Treatment.</u> <i>The resident has the right to refuse treatment, to refuse to participate in experimental research, and to formulate an advance directive as specified in paragraph 8 of 42 CFR 483.10; and</i></p> <p>§483.10(b)(4)</p>	<p>“Treatment” is defined as care provided for purposes of maintaining / restoring health, improving functional level, or relieving symptoms.</p> <p>“Experimental research” is defined as development and testing of clinical treatments, such as an investigational drug or therapy that involve treatment and/or control groups. For example, a clinical trial of an investigational drug would be experimental research.</p> <p>“Advance directive” means a written instruction, such as living will or durable power of attorney for health care, recognized under state law, relating to the provisions of health care when the individual is incapacitated.</p> <p>A resident who has the capacity to make a health care decision and who withholds consent to treatment or makes an explicit refusal of treatment either directly or through an advance directive, may not be treated against his/her wishes.</p> <p>The resident has the right to refuse to participate in experimental research. A resident being considered for participation in experimental research must be fully informed of the nature of the experiment and understand the possible consequences of participating. The opportunity to refuse to participate in experimental research must occur prior to the start of the research. Aggregated resident statistics that do not identify individual residents may be used for studies without obtaining resident permission.</p>	<p><u>INTERVIEW AND OBSERVATION</u></p> <p>If the facility participates in any experimental research involving residents, does it have an Institutional Review Board or other committee that reviews and approves research protocols?</p> <p>The requirement at <u>§483.75(c)</u> “Relationship to Other HHC Regulations may apply,” see <u>45 CFR Part 46</u>, Protection of Human Subjects of Research. “Although these regulations at §483.75(c) are not in themselves considered requirements under this part, their violation may result in the termination or suspension of, or the refusal to grant or continue payment with Federal funds.”</p> <p><u>DOCUMENT REVIEW</u></p> <p>Review the facility’s policies on refusal of care and advance directives to determine that the requirement is met.</p> <p><u>CHART REVIEW AND INTERVIEW</u></p> <p>Verify that the advance directive is being enforced, is included in the plan of care, and does not preclude the provision of supportive care delivery.</p>	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

SWING BEDS

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>32.01.04 Medicaid & Medicare Notification. <i>The facility must--</i> (i) <i>Inform each resident who is entitled to Medicaid benefits, in writing, at the time of admission to the nursing facility or, when the resident becomes eligible for Medicaid of-</i> (A) <i>The items and services that are included in nursing facility services under the State plan and for which the resident may not be charged;</i> (B) <i>Those other items and services that the facility offers and for which the resident may be charged, and the amount of charges for those services; and</i> (ii) <i>Inform each resident when changes are made to the items and services specified in paragraphs (5)(i)(A) and (B) of 42 CFR 483.10.</i></p> <p>§483.10(b)(5)</p> <p><i>The facility must inform each resident before, or at the time of admission, and periodically during the resident's stay, of services available in the facility and of charges for those services,</i></p>	<p>If Medicare or Medicaid does not make payment for services, the provider must fully inform the resident of any related charges both at the time of admission and prior to the time that changes will occur in their bills.</p> <p>Listed below are general categories and examples of items and services that the facility may charge to resident funds, if they are requested and agreed to by a resident.</p> <ul style="list-style-type: none"> • Telephone • Television / radio for personal use • Personal comfort items including smoking materials, notions, novelties, and confections • Cosmetic and grooming items and services in excess of those for which payment is made • Personal clothing • Personal reading matter • Gifts purchased on behalf of a resident • Flowers and plants • Social events and entertainment offered outside the scope of the activities program • Non-covered special care services such as privately hired nurses or aides 	<p style="text-align: center;">INTERVIEW</p> <p>Verify that notification of covered services and charges is enforced.</p> <p>Ask the resident about out of pocket expenses for items and services.</p> <ul style="list-style-type: none"> • Who handles payments? • How do they know the cost of items and services? • Do they receive an explanation of charges in their bill? 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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including any charges for services not covered under Medicare or by the facility's per diem rate.

§483.10(b)(6)

- Private room, except when therapeutically required for example, isolation for infection control
- Specially prepared or alternative food requested

32.01.05 Advance Directives.

The facility must comply with the requirements specified in subpart I of part 489 of 42 CFR 489 relating to maintaining written policies and procedures regarding advance directives. These requirements include provisions to inform and provide written information to all adult residents concerning the right to accept or refuse medical or surgical treatment and, at the individual's option, formulate an advance directive.

This includes a written description of the facility's policies to implement advance directives and applicable State law.

Facilities are permitted to contract with other entities to furnish this information but are still legally responsible for ensuring that the

This provision applies to residents admitted on or after December 1, 1991. The regulation at 42 CFR §489.102 specifies that at the time of admission of an adult resident, the facility must:

- Maintain written policies and procedures concerning advance directives with respect to all adult individuals receiving medical care;
- Provide written information concerning his or her rights under State law (whether statutory or recognized by the courts of the State) to make decisions concerning medical care, including the right to accept or refuse medical or surgical treatment, and the right to formulate advance directives;
- Document in the resident's medical record whether or not the individual has executed an advance directive;
- Not condition the provision of care or otherwise discriminate against an individual based on whether or not the individual has executed an advance directive;

CHART REVIEW

1. Review clinical records to determine that advance directives were requested on all patients and copies are available.
2. Review the records of sampled residents admitted on or after December 1, 1991, for facility compliance with advance directive notice requirements.
3. Determine to what extent the facility educates its staff regarding advance directives.
4. Determine to what extent the facility provides education for the community regarding individual rights under State law to formulate advance directives.

- 1 = Compliant
- 2 = Not Compliant

This standard is not met as evidenced by:

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STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p><i>requirements of 42 CFR 483.10 are met.</i></p> <p><i>If an adult individual is incapacitated at the time of admission and is unable to receive information (due to the incapacitating condition or a mental disorder) or articulate whether or not he or she has executed an advance directive, facility may give advance directive information to the individual’s family or surrogate in the same manner that it issues other materials about policies and procedures to the family of the incapacitated individual or to a surrogate or other concerned persons in accordance with State law.</i></p> <p><i>The facility is not relieved of its obligation to provide this information to the individual once he or she is no longer incapacitated or unable to receive such information. Follow-up procedures must be in place to provide the information to the individual directly at the appropriate time.</i></p> <p><i>“Advance directive” means a written instruction, such as a living will or durable power of attorney for health care recognized under State law, relating to the provision of health care</i></p>	<ul style="list-style-type: none"> • Ensure compliance with requirements of State law regarding advance directives; • Provide for educating staff regarding the facility’s policies and procedures on advance directives; and • Provide for community education regarding issues concerning advance directives. <p>The facility is not required to provide care that conflicts with an advance directive. In addition, the facility is also not required to implement an advance directive if, as a matter of conscience, the provider cannot implement an advance directive, and state law allows the provider to conscientiously object.</p> <p>The sum total of the community education efforts must include a summary of the state law, the rights of residents to formulate advance directives, and the facility’s implementation policies regarding advance directives.</p> <p>Video and audio tapes may be used in conducting the community education effort. Individual education programs do not have to address all the requirements if it would be inappropriate for a particular audience.</p>		

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STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
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when the individual is incapacitated.

§483.10(b)(8)

32.01.06 Personal Physician.

The resident has the right to:

- *Choose a personal attending physician.*

§483.10(d)

§483.10(d)(1)

A resident in a swing-bed of a general acute care hospital can choose his/her own physician, unless the hospital requires that physicians of residents in hospital swing-beds have hospital admitting privileges. If this is so, the resident can choose his/her own physician from those with appropriate privileges.

- The right to choose a personal physician does not mean that the physician must serve the resident.
- If the physician of the resident's choosing fails to fulfill a given requirement, such as frequency of physician visits, the facility will have the right, after informing the resident, to seek alternate physician participation to assure provision of appropriate and adequate care and treatment.

A facility may not place barriers in the way of residents choosing their own physician. If a resident does not have a physician, or if the resident's physician becomes unable or unwilling to continue providing care to the resident, the facility must assist the resident in exercising his/her choice in finding another physician. A resident can choose his/her own physician, but cannot have a physician who does not have swing bed admitting privileges.

The requirement for free choice is met if a resident is

DOCUMENT REVIEW

Review the facility's policies to determine that the requirement is met.

INTERVIEW

Interview patients to verify they were given the opportunity to select their own personal physician.

- 1 = Compliant
- 2 = Not Compliant

This standard is not met as evidenced by:

SWING BEDS

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
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allowed to choose a personal physician from among those who have practice privileges.

32.01.07 Informed of Care and Treatment.

The resident has the right to:

- *Be fully informed in advance about care and treatment and of any changes in that care or treatment that may affect the resident's well being.*

§483.10(d)(2)

"Informed in advance," means that the resident receives information necessary to make a health care decision.

The information should include his/her medical condition, changes in his/her medical condition, the benefits and reasonable risks of the recommended treatment, and reasonable alternatives.

If there are any financial costs to the resident in the treatment options, they should be disclosed in advance and in writing to the resident prior to his/her decision.

INTERVIEW

Interview the person responsible for the Swing-bed services to determine how the standards are met.

CHART REVIEW

Review medical records for evidence that the resident has been notified in advance of care and treatment and changes in care.

- 1 = Compliant
- 2 = Not Compliant

This standard is not met as evidenced by:

32.01.08 Participation in Care.
The resident has the right to:

- *Unless adjudged incompetent or otherwise found to be incapacitated under the laws of the State, participate in planning care and treatment or changes in care and treatment.*

§483.10(d)(3)

"Participates in planning care and treatment," means that the resident is afforded the opportunity to select from alternative treatments, to the level of his ability to understand.

This applies both to initial decisions about care and treatment and to decisions about changes in care and treatment.

INTERVIEW

Interview the person responsible for the Swing-bed services to determine how the standards are met.

CHART REVIEW

- Review medical records for evidence that the resident has participated in planning and treatment care changes. There should be a notation in the multidisciplinary care meetings of patient participation.

- 1 = Compliant
- 2 = Not Compliant

This standard is not met as evidenced by:

SWING BEDS

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
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32.01.09 Personal Privacy & Confidentiality.

The resident has the right to personal privacy and confidentiality of his/her personal and clinical records.

(1) *Personal privacy includes accommodations, medical treatment, written and telephone communications, personal care, visits, and meetings of family and*

“Right to privacy” means the resident has the right to privacy with whomever the resident wishes to be private and this privacy should include full visual, and to the extent desired, for visits and other activities, auditory privacy. **Private space may be created flexibly and need not be dedicated solely for visitation purposes.**

- For example, privacy for visitation or meetings might be arranged by using a dining area between meals, a vacant chapel, office or room; or an

- Look for evidence that the resident was afforded the right to participate in care planning or was consulted about care and treatment changes.
- If there appears to be a conflict between a resident’s right and the resident’s health or safety, determine if the facility attempted to accommodate both the exercise of the resident’s rights and the resident’s health, including exploration of care alternatives through a thorough care planning process in which the resident may participate.
- If a resident whose ability to make decisions about care and treatment is impaired, was he kept informed and consulted on personal preferences to the level of his ability to understand?

INTERVIEW

Interview a select sample of residents to determine that they understand they have the right to personal privacy in their care and treatment, and of their clinical records.

OBSERVATION

1. Observe the area to assure there is knocking on the door before entering a residents room and that there are privacy curtains pulled when a treatment is given. Look for breeches

- 1 = Compliant
- 2 = Not Compliant

This standard is not met as evidenced by:

SWING BEDS

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p><i>resident groups but this does not require the facility to provide a private room for each resident.</i></p> <p>(2) <i>Except as provided in paragraph (e)(3) of 42 CFR 483.10, the resident may approve or refuse the release of personal and clinical records to any individual outside the facility.</i></p> <p>(3) <i>The resident's right to refuse release of personal and clinical records does not apply when—</i></p> <p>(i) <i>The resident is transferred to another healthcare institution.</i></p> <p>(ii) <i>Record release is required by law.</i></p> <p>§483.10(e) §483.10(e)(1) §483.10(e)(2) §483.10(e)(3) §483.10(e)(3)(i) §483.10(e)(3)(ii)</p>	<p>activities area when activities are not in progress. Arrangements for private space could be accomplished through cooperation between the facility's administration and resident or family groups so that private space is provided for those requesting it without infringement on the rights of other residents.</p> <p>Facility staff must examine and treat residents in a manner that maintains the privacy of their bodies. A resident must be granted privacy when going to the bathroom and in other activities of personal hygiene. If an individual requires assistance, authorized staff should respect the individual's need for privacy.</p> <p>Only authorized staff directly involved in treatment should be present when treatments are given. People not involved in the care of the individual should not be present without the individual's consent while he/she is being examined or treated. Staff should pull privacy curtains, close doors, or otherwise remove residents from public view and provide clothing or draping to prevent unnecessary exposure of body parts during the provision of personal care and services.</p>	<p>of visual and audible privacy as well as security of the medical record.</p> <p>2. Document any instances where you observe a resident's privacy being violated. Completely document how the resident's privacy was violated.</p> <p>3. Documentation Example: Resident #12 left without gown or bed covers and unattended on 2B Corridor at 3:30 p.m. February 25, 2001. Identify the responsible party, if possible.</p>	

SWING BEDS

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>32.01.10 Work. <i>The resident has the right to:</i> (1) <i>Refuse to perform services for the facility.</i> (2) <i>Perform services for the facility, if he or she chooses, when-</i> (i) <i>The facility has documented the need or desire for work in the plan of care.</i> (ii) <i>The plan specifies the nature of the services performed, and whether the services are voluntary or paid.</i> (iii) <i>Compensation for paid services is at or above prevailing rates.</i> (iv) <i>The resident agrees to the work arrangement described in the plan of care.</i></p> <p>§483.10(h)(1) §483.10(h)(2) §483.10(h)(2)(i) §483.10(h)(2)(ii) §483.10(h)(2)(iii) §483.10(h)(2)(iv)</p>	<p>All resident work, whether of a voluntary or paid nature, shall be part of the plan of care.</p> <p>A resident’s desire for work is subject to medical appropriateness. As part of the plan of care, a therapeutic work assignment must be agreed to by the resident.</p> <p>The resident also has the right to refuse such treatment at any time that he or she wishes.</p> <p>At the time of development or review of the plan, voluntary or paid work can be negotiated.</p> <p>The “prevailing rate” is the wage paid to workers in the community surrounding the facility for the same type, quality, and quantity of work requiring comparable skills.</p>	<p style="text-align: center;"><u>INTERVIEW</u></p> <p>Interview the person responsible for the Swing bed unit to determine that the requirement was met.</p> <ol style="list-style-type: none"> Are residents engaged in work (e.g., doing housekeeping, doing laundry, preparing meals)? Pay special attention to the possible work activities of residents with intellectual disabilities or mental illness. If a resident is performing work, determine whether it is voluntary, and whether it is described in the plan of care. Is the work mutually agreed upon between the resident and the treatment team? <p style="text-align: center;"><u>CHART REVIEW</u></p> <p>Review a select sample of residents’ records to determine that the required documentation was in the chart—inclusion in the plan of care, consent of the patient, and whether the patient is compensated and at what rate.</p>	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

SWING BEDS

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>32.01.11 Mail. <i>The resident has the right to privacy in written communications, including the right to:</i></p> <p>(1) <i>Send and promptly receive mail that is unopened.</i></p> <p>(2) <i>Have access to stationery, postage, and writing implements at the resident's own expense.</i></p> <p>§483.10(i) §483.10(i)(1) §483.10(i)(2)</p>	<p>"Promptly" means delivery of mail or other materials to the resident within 24 hours of delivery by the postal service (including a post office box) and delivery of outgoing mail to the postal service within 24 hours of regularly scheduled postal delivery and pickup service.</p>	<p style="text-align: center;"><u>INTERVIEW</u></p> <ul style="list-style-type: none"> Interview the person responsible for the Swing bed unit to determine how the requirement was met. Interview a resident to determine that the requirement was met. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>
<p>32.01.12 Access & Visitation Rights. <i>The resident has the right and the facility must provide immediate access to any resident by the following:</i></p> <ul style="list-style-type: none"> <i>Subject to the resident's right to deny or withdraw consent at any time, immediate family or other relatives of the resident.</i> <i>Subject to reasonable restrictions and the resident's right to deny or withdraw consent at any time, others who are visiting with the consent of the resident.</i> 	<p>The facility may set reasonable hours for visitation.</p> <p>If it would violate the rights of a roommate to have visitors in the resident's room, the facility must establish alternate areas in the facility for visiting. These areas could include the chapel, a suitable office area, a dining room, or a porch or patio area.</p>	<p style="text-align: center;"><u>DOCUMENT REVIEW</u></p> <p>Review the policy or process for visitation in the facility to ensure that reasonable guidelines are in place and that there is a clear patient consent process for visitors defined.</p> <p style="text-align: center;"><u>INTERVIEW</u></p> <p>Interview patients to determine the process is in force.</p>	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

SWING BEDS

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
§483.10(j) §483.10(j)(1) §483.10(j)(1)(vii) §483.10(j)(1)(viii)	<p>32.01.13 Personal Property. <i>The resident has the right to retain and use personal possessions, including some furnishings, and appropriate clothing, as space permits, unless to do so would infringe upon the rights or health and safety of other residents.</i></p> <p>The intent of this regulation is to encourage residents to bring personal possessions into the facility, as space, safety considerations and fire code permits.</p> <p>All residents’ possessions must be treated with respect and safeguarded.</p>	<p><u>DOCUMENT REVIEW</u> Review the facility’s policies to determine that the requirement is met.</p> <p><u>OBSERVATION</u> Observe the patient rooms to determine that residents have personal possessions.</p> <p>If residents’ rooms have few personal possessions, ask residents and families if:</p> <ul style="list-style-type: none"> • They are encouraged to have and to use personal items; • Their personal property is safe in the facility. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>
§483.10(l)	<p>The facility has the right to limit personal property due to space limitations in the facility or for safety considerations.</p>	<p>If residents’ rooms have few personal possessions, ask residents and families if:</p> <ul style="list-style-type: none"> • They are encouraged to have and to use personal items; • Their personal property is safe in the facility. 	
<p>32.01.14 Married Couples. <i>The resident has the right to share a room with his or her spouse when married residents live in the same facility and both spouses consent to the arrangement.</i></p>	<p>The requirement means that when a room is available for a married couple to share, the facility must permit them to share it if they choose.</p>	<p><u>DOCUMENT REVIEW</u> Review the facilities policies to determine that the requirement is met.</p> <p><u>OBSERVATION</u> Observe the residents area to determine that if married residents are patients they have the arrangement if they request it.</p>	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>
§483.10(m)			

SWING BEDS

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>32.01.15 Transfer and Discharge: Definition. <i>(1) Transfer and discharge includes movement of a resident to a bed outside of the certified facility whether that bed is in the same physical plant or not.</i></p> <p><i>Transfer and discharge does not refer to movement of a resident to a bed within the same certified facility.</i></p> <p>§483.12(a) §483.12(a)(1)</p>	<p>The intent of the regulation on transfer and discharge provisions is to significantly restrict a facility’s ability to transfer or discharge a resident once that resident has been admitted to the facility to prevent dumping of high care or difficult residents.</p> <p>This requirement applies to transfer or discharges that are initiated by the facility, not by the resident.</p>	<p>CHART REVIEW</p> <p>Review the records of at least 5 swing-bed patients transferred / discharged from the facility since the last survey in order to determine the reasons for transfer / discharge documented by the physician</p>	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>
<p>32.01.16 Transfer & Discharge Requirements. <i>The facility must permit each resident to remain in the facility, and not transfer or discharge the resident from the facility unless—</i></p> <p><i>(i) The transfer or discharge is necessary for the resident’s welfare and the resident’s needs cannot be met in the facility.</i></p> <p><i>(ii) The transfer or discharge is appropriate because the resident’s health has improved sufficiently so the resident no longer needs the services</i></p>	<p>If transfer is due to a significant change in the resident’s condition, the facility must conduct the appropriate assessment, prior to any transfer or discharge to determine if a new care plan would allow the facility to meet the resident’s needs.</p> <p>If the significant change in the resident’s condition is an emergency, immediate transfer should be arranged.</p>	<p>CHART REVIEW</p> <p>During closed record review, determine the reasons for transfer / discharge.</p> <ol style="list-style-type: none"> Do records document accurate assessments and attempts through care planning to address the resident’s needs through multidisciplinary interventions, accommodation of individual needs, and attention to the resident’s customary routine? Did the resident’s physician document the record if the resident was transferred / discharged for the sake of the resident’s welfare and the resident’s needs could not be met in the facility (e.g., a resident 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

SWING BEDS

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p><i>provided by the facility.</i></p> <p>(iii) <i>The safety of individuals in the facility is endangered.</i></p> <p>(iv) <i>The health of individuals in the facility would otherwise be endangered.</i></p> <p>(v) <i>The resident has failed, after reasonable and appropriate notice, to pay for (or to have paid under Medicare or Medicaid) a stay at the facility. For a resident who becomes eligible for Medicaid after admission to a facility, the facility may charge resident allowable charges only under Medicaid.</i></p> <p>(vi) <i>The facility ceases to operate.</i></p> <p>§483.12(a)(2) §483.12(a)(2)(i) §483.12(a)(2)(ii) §483.12(a)(2)(iii) §483.12(a)(2)(iv) §483.12(a)(2)(v) §483.12(a)(2)(vi)</p>		<p>develops an acute condition requiring hospitalization) or the resident’s health improved to the extent that the transferred / discharged resident no longer needed the services of the facility?</p> <p>3. Did a physician document in the record if residents were transferred because the health of individuals in the facility is endangered?</p> <p>4. Do the records of residents transferred / discharged due to safety reasons reflect the process by which the facility concluded that in each instance transfer or discharge was necessary?</p> <p>5. If the entity to which the resident was discharged is another long term care facility, evaluate the extent to which the discharge summary and the resident’s physician justify why the facility could not meet the needs of this resident.</p>	

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STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>32.01.17 Documentation. <i>When the facility transfers or discharges a resident under any of the circumstances specified in paragraphs (a)(2)(i) through (v) of 42 CFR 483.12, the resident's clinical record must be documented.</i></p> <p><i>The documentation must be made by--</i></p> <p><i>(i) The resident's physician when transfer or discharge is necessary under paragraph (a)(2)(i) or paragraph (a)(2)(ii) of 42 CFR 483.12; and</i></p> <p><i>(ii) A physician when transfer or discharge is necessary under paragraph (a)(2)(iv) of 42 CFR 483.12.</i></p> <p>§483.12(a)(3) §483.12(a)(3)(i) §483.12(a)(3)(ii)</p>	<p>Documentation of the transfer/discharge may be completed by a physician extender unless prohibited by State law or facility policy.</p>	<p>CHART REVIEW</p> <p>Verify upon chart review of patients who were transferred that documentation of the reason for transfer was documented by a physician.</p>	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>32.01.18 Notice Before Transfer. <i>Before a facility transfers or discharges a resident, the facility must--</i></p> <p>(i) <i>Notify the resident and, if known, a family member or legal representative of the resident of the transfer or discharge and the reasons for the move in writing and in a language and manner they understand.</i></p> <p>(ii) <i>Record the reasons in the resident’s clinical record; and</i></p> <p>(iii) <i>Include in the notice the items described in paragraph (a)(6) of 42 CFR 483.12.</i></p> <p>§483.12(a)(4) §483.12(a)(4)(i) §483.12(a)(4)(ii) §483.12(a)(4)(iii)</p>	<p>Self-explanatory.</p>	<p><u>DOCUMENT REVIEW</u> Review the policies and procedures to verify all required elements were addressed.</p> <p><u>CHART REVIEW</u> Review at least 5 transferred or discharged patient records to determine that the documentation was complete, including all required criteria.</p>	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

SWING BEDS

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>32.01.19 <u>Timing of the Notice.</u> (i) <i>Except when specified in paragraph (a)(5)(ii) of 42 CFR 483.12, the notice of transfer or discharge required under paragraph (a)(4) of 42 CFR 483.12 must be made by the facility at least 30 days before the resident is transferred or discharged.</i></p> <p>(ii) <i>Notice may be made as soon as practicable before transfer or discharge when—</i></p> <p>(A) <i>The safety of individuals in the facility would be endangered under paragraph (a)(2)(iii) of 42 CFR 483.12;</i></p> <p>(B) <i>The health of individuals in the facility would be endangered, under paragraph (a)(2)(iv) of 42 CFR 483.12;</i></p> <p>(C) <i>The resident’s health improves sufficiently to allow a more immediate transfer or discharge, under paragraph (a)(2)(ii) of 42 CFR 483.12;</i></p>	<p>Self-explanatory.</p>	<p style="text-align: center;"><u>DOCUMENT REVIEW</u></p> <p>Review the policy to verify the requirement was met.</p> <p style="text-align: center;"><u>CHART REVIEW</u></p> <p>Review a minimum of 3 transfer/ discharge records to determine compliance.</p>	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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(D) *An immediate transfer or discharge is required by the resident's urgent medical needs, under paragraph (a)(2)(i) of **42 CFR 483.12**; or*

(E) *A resident has not resided in the facility for 30 days.*

- §483.12(a)(5)
- §483.12(a)(5)(i)
- §483.12(a)(5)(ii)
- §483.12(a)(5)(ii)(A)
- §483.12(a)(5)(ii)(B)
- §483.12(a)(5)(ii)(C)
- §483.12(a)(5)(ii)(D)
- §483.12(a)(5)(ii)(E)

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STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>32.01.20 Contents of the Notice <i>The written notice specified in paragraph (a)(4) of 42 CFR 483.12 must include the following:</i></p> <ul style="list-style-type: none"> (i) <i>The reason for transfer or discharge.</i> (ii) <i>The effective date of transfer or discharge.</i> (iii) <i>The location to which the resident is transferred or discharged.</i> (iv) <i>A statement that the resident has the right to appeal the action to the State.</i> (v) <i>The name, address and telephone number of the State long term care ombudsman.</i> (vi) <i>For nursing facility residents with developmental disabilities, the mailing address and telephone number of the agency responsible for the protection and advocacy of developmentally disabled individuals established under Part C of the Developmental Disabilities Assistance and Bill of Rights Act; and.</i> 	<p>Self-explanatory.</p>	<p style="text-align: center;"><u>CHART REVIEW</u></p> <p>Review a minimum of 3 transfer / discharge records to determine compliance.</p>	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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(vii) *For nursing facility residents who are mentally ill, the mailing address and telephone number of the agency responsible for the protection and advocacy of mentally ill individuals **established under the Protection and Advocacy for Mentally Ill Individuals Act.***

- §483.12(a)(6)
- §483.12(a)(6)(i)
- §483.12(a)(6)(ii)
- §483.12(a)(6)(iii)
- §483.12(a)(6)(iv)
- §483.12(a)(6)(v)
- §483.12(a)(6)(vi)
- §483.12(a)(6)(vii)

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STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>32.01.21 Orientation for Transfer or Discharge. <i>A facility must provide sufficient preparation and orientation for residents to ensure safe and orderly transfer or discharge from the facility.</i></p> <p>§483.12(a)(7)</p>	<p>“Sufficient preparation” means the facility informs the resident where he or she is going and takes steps within its control to assure safe transportation.</p> <p>Some examples of orientation may include:</p> <ul style="list-style-type: none"> • Trial visits, if possible, by the resident to a new location. • Working with family in requesting their assistance in assuring the resident that valued possessions are not left behind or lost. • Orienting staff in the receiving facility to resident’s daily patterns. • Reviewing with staff routines for handling transfers and discharges in a manner that minimizes unnecessary and avoidable anxiety or depression and recognizes characteristic resident reactions identified by the care plan. <p>There shall be documentation in the medical record of the preparation and orientation.</p>	<p>CHART REVIEW</p> <p>Review social service notes to see if appropriate referrals have been made and, if necessary, resident counseling has occurred.</p>	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

SWING BEDS

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>32.02.01 Restraints. <i>The facility has a policy that states:</i></p> <ul style="list-style-type: none"> <i>The resident has the right to be free from any physical or chemical restraints imposed for purposes of discipline or convenience, and not required to treat the resident's medical symptoms.</i> <p>§483.13 §483.13(a)</p>	<p>The intent of this requirement is for each person to reach his/her highest practicable well-being in an environment that prohibits the use of restraints for discipline or convenience and limits restraint use to circumstances in which the resident has medical symptoms that warrant the use of restraints.</p> <p>“Physical restraints” are defined as any manual method or physical or mechanical device, material, or equipment attached or adjacent to the resident’s body that the individual cannot remove easily and that restricts freedom of movement or normal access to one’s body.</p> <p>“Chemical Restraint” is defined as a psychopharmacologic drug that is used for discipline or convenience and not required to treat medical symptoms.</p> <p>“Discipline” is defined as any action taken by the facility for the purpose of punishing or penalizing residents.</p> <p>“Convenience” is defined as any action taken by the facility to control resident behavior or maintain residents with a lesser amount of effort by the facility and not in the resident’s best interest.</p> <p>Medical symptoms that would warrant the use of restraints should be reflected in the comprehensive assessment and care planning. The facility must engage in a systematic and gradual process toward reducing restraints (e.g., gradually increasing the time</p>	<p><u>DOCUMENT REVIEW</u></p> <p>Review the policy of the facility to determine it meets the requirement.</p> <p><u>CHART REVIEW</u></p> <p>Request clinical records for residents who have been restrained and review for the following information.</p> <ol style="list-style-type: none"> Determine if the facility follows a systematic process of evaluation and care planning prior to using restraints. Determine if the interdisciplinary team addressed the risk of decline at the time restraint use was initiated. Did the team institute measures in the care plan to address reversal of any decline in health status? Determine the intended use of any restraints. Was the use for convenience or discipline? 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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for ambulation and muscle strengthening activities).

32.02.02 Abuse.

The facility shall have a policy that states:

- *The resident has a right to be free from verbal, sexual, physical, and mental abuse, corporal punishment, and involuntary seclusion.*

§483.13(b)

The intent of this regulation is to assure that each resident is free from abuse, corporal punishment, and involuntary seclusion. The facility is responsible for preventing abuse, but also for those practices and omissions, neglect and misappropriation of property, which if left unchecked, lead to abuse.

Residents must not be subjected to abuse by anyone, including, but not limited to, facility staff, other residents, consultants or volunteers, staff of other agencies serving the individual, family members or legal guardians, friends, or other individuals.

“**Abuse**” is defined as the willful infliction of injury, unreasonable confinement, intimidation, or punishment with resulting physical harm or pain or mental anguish, or deprivation by an individual, including a caretaker, of goods or services that are necessary to attain or maintain physical, mental, and psychosocial well being.

This presumes that instances of abuse of all residents, even those in a coma, cause physical harm, or pain or mental anguish.

“**Verbal abuse**” is defined as any use of oral, written or gestured language that willfully includes disparaging and derogatory terms to residents or their

DOCUMENT REVIEW

Review the policy on abuse to determine it addresses the 6 types of abuse identified in the standard.

Request a select group of accident / incident reports in the last three months to determine if there have been predisposing factors for abuse or neglect.

INTERVIEW

Interview patients to determine their impressions regarding safety in the facility, and mechanisms to report perceived abuse.

OBSERVATION

Observe for lack of compliance during unit tours.

Offsite, pre-survey review of complaints can focus the survey team’s on-site review of actual incidents and predisposing factors to abuse or neglect and misappropriation of property.

Report and record any instances where the survey team observes an abusive incident.

- Completely document who committed the abusive act, the nature of the abuse, and

- 1 = Compliant
- 2 = Not Compliant

This standard is not met as evidenced by:

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STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
	<p>families, or within their hearing distance, regardless of their age, ability to comprehend, or disability. Examples of verbal abuse include, but are not limited to: threats of harm; and saying things to frighten a resident, such as telling a resident that she will never be able to see her family again.</p> <p>“Sexual abuse” includes, but is not limited to, sexual harassment, sexual coercion, or sexual assault.</p> <p>“Physical abuse” includes hitting, slapping, pinching and kicking. It also includes controlling behavior through corporal punishment and restraints.</p> <p>“Mental abuse” includes, but is not limited to, humiliation, harassment, and threats of punishment or deprivation.</p> <p>“Involuntary seclusion” is defined as separation of a resident from other residents or from his or her room or confinement to his or her room (with or without roommates) against the resident’s will, or the will of the resident’s legal representative. Emergency or short term monitored separation from other residents will not be considered involuntary seclusion and may be permitted if used for a limited period of time as a therapeutic intervention to reduce agitation until professional staff can develop a plan of care to meet the resident’s needs.</p>	<p>where and when it occurred.</p> <ul style="list-style-type: none"> • Ensure that the facility addresses that incident immediately. <p>If the survey team’s observations and resident’s responses signal the presence of abuse, determine how the facility prevents and reports abusive behavior.</p> <p>If a resident is being temporarily separated from other residents, for less than 24 hours, as an emergency short-term intervention, answer these questions--</p> <ol style="list-style-type: none"> 1. What are the symptoms that led to the consideration of the separation? 2. Are these symptoms caused by failure to: <ul style="list-style-type: none"> • Meet individual needs; • Provide meaningful activities; • Manipulate the resident’s environment? 3. Can the cause(s) be removed? 4. If the cause(s) cannot be removed, has the facility attempted to use alternatives short of separation? 5. Does the facility use the separation for the least amount of time? 6. To what extent has the resident, surrogate or representative participated in care planning 	

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and made an informed choice about separation?

7. Does the facility monitor and adjust care to reduce negative outcomes, while continually trying to find and use less restrictive alternatives?
8. If residents are temporarily separated in secured units, staff should carry keys to these units at all times.
9. If the purpose of the unit is to provide specialized care for residents who are cognitively impaired (through a program of therapeutic activities designed to enable residents to attain and maintain the highest practicable physical, mental or psychosocial well-being) then placement in the unit is not in violation of resident rights, as long as the resident's individual care plan indicates the need for the stated purpose and services provided in the unit and the resident, surrogate, or representative has participated in the placement decision.

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STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>32.02.03 Staff Treatment of Residents. <i>The facility must develop and implement written policies and procedures that prohibit mistreatment, neglect, and abuse of residents and misappropriation of resident property.</i></p> <p><i>The facility must:</i> (1) <i>Not use verbal, mental, sexual, or physical abuse, corporal punishment or involuntary seclusion.</i></p> <p>§483.13(c) §483.13(c)(1)(i)</p>	<p>The intent of this regulation is to assure that the facility has in place an effective system that prevents mistreatment, neglect and abuse of residents, and misappropriation of resident’s property.</p> <p>“Misappropriation of resident’s property” is defined as the patterned or deliberate misplacement, exploitation, or wrongful, temporary or permanent use of a resident’s belongings or money without the resident’s consent.</p>	<p><u>DOCUMENT REVIEW, CHART REVIEW & INTERVIEW</u></p> <ol style="list-style-type: none"> 1. Request a select group of accident/incident reports in the last three months to determine if there have been complaints of abuse. 2. Review charts of patients who were restrained or secluded. Look for situations where predisposing factors for mistreatment may have been an issue. 3. Interview patients to determine their impressions regarding safety in the facility, and mechanisms to report perceived abuse. <p>During Sample Selection-- If the team has identified a problem in mistreatment, neglect or abuse of residents or misappropriation of their property, then request—</p> <ol style="list-style-type: none"> 1. A copy of the facility’s policies and procedures regarding abuse prevention. Note particularly the extent to which those policies concern the areas uncovered through complaints and/or previous survey; 2. Reports of action(s) by a court of law against employees; 3. Reports of alleged violations involving mistreatment, neglect, abuse, injuries of unknown source, and misappropriation of resident’s property; 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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32.02.04 Screening of Staff.

*The facility must **not employ individuals who have been:***

- (A) *Found guilty of abusing, neglecting, or mistreating residents by a court of law; or*
- (B) *Have had a finding entered into the State nurse aide registry concerning abuse, neglect, mistreatment of residents or misappropriation of their property; AND*
- (iii) *Report any knowledge it has of actions by a court of law against an employee, which would indicate unfitness for serve as a nurse aide or other facility staff to the state nurse aide registry or licensing authorities.*

§483.13(c)(1)(ii)
 §483.13(c)(1)(ii)(A)
 §483.13(c)(1)(ii)(B)
 §483.13(c)(1)(ii)(B)(iii)

The intent of this regulation is to prevent employment of individuals who have been convicted of abusing, neglecting, or mistreating individuals in a health care related setting.

In addition to inquiry of the State nurse aide registry or other licensing authorities, the facility should check all staff references and make reasonable efforts to uncover information about any past criminal prosecutions.

“Found guilty...by a court of law” applies to situations where the defendant pleads guilty, is found guilty, or pleads *nolo contendere*.

- 4. Reports of the results of these investigations; and
- 5. Records of corrective actions taken.

DOCUMENT REVIEW

Review human resource policies and procedures on background and reference checks prior to hire.

- 1 = Compliant
- 2 = Not Compliant

FILE REVIEW

- 1. Review employee files to determine that a background and reference check has been done prior to hire for all staff.
- 2. Spot check employment applications for questions about convictions or mistreatment, neglect or abuse of residents, or misappropriation of their property.
 - Determine if applicants have answered these questions and if affirmative answers had resulted in rejections of employment candidates.

This standard is not met as evidenced by:

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STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>32.02.05 <u>Reporting of Patient Mistreatment, Neglect, or Abuse.</u> <i>The facility must:</i></p> <ul style="list-style-type: none"> Ensure that all alleged violations involving mistreatment, neglect, or abuse, including injuries of unknown source and misappropriation of resident property are reported immediately to the administrator of the facility and to other officials in accordance with state law through established procedures (including to the State survey and certification agency). <p>§483.13(c)(2)</p>	<p>“Finding” is defined as a determination made by the State that validates allegations of abuse, neglect, mistreatment of residents or misappropriation of their property.</p> <p>Any facility staff found guilty of neglect, abuse, or mistreating residents or misappropriation of property by a court of law, must have his or her name entered into the nurse aide registry, or reported to the licensing authority, as appropriate.</p>	<p><u>INTERVIEW</u></p> <p>On interview determine if the facility has had any of the alleged violations and ask how these were handled.</p> <p><u>DOCUMENT REVIEW</u></p> <ol style="list-style-type: none"> Review the policy and procedure to determine that it meets the requirement. Contact the State Nurse Aide Registry or Board of Nursing, as appropriate. Determine if applicants with a finding concerning mistreatment, neglect, and abuse of residents or misappropriation of their property have been rejected. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>
<p>32.02.06 <u>Investigation of Alleged Abuse.</u> <i>The facility must:</i></p> <ul style="list-style-type: none"> Have evidence that all alleged violations are thoroughly investigated and must prevent further potential abuse while the investigation is in progress. <p>§483.13(c)(3)</p>	<p>Investigations should occur as close to the time of the incident as possible.</p> <p>The chain of evidence should be secured in a safe place.</p>	<p><u>DOCUMENT REVIEW</u></p> <p>Review the policy and procedure to determine it meets the requirement.</p> <p>Verify that reported cases of abuse have been investigated by review of the documentation.</p>	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>32.02.07 Reporting of Investigations. The facility must ensure:</p> <ul style="list-style-type: none"> <i>The results of all investigations must be reported to the administrator or his designated representative and to other officials in accordance with State law (including to the State survey and certification agency) within 5 working days of the incident, and if the alleged violation is verified appropriate corrective action must be taken.</i> <p>§483.13(c)(4)</p>	<p>Self-explanatory.</p>	<p style="text-align: center;"><u>DOCUMENT REVIEW</u></p> <p>Review the policy and procedure to determine the requirement was met.</p> <p style="text-align: center;"><u>INTERVIEW</u></p> <p>Interview the administrator to determine if there have been any allegations that have been investigated and what corrective action was taken.</p> <p>Ask for the results of any in-house investigations of mistreatment, neglect, or abuse of residents, misappropriation of their property, or injuries of unknown sources.</p> <ol style="list-style-type: none"> Was the administrator notified of the incident and when? Did investigations begin promptly after the report of the problem? Is there a record of statements or interviews of the resident, suspect (if one is identified), any eye witnesses and any circumstantial witnesses? Was relevant documentation reviewed and preserved (e.g., dated dressing which was not changed when treatment recorded change)? Was the alleged victim examined promptly (if injury was suspected) and the finding documented in the report? 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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6. What steps were taken to protect the alleged victim from further abuse (particularly where no suspect has been identified)?
7. What actions were taken as a result of the investigation?
8. What corrective action was taken, including informing the nurse aide registry, State licensure authorities, and other agencies (e.g., long-term care ombudsman; adult protective services; Medicaid fraud and abuse unit)?

32.03.01 Not Applicable.

32.03.02 Activities.

The facility must provide for an ongoing program of activities designed to meet, in accordance with the comprehensive assessment, the interests and the physical, mental, and psychosocial well-being of each resident.

The activities program must be directed by a qualified professional who is a qualified therapeutic recreation specialist or an activities professional who:

A “recognized accreditation body” refers to those organizations or associations recognized as such by certified therapeutic recreation specialists or certified activity professional or registered occupational therapists.

Because the activities program should occur within the context of each resident’s care plan, it should be multi-faceted and reflect each individual resident’s needs. Therefore, the activities program should provide stimulation or solace; promote physical, cognitive and/or emotional health enhance, to the extent practicable, each resident’s physical and

OBSERVATION, CHART REVIEW, AND INTERVIEW

Observe individual, group and bedside activities.

1. Are residents who are confined or choose to remain in their rooms provided with suitable in-room activities (e.g., music, reading, visits with individuals who share their interests)? Do any facility staff members assist the resident with activities?
2. If residents sit for long periods of time with no apparently meaningful activities, is the cause-
 - The resident’s choice;

- 1 = Compliant
 2 = Not Compliant

This standard is not met as evidenced by:

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<p>A. <i>Is licensed or registered, if applicable by the state in which practicing; and</i></p> <p>B. <i>Is eligible for certification as a therapeutic recreation specialist or as an activities professional by a recognized accrediting body on or after October 1, 1990; or</i></p> <p>(ii) <i>has 2 years of experience in a social or recreational program within the last 5 years, 1 of which was full-time in a patient activities program in a health care setting; or</i></p> <p>(iii) <i>is a qualified occupational therapist or occupational therapy assistant; or</i></p> <p>(iv) <i>has completed a training course approved by the State.</i></p> <p>§483.15(f) §483.15(f)(1) §483.15(f)(2) §483.15(f)(2)(i) §483.15(f)(2)(i)(A) §483.15(f)(2)(i)(B) §483.15(f)(2)(ii) §483.15(f)(2)(iii) §483.15(f)(2)(iv)</p>	<p>mental status; and promote each resident’s self-respect by providing, for example activities that allow for self-expression, personal responsibility and choice.</p> <p>The activities program should be multi-faceted and reflect individual resident’s needs on their care plan.</p> <p>Activities can occur at anytime and are not limited to formal activities being provided by activity staff. Others involved may be any facility staff, volunteers, and visitors.</p>	<ul style="list-style-type: none"> • Failure of any staff or volunteers either to inform residents when activities are occurring or to encourage resident involvement in activities; • Lack of assistance with ambulation; • Lack of sufficient supplies and/or staff to facilitate attendance and participation in the activity programs; • Program design that fails to reflect the interests or ability levels of residents, such as activities that are too complex? <p>3. For residents selected for review, determine to what extent the activities reflect the individual resident’s assessment.</p> <p>4. Review the activity calendar for the month prior to the survey to determine if the formal activity program:</p> <ul style="list-style-type: none"> • Reflects the schedules, choices and rights of the residents; • Offers activities at hours convenient to the residents (e.g., morning, afternoon, some evenings and weekends); 	

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- Reflects the cultural and religious interests of the resident population; and
 - Would appeal to both men and women and all age groups living in the facility.
5. Review clinical records and activity attendance records of residents to determine if--
 - Activities reflect individual resident history indicated by the comprehensive assessment;
 - Care plans address activities that are appropriate for each resident based on the comprehensive assessment;
 - Activities occur as planned; and
 - Outcomes / responses to activities interventions are identified in the progress notes of each resident.
 6. If there are problems with provision of activities, determine if these services are provided by qualified staff.

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32.03.03 Not Applicable.

32.03.04 Social Services.

The facility must provide medically-related social services to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident.

§483.15(g)
§483.15(g)(1)

“Medically-related social services” means services provided by the facility’s staff to assist residents in maintaining or improving their ability to manage their everyday physical, mental, and psychosocial needs.

These services **could** include, for example:

1. Making arrangements for obtaining needed adaptive equipment, clothing, and personal items.
2. Maintaining contact with family (with resident’s permission) to report on changes in health, current goals, discharge planning, and encouragement to participate in care planning.
3. **Assisting staff to inform residents and those they designate about the resident’s health status and health care choice.**
4. Making referral and obtaining services from outside entities (e.g. talking books, absentee ballots, community wheelchair transportation).
5. Assisting residents with financial and legal matters (e.g., applying for pensions, referrals to lawyers, referrals to funeral homes for preplanning arrangements).
6. Discharge planning services (**e.g., helping to place a resident on a waiting list for community**

CHART REVIEW

Review medical records to find evidence that social service interventions successfully address resident’s needs and link social supports, physical care, and physical environment with resident’s needs and individuality.

For residents selected for review—

1. How do facility staff implement social services interventions to assist the resident in meeting treatment goals?
2. How do staff that are responsible for social work monitor the resident’s progress in improving physical, mental and psychosocial functioning? Has goal attainment been evaluated and the care plan changed accordingly?
3. How does the care plan link goals to psychosocial functioning / well-being?
4. Has the staff responsible for social work established and maintained relationships with the resident’s family or legal representative?
5. What attempts does the facility make to access services for Medicaid recipients when

- 1 = Compliant
- 2 = Not Compliant

This standard is not met as evidenced by:

SWING BEDS

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
	<p>congregate living, arranging intake for home care services for residents returning home, assisting with transfer arrangements to other facilities).</p> <p>7. Providing or arranging provision of needed counseling services;</p> <p>8. Assisting residents to determine how they would like to make decisions about their health care, and whether or not they would like anyone else to be involved in those decisions;</p> <p>9. Finding options that meet the physical and emotional needs of each resident;</p> <p>10. Meeting the needs of residents who are grieving; and</p> <p>11. Assisting residents with dental/denture care, podiatric care; eye care; hearing services, and obtaining equipment for mobility or assistive eating devices.</p> <p>Where needed services are not covered by the Medicaid State Plan, nursing facilities are still required to obtain these services.</p>	<p>those services are not covered by a Medicaid State Plan?</p> <p>6. Look for evidence that social services interventions successfully address residents' needs and link social supports, physical care, and physical environment with residents' needs and individuality.</p>	

SWING BEDS

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>32.03.05 Qualification of Social Worker. <i>A facility with more than 120 beds must employ a qualified social worker on a full-time basis.</i></p> <p><i>A qualified social worker is an individual with:</i></p> <p>(i) Qualifications of social worker. <i>A bachelor’s degree in social work or a bachelor’s degree in a human services field including but not limited to sociology, special education, rehabilitation counseling, and psychology; and</i></p> <p>(ii) One year of supervised social work experience in a health care setting working directly with individuals.</p> <p>§483.15(g)(2) §483.15(g)(3) §483.15(g)(3)(i) §483.15(g)(3)(ii)</p>	<p>The intent of this regulation is to assure that all facilities provide for the medically-related social services needs of each resident.</p> <p>This requirement specifies that facilities aggressively identify the need for medically-related social services, and pursue the provision of these services.</p> <p>A qualified social worker need not personally provide all of these services. It is the responsibility of the facility to identify the medically-related social service needs of the resident and assure that the needs are met by the appropriate discipline.</p>	<p>DOCUMENT REVIEW AND FILE REVIEW</p> <ol style="list-style-type: none"> 1. Review the resume of the social worker and the job description to determine that the standard is met. 2. Review the job description. Does it state this is a full-time position? 3. Review the credentials of the social worker to verify compliance. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

SWING BEDS

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>32.03.06 Discharge Summary. <i>When the facility anticipates discharge a resident must have a discharge summary that includes:</i></p> <p>(1) <i>A recapitulation of the resident’s stay,</i></p> <p>(2) <i>A final summary of the resident’s status to include items in paragraph (b)(2) of 42 CFR 483.20, at the time of the discharge that is available for a release to authorized persons and agencies, with the consent of the resident or legal representative, and</i></p> <p>(3) <i>A post-discharge plan of care that is developed with the participation of the resident and his or her family, which will assist the resident to adjust to his or her new living environment.</i></p> <p>§483.20(l) §483.20(l)(1) §483.20(l)(2) §483.20(l)(3)</p>	<p>The intent of this regulation is to ensure appropriate discharge planning and communication of necessary information to the continuing care provider.</p> <p>“Post discharge plan of care” means the discharge planning process, which includes assessing continuing care needs and developing a plan designed to ensure the individual’s needs will be met after discharge from the facility into the community.</p> <p>When the facility “anticipates discharge” means that the discharge was not an emergency discharge (e.g., hospitalization for an acute condition), or due to the resident’ death.</p> <p>“Adjust to his or her new living environment” means that the post-discharge plan should describe the resident’s and family’s preferences for care, and how care should be coordinated if continuing treatment involves multiple care givers.</p> <p>It should identify specific resident needs after discharge, such as:</p> <ul style="list-style-type: none"> • personal care, • sterile dressing, and • physical therapy, as well as • describe resident/caregiver education needs to prepare the resident for discharge. 	<p style="text-align: center;">CHART REVIEW</p> <p>Review a select group of medical records to determine the requirement was met.</p> <ol style="list-style-type: none"> 1. Does the discharge summary have information pertinent to continuing care for the resident? 2. Is there evidence of discharge planning in the records of discharged residents who had an anticipated discharge or those residents to be discharged shortly (e.g., in the next 7-14 days)? 3. Do discharge plans address necessary post discharge care? 4. Has the facility aided the resident and his/her family in locating and coordinating post discharge services? 5. What types of pre-discharge preparation and education has the facility provided the resident and his/her family? 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

SWING BEDS

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>32.04.01 Specialized Rehabilitative Services: Provision of Services. <i>If specialized rehabilitative services such as, but not limited to, physical therapy, speech-language pathology, occupational therapy, and health rehabilitative services for mental illness and intellectual disability, are required in the resident’s comprehensive plan of care, the facility must:</i></p> <p>(1) <i>Provide the required services; or</i></p> <p>(2) <i>Obtain the required services from an outside resource (in accordance with §483.75(h) of 42 CFR 483.75) from a provider of specialized rehabilitative services.</i></p> <p>§483.45 §483.45(a) §483.45(a)(1) §483.45(a)(2)</p>	<p>The intent of this regulation is to assure that residents receive necessary specialized rehabilitative services as determined by the comprehensive assessment and care plan, to prevent avoidable physical and mental deterioration and to assist them in obtaining or maintaining their highest practicable level of functional and psychosocial well being.</p> <p>Specialized rehabilitative services are considered a facility service and are included within the scope of facility services. They must be provided to residents who need them even when the services are not specifically enumerated in the State plan. No fee can be charged a Medicaid recipient for specialized rehabilitative services because they are covered facility services.</p> <p>A facility is not obligated to provide specialized rehabilitative services if it does not have residents who require these services.</p> <p>If a resident develops a need for these services after admission, the facility must either provide the services, or, where appropriate, obtain the service from an outside resource.</p> <p>For a resident with mental illness (MI) or intellectual disability (ID) to have his or her specialized needs met, the individual must receive all services necessary to assist the individual in maintaining or achieving as much independence and self determination as possible.</p>	<p style="text-align: center;">CHART REVIEW</p> <p>Review the medical record for physical therapy.</p> <p>Determine the extent of follow through with the comprehensive care plan. Verify from the chart that the resident is receiving frequency and type of therapy as outlined in the care plan.</p> <p>1. Physical Therapy</p> <ul style="list-style-type: none"> • What did the facility do to improve the resident’s muscle strength? The resident’s balance? • What did the facility do to determine if an assistive device would enable the resident to reach or maintain his/her highest practicable level of physical function? • If the resident has an assistive device, is he/she encouraged to use it on a regular basis? • What did the facility do to increase the amount of physical activity the resident could do (for example, the number of repetitions of an exercise, the distance walked)? • What did the facility do to prevent or minimize contractures, which could lead to decreased mobility and increased risk 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

SWING BEDS

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
	<p>Specialized services for mental illness or intellectual disability refers to those services to be provided by the State which can only be delivered by personnel or programs other than those of the nursing facility (NF) because the overall level of NF services is not as intense as necessary to meet the individual’s needs.</p> <p>“Mental health rehabilitative services for MI and ID” refers to those services of lesser frequency or intensity to be implemented by all levels of nursing facility staff who come into contact with the resident who is mentally ill or who has intellectual disabilities. These services are necessary regardless of whether or not they require additional services to be provided for or arranged by the State as specialized services.</p> <p>Mental health rehabilitative services for MI and ID may include, but are not limited to:</p> <ol style="list-style-type: none"> 1. Consistent implementation during the resident’s daily routine and across settings, of systematic plans which are designed to change inappropriate behavior. 2. Drug therapy and monitoring of the effectiveness and side effects of medications which have been prescribed to change inappropriate behavior or to alter manifestations of psychiatric illness. 3. Provision of a structured environment for those individuals who are determined to need such structure (e.g., structured socialization activities to diminish tendencies toward isolation and withdrawal). 	<p>of pressure ulcer occurrence?</p> <p>2. Occupational Therapy</p> <ul style="list-style-type: none"> • What did the facility do to decrease the amount of assistance needed to perform a task? • What did the facility do to decrease behavioral symptoms? • What did the facility do to improve gross and fine motor coordination? • What did the facility do to improve sensory awareness, visual-spatial awareness, and body integration? • What did the facility do to improve memory, problem solving, attention span, and the ability to recognize safety hazards? <p>3. Speech, Language Pathology</p> <ul style="list-style-type: none"> • What did the facility do to improve auditory comprehension? • What did the facility do to improve speech production? • What did the facility do to improve expressive behavior? 	

SWING BEDS

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
	<p>4. Development, maintenance and consistent implementation across settings of those programs designed to each individuals the daily living skills they need to be more independent and self-determining, including, but not limited to, grooming, personal hygiene, mobility, nutrition, vocational skills, health, drug therapy, and mental health education, money management, and maintenance of the living environment.</p> <p>5. Crisis intervention services.</p> <p>6. Individual, group, and family psychotherapy.</p> <p>7. Development of appropriate personal support networks.</p> <p>8. Formal behavior modification programs.</p>	<ul style="list-style-type: none"> • What did the facility do to improve the functional abilities of residents with moderate to severe hearing loss who have received an audiologic evaluation? • For the resident who cannot speak, did the facility assess for a communication board or an alternate means of communication? <p>4. Rehabilitative Services For MI And ID</p> <ul style="list-style-type: none"> • What did the facility do to decrease incidents of inappropriate behaviors, for individuals with ID, or behavioral symptoms for persons with MI? To increase appropriate behavior? • What did the facility do to identify and treat the underlying factors behind tendencies toward isolation and withdrawal? • What did the facility do to develop and maintain necessary daily living skills? • How has the facility modified the training strategies it uses with its residents to account for the special learning needs of its residents with MI or ID? 	

SWING BEDS

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>32.04.02 Rehabilitative Service Orders: Qualifications. <i>Specialized rehabilitative services must be provided under the written order of a physician by qualified personnel.</i></p> <p>§483.45(b)</p>	<p>Specialized rehabilitative services are provided for individuals under a physician’s order by a qualified professional.</p> <p>Once the assessment for specialized rehabilitative services is completed, a care plan must be developed, followed, and monitored by a licensed professional.</p> <p>Once a resident has met his or her care plan goals, a licensed professional can either discontinue treatment or initiate a maintenance program which either nursing or restorative aides will follow to maintain functional and physical status.</p> <p>“Qualified personnel,” means that professional staff are licensed, certified or registered to provide specialized therapy/rehabilitative services in accordance with applicable State laws.</p> <p>Health rehabilitative services for MI and ID must be implemented consistently by all staff unless the nature of the services is such that they are designated</p>	<p>Questions to ask individuals with MI or ID--</p> <ul style="list-style-type: none"> • Who do you talk to when you have a problem or need something? • What do you do when you feel happy? Sad? Can’t sleep at night? • In what activities are you involved, and how often? <p>CHART REVIEW</p> <p>Review medical records for physician orders and the record for the services performed.</p> <ol style="list-style-type: none"> 1. Determine if there are any problems in quality of care related to maintaining or improving functional abilities. Determine if these problems are attributable in part to the qualifications of specialized rehabilitative services staff. 2. Determine from the care plan and record that rehabilitative services are provided under the written order of a physician and by qualified personnel. If a problem in a resident’s rehabilitative care is identified that is related to the qualifications of the care providers, it may be necessary to validate the care provider’s qualifications. 3. If the facility does not employ professional staff who have experience working directly 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

SWING BEDS

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
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or required to be implemented only by licensed or credentialed personnel.

with or designing training or treatment programs to meet the needs of individuals with MI or ID, how has the facility arranged for the necessary direct or staff training services to be provided?

32.05.01 Dental Services.

The facility must assist residents in obtaining routine and 24-hour emergency dental care.

§483.55

This requirement makes the facility directly responsible for the dental care needs of its residents.

The facility must ensure that a dentist is available for residents. They can satisfy this requirement by employing a staff dentist or having a contract / arrangement with a dentist to provide services.

For Medicare and private pay residents, facilities are responsible for having the services available, but they may impose an additional charge for the services.

Medicaid residents may not be charged.
For all residents of the facility, if they are unable to pay for needed dental services, the facility should attempt to find alternative funding sources or alternative service delivery systems so that the resident is able to maintain his/her highest practicable level of well-being.

INTERVIEW & DOCUMENT REVIEW

- Interview the person in charge of the swing bed unit to determine how dental services are provided.
- If there are contract services, review the contract.

- 1 = Compliant
- 2 = Not Compliant

This standard is not met as evidenced by:

SWING BEDS

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>32.05.02 SKILLED NURSING FACILITY: <u>Patient Liability for Dental Care.</u> <i>A facility –</i> (1) <i>Must provide or obtain from an outside resource, in accordance with §483.75(h) of 42 CFR 483.75, routine and emergency dental services to meet the needs of each resident.</i> (2) <i>May charge a Medicare resident an additional amount for routine and emergency dental services.</i> §483.55(a)(1) §483.55(a)(2)</p>	<p>For Medicare and private pay residents, facilities are responsible for having the services available, but they may impose an additional charge for the services.</p> <p>For Medicaid residents, the facility must provide the resident, without charge, all emergency dental services, as well as those routine dental services that are covered under the state plan.</p> <p>For all residents of the facility, if they are unable to pay for needed dental services, the facility should attempt to find alternative funding sources or alternative service delivery systems so that the resident is able to maintain his/her highest practicable level of well being.</p> <p>“Routine dental services” means an annual inspection of the oral cavity for signs of disease, diagnosis of dental disease, dental radiographs as needed, dental cleaning, fillings (new and repairs), minor dental plate adjustments, smoothing of broken teeth, and limited prosthodontic procedures (e.g., taking impressions for dentures and fitting dentures).</p> <p>“Emergency dental services” includes services needed to treat an episode of acute pain in teeth, gums, or palate; broken, or otherwise damaged teeth, or any other problem of the oral cavity, appropriately treated by a dentist that requires immediate attention.</p> <p>“Prompt referral” means, within reason, as soon as the dentures are lost or damaged. Referral does not</p>	<p style="text-align: center;"><u>DOCUMENT REVIEW</u></p> <p>Review the policies and procedures to determine the requirement was met.</p>	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant <input type="checkbox"/> Not Applicable if a Nursing Facility</p> <p>This standard is not met as evidenced by:</p>

SWING BEDS

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
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mean that the resident must see the dentist at that time, but does mean that an appointment (referral) is made, or that the facility is aggressively working at replacing the dentures.

**32.05.03 SKILLED NURSING FACILITY:
Resident Dental Appointments.**

The facility *must, if necessary, assist the resident:*

- (i) *in making appointments; and*
- (ii) *by arranging for transportation to and from the dentist’s office; and*

Promptly refer residents with lost or damaged dentures to a dentist.

- §483.55(a)(3)
- §483.55(a)(3)(i)
- §483.55(a)(3)(ii)
- §483.55(a)(4)

NOTE:

- §483.55(b) Nursing Facilities does not usually apply to Medicare reimbursed swing-bed residents because Medicare swing-bed residents receive skilled nursing care comparable to services

“**Routine dental services**” means inspection of the oral cavity for signs of disease, diagnosis of the dental plate adjustments, smoothing of broken teeth, and limited prosthodontics, e.g. taking impressions for dentures and fitting dentures.

“**Emergency dental services**” includes services needed to treat an episode of acute pain in teeth, gums, or palate; broken or otherwise damaged teeth; or any other problems of the oral cavity that require immediate attention.”

“**Prompt referral**” means, within reason, as soon as the dentures are lost or damaged.

Referral does not mean the resident must see a dentist at that time, but does mean that an appointment (referral) is made, or that the facility is aggressively working at replacing dentures.

DOCUMENT REVIEW

Review the policy and procedure to determine the requirement was met.

INTERVIEW

Interview staff / patients to determine if the policy defines actual practice.

1. Do residents selected for comprehensive or focused reviews, as appropriate, with dentures, use them?
2. Are residents missing teeth and may be in need of dentures?
3. Do sampled residents have problems eating and maintaining nutritional status because of poor oral health or oral hygiene?
4. Are resident’s dentures intact? Properly fitted?

- 1 = Compliant
- 2 = Not Compliant
- Not Applicable if a Nursing Facility**

This standard is not met as evidenced by:

SWING BEDS

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
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provided in a SNF not a NF.

- If a swing-bed resident is a NF level patient, apply standard §483.55(b) as appropriate.

**32.05.04 NURSING FACILITIES:
Provision of Dental Services.**

The facility-

(1) *Must provide or obtain from an outside resource, in accordance with §483.75(h) of 42 CFR 483.75, the following dental services to meet the needs of each resident:*

(i) *Routine dental services (to the extent covered under the State plan)*

(ii) *Emergency dental services*

§483.55(b)
§483.55(b)(1)
§483.55(b)(1)(i)
§483.55(b)(1)(ii)

If the facility does not employ a qualified professional person to furnish a specific service to be provided by the facility, the facility must have that service furnished to residents by a person or agency outside the facility.

“**Routine dental services**” means an annual inspection of the oral cavity for signs of disease, diagnosis of dental disease, dental radiographs as needed, dental cleaning, fillings (new and repairs), minor dental plate adjustments, smoothing of broken teeth, and limited prosthodontic procedures (e.g., taking impressions for dentures and fitting dentures).

“**Emergency dental services**” includes services needed to treat an episode of acute pain in teeth, gums, or palate; broken, or otherwise damaged teeth, or any other problem of the oral cavity, appropriately treated by a dentist that requires immediate attention.

“**Prompt referral**” means, within reason, as soon as the dentures are lost or damaged. Referral does not mean that the resident must see the dentist at that time, but does mean that an appointment (referral) is made, or that the facility is aggressively working at replacing the dentures.

DOCUMENT REVIEW

Review the policy to determine it meets the requirement.

Observe and interview patients to determine if the policy is being followed.

- 1 = Compliant
- 2 = Not Compliant
- Not Applicable if Skilled Nursing Facility**

This standard is not met as evidenced by:

SWING BEDS

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>32.05.05 NURSING FACILITIES: <u>Appointments and Referrals.</u> <i>The facility must, if necessary, assist the resident—</i> <i>(i) In making appointments.</i> <i>(ii) By arranging for transportation to and from the dentist’s office.</i> <i>Must promptly refer residents with lost or damaged dentures to a dentist.</i> §483.55(b)(2) §483.55(b)(2)(i) §483.55(b)(2)(ii) §483.55(b)(3)</p>	<p>Self-explanatory.</p>	<p><u>OBSERVATION, INTERVIEW & CHART REVIEW</u></p> <ol style="list-style-type: none"> 1. Do residents selected for comprehensive or focused reviews, as appropriate, with dentures, use them? 2. Are residents missing teeth and may be in need of dentures? 3. Do sampled residents have problems eating and maintaining nutritional status because of poor oral health or oral hygiene? 4. Are resident’s dentures intact? Properly fitted? 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant <input type="checkbox"/> Not Applicable if a Skilled Nursing Facility</p> <p>This standard is not met as evidenced by:</p>

PROSPECTIVE PAYMENT SYSTEM EXCLUDED (PPS EXCLUDED UNIT) & DISTINCT PART UNIT – PHYSICAL REHABILITATION UNIT

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
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DISTINCT PART REHABILITATION UNIT / PROSPECTIVE PAYMENT SYSTEM EXCLUDED UNIT.

Medicare Prospective Payment System Excluded Rehabilitation Unit

Requirements for Medicare PPS Excluded Rehabilitation Units include the following:

- 42 CFR 482 - Conditions of Participation for hospitals;
- 42 CFR 412.25 - Excluded hospital units: Common Requirements; and
- 42 CFR 412.29 - Excluded Rehabilitation Units: Additional Requirements

Standards 33.00.01 through 33.01.10 apply ONLY to Rehabilitation Units that have been designated by Medicare to be an excluded Prospective Payment System (PPS) unit.

INTERVIEW AND DOCUMENT REVIEW

Score based on the scoring for:

- Standards 33.00.01 through 33.00.29, and
- Standards 33.01.01 through 33.01.10

NA = Facility has no DPU Rehabilitation Unit

PROSPECTIVE PAYMENT SYSTEM EXCLUDED (PPS EXCLUDED UNIT) & DISTINCT PART UNIT – PHYSICAL REHABILITATION UNIT

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
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**33.00.01 PPS Excluded Hospital Units:
Basis for Exclusion.**

In order to be excluded from the Prospective Payment Systems (PPS) specified in §412.1(a)(1), a rehabilitation unit must meet the following requirements in addition to all criteria under subpart B of part 412 of 42 CFR 412:

Be part of an institution that-

- *Has in effect an agreement under part 489 (42 CFR 489) to participate as a hospital and*
- *Is not excluded in its entirety from the prospective payment systems and*
- *Has enough beds that are not excluded from the inpatient prospective payment systems to permit the provision of adequate cost information, as required by §413.24(c) of 42 CFR 413.24.*

§412.25(a)
§412.25(a)(1)

The surveyor should check State Agency records and/or verify with the Regional Office (RO) to ensure the hospital has an agreement to participate in the Medicare program and to ensure that the hospital is not already excluded in its entirety from IPPS, such as a rehabilitation hospital. In other words, the unit seeking exclusion cannot comprise the entire hospital.

INTERVIEW & DOCUMENT REVIEW

Verify:

1. The hospital has an agreement to participate in the Medicare **PPS Exclusion** program.
2. The hospital is not already excluded in its entirety from PPS, such as a rehabilitation hospital.

- 1 = Compliant
 2 = Not Compliant

This standard is not met as evidenced by:

PROSPECTIVE PAYMENT SYSTEM EXCLUDED (PPS EXCLUDED UNIT) & DISTINCT PART UNIT – PHYSICAL REHABILITATION UNIT

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
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33.00.02 PPS Excluded Hospital

Units: Admission Criteria.

In order to be excluded for the Medicare PPS System, the unit must meet the following criteria:

- *Have written admission criteria that are applied uniformly to both Medicare and non-Medicare patients.*

§412.25(a)(2)

The hospital has **written** admission criteria.

The approved admission criteria are consistently followed for **both Medicare and non-Medicare** patients.

DOCUMENT REVIEW & CHART REVIEW

Review policies. Review open and closed records.

1. Verify written admission criteria are in place.
2. Verify the approved admission criteria are followed for all patients.

- 1 = Compliant
 2 = Not Compliant

This standard is not met as evidenced by:

33.00.03 PPS Excluded Hospital

Units: Separate Medical Records.

In order to be excluded for the Medicare PPS System, the unit must meet the following criteria:

- *Have admission and discharge records that are separately identified from those of the hospital in which it is located and are readily available.*

§412.25(a)(3)

PPS exempt units have medical records **that** are separate and not commingled with other hospital records. These records are readily available for review.

OBSERVATION

Verify the PPS excluded unit:

- The medical records **for the exempt unit** are separate and are not commingled with other hospital records; these are readily available for review.

- 1 = Compliant
 2 = Not Compliant

This standard is not met as evidenced by:

PROSPECTIVE PAYMENT SYSTEM EXCLUDED (PPS EXCLUDED UNIT) & DISTINCT PART UNIT – PHYSICAL REHABILITATION UNIT

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>33.00.04 PPS Excluded Hospital <u>Units: Availability of Clinical Records & Information.</u> <i>In order to be excluded for the Medicare PPS System, the unit must meet the following criteria:</i></p> <ul style="list-style-type: none"> • <i>Have policies specifying that necessary clinical information is transferred to the unit when a patient of the hospital is transferred to the unit.</i> <p>§412.25(a)(4)</p>	<p>The hospital has a written policy that specifies the clinical information that is to accompany the patient when transferred to the exempt rehabilitation unit.</p>	<p><u>DOCUMENT REVIEW & CHART REVIEW</u> Review facility policies. Review medical records. Verify:</p> <ol style="list-style-type: none"> 1. The hospital has a policy detailing the prompt transfer of clinical information for patients transferred to the rehabilitation unit. 2. The medical record reflects that clinical information is promptly transferred with the record. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>
<p>33.00.05 PPS Excluded Hospital <u>Units: State Licensure Requirements.</u> <i>In order to be excluded for the Medicare PPS System, the unit must meet the following criteria:</i></p> <ul style="list-style-type: none"> • <i>Meet applicable State licensure laws.</i> <p>§412.25(a)(5)</p>	<p>Hospital Licensing</p> <ul style="list-style-type: none"> • The hospital demonstrates that all applicable State licensure laws are met. • The hospital provides documentation of any and all unmet State licensure requirements including documentation for deficient practices. • The unit meets special licensing requirements issued by the State, as required. <p>Professional Staff The hospital has current licenses for its professional staff. The professional staff are licensed by the State in which the hospital is located.</p>	<p><u>DOCUMENT REVIEW</u></p> <p>Verify:</p> <ol style="list-style-type: none"> 1. All applicable state licensure laws are met, including any special licensing requirements issued by the state. 2. All professional staff files have current licenses. 3. The hospital has current licenses for its professional staff issued by the State in which the unit is located. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

PROSPECTIVE PAYMENT SYSTEM EXCLUDED (PPS EXCLUDED UNIT) & DISTINCT PART UNIT – PHYSICAL REHABILITATION UNIT

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
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33.00.06 PPS Excluded Hospital

Units: Utilization Review

Requirements.

In order to be excluded for the Medicare PPS System, the unit must meet the following criteria:

- *Have utilization review standards applicable for the type of care offered in the unit.*

§412.25(a)(6)

The hospital has a Utilization Review Plan that includes the review of Rehabilitation services.

(No utilization review standards are required if the QIO is conducting review activities.)

DOCUMENT REVIEW

Verify:

- The Utilization Review Plan includes the review of rehabilitation services, either internally or through the QIO.

- 1 = Compliant
 2 = Not Compliant

This standard is not met as evidenced by:

33.00.07 PPS Excluded Hospital

Units: Distinct Unit Structure.

In order to be excluded for the Medicare PPS System, the unit must meet the following criteria:

- *Have beds physically separate from (that is, not commingled with) the hospital's other beds.*

§412.25(a)(7)

The PPS exempt rehabilitation beds are physically separate from the beds in other units of the hospital.

OBSERVATION

Verify:

- The PPS exempt rehabilitation beds are physically separate from other units of the hospital.

- 1 = Compliant
 2 = Not Compliant

This standard is not met as evidenced by:

PROSPECTIVE PAYMENT SYSTEM EXCLUDED (PPS EXCLUDED UNIT) & DISTINCT PART UNIT – PHYSICAL REHABILITATION UNIT

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33.00.08 PPS Excluded Hospital
Units: Fiscal Intermediary.
In order to be excluded from the Medicare PPS System, the unit must meet the following criteria:

- *Be serviced by the same fiscal intermediary as the hospital.*

§412.25(a)(8)

Self-explanatory.

DOCUMENTS

Verify the PPS excluded unit:

- Uses the same fiscal intermediary as the hospital.

- 1 = Compliant
- 2 = Not Compliant

This standard is not met as evidenced by:

33.00.09 PPS Excluded Hospital
Units: Separate Cost Center.
In order to be excluded from the Medicare PPS System, the unit must meet the following criteria:

- *Be treated as a separate cost center for cost finding and apportionment purposes.*

§412.25(a)(9)

Self-explanatory.

DOCUMENTS

Verify the PPS excluded unit:

- Is treated as a separate Cost Center for cost finding and apportionment purposes.

- 1 = Compliant
- 2 = Not Compliant

This standard is not met as evidenced by:

PROSPECTIVE PAYMENT SYSTEM EXCLUDED (PPS EXCLUDED UNIT) & DISTINCT PART UNIT – PHYSICAL REHABILITATION UNIT

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33.00.10 PPS Excluded Hospital
Units: Allocate Costs.
In order to be excluded from the Medicare PPS System, the unit must meet the following criteria:

- *Use an accounting system that properly allocates costs.*

§412.25(a)(10)

Self-explanatory.

DOCUMENTS

Verify the PPS excluded unit:

- **Uses an accounting system that properly allocates costs.**

- 1 = Compliant
 2 = Not Compliant

This standard is not met as evidenced by:

33.00.11 PPS Excluded Hospital
Units: Statistical Data.
In order to be excluded from the Medicare PPS System, the unit must meet the following criteria:

- *Maintain adequate statistical data to support the basis of allocation.*

§412.25(a)(11)

Self-explanatory.

DOCUMENTS

Verify the PPS excluded unit:

- **Maintains adequate statistical data to support the basis of allocation.**

- 1 = Compliant
 2 = Not Compliant

This standard is not met as evidenced by:

PROSPECTIVE PAYMENT SYSTEM EXCLUDED (PPS EXCLUDED UNIT) & DISTINCT PART UNIT – PHYSICAL REHABILITATION UNIT

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<p>33.00.12 PPS Excluded Hospital <u>Units: Cost Report.</u> <i>In order to be excluded from the Medicare PPS System, the unit must meet the following criteria:</i></p> <ul style="list-style-type: none"> <i>Report its costs in the hospital's cost report covering the same fiscal period and using the same method of apportionment as the hospital.</i> <p>§412.25(a)(12)</p>	<p>Self-explanatory.</p>	<p align="center"><u>DOCUMENTS</u></p> <p>Verify the PPS excluded unit:</p> <ul style="list-style-type: none"> Reports its costs in the hospital's cost report covering the same fiscal period and using the same method of apportionment as the hospital. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>
<p>33.00.13 PPS Excluded Hospital <u>Units: Requirements on the First Day of the First Cost Reporting Period.</u> <i>In order to be excluded from the Medicare PPS System, the unit must meet the following criteria:</i></p> <ul style="list-style-type: none"> <i>As of the first day of the first cost reporting period for which all other exclusion requirements are met, the unit is fully equipped and staffed and is capable of providing hospital inpatient psychiatric or rehabilitation care regardless of whether there are any inpatients in the unit on that date.</i> <p>§412.25(a)(13)</p>	<p>Self-explanatory.</p>	<p align="center"><u>DOCUMENTS</u></p> <p>Verify the PPS excluded unit:</p> <ul style="list-style-type: none"> Is fully equipped and staffed and is capable of providing hospital inpatient rehabilitation care, regardless of whether there are any inpatients in the unit. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

PROSPECTIVE PAYMENT SYSTEM EXCLUDED (PPS EXCLUDED UNIT) & DISTINCT PART UNIT – PHYSICAL REHABILITATION UNIT

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**33.00.14 PPS Excluded Hospital
Units: Changes in the Size of Excluded
Units.**

Except in the special cases noted at the end of this paragraph, changes in the number of beds or square footage considered to be part of an excluded unit under this section are allowed one time during a cost reporting period if the hospital notifies its Medicare contractor and the CMS RO in writing of the planned change at least 30 days before the date of the change. The hospital must maintain the information needed to accurately determine costs that are attributable to the excluded unit.

A change in bed size or a change in square footage may occur at any time during a cost reporting period and must remain in effect for the rest of that cost reporting period.

Changes in bed size or square footage may be made at any time if these changes are made necessary by relocation of a unit to permit construction or renovation necessary for compliance with changes in Federal, State, or local law affecting the physical facility or because of

Self-explanatory.

DOCUMENT REVIEW AND INTERVIEW

Determine if the PPS excluded unit has had a change in the number of beds or a change in square footage during this accreditation cycle.

- **If yes, has the facility notified the Medicare contractor and the CMS Regional Office (RO) in writing at least 30 days prior to the change? Did the communication clearly define the unit costs?**

- 1 = Compliant
- 2 = Not Compliant
- N/A = Not Applicable

This standard is not met as evidenced by:

PROSPECTIVE PAYMENT SYSTEM EXCLUDED (PPS EXCLUDED UNIT) & DISTINCT PART UNIT – PHYSICAL REHABILITATION UNIT

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catastrophic events such as fires, floods, earthquakes, or tornadoes.

§412.25(b)

33.00.15 PPS Excluded Hospital Units: Change in Status of Hospital Units.

Self-explanatory.

For purposes of exclusions from the prospective payment systems under this section, the status of each hospital unit (excluded or not excluded) is determined as specified in paragraphs (c)(1) and (c)(2) of 42 CFR 412.25.

- (1) *The status of a hospital unit may be changed from not excluded to exclude only at the start of the cost reporting period. If a unit is added to a hospital after the start of a cost reporting period, it cannot be excluded from the prospective payment systems before the start of a hospital's next cost reporting period.*
- (2) *The status of a hospital unit may be changed from excluded to not excluded at any time during a cost reporting period, but only if the hospital notifies the fiscal intermediary and the CMS*

DOCUMENT REVIEW AND INTERVIEW

Determine if the PPS excluded unit has had a change of status during this accreditation cycle.

- **If yes, has the facility notified the fiscal intermediary and the CMS Regional Office in writing within 30 days before the change?**

- 1 = Compliant
- 2 = Not Compliant
- N/A = Not Applicable

This standard is not met as evidenced by:

PROSPECTIVE PAYMENT SYSTEM EXCLUDED (PPS EXCLUDED UNIT) & DISTINCT PART UNIT – PHYSICAL REHABILITATION UNIT

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Regional Office in writing of the change at least 30 days before the date of the change, and maintains the information needed to accurately determine costs that are or are not attributable to the excluded unit. A change in the status of a unit from excluded to not excluded that is made during a cost reporting period must remain in effect for the rest of that cost reporting period.

§412.25(c)(1)
§412.25(c)(2)

33.00.16 PPS Excluded Hospital Units: Number of Excluded Units.
Each hospital may have only one unit of each type (psychiatric or rehabilitation) excluded from the prospective payment systems.
§412.25(d)

The hospital may have one (1) PPS excluded Rehabilitation Unit.

The hospital may also have one (1) PPS excluded Psychiatric Unit.

INTERVIEW AND OBSERVATION

- Verify that there is only one (1) PPS excluded rehabilitation unit in this facility.

1 = Compliant
 2 = Not Compliant

This standard is not met as evidenced by:

33.00.17 Satellite Facility: Define.
For purposes of paragraphs (e)(2) through (e)(5) of 42 CFR 412.25, a satellite facility is:

- A part of a hospital unit that provides inpatient services in a building also used by another hospital, or*

Self-explanatory.

INTERVIEW AND OBSERVATION

Verify the satellite facility:

- Provides inpatient services consistent with requirement.
- Is located consistent with requirement.

1 = Compliant
 2 = Not Compliant

This standard is not met as evidenced by:

PROSPECTIVE PAYMENT SYSTEM EXCLUDED (PPS EXCLUDED UNIT) & DISTINCT PART UNIT – PHYSICAL REHABILITATION UNIT

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- In one or more entire buildings located on the same campus as buildings used by another hospital.*

§412.25(e); §412.25(e)(1)

33.00.18 Satellite Facility: Criteria. *Except as provided in paragraphs (e)(3) and (e)(6) of 42 CFR 412.25, effective for cost reporting periods beginning on or after October 1, 1999, a hospital that has a satellite facility must meet the following criteria in order to be excluded from the acute care hospital inpatient prospective payment systems for any period:*

(i) In the case of a unit excluded from the prospective payment systems for the most recent cost reporting period beginning before October 1, 1997, the unit’s number of State-licensed and Medicare-certified beds, including those at the satellite facility, does not exceed the unit’s number of state-licensed and Medicare-certified beds on the last day of the unit’s last cost reporting period beginning before October 1, 1997.

Self-explanatory.

INTERVIEW AND DOCUMENT REVIEW

Verify the satellite facility:

- Meets criteria for exclusion from PPS consistent with requirement.
- The unit’s number of State-licensed and Medicare-certified beds, including those at the satellite facility, does not exceed the unit’s number of state-licensed and Medicare-certified beds on the last day of the unit’s last cost reporting period.

- 1 = Compliant
- 2 = Not Compliant

This standard is not met as evidenced by:

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- (ii) *The satellite facility independently complies with—*
- (A) *For a Rehabilitation Unit, the requirements under §412.29 of this subpart in 42 CFR 412.29.*
 - (B) *For a psychiatric unit, the requirements under §412.27(a).*

§412.25(e)(2)
 §412.25(e)(2)(i)
 §412.25(e)(2)(ii)
 §412.25(e)(2)(ii)(A)
 §412.25(e)(2)(ii)(B)

33.00.19 Satellite Facility: Separate Governing Body.
The satellite facility meets all the following requirements:

- *Effective for cost reporting periods beginning on or after October 1, 2002, it is not under the control of the governing body or chief executive officer of the hospital in which it is located, and it furnishes inpatient care through the use of medical personnel who are not under the control of the medical staff or chief medical*

Self-explanatory.

INTERVIEW AND DOCUMENT REVIEW

- **Verify the governing body/CEO of the satellite facility is different than that for the hospital.**
- **Verify the care provided is not under control of the hospital medical staff and chief medical officer.**

1 = Compliant
 2 = Not Compliant

This standard is not met as evidenced by:

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officer of the hospital in which it is located.

§412.25(e)(2)(iii)(A)

**33.00.20 Satellite Facility:
Admission and Discharge Records.**
The satellite facility meets all the following requirements:

Self-explanatory.

- *It maintains admission and discharge records that are separately identified from those of the hospital in which it is located and are readily available.*

DOCUMENT REVIEW

- **Verify the satellite facility maintains admission and discharge records separate from the hospital; these records are readily available.**

- 1 = Compliant
- 2 = Not Compliant

This standard is not met as evidenced by:

§412.25(e)(2)(iii)(B)

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**33.00.21 Satellite Facility:
Beds are Physically Separate.**
The satellite facility meets all the following requirements:

- It has beds that are physically separate from (that is, not commingled with) the beds of the hospital in which it is located.*

§412.25(e)(2)(iii)(C)

Self-explanatory.

INTERVIEW AND OBSERVATION

- Verify the beds of the satellite facility are physically separate from the beds of the hospital.

1 = Compliant
 2 = Not Compliant

This standard is not met as evidenced by:

**33.00.22 Satellite Facility:
Fiscal Intermediary.**
The satellite facility meets all the following requirements:

- It is serviced by the same fiscal intermediary as the hospital unit of which it is a part.*

§412.25(e)(2)(iii)(D)

Self-explanatory.

DOCUMENT REVIEW

- Verify the satellite facility uses the same fiscal intermediary as the hospital of which it is a part.

1 = Compliant
 2 = Not Compliant

This standard is not met as evidenced by:

PROSPECTIVE PAYMENT SYSTEM EXCLUDED (PPS EXCLUDED UNIT) & DISTINCT PART UNIT – PHYSICAL REHABILITATION UNIT

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**33.00.23 Satellite Facility:
Separate Cost Center.**

The satellite facility meets all the following requirements:

- *It is treated as a separate cost center of the hospital unit of which it is a part.*

§412.25(e)(2)(iii)(E)

Self-explanatory.

DOCUMENT REVIEW

- **Verify the satellite facility is a separate cost center of the hospital of which it is a part.**

- 1 = Compliant
 2 = Not Compliant

This standard is not met as evidenced by:

**33.00.24 Satellite Facility:
Accounting System.**

The satellite facility meets all the following requirements:

- *For cost reporting and apportionment purposes, it uses an accounting system that properly allocates costs and maintains adequate statistical data to support the basis of allocation.*

§412.25(e)(2)(iii)(F)

Self-explanatory.

DOCUMENT REVIEW

- **Verify the satellite facility uses an accounting system that properly allocates costs and maintains adequate statistical data to support the basis of allocation.**

- 1 = Compliant
 2 = Not Compliant

This standard is not met as evidenced by:

PROSPECTIVE PAYMENT SYSTEM EXCLUDED (PPS EXCLUDED UNIT) & DISTINCT PART UNIT – PHYSICAL REHABILITATION UNIT

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**33.00.25 Satellite Facility:
Hospital Cost Report.**

The satellite facility meets all the following requirements:

- *It reports its costs on the cost report of the hospital of which it is a part, covering the same fiscal period and using the same method of apportionment as the hospital of which it is a part.*

§412.25(e)(2)(iii)(G)

Self-explanatory.

DOCUMENT REVIEW

- **Verify the satellite facility reports its costs on the cost report of the hospital of which it is a part, using the same fiscal period and same method of apportionment as the hospital.**

- 1 = Compliant
- 2 = Not Compliant

This standard is not met as evidenced by:

**33.00.26 Satellite Facility:
Exception.**

Except as specified in paragraphs (e)(4) and (e)(5) of 42 CFR 412.25, the provisions of paragraph (e)(2) of 42 CFR 412.25 do not apply to any unit structured as a satellite facility on September 30, 1999, and excluded from the prospective payment systems on that date, to the extent the unit continues operating under the same terms and conditions, including the number of beds and square footage considered to be part of the unit at the satellite facility on September 30, 1999.

§412.25(e)(3)

Self-explanatory.

DOCUMENT REVIEW

Review documents to determine the satellite facility meets this requirement.

Determine if this unit was structured as a satellite facility on September 30, 1999, and excluded from the prospective payment systems on that date.

- **If yes, has the unit continued to operate under the same terms and conditions, including the number of beds and square footage considered to be part of the unit at the satellite facility on September 30, 1999.**

- 1 = Compliant
- 2 = Not Compliant
- Not Applicable

This standard is not met as evidenced by:

PROSPECTIVE PAYMENT SYSTEM EXCLUDED (PPS EXCLUDED UNIT) & DISTINCT PART UNIT – PHYSICAL REHABILITATION UNIT

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<p>33.00.27 <u>Satellite Facility:</u> <u>Increase / Decrease the Square Footage or Decrease the Number of Beds.</u> <i>In applying the provisions of paragraph (e)(3) of 42 CFR 412.25, any unit structured as a satellite facility on September 30, 1999, may increase or decrease the square footage of the satellite facility or may decrease the number of beds in the satellite facility considered to be part of the satellite facility at any time, if these changes are made by the relocation of a facility—</i> <i>(i) To permit construction or renovation necessary for compliance with changes in federal, state, or local law affecting the physical facility.</i> <i>(ii) Because of catastrophic events such as fires, floods, earthquakes, or tornadoes.</i></p> <p>§412.25(e)(4) §412.25(e)(4)(i) §412.25(e)(4)(ii)</p>	<p>An increase / decrease in the square footage or a decrease in the number of beds is acceptable for the following reasons:</p> <ol style="list-style-type: none"> 1. To permit construction or renovation necessary for compliance with federal, state, or local law. 2. Due to a catastrophic event. 	<p align="center"><u>INTERVIEW AND OBSERVATION</u></p> <p>Determine if the satellite facility increased / decreased the square footage of the satellite facility or decreased the number of beds.</p> <p>If yes, were these changes:</p> <ul style="list-style-type: none"> • To permit construction or renovation necessary for compliance with federal, state, or local law? • Due to a catastrophic event? 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant <input type="checkbox"/> Not Applicable</p> <p>This standard is not met as evidenced by:</p>

PROSPECTIVE PAYMENT SYSTEM EXCLUDED (PPS EXCLUDED UNIT) & DISTINCT PART UNIT – PHYSICAL REHABILITATION UNIT

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<p>33.00.28 <u>Satellite Facility: Structure Changes After October 1, 2006.</u> <i>For the cost reporting periods beginning on or after October 1, 2006, in applying the provisions of Medicare paragraph (e)(3) of 42 CFR 412.25—</i></p> <p><i>(i) Any unit structured as a satellite facility on September 30, 1999, may increase the square footage of the unit only at the beginning of a cost reporting period or decrease the square footage or number of beds considered to be part of the satellite facility subject to the provisions of paragraph (b)(2) of 42 CFR 412.25, without affecting the provisions of paragraph (e)(3) of 42 CFR 412.25; and</i></p> <p><i>(ii) If the unit structured as a satellite facility decreases its number of beds below the number of beds considered to be part of the satellite facility on September 30, 1999, subject to the provisions of paragraph (b)(2) of 42 CFR 412.25, it may subsequently</i></p>	<p>For any unit that was a structure of satellite facility on September 30, 1999, it is acceptable for the satellite facility to increase / decrease the square footage of the satellite facility or decrease the number of beds.</p>	<p align="center"><u>INTERVIEW AND OBSERVATION</u></p> <p>Determine if the unit was a structure of satellite facility on September 30, 1999.</p> <ul style="list-style-type: none"> If yes, determine if the satellite facility increased / decreased the square footage of the satellite facility or decreased the number of beds, these changes were consistent with the requirement. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant <input type="checkbox"/> Not Applicable</p> <p>This standard is not met as evidenced by:</p>

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increase the number of beds at the beginning or a cost reporting period as long as the resulting total number of beds considered to be part of the satellite facility does not exceed the number of beds at the satellite facility on September 30, 1999.

§412.25(e)(5)
 §412.25(e)(5)(i)
 §412.25(e)(5)(ii)

**33.00.29 Satellite Facility:
 Inpatient Rehabilitation Facility.**
The provisions of Medicare paragraph (e)(2)(i) of 42 CFR 412.25—

Self-explanatory.

DOCUMENT REVIEW

- Review documents to determine the satellite facility is compliant with the requirement.

- 1 = Compliant
- 2 = Not Compliant
- Not Applicable

This standard is not met as evidenced by:

- *Do not apply to any inpatient rehabilitation facility that is subject to the inpatient rehabilitation facility prospective payment system under subpart P of 42 CFR 412.25, effective for cost reporting periods beginning on or after October 1, 2003.*

§412.25(e)(6)

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<p>33.00.30 <u>Changes in Classification of Hospital Units.</u> <i>For purposes of exclusions from the prospective payment system under 42 CFR 412.25—</i></p> <ul style="list-style-type: none"> <i>The classification of a hospital unit is effective for the unit’s entire cost reporting period. Any changes in the classification of a hospital unit are made only at the start of a cost reporting period.</i> 	<p>Self-explanatory.</p>	<p><u>INTERVIEW AND DOCUMENT REVIEW</u> Review documents. Determine if the satellite facility made any changes in the classification of a unit.</p> <ul style="list-style-type: none"> If yes, were these changes only made at the start of a cost reporting period? 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant <input type="checkbox"/> Not Applicable</p> <p>This standard is not met as evidenced by:</p>
<p>§412.25(f)</p> <p>33.01.00 <u>Inpatient Rehabilitation Facility (IRF) Prospective Payment System: Classification Criteria for Payment.</u> <i>To be excluded from the prospective payment systems described in §412(a)(1) and to be paid under the prospective payment system specified in §412.1(a)(3), an inpatient rehabilitation unit of a hospital (otherwise referred to as an IRF) must meet the following requirements:</i></p> <p>§412.29</p>	<p>Self-explanatory.</p>	<p><u>INTERVIEW AND DOCUMENT REVIEW</u> The surveyor will score this standard based on compliance with standards 33.01.01 through 33.01.10.</p>	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant <input type="checkbox"/> NA</p> <p>This standard is not met as evidenced by:</p>

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STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>33.01.01 <u>Inpatient Rehabilitation Facility (IRF): Provider Agreement.</u></p> <ul style="list-style-type: none"> <i>Have (or be part of a hospital that has) a provider agreement under part 489 of 42 CFR 489 to participate as a hospital.</i> <p>§412.29(a)</p>	<p>Self-explanatory.</p>	<p align="center"><u>INTERVIEW AND DOCUMENT REVIEW</u></p> <ul style="list-style-type: none"> Verify the facility has an agreement to participate in the Medicare program. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant <input type="checkbox"/> Not Applicable</p> <p>This standard is not met as evidenced by:</p>
<p>33.01.02 <u>Inpatient Rehabilitation Facility (IRF): Requirement to Serve Inpatient Population.</u></p> <p><i>Except in the case of a “new” IRF or “new” IRF beds, as defined in paragraph (c) of 42 CFR 412.29, an IRF must show that, during its most recent, consecutive, and appropriate 12-month time period (as defined by CMS or the Medicare contractor), it served an inpatient population that meets the following criteria:</i></p> <p>(1) <i>For cost reporting periods beginning on or after July 1, 2004, and before July 1, 2005, the IRF served an inpatient population of whom at least 50 percent, and for cost reporting periods beginning on or after July 1, 2005, the IRF served an inpatient population of whom at least 60 percent</i></p>	<p>Self-explanatory.</p>	<p align="center"><u>DOCUMENT REVIEW</u></p> <p>The surveyor will verify the facility inpatient population for the most recent consecutive 12 month time period that 60 percent of the patients were admitted for intensive rehabilitation services as defined in the standard.</p>	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant <input type="checkbox"/> Not Applicable</p> <p>This standard is not met as evidenced by:</p>

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required intensive rehabilitation services for treatment of one or more of the conditions specified at paragraph (b)(2) of 42 CFR 412.29.

A patient with a comorbidity, as defined at §412.602 of 42 CFR 412.602, may be included in the inpatient population that counts toward the required applicable percentage if—

- (i) The patient is admitted for inpatient rehabilitation for a condition that is not one of the conditions specified in paragraph (b)(2) of 42 CFR 412.29;*
- (ii) The patient has a comorbidity that falls in one of the conditions specified in paragraph (b)(2) of 42 CFR 412.29; and*
- (iii) The comorbidity has caused significant decline in functional ability in the individual that, even in the absence of the admitting condition, the individual*

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would require the intensive rehabilitation treatment that is unique to inpatient rehabilitation facilities paid under subpart P of 42 CFR 412 and that cannot be appropriately performed in another care setting covered under this title.

(2) **List of conditions.**

- (i) **Stroke**
- (ii) **Spinal cord injury**
- (iii) **Congenital deformity**
- (iv) **Amputation**
- (v) **Major multiple trauma**
- (vi) **Fracture of femur (hip fracture)**
- (vii) **Brain injury**
- (viii) **Neurological disorders, including multiple sclerosis, motor neuron diseases, polyneuropathy, muscular dystrophy, and Parkinson's disease**

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- (ix) *Burns*

- (x) *Active polyarticular rheumatoid arthritis, psoriatic arthritis, and seronegative arthropathies resulting in significant functional impairment of ambulation and other activities of daily living that have not improved after an appropriate, aggressive, and sustained course of outpatient therapy services or services in other less intensive rehabilitation settings immediately preceding the inpatient rehabilitation admission or that result from a systemic disease activation immediately before admission, but have the potential to improve with more intensive rehabilitation.*

- (xi) *Systemic vasculidities with joint inflammation, resulting in significant functional impairment of*

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ambulation and other activities of daily living that have not improved after an appropriate, aggressive, and sustained course of outpatient therapy services or services in other less intensive rehabilitation settings immediately preceding the inpatient rehabilitation admission or that result from a systemic disease activation immediately before admission, but have the potential to improve with more intensive rehabilitation.

- (xii) *Severe or advanced osteoarthritis (osteoarthrosis or degenerative joint disease) involving two or more major weight bearing joints (elbow, shoulders, hips, or knees, but not counting a joint with a prosthesis) with joint deformity and substantial loss of range of motion, atrophy of muscles surrounding the joint,*

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significant functional impairment of ambulation and other activities of daily living that have not improved after the patient has participated in an appropriate, aggressive, and sustained course of outpatient therapy services or services in other less intensive rehabilitation settings immediately preceding the inpatient rehabilitation admission but have the potential to improve with more intensive rehabilitation. (A joint replaced by a prosthesis no longer is considered to have osteoarthritis, or other arthritis, even though this condition was the reason for the joint replacement.)

(xiii) *Knee or hip joint replacement, or both, during an acute hospitalization immediately preceding the inpatient rehabilitation stay and also meet one or more of the*

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following specific criteria:

- (A) *The patient underwent bilateral knee or bilateral hip joint replacement surgery during the acute hospital admission immediately preceding the IRF admission.*

- (B) *The patient is extremely obese with a Body Mass Index of at least 50 at the time of admission to the IRF.*

- (C) *The patient is age 85 or older at the time of admission to the IRF.*

§412.29(b); §412.29(b)(1); §412.29(b)(1)(i);
 §412.29(b)(1)(ii); §412.29(b)(2);
 §412.29(b)(2)(i); §412.29(b)(2)(ii);
 §412.29(b)(2)(iii); §412.29(b)(2)(iv);
 §412.29(b)(2)(v); §412.29(b)(2)(vi);
 §412.29(b)(2)(vii); §412.29(b)(2)(viii);
 §412.29(b)(2)(ix); §412.29(b)(2)(x);
 §412.29(b)(2)(xi); §412.29(b)(2)(xii);

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§412.29(b)(2)(xiii); §412.29(b)(2)(xiii)(A);
 §412.29(b)(2)(xiii)(B); §412.29(b)(2)(xiii)(C)

33.01.03 Inpatient Rehabilitation Facility (IRF): Written Certification For New IRFs.

In the case of new IRFs (as defined in paragraph (c)(1) of 42 CFR 412.29) or new IRF beds (as defined in paragraph (c)(2) of 42 CFR 412.29), the IRF must provide a written certification that the inpatient population it intends to serve meets the requirements of paragraph (b) of 42 CFR 412.29.

This written certification will apply until the end of the IRF's first full 12-month cost reporting period or, in the case of new IRF beds, until the end of the cost reporting period during which the new beds are added to the IRF.

(1) **New IRFs.**

An IRF hospital or IRF unit is considered new if it has not been paid under the IRF PPS in subpart P of this part (42 CFR 412.25) for at least 5 calendar years. A new IRF will be considered new from the point

The rehabilitation facility has submitted a written attestation statement as well as Form CMS 4378 (rehabilitation hospital worksheet) to the state agency as a part of the application packet, or as determined by CMS to maintain the IPPS excluded status.

If a rehabilitation hospital has been closed for 5 years, it can open its doors as a new rehabilitation hospital.

DOCUMENT REVIEW

For new units:

1. Verify that the attestation statement and rehabilitation hospital worksheet has been submitted to the state agency.
2. Verify that the rehabilitation unit has not been paid under PPS for at least 5 calendar years.
3. Verify that the added beds, if applicable, were approved by CMS.

If the rehabilitation unit or hospital has undergone a change of ownership or a merger:

1. Ensure that the new owners have accepted assignment of the previous Medicare provider agreement,
- OR
2. If assignment was not accepted, the facility cannot request continued participation as a PPS excluded rehab hospital.

- 1 = Compliant
- 2 = Not Compliant

This standard is not met as evidenced by:

PROSPECTIVE PAYMENT SYSTEM EXCLUDED (PPS EXCLUDED UNIT) & DISTINCT PART UNIT – PHYSICAL REHABILITATION UNIT

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that it first participates in Medicare as an IRF until the end of its first full 12-month cost reporting period.

(2) **New IRF beds.**

Any IRF beds that are added to an existing IRF must meet all applicable State Certificate of Need and State licensure laws. New IRF beds may be added one time at any point during a cost reporting period and will be considered new for the rest of that cost reporting period. A full 12-month cost reporting period must elapse between the delicensing or decertification of IRF beds in an IRF hospital or IRF unit and the addition of new IRF beds to that IRF hospital or IRF unit. Before an IRF can add new beds, it must receive written approval from the appropriate CMS RO, so that the CMS RO can verify that a full 12-month cost reporting period has elapsed since the IRF has had beds delicensed or decertified. New IRF beds are included in the compliance review calculations

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under paragraph (b) of this section from the time that they are added to the IRF.

(3) **Change of ownership or leasing.**

An IRF hospital or IRF unit that undergoes a change of ownership or leasing, as defined in §489.18 of 42 CFR 489.18, retains its excluded status and will continue to be paid under the prospective payment system specified in §412.1(a)(3) before and after the change of ownership or leasing if the new owner(s) of the IRF accept assignment of the previous owners' Medicare provider agreement and the IRF continues to meet all of the requirements for payment under the IRF prospective payment system. If the new owner(s) do not accept assignment of the previous owners' Medicare provider agreement, the IRF is considered to be voluntarily terminated and the new owner(s) may re-apply to participate in the Medicare program. If the IRF does not continue to meet all of the

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requirements for payment under the IRF prospective payment system, then the IRF loses its excluded status and is paid according to the prospective payment systems described in §412.1(a)(1).

(4) **Mergers.**

If an IRF hospital (or a hospital with an IRF unit) merges with another hospital and the owner(s) of the merged hospital accept assignment of the IRF hospital's provider agreement (or the provider agreement of the hospital with the IRF unit), then the IRF hospital or IRF unit retains its excluded status and will continue to be paid under the prospective payment system specified in §412.1(a)(3) before and after the merger, as long as the IRF hospital or IRF unit continues to meet all of the requirements for payment under the IRF prospective payment system. If the owner(s) of the merged hospital do not accept assignment of the IRF hospital's provider agreement (or the

PROSPECTIVE PAYMENT SYSTEM EXCLUDED (PPS EXCLUDED UNIT) & DISTINCT PART UNIT – PHYSICAL REHABILITATION UNIT

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provider agreement of the hospital with the IRF unit), then the IRF hospital or IRF unit is considered voluntarily terminated and the owner(s) of the merged hospital may reapply to the Medicare program to operate a new IRF.

- §412.29(c)
- §412.29(c)(1)
- §412.29(c)(2)
- §412.29(c)(3)
- §412.29(c)(4)

33.01.04 Inpatient Rehabilitation Facility (IRF): Preadmission Screening.
An inpatient rehabilitation unit must:

- *Have in effect a preadmission screening procedure under which each prospective patient's condition and medical history are reviewed to determine whether the patient is likely to benefit significantly from an intensive inpatient program.*

This procedure must ensure that the preadmission screening for

The facility has a preadmission screening procedure to determine whether the patient is likely to benefit from the rehabilitation program.

DOCUMENT REVIEW AND CHART REVIEW

Review five patient records from the unit.
 Verify:

1. The unit has preadmission screening procedures in place that address whether the patient is likely to benefit significantly from an intensive inpatient program or assessment.
2. The medical records indicate that the criteria are used and patients would benefit significantly from an intensive inpatient program or assessment.

- 1 = Compliant
- 2 = Not Compliant

This standard is not met as evidenced by:

PROSPECTIVE PAYMENT SYSTEM EXCLUDED (PPS EXCLUDED UNIT) & DISTINCT PART UNIT – PHYSICAL REHABILITATION UNIT

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each Medicare Part A Fee-for-Service patient is reviewed and approved by a rehabilitation physician prior to the patient's admission to the IRF.

§412.29(d)

33.01.05 Medical Supervision.
An inpatient rehabilitation unit must:

- *Have in effect a procedure to ensure that patients receive close medical supervision, as evidenced by at least 3 face-to-face visits per week by a licensed physician with specialized training and experience in inpatient rehabilitation to assess the patient both medically and functionally, as well as to modify the course of treatment as needed to maximize the patient's capacity to benefit from the rehabilitation process.*

Facility policies define:

1. Required medical supervision
2. Special training and experience requirements for inpatient rehabilitation medical staff.

DOCUMENT REVIEW AND CHART REVIEW

1. Review five patient records from the unit.
 - Determine each record contains documentation of a minimum of 3 face-to-face visits per week by a licensed physician with specialized training and experience in inpatient rehabilitation.
2. Determine the facility policy addresses the required elements.

- 1 = Compliant
 2 = Not Compliant

This standard is not met as evidenced by:

§412.29(e)

PROSPECTIVE PAYMENT SYSTEM EXCLUDED (PPS EXCLUDED UNIT) & DISTINCT PART UNIT – PHYSICAL REHABILITATION UNIT

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<p>33.01.06 <u>Personnel Qualifications.</u> An inpatient rehabilitation unit must:</p> <ul style="list-style-type: none"> <i>Furnish, through the use of qualified personnel, rehabilitation nursing, physical therapy, and occupational therapy, plus, as needed, speech-language pathology, social services, psychological services (including neuropsychological services), and orthotic and prosthetic services.</i> 	<p>All licenses of the professional staff are current and are issued by the State in which the personnel are providing services.</p> <p>The hospital has a means of ensuring that its personnel are qualified and competent, consistent with State law.</p>	<p><u>DOCUMENT REVIEW, CHART REVIEW, AND FILE REVIEW</u></p> <ol style="list-style-type: none"> Verify that all licenses for the professional staff are current and are issued by the State in which the personnel are providing services. Verify the hospital has a means of ensuring that its personnel are qualified and competent. Verify the hospital has policies that establish the qualifications of personnel providing rehabilitation services. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>
<p>§412.29(f)</p>			
<p>33.01.07 <u>Medical Director of Rehabilitation – Qualifications.</u> An inpatient rehabilitation unit must have a director of rehabilitation who:</p> <ol style="list-style-type: none"> <i>Provides services to the IRF hospital and its inpatients on a full-time basis or, in the case of a rehabilitation unit, at least 20 hours per week;</i> <i>Is a doctor of medicine or osteopathic medicine;</i> <i>Is licensed under State law to practice medicine or surgery; and</i> 	<p>The medical director of the rehabilitation unit provides at least 20 service hours per week. The 20 hours may be any combination of patient services and administration.</p> <p>These 20 hours cannot be delegated to a Physician Assistant or any other qualified professional.</p>	<p><u>DOCUMENT REVIEW & FILE REVIEW</u></p> <p>Review the personnel file of the director as well as personnel time cards / logs, etc.</p> <p>Verify:</p> <ol style="list-style-type: none"> The rehabilitation unit has a medical director of rehabilitation. The director is a doctor of medicine or osteopathic medicine. The medical director provides at least 20 service hours per week. The license of the director is current and issued by the State in which the service is being provided. The medical director has met the criteria for 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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4. *Has had, after completing a one-year hospital internship, at least two years of training or experience in the medical management of inpatients requiring rehabilitation services.*

§412.29(g)

internship plus 2 years of training or experience.

33.01.08 Plan of Treatment.

The inpatient rehabilitation unit must:

- *Have a plan of treatment for each inpatient that is established, reviewed, and revised as needed by a physician in consultation with other professional personnel who provide services to the patient.*

§412.29(h)

The treatment plan includes measurable long-term and short-term goals with estimated time frames for achieving these.

This treatment plan identifies goals, services and interventions to assist the patient in regaining independence, reducing pain, and / or adapting to limitations in activities of daily living.

CHART REVIEW

Review a sample of closed records. Sample volumes as appropriate to evaluate inpatient care.

1. Determine that each patient has a plan of treatment in their medical record.
2. The physician and other professional personnel participate in the establishment, review and revision of the plan of treatment. (This could be a signature, a record of a conference, or record of consultation.)

- 1 = Compliant
- 2 = Not Compliant

This standard is not met as evidenced by:

PROSPECTIVE PAYMENT SYSTEM EXCLUDED (PPS EXCLUDED UNIT) & DISTINCT PART UNIT – PHYSICAL REHABILITATION UNIT

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<p>33.01.09 <u>Coordinated Interdisciplinary Team Approach.</u> <i>The inpatient rehabilitation unit must:</i></p> <ul style="list-style-type: none"> • <i>Use a coordinated interdisciplinary team approach in the rehabilitation of each inpatient, as documented by the periodic clinical entries made in the patient's medical record to note the patient's status in relationship to goal attainment and discharge plans, and that team conferences are held at least once per week to determine the appropriateness of treatment.</i> 	<p>Facility policy addresses the functioning of the interdisciplinary team approach:</p> <ol style="list-style-type: none"> 1. Planning patient care 2. Establishing goals 3. Documentation expectations, and 4. Frequency of team meetings. 	<p><u>DOCUMENT REVIEW AND CHART REVIEW</u></p> <ol style="list-style-type: none"> 1. Review facility documents. <ul style="list-style-type: none"> • Determine the facility policies address the required elements. 2. Review a sample of closed records. Sample volumes as appropriate to evaluate inpatient care. <ul style="list-style-type: none"> • Determine that an interdisciplinary team approach is utilized for the rehabilitation of each patient. • Determine that weekly team conferences are held to determine appropriateness of treatment. • Determine that medical records contain periodic clinical entries related to achievement of goals. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant <input type="checkbox"/> Not Applicable</p> <p>This standard is not met as evidenced by:</p>
<p>§412.29(i)</p> <p>33.01.10 <u>Retroactive Adjustments.</u> <i>If a new IRF (or new beds that are added to an existing IRF) are excluded from the prospective payment systems specified in §412.1(a)(1) and paid under the prospective payment system specified in §412.1(a)(3) for a cost reporting period under paragraph (c) of 42 CFR 412.29, but the inpatient population actually treated during that period does not meet the requirements of paragraph (b) of 42 CFR 412.29, we</i></p>	<p>New IRFs must meet the requirements of this section to receive retroactive payment.</p>	<p><u>DOCUMENT REVIEW</u></p> <p>Review facility documents.</p> <ul style="list-style-type: none"> • Determine the facility policies address the required elements. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant <input type="checkbox"/> Not Applicable</p> <p>This standard is not met as evidenced by:</p>

PROSPECTIVE PAYMENT SYSTEM EXCLUDED (PPS EXCLUDED UNIT) & DISTINCT PART UNIT – PHYSICAL REHABILITATION UNIT

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adjust payments to the IRF retroactively in accordance with the provisions in §412.130.

§412.29(j)

33.02.01 Multidisciplinary Team.

The rehabilitation program uses an integrated, multidisciplinary approach to patient care. The rehabilitation program’s core team may include, but is not necessarily limited to:

1. Physician
2. Rehabilitation RN
3. Speech Therapist
4. Occupational Therapist
5. Social Worker
6. Physical Therapist
7. Therapeutic Recreational Specialist for inpatient facilities

The disciplines represented in the core team will vary depending upon the mission and objective of the facility.

Other healthcare workers may be included as appropriate, such as:

- Psychologist
- Psychiatrist
- Neuropsychologist
- Orthotist
- Prosthetist
- Exercise physiologist
- Vocational rehabilitation counselor
- Audiologist

DOCUMENT REVIEW

Review the organizational chart for the integrated, multidisciplinary rehabilitation services program to determine it meets the requirement.

- 1 = Compliant
- 2 = Not Compliant

This standard is not met as evidenced by:

33.02.02 Physician Responsibility.

Each patient in the rehabilitation service has a physician member of the Medical Staff responsible for his/her medical condition.

All physical rehabilitation outpatients and inpatients have accessibility to the same level of quality health care. That care may require that a local family physician is responsible for overseeing the management of care for a remotely located specialist.

CHART REVIEW

Review a sample of inpatient and out-patient records.

- Determine that each patient is under the care of a member of the Medical Staff.

- 1 = Compliant
- 2 = Not Compliant

This standard is not met as evidenced by:

PROSPECTIVE PAYMENT SYSTEM EXCLUDED (PPS EXCLUDED UNIT) & DISTINCT PART UNIT – PHYSICAL REHABILITATION UNIT

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>33.02.03 Nursing Care. A registered nurse must be responsible for supervising the quality of nursing care rendered and be competent to participate in the interdisciplinary formulation of individual rehabilitation plans.</p>	<p>The registered nurse should be knowledgeable by education and/or experience in the care of rehabilitation patients.</p>	<p align="center"><u>DOCUMENT REVIEW & INTERVIEW</u></p> <p>Review the job description of the supervising registered nurse. Interview the supervising registered nurse.</p> <ul style="list-style-type: none"> Determine the RN has the necessary knowledge, experience and capabilities. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>
<p>33.02.04 Organizational Plan. There should be a written description of the program which includes, but need not be limited to the following:</p> <ol style="list-style-type: none"> The scope of services provided and how these services relate to each other. Services specific to inpatient or outpatient programs including: <ol style="list-style-type: none"> Admission criteria The assessment and evaluation process A program evaluation system including treatment criteria and outcome measures, e.g., functional index measurement (FIM) and referral / discharge procedures. 	<p>Self-explanatory.</p>	<p align="center"><u>DOCUMENT REVIEW</u></p> <p>Review the program for treatment criteria, assessment and evaluation including outcome measures.</p> <ul style="list-style-type: none"> Determine an Organizational Plan for the rehabilitation program is available for review. The plan includes all required components. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

PROSPECTIVE PAYMENT SYSTEM EXCLUDED (PPS EXCLUDED UNIT) & DISTINCT PART UNIT – PHYSICAL REHABILITATION UNIT

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>33.02.05 Collaborative Goals. The goals are developed in collaboration with the patient, and family, as appropriate.</p> <p>The goals include monitoring and treatment of pain using a quantifiable tool such as:</p> <ul style="list-style-type: none"> • A visual scale of zero to ten, or • The “FACES” tool for children. 	<p>The patient, and family when appropriate, assists with planning the treatment goals. The goals reflect their understanding of life styles and activities.</p>	<p align="center"><u>CHART REVIEW</u></p> <p>Review at least ten recently closed rehabilitation records. Choose the sample based upon distribution of inpatient and outpatient volumes.</p> <ul style="list-style-type: none"> • Determine the goals are developed in collaboration with the patient and family, as appropriate. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>
<p>33.02.06 Patient / Family Education. The patient, and/or family when appropriate, is informed of all aspects of the nature of the problem, injury(ies), alternative treatments and devices, and methods of achieving and maintaining progress in the identified goals.</p>	<p>Education of patients and families is documented in the medical record. Such education includes methods to reduce the potential for reinjury.</p>	<p align="center"><u>CHART REVIEW</u></p> <p>Review at least ten recently closed rehabilitation records. Choose the sample based upon distribution of inpatient and outpatient volumes.</p> <ul style="list-style-type: none"> • Determine that patient / family education is provided appropriate to the nature of the patient problems and interventions. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant <input type="checkbox"/> NA =Not Applicable</p> <p>This standard is not met as evidenced by:</p>

PROSPECTIVE PAYMENT SYSTEM EXCLUDED (PPS EXCLUDED UNIT) & DISTINCT PART UNIT – PHYSICAL REHABILITATION UNIT

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33.02.07 Quality Assessment Performance Improvement (QAPI).
 Rehabilitation services shall be integrated into the facility-wide QAPI plan.

Self-explanatory.

DOCUMENT REVIEW

Review the QAPI plan and minutes.
 Verify:

1. Rehabilitation Services are integrated into the facility wide QAPI Plan.
2. Rehabilitation services related data is collected and utilized to improve the quality of patient care and patient safety. Improvements are monitored to insure improvement in outcomes/results.

- 1 = Compliant
- 2 = Not Compliant

This standard is not met as evidenced by:

PROSPECTIVE PAYMENT SYSTEM EXCLUDED (PPS EXCLUDED UNIT) & DISTINCT PART UNIT - PSYCHIATRIC UNIT

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DISTINCT PART PSYCHIATRIC UNIT / PROSPECTIVE PAYMENT SYSTEM EXCLUDED UNIT.

Requirements for Medicare PPS Excluded Psychiatric Units include the following:

- 42 CFR 482 - Conditions of Participation for hospitals;
- 42 CFR 412.25 - Excluded hospital units: Common Requirements; and
- 42 CFR 412.27 - Excluded psychiatric units: Additional Requirements

Standards 34.00.01 through 34.00.30 are applicable **ONLY** for a Medicare PPS Excluded Psychiatric Unit.

A PPS excluded psychiatric unit is regulated by both the hospital CoP at 42 CFR 482 (also found in Appendix A of the SOM) and the PPS excluded psychiatric unit requirements at 42 CFR 412.27.

DOCUMENT REVIEW, OBSERVATION, & CHART REVIEW

Score based on the scoring for:

- Standards 34.00.01 through 34.00.30, and
- Standards 34.01.01 through 34.01.36

NA = Facility has no DPU Psychiatric Unit

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**34.00.01 PPS Excluded Hospital Units:
Basis for Exclusion.**

In order to be excluded from the Prospective Payment Systems (PPS) specified in §412.1(a)(1), a psychiatric unit must meet the requirements in addition to all criteria under subpart B of part 412 of 42 CFR 412:

1. *Be part of an institution that -*
 - i. *Has in effect an agreement under part 489 of 42 CFR 489 to participate as a hospital;*
 - ii. *Is not excluded in its entirety from the prospective payment systems; and*
 - iii. *Has enough beds that are not excluded from the prospective payment systems to permit the provision of adequate cost information as required by §413.24(c) 42 CFR 413.24.*

- §412.25
- §412.25(a)
- §412.25(a)(1)
- §412.25(a)(1)(i)
- §412.25(a)(1)(ii)
- §412.25(a)(1)(iii)

The hospital has a current agreement from the CMS Regional Office to participate in the Medicare program.

INTERVIEW & DOCUMENT REVIEW

Verify:

1. The hospital has an agreement to participate in the Medicare program.
2. The hospital is not already excluded in its entirety from PPS, such as a Psychiatric hospital.

- 1 = Compliant
- 2 = Not Compliant

This standard is not met as evidenced by:

PROSPECTIVE PAYMENT SYSTEM EXCLUDED (PPS EXCLUDED UNIT) & DISTINCT PART UNIT - PSYCHIATRIC UNIT

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>34.00.02 PPS Excluded Hospital Units: Admission Criteria. <i>In order to be excluded from the Medicare PPS System, the unit must meet the following criteria:</i></p> <ul style="list-style-type: none"> Have written admission criteria that are applied uniformly to both Medicare and non-Medicare patients. <p>§412.25(a)(2)</p>	<p>The hospital has written admission criteria.</p> <p>The approved admission criteria are followed for all patients.</p>	<p align="center"><u>DOCUMENT REVIEW & CHART REVIEW</u></p> <p>Review policies and open and closed records. Verify:</p> <ol style="list-style-type: none"> Written admission criteria are in place. The approved admission criteria are followed for all patients. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>
<p>34.00.03 PPS Excluded Hospital Units: Separate Medical Records. <i>In order to be excluded from the Medicare PPS System, the unit must meet the following criteria:</i></p> <ul style="list-style-type: none"> Have admission and discharge records that are separately identified from those of the hospital in which it is located and are readily available. <p>§412.25(a)(3)</p>	<p>PPS exempt units have medical records that are separate and not commingled with other hospital records and are readily available for review.</p>	<p align="center"><u>OBSERVATION</u></p> <p>Verify the PPS excluded unit:</p> <ul style="list-style-type: none"> Has medical records that are separate and are not commingled with other hospital records; these are readily available for review. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

PROSPECTIVE PAYMENT SYSTEM EXCLUDED (PPS EXCLUDED UNIT) & DISTINCT PART UNIT - PSYCHIATRIC UNIT

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34.00.04 PPS Excluded Hospital
Units: Availability of Clinical Records & Information.

In order to be excluded from the Medicare PPS System, the unit must meet the following criteria:

- *Have policies specifying that necessary clinical information is transferred to the unit when a patient of the hospital is transferred to the unit.*

§412.25(a)(4)

The hospital has a written policy that specifies the clinical information that is to accompany the patient when transferred to the exempt rehabilitation unit.

DOCUMENT REVIEW & CHART REVIEW

Review facility policies. Review medical records. Verify:

1. The hospital has a policy detailing the prompt transfer of clinical information for patients transferred to the psychiatric unit.
2. The medical record reflects that clinical information is promptly transferred with the record.

- 1 = Compliant
 2 = Not Compliant

This standard is not met as evidenced by:

34.00.05 PPS Excluded Hospital
Units: State Licensure Requirements.

In order to be excluded from the Medicare PPS System, the unit must meet the following criteria:

- *Meet applicable State licensure laws.*

§412.25(a)(5)

The hospital provides evidence that all applicable State licensure laws are met.

The hospital provides documentation of any and all unmet State licensure requirements including documentation for deficient practices.

The hospital has current licenses for its professional staff. **The professional staff are licensed** by the State in which the hospital is located.

The unit meets special licensing requirements issued by the State, **as required.**

DOCUMENT REVIEW

Verify:

1. The hospital has current licenses **for its professional staff** issued by the state in which the unit is **located.**
2. All applicable state licensure laws are met, including any special licensing requirements issued by the state.
3. All professional staff files have current licenses.

- 1 = Compliant
 2 = Not Compliant

This standard is not met as evidenced by:

PROSPECTIVE PAYMENT SYSTEM EXCLUDED (PPS EXCLUDED UNIT) & DISTINCT PART UNIT - PSYCHIATRIC UNIT

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
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34.00.06 PPS Excluded Hospital

Units: Utilization Review

Requirements.

In order to be excluded from the Medicare PPS System, the unit must meet the following criteria:

- *Have utilization review standards applicable for the type of care offered in the unit.*

§412.25(a)(6)

The hospital has a Utilization Review Plan that includes the review of rehab services. (No utilization review standards are required if the QIO is conducting review activities.)

DOCUMENT REVIEW

Verify:

- The hospital has a Utilization Review Plan that includes the review of psychiatric services, either internally or through the QIO.

- 1 = Compliant
 2 = Not Compliant

This standard is not met as evidenced by:

34.00.07 PPS Excluded Hospital

Units: Distinct Unit Structure.

In order to be excluded from the Medicare PPS System, the unit must meet the following criteria:

- *Have beds physically separate from (that is, not commingled with) the hospital's other beds.*

§412.25(a)(7)

The PPS exempt psychiatric beds are physically separate from the beds in other units of the hospital.

OBSERVATION

Verify:

- **The unit which contains psychiatric beds is physically separate from the beds in other units of the hospital.**

- 1 = Compliant
 2 = Not Compliant

This standard is not met as evidenced by:

PROSPECTIVE PAYMENT SYSTEM EXCLUDED (PPS EXCLUDED UNIT) & DISTINCT PART UNIT - PSYCHIATRIC UNIT

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
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34.00.08 PPS Excluded Hospital
Units: Fiscal Intermediary.
In order to be excluded from the Medicare PPS System, the unit must meet the following criteria:

- *Be serviced by the same fiscal intermediary as the hospital.*

§412.25(a)(8)

Self-explanatory.

DOCUMENTS

Verify the PPS excluded unit:

- **Uses the same fiscal intermediary as the hospital.**

- 1 = Compliant
 2 = Not Compliant

This standard is not met as evidenced by:

34.00.09 PPS Excluded Hospital
Units: Separate Cost Center.
In order to be excluded from the Medicare PPS System, the unit must meet the following criteria:

- *Be treated as a separate cost center for cost finding and apportionment purposes.*

§412.25(a)(9)

Self-explanatory.

DOCUMENTS

Verify the PPS excluded unit:

- **Uses a separate cost center for cost finding as that used by the hospital.**

- 1 = Compliant
 2 = Not Compliant

This standard is not met as evidenced by:

PROSPECTIVE PAYMENT SYSTEM EXCLUDED (PPS EXCLUDED UNIT) & DISTINCT PART UNIT - PSYCHIATRIC UNIT

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
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34.00.10 PPS Excluded Hospital
Units: Allocate Costs.
In order to be excluded from the Medicare PPS System, the unit must meet the following criteria:

- *Use an accounting system that properly allocates costs.*

§412.25(a)(10)

Self-explanatory.

DOCUMENTS

Verify the PPS excluded unit:

- Uses an accounting system that properly allocates costs.

1 = Compliant
 2 = Not Compliant

This standard is not met as evidenced by:

34.00.11 PPS Excluded Hospital
Units: Statistical Data.
In order to be excluded from the Medicare PPS System, the unit must meet the following criteria:

- *Maintain adequate statistical data to support the basis of allocation.*

§412.25(a)(11)

Self-explanatory.

DOCUMENTS

Verify the PPS excluded unit:

- Maintains adequate statistical data to support the basis of allocation.

1 = Compliant
 2 = Not Compliant

This standard is not met as evidenced by:

PROSPECTIVE PAYMENT SYSTEM EXCLUDED (PPS EXCLUDED UNIT) & DISTINCT PART UNIT - PSYCHIATRIC UNIT

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>34.00.12 PPS Excluded Hospital <u>Units: Cost Report.</u> <i>In order to be excluded from the Medicare PPS System, the unit must meet the following criteria:</i></p> <ul style="list-style-type: none"> <i>Report its costs in the hospital's cost report covering the same fiscal period and using the same method of apportionment as the hospital.</i> 	<p>Self-explanatory.</p>	<p align="center"><u>DOCUMENTS</u></p> <p>Verify the PPS excluded unit:</p> <ul style="list-style-type: none"> Reports its costs in the hospital's cost report covering the same fiscal period and using the same method of apportionment as the hospital. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>
<p>§412.25(a)(12)</p> <p>34.00.13 PPS Excluded Hospital <u>Units: Requirements on the First Day of the First Cost Reporting Period.</u> <i>In order to be excluded from the Medicare PPS System, the unit must meet the following criteria:</i></p> <ul style="list-style-type: none"> <i>As of the first day of the first cost reporting period for which all other exclusion requirements are met, the unit is fully equipped and staffed and is capable of providing hospital inpatient psychiatric or rehabilitation care regardless of whether there are any inpatients in the unit on that date.</i> 	<p>Self-explanatory.</p>	<p align="center"><u>DOCUMENTS</u></p> <p>Verify the PPS excluded unit:</p> <ul style="list-style-type: none"> Is fully equipped and staffed and is capable of providing hospital inpatient psychiatric care. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>
<p>§412.25(a)(13)</p>			

PROSPECTIVE PAYMENT SYSTEM EXCLUDED (PPS EXCLUDED UNIT) & DISTINCT PART UNIT - PSYCHIATRIC UNIT

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>34.00.14 PPS Excluded Hospital Unit: Change in Size. <i>Changes in the size of excluded units. Except in the special cases noted at the end of this paragraph, changes in the number of beds or square footage considered to be part of an excluded unit under this section are allowed one time during a cost reporting period if the hospital notifies its Medicare contractor and the CMS RO in writing of the planned change at least 30 days before the date of the change.</i></p> <p><i>The hospital must maintain the information needed to accurately determine costs that are attributable to the excluded unit.</i></p> <p><i>A change in bed size or a change in square footage may occur at any time during a cost reporting period and must remain in effect for the rest of that cost reporting period.</i></p> <p><i>Changes in bed size or square footage may be made at any time if these changes are made necessary by relocation of a unit to permit construction or renovation necessary for compliance with changes in</i></p>	<p>Self-explanatory.</p>	<p align="center"><u>DOCUMENT REVIEW AND INTERVIEW</u></p> <ul style="list-style-type: none"> Verify there have been no changes to the number of beds or square footage of the rehab unit within this accreditation cycle, which would make this standard not applicable <p align="center">OR,</p> <ul style="list-style-type: none"> Verify that the CMS RO was notified at least 30 days prior to the change in writing, and that unit costs are clearly defined. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

PROSPECTIVE PAYMENT SYSTEM EXCLUDED (PPS EXCLUDED UNIT) & DISTINCT PART UNIT - PSYCHIATRIC UNIT

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
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Federal, State, or local law affecting the physical facility or because of catastrophic events such as fires, floods, earthquakes, or tornadoes.
§412.25(b)

34.00.15 PPS Excluded Hospital Unit: Self-explanatory.
Change in Status:

(c) Changes in the status of hospital units. For purposes of exclusions from the prospective payment systems under this section, the status of each hospital unit (excluded or not excluded) is determined as specified in paragraphs (c)(1) and (c)(2) of 42 CFR 412.25.

(1) The status of a hospital unit may be changed from not excluded to excluded only at the start of the cost reporting period. If a unit is added to a hospital after the start of a cost reporting period, it cannot be excluded from the prospective payment systems before the start of a hospital's next cost reporting period.

DOCUMENT REVIEW AND INTERVIEW

- **Verify that appropriate notification has occurred if a change of status has occurred within this accreditation cycle, consistent with the standard.**

- 1 = Compliant
- 2 = Not Compliant

This standard is not met as evidenced by:

PROSPECTIVE PAYMENT SYSTEM EXCLUDED (PPS EXCLUDED UNIT) & DISTINCT PART UNIT - PSYCHIATRIC UNIT

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
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(2) *The status of a hospital unit may be changed from excluded to not excluded at any time during a cost reporting period, but only if the hospital notifies the fiscal intermediary and the CMS Regional Office in writing of the change at least 30 days before the date of the change, and maintains the information needed to accurately determine costs that are or are not attributable to the excluded unit. A change in the status of a unit from excluded to not excluded that is made during a cost reporting period must remain in effect for the rest of that cost reporting period.*

§412.25(c)
 §412.25(c)(1)
 §412.25(c)(2)

PROSPECTIVE PAYMENT SYSTEM EXCLUDED (PPS EXCLUDED UNIT) & DISTINCT PART UNIT - PSYCHIATRIC UNIT

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>34.00.16 <u>PPS Excluded Hospital Unit: Number of Excluded Units.</u></p> <ul style="list-style-type: none"> <i>Each hospital may have only one unit of each type (psychiatric or rehabilitation) excluded from the prospective payment systems.</i> <p>§412.25(d)</p>	<p>The hospital may have one (1) PPS excluded Rehabilitation Unit.</p> <p>The hospital may also have one (1) PPS excluded Psychiatric Unit.</p>	<p align="center"><u>INTERVIEW AND OBSERVATION</u></p> <ul style="list-style-type: none"> Verify there is only one (1) PPS Excluded psychiatric unit in this facility. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>
<p>34.00.17 <u>Satellite Facilities: Define.</u> For purposes of paragraphs (e)(2) through (e)(5) of 42 CFR 412.25, a <i>satellite facility is</i></p> <ul style="list-style-type: none"> <i>A part of a hospital unit that provides inpatient services in a building also used by another hospital, or</i> <i>In one or more entire buildings located on the same campus as buildings used by another hospital.</i> <p>§412.25(e) §412.25(e)(1)</p>	<p>Self-explanatory.</p>	<p align="center"><u>INTERVIEW AND OBSERVATION</u></p> <p>Verify the satellite facility:</p> <ul style="list-style-type: none"> Provides inpatient services consistent with requirement. Is located consistent with requirement. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

PROSPECTIVE PAYMENT SYSTEM EXCLUDED (PPS EXCLUDED UNIT) & DISTINCT PART UNIT - PSYCHIATRIC UNIT

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>34.00.18 <u>Satellite Facility: Criteria.</u> <i>Except as provided in paragraphs (e)(3) and (e)(6) of 42 CFR 412.25, effective for cost reporting periods beginning on or after October 1, 1999, a hospital that has a satellite facility must meet the following criteria in order to be excluded from the acute care hospital inpatient prospective payment systems for any period:</i></p> <p><i>(i) In the case of a unit excluded from the prospective payment systems for the most recent cost reporting period beginning before October 1, 1997, the unit's number of State-licensed and Medicare-certified beds, including those at the satellite facility, does not exceed the unit's number of state-licensed and Medicare-certified beds on the last day of the unit's last cost reporting period beginning before October 1, 1997.</i></p> <p><i>(ii) The satellite facility independently complies with—</i></p> <p><i>(A) For a rehabilitation unit, the requirements under 412.29 of 42 CFR 412.29; or</i></p>	<p>Self-explanatory.</p>	<p align="center"><u>INTERVIEW AND DOCUMENT REVIEW</u></p> <p>Verify the satellite facility:</p> <ul style="list-style-type: none"> • Meets criteria for exclusion from PPS consistent with requirement. • The unit's number of State-licensed and Medicare-certified beds, including those at the satellite facility, <u>does not exceed</u> the unit's number of state-licensed and Medicare-certified beds on the last day of the unit's last cost reporting period. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

PROSPECTIVE PAYMENT SYSTEM EXCLUDED (PPS EXCLUDED UNIT) & DISTINCT PART UNIT - PSYCHIATRIC UNIT

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
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(B) *For a psychiatric unit, the requirements under §412.27(a).*

§412.25(e)(2)
 §412.25(e)(2)(i)
 §412.25(e)(2)(ii)
 §412.25(e)(2)(ii)(A)
 §412.25(e)(2)(ii)(B)

**34.00.19 Satellite Facility:
 Separate Governing Body.**
The satellite facility meets all the following requirements:

- Effective for cost reporting periods beginning on or after October 1, 2002, it is not under the control of the governing body or chief executive officer of the hospital in which it is located, and it furnishes inpatient care through the use of medical personnel who are not under the control of the medical staff or chief medical officer of the hospital in which it is located.*

Self-explanatory.

INTERVIEW AND DOCUMENT REVIEW

- Verify the governing body/CEO of the satellite facility is different than that for the hospital.
- Verify the care provided is not under control of the hospital medical staff and chief medical officer.

1 = Compliant
 2 = Not Compliant

This standard is not met as evidenced by:

§412.25(e)(2)(iii)(A)

PROSPECTIVE PAYMENT SYSTEM EXCLUDED (PPS EXCLUDED UNIT) & DISTINCT PART UNIT - PSYCHIATRIC UNIT

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
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**34.00.20 Satellite Facility:
Admission and Discharge Records.**
The satellite facility meets all the following requirements:

- *It maintains admission and discharge records that are separately identified from those of the hospital in which it is located and are readily available.*

§412.25(e)(2)(iii)(B)

Self-explanatory.

DOCUMENT REVIEW

- Verify the satellite facility maintains admission and discharge records separate from the hospital; these records are readily available.

- 1 = Compliant
- 2 = Not Compliant

This standard is not met as evidenced by:

**34.00.21 Satellite Facility:
Beds Are Physically Separate.**
The satellite facility meets all the following requirements:

- *It has beds that are physically separate from (that is, not commingled with) the beds of the hospital in which it is located.*

§412.25(e)(2)(iii)(C)

Self-explanatory.

INTERVIEW AND OBSERVATION

- Verify the beds of the satellite facility are physically separate from the beds of the hospital.

- 1 = Compliant
- 2 = Not Compliant

This standard is not met as evidenced by:

PROSPECTIVE PAYMENT SYSTEM EXCLUDED (PPS EXCLUDED UNIT) & DISTINCT PART UNIT - PSYCHIATRIC UNIT

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>34.00.22 <u>Satellite Facility:</u> <u>Fiscal Intermediary.</u> <i>The satellite facility meets all the following requirements:</i></p> <ul style="list-style-type: none"> <i>It is serviced by the same fiscal intermediary as the hospital unit of which it is a part.</i> <p>§412.25(e)(2)(iii)(D)</p>	<p>Self-explanatory.</p>	<p align="center"><u>DOCUMENT REVIEW</u></p> <ul style="list-style-type: none"> Verify the satellite facility uses the same fiscal intermediary as the hospital of which it is a part. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>
<p>34.00.23 <u>Satellite Facility:</u> <u>Separate Cost Center.</u> <i>The satellite facility meets all the following requirements:</i></p> <ul style="list-style-type: none"> <i>It is treated as a separate cost center of the hospital unit of which it is a part.</i> <p>§412.25(e)(2)(iii)(E)</p>	<p>Self-explanatory.</p>	<p align="center"><u>DOCUMENT REVIEW</u></p> <ul style="list-style-type: none"> Verify the satellite facility is a separate cost center of the hospital of which it is a part. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

PROSPECTIVE PAYMENT SYSTEM EXCLUDED (PPS EXCLUDED UNIT) & DISTINCT PART UNIT - PSYCHIATRIC UNIT

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>34.00.24 <u>Satellite Facility: Accounting System.</u> <i>The satellite facility meets all the following requirements:</i></p> <ul style="list-style-type: none"> <i>For cost reporting and apportionment purposes, it uses an accounting system that properly allocates costs and maintains adequate statistical data to support the basis of allocation.</i> <p>§412.25(e)(2)(iii)(F)</p>	<p>Self-explanatory.</p>	<p align="center"><u>DOCUMENT REVIEW</u></p> <ul style="list-style-type: none"> Verify the satellite facility uses an accounting system that properly allocates costs and maintains adequate statistical data to support the basis of allocation. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>
<p>34.00.25 <u>Satellite Facility: Hospital Cost Report.</u> <i>The satellite facility meets all the following requirements:</i></p> <ul style="list-style-type: none"> <i>It reports its costs on the cost report of the hospital of which it is a part, covering the same fiscal period and using the same method of apportionment as the hospital of which it is a part.</i> <p>§412.25(e)(2)(iii)(G)</p>	<p>Self-explanatory.</p>	<p align="center"><u>DOCUMENT REVIEW</u></p> <ul style="list-style-type: none"> Verify the satellite facility reports its costs on the cost report of the hospital of which it is a part, using the same fiscal period and same method of apportionment as the hospital. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

PROSPECTIVE PAYMENT SYSTEM EXCLUDED (PPS EXCLUDED UNIT) & DISTINCT PART UNIT - PSYCHIATRIC UNIT

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>34.00.26 <u>Satellite Facility: Exception.</u> <i>Except as specified in paragraphs (e)(4) and (e)(5) of 42 CFR 412.25, the provisions of paragraph (e)(2) of 42 CFR 412.25 do not apply to any unit structured as a satellite facility on September 30, 1999, and excluded from the prospective payment systems on that date, to the extent the unit continues operating under the same terms and conditions, including the number of beds and square footage considered to be part of the unit at the satellite facility on September 30, 1999.</i></p> <p>§412.25(e)(3)</p>	<p>Self-explanatory.</p>	<p align="center"><u>DOCUMENT REVIEW</u></p> <p>Review documents to determine the satellite facility meets this requirement.</p> <p>Determine if this unit was structured as a satellite facility on September 30, 1999, and excluded from the prospective payment systems on that date.</p> <ul style="list-style-type: none"> If yes, has the unit continued to operate under the same terms and conditions, including the number of beds and square footage considered to be part of the unit at the satellite facility on September 30, 1999. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>
<p>34.00.27 <u>Satellite Facility: Increase/Decrease Square Footage or Decrease Beds.</u> <i>In applying the provisions of paragraph (e)(3) of 42 CFR 412.25, any unit structured as a satellite facility on September 30, 1999, may increase or decrease the square footage of the satellite facility or may decrease the number of beds in the satellite facility considered to be part of the satellite facility at any time, if these changes</i></p>	<p>An increase / decrease in the square footage or a decrease in the number of beds is acceptable for the following reasons:</p> <ol style="list-style-type: none"> To permit construction or renovation necessary for compliance with federal, state, or local law. Due to a catastrophic event. 	<p align="center"><u>INTERVIEW AND OBSERVATION</u></p> <p>Determine if the satellite facility increased / decreased the square footage of the satellite facility or decreased the number of beds.</p> <p>If yes, were these changes:</p> <ul style="list-style-type: none"> To permit construction or renovation necessary for compliance with federal, state, or local law? Due to a catastrophic event? 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

PROSPECTIVE PAYMENT SYSTEM EXCLUDED (PPS EXCLUDED UNIT) & DISTINCT PART UNIT - PSYCHIATRIC UNIT

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
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are made by the relocation of a facility—

- (i) *To permit construction or renovation necessary for compliance with changes in federal, state, or local law affecting the physical facility.*
- (ii) *Because of catastrophic events such as fires, floods, earthquakes, or tornadoes.*

§412.25(e)(4)
 §412.25(e)(4)(i)
 §412.25(e)(4)(ii)

34.00.28 Satellite Facility:
After October 1, 2006.
For the cost reporting periods beginning on or after October 1, 2006, in applying the provisions of Medicare paragraph (e)(3) of 42 CFR 412.25—

- (i) *Any unit structured as a satellite facility on September 30, 1999, may increase the square footage of the unit only at the beginning of a cost reporting period or decrease the square footage or number of beds considered*

For any unit that was a structure of satellite facility on September 30, 1999, it is acceptable for the satellite facility to increase / decrease the square footage of the satellite facility or decrease the number of beds.

INTERVIEW AND OBSERVATION

Determine if the unit was a structure of satellite facility on September 30, 1999.

- If yes, determine if the satellite facility increased / decreased the square footage of the satellite facility or decreased the number of beds, these changes were consistent with the requirement.

1 = Compliant
 2 = Not Compliant

This standard is not met as evidenced by:

PROSPECTIVE PAYMENT SYSTEM EXCLUDED (PPS EXCLUDED UNIT) & DISTINCT PART UNIT - PSYCHIATRIC UNIT

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
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to be part of the satellite facility subject to the provisions of paragraph (b)(2) of 42 CFR 412.25, without affecting the provisions of paragraph (e)(3) of 42 CFR 412.25; and

- (ii) *If the unit structured as a satellite facility decreases its number of beds below the number of beds considered to be part of the satellite facility on September 30, 1999, subject to the provisions of paragraph (b)(2) of 42 CFR 412.25, it may subsequently increase the number of beds at the beginning or a cost reporting period as long as the resulting total number of beds considered to be part of the satellite facility does not exceed the number of beds at the satellite facility on September 30, 1999.*

§412.25(e)(5)
 §412.25(e)(5)(i)
 §412.25(e)(5)(ii)

PROSPECTIVE PAYMENT SYSTEM EXCLUDED (PPS EXCLUDED UNIT) & DISTINCT PART UNIT - PSYCHIATRIC UNIT

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>34.00.29 <u>Satellite Facility: Inpatient Psychiatric Unit.</u> <i>The provisions of Medicare paragraph (e)(2)(i) of 42 CFR 412.25—</i></p> <ul style="list-style-type: none"> <i>Do not apply to any inpatient rehabilitation facility that is subject to the inpatient rehabilitation facility prospective payment system under subpart P of 42 CFR 412.25, effective for cost reporting periods beginning on or after October 1, 2003.</i> <p>§ 412.25(e)(6)</p>	<p>Self-explanatory.</p>	<p align="center"><u>DOCUMENT REVIEW</u></p> <ul style="list-style-type: none"> Review documents to determine the satellite facility is compliant with the requirement. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>
<p>34.00.30 <u>Changes in Classification of Hospital Units.</u> <i>For purposes of exclusions from the prospective payment system under 42 CFR 412.25—</i></p> <ul style="list-style-type: none"> <i>The classification of a hospital unit is effective for the unit's entire cost reporting period. Any changes in the classification of a hospital unit are made only at the start of a cost reporting period.</i> <p>§412.25(f)</p>	<p>Self-explanatory.</p>	<p align="center"><u>INTERVIEW AND DOCUMENT REVIEW</u></p> <p>Review documents. Determine if the satellite facility made any changes in the classification of a unit.</p> <ul style="list-style-type: none"> If yes, were these changes only made at the start of a cost reporting period? 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

PROSPECTIVE PAYMENT SYSTEM EXCLUDED (PPS EXCLUDED UNIT) & DISTINCT PART UNIT - PSYCHIATRIC UNIT

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
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34.01.01 PPS Excluded Psychiatric Units: Additional Requirements.

In order to be excluded from the prospective payment system, a psychiatric unit must meet the requirements in **34.01.02 thru 34.01.17.**

Score this requirement based on scoring from standards 34.01.02 thru 34.01.17.

- 1 = Compliant
- 2 = Not Compliant

This standard is not met as evidenced by:

34.01.02 PPS Excluded Psychiatric Units: Admission Criteria.

The **psychiatric unit** will:

Patients admitted to the PPS excluded unit have a principal psychiatric diagnosis that requires active inpatient treatment.

CHART REVIEW

- Review a select group of clinical records to determine there is a principal diagnosis that meets the requirement.

- 1 = Compliant
- 2 = Not Compliant

This standard is not met as evidenced by:

- *Admit only patients whose admission to the unit is required for active treatment, of an intensity that can be provided appropriately only in an inpatient hospital setting, of a psychiatric principal diagnosis that is listed in the **Fourth Edition, Text Revision** of the American Psychiatric Association’s Diagnostic and Statistical Manual, or in Chapter Five (“Mental Disorders”) of the International Classification of Diseases, Ninth Revision, Clinical Modification.*

§412.27(a)

PROSPECTIVE PAYMENT SYSTEM EXCLUDED (PPS EXCLUDED UNIT) & DISTINCT PART UNIT - PSYCHIATRIC UNIT

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>34.01.03 PPS Excluded Psychiatric Units: Scope of Service. The psychiatric unit will:</p> <ul style="list-style-type: none"> <i>Furnish, through the use of qualified personnel, psychological services, social work services, psychiatric nursing, therapeutic activities.</i> <p>§412.27(b)</p>	<p>Personnel may be contracted or on the regular staff.</p> <p>However, there must be an employed registered nurse supervising care at all times the unit is open and providing care.</p>	<p align="center"><u>DOCUMENT REVIEW</u></p> <ul style="list-style-type: none"> Review the scope of service for the unit to determine all required services are provided. Verify by reviewing staffing sheets that an employed registered nurse is on duty supervising care delivery at all times. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>
<p>34.01.04 PPS Excluded Psychiatric Units: Treatment Plan. The psychiatric unit will:</p> <ul style="list-style-type: none"> <i>Maintain medical records that permit determination of the degree and intensity of the treatment provided to individuals who are furnished services in the unit, and that meet the following requirements.</i> <p>§412.27(c)</p>	<p>The facility ensures each patient record contains a treatment plan.</p>	<p align="center"><u>CHART REVIEW</u></p> <ul style="list-style-type: none"> Review the medical records to determine there is a current treatment plan and diagnosis on all patient records. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

PROSPECTIVE PAYMENT SYSTEM EXCLUDED (PPS EXCLUDED UNIT) & DISTINCT PART UNIT - PSYCHIATRIC UNIT

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>34.01.05 PPS Excluded Psychiatric Units: Development of Assessment / Diagnostic Data. <i>Medical records must stress the psychiatric components of the record, including history of findings and treatment provided for the psychiatric condition for which the inpatient is treated in the unit.</i></p> <p>§412.27(c)(1)</p>	<p>The facility ensures each patient record contains a psychiatric history including treatment provided for the psychiatric condition.</p>	<p align="center"><u>CHART REVIEW</u></p> <ul style="list-style-type: none"> Verify through chart review that all medical records reflect a psychiatric history of findings and treatment. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>
<p>34.01.06 PPS Excluded Psychiatric Units: Legal Status. <i>The medical records must include:</i></p> <ul style="list-style-type: none"> <i>The identification data of the inpatient's legal status.</i> <p>§412.27(c)(1)(i)</p>	<p>Legal status is defined in the State statutes and dictates the circumstances under which the patient was admitted and/or is being treated, i.e., voluntary, involuntary, committed by court, evaluation and recertification are in accordance with state requirements.</p> <p>Any changes in the legal status of the patient must be recorded with the date of change on the medical record.</p>	<p align="center"><u>INTERVIEW</u></p> <ul style="list-style-type: none"> Interview the facility staff about the terminology they use in defining "legal status." If evaluation and recertification of the patient is required by the state, determine that legal documentation supporting this status is present. <p align="center"><u>CHART REVIEW</u></p> <ul style="list-style-type: none"> Verify that any changes in the legal status of the patient are recorded with the date of change on the medical record. Review a select group of medical records to determine the requirement was met. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

PROSPECTIVE PAYMENT SYSTEM EXCLUDED (PPS EXCLUDED UNIT) & DISTINCT PART UNIT - PSYCHIATRIC UNIT

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>34.01.07 PPS Excluded Psychiatric Units: Admission Diagnosis. <i>The medical records must include:</i></p> <ul style="list-style-type: none"> <i>A provisional or admitting diagnosis must be made on every inpatient at the time of admission, and must include the diagnoses of intercurrent diseases as well as the psychiatric diagnoses.</i> <p>§412.27(c)(1)(ii)</p>	<p>There is an admission or working psychiatric diagnosis (including rule-out diagnoses) written in accordance with the most current edition of the American Psychiatric Association’s Diagnostic and Statistical Manual (DSM) or the approved International Classification of Diseases (ICD) nomenclature.</p> <p>The final diagnosis may differ from the initial diagnosis if subsequent evaluation and observation support a change.</p> <p>Diagnosis should include physical illness when present.</p>	<p align="center"><u>CHART REVIEW</u></p> <p>Review a select group of medical records to determine the requirement was met. The admitting diagnosis may be found on the face sheet, in the history and physical, or in the physician progress notes.</p> <p>Determine:</p> <ol style="list-style-type: none"> Were abnormal lab results or H&P findings followed up and justified? Are acute physical illnesses requiring immediate treatment managed appropriately? Is the diagnosis written in DSM nomenclature? If the diagnosis is absent, is there written justification for the omission? (For example, the patient was psychotic on admission and not accompanied by family). Is there an evaluation and treatment plan for identified physical illnesses that may impact the patient’s psychiatric outcome? 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

PROSPECTIVE PAYMENT SYSTEM EXCLUDED (PPS EXCLUDED UNIT) & DISTINCT PART UNIT - PSYCHIATRIC UNIT

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>34.01.08 PPS Excluded Psychiatric Units: Patient Reason for Admission. <i>The medical records must include:</i></p> <ul style="list-style-type: none"> <i>The reasons for admission must be clearly documented as stated by the inpatient or others significantly involved, or both.</i> <p>§412.27(c)(1)(iii)</p>	<p>The purpose of this regulation is to provide an understanding of what caused the patient to come to the hospital, and the patient’s response to admission.</p> <p>The hospital records the statements and reasons for admissions given by the family and by others as well as the patient (preferably verbatim) with informant identified. This information may be documented in a variety of locations within the patient record, e.g., in transfer and admission notes from the physician, nurses and social workers.</p>	<p align="center"><u>CHART REVIEW</u></p> <ul style="list-style-type: none"> Verify that all clinical records reviewed reflected the reason for admission as stated by the patient, family, or other interested parties. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>
<p>34.01.09 PPS Excluded Psychiatric Units: Social History & Assessment <i>The medical records must include:</i></p> <ul style="list-style-type: none"> <i>The social service records, including reports of interviews with inpatients, family members, and others must provide an assessment of home plans and family attitudes, and community resource contacts as well as a social history.</i> <p>§412.27(c)(1)(iv)</p>	<p>The purpose of the social work assessment is to determine the current baseline social functioning (strengths and deficits) of the patient, from which treatment interventions and discharge plans are to be formulated.</p> <p>A psychosocial history / assessment shall be completed for all patients.</p> <p>Three key components to be addressed are:</p> <p>A. Factual and historical information</p> <ol style="list-style-type: none"> Specific reasons for the patient’s admission or readmission. A description of the patient’s past and present biopsychosocial functioning. 	<p align="center"><u>CHART REVIEW</u></p> <p>Select open and closed medical records; review the social service assessment.</p> <ol style="list-style-type: none"> Determine that the patient participated to the extent possible. Determine that family members or others provided information. All three key components must be included in the assessment. High-risk psychosocial issues should be included in the treatment plan. Determine each record contains the required key components: <ol style="list-style-type: none"> Factual and historical information; Social evaluation (baseline social functioning including strengths and weaknesses); and 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

PROSPECTIVE PAYMENT SYSTEM EXCLUDED (PPS EXCLUDED UNIT) & DISTINCT PART UNIT - PSYCHIATRIC UNIT

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
	<ol style="list-style-type: none"> 3. Family and marital history, dynamics, and patient’s relationships with family and significant others. 4. Pertinent religious and cultural factors. 5. History of physical, sexual and emotional abuse. 6. Significant aspects of psychiatric, medical, and substance abuse history and treatment as presented by family members and significant others. 7. Educational, vocational, employment, and military service history. 8. Identification of community resources including previously used treatment sources. 9. Identification of present environmental and financial needs. <p>B. Social Evaluation</p> <ol style="list-style-type: none"> 1. Patient strength and deficits. 2. High risk psychosocial issues requiring early treatment planning and intervention, i.e., unattended children in the home; prior noncompliance; potential obstacles to treatment and discharge planning. 	<p>C. Conclusions and Recommendations (in anticipation of social work’s role in treatment and discharge planning).</p>	

PROSPECTIVE PAYMENT SYSTEM EXCLUDED (PPS EXCLUDED UNIT) & DISTINCT PART UNIT - PSYCHIATRIC UNIT

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
	<p>C. Conclusions and Recommendations resulting from the above assessment</p> <ol style="list-style-type: none"> 1. Anticipated necessary steps for discharge to occur. 2. High-risk patient and/or family psychosocial issues requiring early treatment planning and immediate intervention regardless of the patient’s length of stay. 3. Specific community resources / support systems for utilization in discharge planning. 4. Anticipated social work role in treatment and discharge planning. 		
<p>34.01.10 PPS Excluded Psychiatric Units: Neurological Examination. <i>The medical records must include:</i></p> <ul style="list-style-type: none"> • <i>When indicated, a complete neurological examination must be recorded at the time of the admission physical examination.</i> <p>§412.27(c)(1)(v)</p>	<p>Upon admission the patient must receive a thorough history and physical examination with all indicated laboratory examinations.</p> <p>A thorough history of the patient’s past physical disorders, head trauma, accidents, substance dependence / abuse, exposure to toxic agents, tumors, infections, seizures or temporary loss of consciousness, and headaches, will alert the physician to look for the presence of continuing pathology or possible sequelae any of which may turn out to be significant and pertinent to the present mental illness.</p> <p>In addition to the required history and physical, when indicated, a complete neurological exam must be conducted and recorded.</p>	<p align="center"><u>CHART REVIEW</u></p> <p>Review open and closed medical records to determine that the requirement was met.</p> <ol style="list-style-type: none"> 1. Positive neurological symptomatology found in the systems review (history and physical “screening” neurological exam) should result in a neuralgic workup or consultation. 2. At a minimum, the screening neurological exam includes a detailed description of gross testing for cranial nerves II through XII. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

PROSPECTIVE PAYMENT SYSTEM EXCLUDED (PPS EXCLUDED UNIT) & DISTINCT PART UNIT - PSYCHIATRIC UNIT

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>34.01.11 PPS Excluded Psychiatric Units: Psychiatric Evaluation. <i>Each inpatient must receive a psychiatric evaluation that must:</i></p> <ul style="list-style-type: none"> Comply with requirements found in 34.01.11 – 34.01.17 <p>§412.27(c)(2)</p>	<p>The psychiatric evaluation is done for the purpose of determining the patient’s diagnosis and treatment and, therefore, it must contain the necessary information to justify the diagnosis and planned treatment.</p> <p>The psychiatric evaluation must include the following components:</p> <ul style="list-style-type: none"> Chief complaints, reaction to hospitalization, Past history of any psychiatric problems and treatment, including previous precipitating factors, diagnosis, and course fo treatment, and Past family, educational, vocational, occupational, and social history. <p>The psychiatric evaluation is a total appraisal or assessment of the patient’s illness. It is the physician’s assessment of the contributing factors and forces in the evolution of the patient’s illness including the patient’s perception of his or her illness.</p> <ul style="list-style-type: none"> A physician signature is necessary. <p>In those cases where the mental status portion of the psychiatric evaluation is performed by a nonphysician, there should be evidence that the person is credentialed by the hospital, legally authorized by the state to perform the function, and a physician review and countersignature is present, where required by hospital policy or state law.</p>	<p align="center"><u>CHART REVIEW</u></p> <p>Review a sampling of open and closed medical records to determine that complete psychiatric evaluations were done on all admissions.</p> <p>The psychiatric exam must include the following components:</p> <ol style="list-style-type: none"> Chief complaints, Reaction to hospitalization Past history of any psychiatric problems and treatment, including previous precipitating factors, diagnosis, and course of treatment, and Past family, educational, vocational, occupational and social history. <p>Surveyor note: Score this standard based on the scoring for standards 34.01.11 – 34.01.17.</p>	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

PROSPECTIVE PAYMENT SYSTEM EXCLUDED (PPS EXCLUDED UNIT) & DISTINCT PART UNIT - PSYCHIATRIC UNIT

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>34.01.12 PPS Excluded Psychiatric Units: Psychiatric Evaluation Requirements – Timeframe. <i>Each inpatient must receive a psychiatric evaluation that must:</i></p> <ul style="list-style-type: none"> • <i>Be completed within 60 hours of admission</i> <p>§412.27(c)(2)(i)</p>	<p>Self-explanatory.</p>	<p align="center"><u>CHART REVIEW</u></p> <p>Review a sampling of open and closed medical records to determine that a complete assessment is done within 60 hours for all admissions.</p>	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>
<p>34.01.13 PPS Excluded Psychiatric Units: Psychiatric Evaluation Requirements – Medical History. <i>Each inpatient must receive a psychiatric evaluation that must:</i></p> <ul style="list-style-type: none"> • <i>Include a medical history.</i> <p>§412.27(c)(2)(ii)</p>	<p>Self-explanatory.</p>	<p align="center"><u>CHART REVIEW</u></p> <ol style="list-style-type: none"> 1. Review a sampling of open and closed medical records to determine that a medical history was completed on all admissions. 2. Does the evaluation include any medical conditions that may impact the patient’s recovery / remission? 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

PROSPECTIVE PAYMENT SYSTEM EXCLUDED (PPS EXCLUDED UNIT) & DISTINCT PART UNIT - PSYCHIATRIC UNIT

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>34.01.14 PPS Excluded Psychiatric Units: Psychiatric Evaluation Requirements – Mental status. <i>Each inpatient must receive a psychiatric evaluation that must:</i></p> <ul style="list-style-type: none"> Contain a record of mental status. <p>§412.27(c)(2)(iii)</p>	<p>Self-explanatory.</p>	<p align="center"><u>CHART REVIEW</u></p> <p>Review a sampling of open and closed medical records.</p> <ol style="list-style-type: none"> Determine that the psychiatric evaluation included a record of mental status. Does the mental status record describe the appearance, behavior, emotional response, verbalization, thought content, and cognition of the patient? 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>
<p>34.01.15 PPS Excluded Psychiatric Units: Psychiatric Evaluation Requirements – Onset of Illness. <i>Each inpatient must receive a psychiatric evaluation that must:</i></p> <ul style="list-style-type: none"> Note the onset of illness and the circumstances leading to admission; <p>§412.27(c)(2)(iv)</p>	<p>Self-explanatory.</p>	<p align="center"><u>CHART REVIEW</u></p> <p>Review a sampling of open and closed medical records.</p> <ol style="list-style-type: none"> Determine that the psychiatric evaluation includes documentation of the onset of the illness and the circumstances leading to admission. Are the identified problems related to the patient’s need for admission? 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

PROSPECTIVE PAYMENT SYSTEM EXCLUDED (PPS EXCLUDED UNIT) & DISTINCT PART UNIT - PSYCHIATRIC UNIT

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>34.01.16 PPS Excluded Psychiatric Units: Psychiatric Evaluation Requirements – Description of Attitudes and Behaviors. <i>Each inpatient must receive a psychiatric evaluation that must:</i></p> <ul style="list-style-type: none"> Describe attitudes and behavior; <p>§412.27(c)(2)(v)</p>	<p>Self-explanatory.</p>	<p align="center"><u>CHART REVIEW</u></p> <p>Review a sampling of open and closed medical records.</p> <ol style="list-style-type: none"> Determine that the psychiatric evaluation includes documentation describing attitudes and patient behavior. Does the problem statement describe the behavior(s) which require modification in order for the patient to function in a less restrictive environment? 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>
<p>34.01.17 PPS Excluded Psychiatric Units: Psychiatric Evaluation Requirements – Cognition. <i>Each inpatient must receive a psychiatric evaluation that must:</i></p> <ul style="list-style-type: none"> Estimate intellectual functioning, memory functioning, and orientation; <p>§412.27(c)(2)(vi)</p>	<p>Self-explanatory.</p>	<p align="center"><u>CHART REVIEW</u></p> <p>Review a sampling of open and closed medical records.</p> <ul style="list-style-type: none"> Determine that the psychiatric evaluation includes documentation of intellectual functioning, memory functioning, and orientation. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

PROSPECTIVE PAYMENT SYSTEM EXCLUDED (PPS EXCLUDED UNIT) & DISTINCT PART UNIT - PSYCHIATRIC UNIT

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>34.01.18 PPS Excluded Psychiatric Units: Psychiatric Evaluation Requirements – Assets. <i>Each inpatient must receive a psychiatric evaluation that must:</i></p> <ul style="list-style-type: none"> • <i>Include an inventory of the inpatient’s assets in descriptive, not interpretative fashion.</i> <p>§412.27(c)(2)(vii)</p>	<p>Self-explanatory.</p>	<p align="center"><u>CHART REVIEW</u></p> <p>Review a sampling of open and closed medical records.</p> <ol style="list-style-type: none"> 1. Determine that the psychiatric evaluation includes documentation of patient assets. 2. For the purposes of this regulation, words such as “youth”, “pretty”, “social security income” and “has a car” do not represent assets. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>
<p>34.01.19 PPS Excluded Psychiatric Units: Treatment Plan. <i>Each inpatient must have an individual comprehensive treatment plan that shall be based on an inventory of the inpatient’s strengths and disabilities.</i></p> <p><i>The written plan must include:</i></p> <ul style="list-style-type: none"> • <i>a substantiated diagnosis;</i> • <i>short-term, and</i> • <i>long term goals;</i> • <i>the specific treatment modalities utilized; and</i> • <i>responsibilities of each member of</i> 	<p>The patient and treatment team collaboratively develop the patient’s treatment plan.</p> <p>The treatment plan is the outline of what the facility has committed itself to do for the patient based on an assessment of the patient’s needs.</p> <p>The facility selects its format for treatment plans and treatment plan updates.</p>	<p align="center"><u>OBSERVATION</u></p> <p>Observe, as available, scheduled treatment program meetings (individual, group, family meetings, therapeutic activities, and therapeutic procedures) and treatment planning meetings.</p> <ul style="list-style-type: none"> • Are all disciplines required to meet the patient’s needs represented at planning meetings? <p align="center"><u>CHART REVIEW</u></p> <p>Review a select group of treatment plans. Determine:</p> <ol style="list-style-type: none"> 1. An individualized treatment plan has been developed for each patient, based on the assessments and evaluations. 2. The patient’s response toward meeting planned goals is reviewed periodically and 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

PROSPECTIVE PAYMENT SYSTEM EXCLUDED (PPS EXCLUDED UNIT) & DISTINCT PART UNIT - PSYCHIATRIC UNIT

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p><i>the treatment team; and</i></p> <ul style="list-style-type: none"> • <i>adequate documentation to justify the diagnosis and the treatment and</i> • <i>rehabilitation activities carried out.</i> <p>§412.27(c)(3)(i)</p>		<p>modified as necessary.</p> <ol style="list-style-type: none"> 3. The plans must reflect an integrated approach to care planning and delivery, including all disciplines caring for the patient. 4. The treatment plan is a result of collaboration between the patient and the treatment team. 5. The treatment plan is individualized. 6. There is a primary diagnosis upon which the treatment interventions are based. The treatment plan goals are written in a manner that allows for changes in the patient’s behavior to be measured. 7. The treatment plan goals are relevant to the patient’s condition. 8. The treatment team encourages the patient’s active participation and responsibility for engaging in the treatment regimen. 9. For patients who have been secluded or restrained, less restrictive interventions were considered prior to the use of seclusion or restraints. 10. There is rationale for use of seclusion and/or restraints. 	

PROSPECTIVE PAYMENT SYSTEM EXCLUDED (PPS EXCLUDED UNIT) & DISTINCT PART UNIT - PSYCHIATRIC UNIT

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
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34.01.20 PPS Excluded Psychiatric Units: Documentation of Active Treatment.

The treatment received by the inpatient must be documented in such a way as to assure that all active therapeutic efforts are included.

§412.27(c)(3)(ii)

There are sufficient resources to provide physical and psychosocial therapeutic activities to meet the needs of the patient populations.

Active treatment is an essential requirement for inpatient psychiatric care. Active treatment is a clinical process involving ongoing assessment, diagnosis, intervention, evaluation of care and treatment, and planning for discharge and aftercare, under the direction of a psychiatrist.

The patient is in the hospital because it has been determined that the patient requires intensive, 24-hour, specialized psychiatric intervention that cannot be provided outside the psychiatric unit or hospital.

11. If the use of seclusion and/or restraints is a frequent occurrence, does the treatment plan document alternative interventions to address and treat negative patient behavior?

CHART REVIEW & DOCUMENT REVIEW

Review open and closed medical records.

1. Determine that treatment modalities were provided with sufficient frequency and intensity to assure that the patient achieves an optimal level of functioning.
2. Does the patient require 24 hour specialized psychiatric care?
3. Is the patient receiving all aspects of treatment to which the unit has committed itself, based on the assessment, evaluation, and plan of care?

Review policies and procedures on therapeutic use of restrictions, such as visitors, mail, and phone calls to validate patient rights are being protected.

1. Do the policies and procedures adequately direct staff on alternatives or less restrictive interventions prior to the use of seclusion and restraints?
2. Has the staff documented that less restrictive

- 1 = Compliant
 2 = Not Compliant

This standard is not met as evidenced by:

PROSPECTIVE PAYMENT SYSTEM EXCLUDED (PPS EXCLUDED UNIT) & DISTINCT PART UNIT - PSYCHIATRIC UNIT

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
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34.01.21 PPS Excluded Psychiatric Units: Progress Notes Requirements.
Progress notes must be recorded by the doctor of medicine or osteopathic medicine responsible for the care of the inpatient, a nurse, social worker and, when appropriate others significantly involved in active treatment modalities.

*The frequency of progress notes is determined by the condition of the inpatient **but must** be recorded at least weekly for the first two months and at least once a month thereafter and **must** contain recommendations for revisions in the treatment plan as indicated as well as precise assessment of the inpatient's progress in accordance with the original or revised treatment plan.*

§412.27(c)(4)

Once developed, the individualized treatment plan guides the formulation of progress notations.

Notations formatted by individual disciplines address patient progress in achieving identified behaviors in response to the listed problems and goals.

Progress notes of an individual team member may be integrated as long as all participants present are identified by title and discipline. **It would be expected** to see **progress notes in** greater frequency when patients are more acutely ill and/or in crisis of some kind.

Progress notes must be dated and signed.

therapeutic interventions have been reviewed and/or attempted?

CHART REVIEW

Review open and closed patient records.

Review progress notations for patient progress.

1. Select two or more identified problems and goal statements to trace in the progress notes.
2. Entries must be dated and signed with the discipline identified.
3. **Are the progress note entries reflective of the acuity of the patient and completed within appropriate frequency consistent with patient acuity?**

Does the content of the treatment notes and progress notes **support**:

1. The treatment plan?
2. What the staff is doing to carry out the treatment plan?
3. The patient's response?

- 1 = Compliant
- 2 = Not Compliant

This standard is not met as evidenced by:

PROSPECTIVE PAYMENT SYSTEM EXCLUDED (PPS EXCLUDED UNIT) & DISTINCT PART UNIT - PSYCHIATRIC UNIT

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
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34.01.22 PPS Excluded Psychiatric Units: Discharge Planning & Discharge Summary.

The record of each patient who has been discharged must have a discharge summary that includes a recapitulation of the inpatient's hospitalization in the unit and recommendations from appropriate services concerning follow-up or after care as well as a brief summary of the patient's condition on discharge.

§412.27(c)(5)

- The Discharge Summary includes:**
- 1. The reason for admission,**
 - 2. Treatment achieved during hospitalization,**
 - 3. A baseline of the psychiatric and social functioning of the patient at the time of discharge, and**
 - 4. The patient and family response to the intervention.**

The patient's behavioral condition at discharge is described in relation to the achievement of long and short-term goals identified in the individualized master treatment plan. Concurrent physical problems are identified with treatment and outcomes.

All relevant elements of the aftercare plan are listed to include identification of the community resources identified.

Many states have a range of services offered through the department of health. Examples include, but are not limited to core mental health services such as counseling, individual and group therapy, medication, and medication monitoring, outpatient residential services, and specialized programs for children and adolescents.

CHART REVIEW

Review closed patient records.

Determine the following required elements are addressed in the Discharge Summary:

1. The patient's behavioral condition in relation to short and long term goals in the treatment plan.
2. Concurrent physical problems identified with treatment and outcomes.
3. Relevant facts about the aftercare plan and community resources.
4. Documentation of psych-education **provided to the patient and family regarding signs** and symptoms of illness, **strategies** to prevent re-hospitalization, and **how to** improve their disease management skills.
5. Does the discharge planning process include the participation of the multidisciplinary staff and the patient?
6. Are the details of the discharge plan communicated to the post-hospital treatment entity?

- 1 = Compliant
- 2 = Not Compliant

This standard is not met as evidenced by:

PROSPECTIVE PAYMENT SYSTEM EXCLUDED (PPS EXCLUDED UNIT) & DISTINCT PART UNIT - PSYCHIATRIC UNIT

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>34.01.23 PPS Excluded Psychiatric Units: Staffing Requirements. <i>The unit must:</i></p> <p><i>Meet special staff requirements in that the unit must have adequate numbers of qualified professional and supportive staff to evaluate inpatients, formulate written, individualized, comprehensive treatment plans, provide active treatment measures and engage in discharge planning.</i></p> <p><i>The unit must employ or undertake to provide adequate numbers of qualified professional, technical, and consultative personnel to—</i></p> <ul style="list-style-type: none"> <i>Evaluate inpatients</i> <p>§412.27(d)(1)(i)</p>	<p>The facility should be adequately staffed with qualified mental health professionals to carry out an intensive and comprehensive active treatment program to protect and promote the physical and mental health of its patients.</p>	<p><u>OBSERVATION, INTERVIEW & CHART REVIEW</u></p> <ol style="list-style-type: none"> Through observation, interview and record review determine if numbers and/or deployment of qualified staff is a concern. Review incident reports, medication error reports, and patient and staff injury reports for indications that staffing is an issue. Is there adequate staff to ensure that admission work-ups are completed in a timely manner? <p align="center"><u>DOCUMENT REVIEW</u></p> <ol style="list-style-type: none"> Review the planned and actual staffing patterns. Review the treatment calendar. Review admission and discharge logs to determine patterns. Correlate these findings with open and closed patient record review, looking at documentation for assessments and treatments as well as restraint and seclusion utilization to determine if staffing was having a negative impact on outcomes. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

PROSPECTIVE PAYMENT SYSTEM EXCLUDED (PPS EXCLUDED UNIT) & DISTINCT PART UNIT - PSYCHIATRIC UNIT

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>34.01.24 PPS Excluded Psychiatric Units: Staffing Requirements. The unit must <i>employ or undertake to provide adequate numbers of qualified professional, technical, and consultative personnel to—</i></p> <ul style="list-style-type: none"> Formulate written, individualized comprehensive treatment plans <p>§412.27(d)(1)(ii)</p>	<p>The facility has adequate number of appropriate staff to formulate written, individualized comprehensive treatment plans in a timely manner.</p>	<p><u>OBSERVATION, INTERVIEW, & CHART REVIEW</u></p> <ol style="list-style-type: none"> Through observation, interview and record review determine if numbers and/or deployment of qualified staff is a concern. Are all members of the treatment team able to contribute their data and perspectives toward formulation of the treatment plan? <p align="center"><u>DOCUMENT REVIEW</u></p> <ol style="list-style-type: none"> Review the planned and actual staffing patterns. Review the treatment calendar. Review admission and discharge logs to determine patterns. Correlate these findings with open and closed patient record review. Look at documentation for assessments and treatments as well as restraint and seclusion utilization to determine if staffing was having a negative impact on outcomes. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>
<p>34.01.25 PPS Excluded Psychiatric Units: Staffing Requirements. The unit must <i>employ or undertake to provide adequate numbers of qualified professional, technical, and consultative personnel to—</i></p> <ul style="list-style-type: none"> Provide active treatment measures <p>§412.27(d)(1)(iii)</p>	<p>The facility has adequate number of appropriate staff to provide active treatment measures in a timely manner.</p>	<p><u>OBSERVATION, INTERVIEW & CHART REVIEW</u></p> <ol style="list-style-type: none"> Through observation, interview and record review determine if numbers and/or deployment of qualified staff is a concern. Review incident reports, medication error reports, and patient and staff injury reports for indications that staffing is an issue. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

PROSPECTIVE PAYMENT SYSTEM EXCLUDED (PPS EXCLUDED UNIT) & DISTINCT PART UNIT - PSYCHIATRIC UNIT

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
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34.01.26 PPS Excluded Psychiatric Units: Staffing Requirements.
 The unit must *employ or undertake to provide adequate numbers of qualified professional, technical, and consultative personnel to—*

- *Engage in discharge planning.*

§412.27(d)(1)(iv)

The facility has adequate number of appropriate staff to engage in discharge planning in a timely manner.

3. Is the distribution of staff consistent with particular patient needs?

DOCUMENT REVIEW

1. Review the planned and actual staffing patterns. Review the treatment calendar. Review admission and discharge logs to determine patterns.
2. Correlate these findings with open and closed patient record review, looking at documentation for assessments and treatments as well as restraint and seclusion utilization to determine if staffing was having a negative impact on outcome.

OBSERVATION, INTERVIEW & CHART REVIEW

1. Through observation, interview and record review determine if numbers and/or deployment of qualified staff is a concern.
2. Does the record indicate that staff has participated in discharge planning?
3. Are staff aware of discharge plans for the patients they are working with?

- 1 = Compliant
- 2 = Not Compliant

This standard is not met as evidenced by:

DOCUMENT REVIEW

1. Review the planned and actual staffing patterns. Review the treatment calendar. Review admission and discharge logs to

PROSPECTIVE PAYMENT SYSTEM EXCLUDED (PPS EXCLUDED UNIT) & DISTINCT PART UNIT - PSYCHIATRIC UNIT

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
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34.01.27 PPS Excluded Psychiatric Units: Director of Inpatient Psychiatric Services: Medical Staff.

Inpatient psychiatric services must be under the supervision of a clinical director, service chief, or equivalent who is qualified to provide the leadership required for an intensive treatment program.

The number and qualifications of doctors of medicine and osteopathic medicine must be adequate to provide essential psychiatric services.

§412.27(d)(2)

Of the members of the organized Medical Staff one is named as Clinical Director.

There are sufficient Medical Staff members to provide services; the number depends upon the size of the facility or unit and the scope of services provided.

The Clinical (**Medical**) Director is ultimately responsible for the medical and psychiatric care that is provided to patients.

The education, training, and experience for the medical director are established.

determine patterns.

2. Correlate these findings with open and closed patient record review, looking at documentation for assessments and treatments as well as restraint and seclusion utilization to determine if staffing was having a negative impact on outcomes.

FILE REVIEW

1. Determine that there is a named Clinical (Medical) Director.
2. **Determine the Medical Director meets the qualifications established for the role.**

- 1 = Compliant
 2 = Not Compliant

This standard is not met as evidenced by:

INTERVIEW

1. Determine that there are enough qualified Medical Staff to provide the services offered. The services must be provided in a timely manner.
2. Determine if coverage is adequate to meet the needs of the patients.
3. There should be at least one qualified physician to provide back- up / relief services for the Clinical (Medical) Director.

PROSPECTIVE PAYMENT SYSTEM EXCLUDED (PPS EXCLUDED UNIT) & DISTINCT PART UNIT - PSYCHIATRIC UNIT

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>34.01.28 PPS Excluded Psychiatric Units: Medical Director Qualifications. <i>The Clinical Director, service chief, or equivalent must meet the training and experience requirements for examination by:</i></p> <ul style="list-style-type: none"> the American Board of Psychiatry and Neurology or the American Osteopathic Board of Neurology and Psychiatry. <p>§412.27(d)(2)(i)</p>	<p>The Clinical (Medical) Director has completed an approved residency program and has been certified, or is eligible for examination to become certified, by the AOA or the ABMS.</p>	<p align="center"><u>FILE REVIEW</u></p> <ol style="list-style-type: none"> Determine that the Clinical (Medical) Director meets the residency requirements of a psychiatry / neurology program, approved by the ABPN/AOBNP. Determine his/her Board status. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>
<p>34.01.29 PPS Excluded Psychiatric Units: Medical Director Responsibilities. <i>The director must monitor and evaluate the quality and appropriateness of services and treatment provided by the medical staff.</i></p> <p>§412.27(d)(2)(ii)</p>	<p>The Clinical Director is accountable for the oversight of the QAPI program of service provided by the Professional Staff.</p> <p>The Clinical (Medical) Director should ascertain that quality improvement programs are in place to monitor patient care.</p>	<p align="center"><u>DOCUMENT REVIEW & INTERVIEW</u></p> <ol style="list-style-type: none"> Determine that the Clinical Director is knowledgeable of and accountable for the Professional Staff QAPI program. Review the job description to determine that quality improvement program is a responsibility of the clinical (medical) director, as well as implementation of educational programs for all levels of staff. Are there appropriate professional staff available to provide necessary medical and treatment services? 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

PROSPECTIVE PAYMENT SYSTEM EXCLUDED (PPS EXCLUDED UNIT) & DISTINCT PART UNIT - PSYCHIATRIC UNIT

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
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4. Does the unit have policies and procedures to direct medical and direct care staff in situations when patients become agitated and aggressive, posing a potential threat to self or others?

34.01.30 PPS Excluded Psychiatric Units: Nursing Services.

The unit must have a qualified director of psychiatric nursing services.

In addition to the director of nursing, there must be adequate numbers of registered nurses, licensed practical nurses, and mental health workers to provide nursing care necessary under each inpatient's active treatment program and to maintain progress notes on each inpatient.

§412.27(d)(3)

The organization has a Director of Psychiatric Nursing Services.

Score this standard based on the results of standards 34.01.30 and 34.01.31.

- 1 = Compliant
 2 = Not Compliant

This standard is not met as evidenced by:

PROSPECTIVE PAYMENT SYSTEM EXCLUDED (PPS EXCLUDED UNIT) & DISTINCT PART UNIT - PSYCHIATRIC UNIT

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>34.01.31 PPS Excluded Psychiatric Units: Nursing Services Leadership <i>The director of psychiatric nursing services must be:</i></p> <ul style="list-style-type: none"> <i>a registered nurse who has a master's degree in psychiatric and mental health nursing, or its equivalent, from a school of nursing accredited by the National League for Nursing, or</i> <i>be qualified by education and experience in the care for the mentally ill.</i> <p><i>The director must demonstrate competence:</i></p> <ul style="list-style-type: none"> <i>to participate in interdisciplinary formulation of individual treatment plans;</i> <i>to give skilled nursing care and therapy; and</i> <i>to direct, monitor, and evaluate the nursing care furnished.</i> <p>§412.27(d)(3)(i)</p>	<p>The facility has established the education, training, and experience requirements for the Director of Psychiatric Nursing position.</p> <p>The duties, functions, and responsibilities of the Director of Psychiatric Nursing are clearly delineated and include the following:</p> <ol style="list-style-type: none"> Supervision and evaluation of nursing and paraprofessional staff. Participation in the formulation of patient treatment plans. Medication teaching. Management of therapeutic milieus. Provision of mandatory and voluntary in-service training of specialized treatments and therapies, such as individual group and family therapies that require the expertise of the professional psychiatric nurse. 	<p align="center"><u>INTERVIEW & FILE REVIEW</u></p> <p>Determine that there is a qualified individual named as the Psychiatric Nursing Director.</p> <p>Review the Psychiatric Nursing Director's personnel file. Determine the Director meets the established qualifications.</p> <p>Education / experience in the care of the mentally ill may be evidenced by either:</p> <ol style="list-style-type: none"> A master's degree in psychiatric / mental health nursing. A RN with a related master's, such as psychology or nursing education, with 2 years of psychiatric inpatient nursing care. A BSN, ADN, or diploma in nursing with at least 2 years of psychiatric inpatient nursing care and documented educational programs focused on psychiatric nursing, occurring at sufficient intervals to keep the Director of Psychiatric Nursing current. Documented clinical consultation / supervision from a master's prepared psychiatric nurse. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

PROSPECTIVE PAYMENT SYSTEM EXCLUDED (PPS EXCLUDED UNIT) & DISTINCT PART UNIT - PSYCHIATRIC UNIT

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>34.01.32 PPS Excluded Psychiatric Units: Staffing. <i>The staffing pattern shall ensure the availability of a registered nurse 24 hours each day.</i></p> <p><i>There must be adequate numbers of registered nurses, licensed practical nurses, and mental health workers to provide the nursing care necessary under each inpatient's active treatment program.</i></p> <p>§412.27(d)(3)(ii)</p>	<p>There is at least one RN for each distinct (program) unit in the facility for each shift of operation. "On call" RNs do not constitute coverage.</p> <p>Additional professional and supportive nursing staff is provided to adequately implement the philosophy of care and to meet identified needs of the patient populations.</p>	<p align="center"><u>DOCUMENT REVIEW & INTERVIEW</u></p> <ol style="list-style-type: none"> 1. Verify the availability of at least one RN per shift for each facility unit. Request calculations regarding planned and actual staffing in raw numbers and full time equivalencies. 2. Determine if nurse staffing is diluted by their performance of non-nursing activities such as housekeeping and escort services. 3. Determine if the program uses nurses in group facilitation, 1:1 interventions, etc. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>
<p>34.01.33 PPS Excluded Psychiatric Units: Psychological Services. <i>The unit must provide or have available psychological services to meet the needs of the inpatients.</i></p> <p><i>The services must be furnished in accordance with acceptable standards of practice, service objectives, and established policies and procedures.</i></p> <p>§412.27(d)(4)</p>	<p>There may be a psychologist at the facility or the psychologist services may be provided through a contracted agreement.</p>	<p align="center"><u>DOCUMENT REVIEW & INTERVIEW</u></p> <ol style="list-style-type: none"> 1. Determine the number of full-time, part-time, and consulting psychologists. If contractual services are utilized, determine their availability to provide needed services to patients. 2. Determine the extent that psychological testing is requested, the response time and the availability of the results. 3. Are the patients in need of psychological therapy or testing receiving those services in a timely manner, and with sufficient intensity? 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

PROSPECTIVE PAYMENT SYSTEM EXCLUDED (PPS EXCLUDED UNIT) & DISTINCT PART UNIT - PSYCHIATRIC UNIT

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>34.01.34 PPS Excluded Psychiatric Units: Social Services. <i>There must be a director of social services who monitors and evaluates the quality and appropriateness of social services furnished.</i></p> <p><i>The services must be furnished in accordance with accepted standards of practice and established policies and procedures.</i></p> <p><i>Social service staff responsibilities must include, but are not limited to,</i></p> <ul style="list-style-type: none"> • <i>participating in discharge planning,</i> • <i>arranging for follow-up care, and</i> • <i>developing mechanisms for exchange of appropriate information with sources outside the hospital.</i> <p>§412.27(d)(5)</p>	<p>The duties, functions, and responsibilities of the director of social services should be clearly delineated and documented in the facility's policies and procedures.</p> <p>Social work contact with the patient, family, and significant others should occur during, or as soon as possible, after the admission.</p> <p>High-risk case finding should result in significant data being available for early integration into the treatment plan and subsequent social work action as indicated.</p> <p>The treatment team for possible inclusion into the patient's treatment plan should consider the anticipated social work role and expected interventions as recommended in the psychosocial assessment.</p> <p>The role of the social worker must reflect psycho-education of patients and families on signs and symptoms of illness to prevent re-hospitalization and improve their disease management skills.</p>	<p><u>FILE REVIEW, INTERVIEW, AND CHART REVIEW</u></p> <ol style="list-style-type: none"> 1. Determine that there is a qualified individual named as the Director of Social Services. 2. Review the job description and qualifications of the director of social work to determine the requirement was met. 3. Interview the social worker to determine how services are provided to patients. 4. Does the director of social services periodically audit the quality of social work services? 5. Review a select group of medical records to determine the requirement was met. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

PROSPECTIVE PAYMENT SYSTEM EXCLUDED (PPS EXCLUDED UNIT) & DISTINCT PART UNIT - PSYCHIATRIC UNIT

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>34.01.35 PPS Excluded Psychiatric Units: Therapeutic Activities. <i>The unit must provide a therapeutic activities program.</i></p> <p>§412.27(d)(6)</p>	<p>Self-explanatory.</p>	<p align="center"><u>INTERVIEW & OBSERVATION</u></p> <ul style="list-style-type: none"> Verify there is a therapeutic activities program which provides a variety of activities throughout the week. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>
<p>34.01.36 PPS Excluded Psychiatric Units: Program Scope <i>The program must be appropriate to the needs and interests of inpatients and be directed toward restoring and maintaining optimal levels of physical and psychosocial functioning.</i></p> <p>§412.27(d)(6)(i)</p>	<p>The program has sufficient resources to provide physical and psychosocial therapeutic activities, to meet the needs of the patient populations.</p> <p>Therapeutic activities are provided within the program schedule on the day and evening shifts each day of the week, including weekends. Activities do not present undue hazard to the therapeutic milieu.</p>	<p align="center"><u>INTERVIEW & OBSERVATION</u></p> <ol style="list-style-type: none"> Determine the adequacy of activities in providing safe and meaningful outlets that correlate to the identified needs of the patient population. Has the unit ensured consistent availability and provision of individualized therapeutic activities and rehabilitative services based on patient’s needs? 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>
<p>34.01.37 PPS Excluded Psychiatric Units: Program Staffing. <i>The number of qualified therapists, support personnel, and consultants must be adequate to provide comprehensive therapeutic activities consistent with each inpatient’s active treatment program.</i></p> <p>§412.27(d)(6)(ii)</p>	<p>There are adequate numbers of qualified therapists and support personnel to support the physical and psychosocial therapeutic activities to meet the needs of the patient populations.</p> <p>Therapeutic activities are provided within the program schedule on the day and evening shifts each day of the week, including weekends. Activities do not present undue hazard to the therapeutic milieu.</p> <p>Activities may be planned / directed by:</p>	<p align="center"><u>INTERVIEW & OBSERVATION</u></p> <ol style="list-style-type: none"> Determine the number of full time, part time and consulting therapeutic activity staff. Determine their roles and responsibilities in accomplishing the philosophy of the program. Determine the adequacy of activities in providing safe and meaningful outlets that correlate to the identified needs of the patient population. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

PROSPECTIVE PAYMENT SYSTEM EXCLUDED (PPS EXCLUDED UNIT) & DISTINCT PART UNIT - PSYCHIATRIC UNIT

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- 1) An occupational therapist,
- 2) **Bachelor of Science (BS) prepared** recreational therapist, or
- 3) **A Bachelor of Science (BS) or Bachelor of Arts (BA) prepared** music or other related therapist

4. Are there clearly defined monitoring and evaluation mechanisms to conduct consistent and timely review of the quality and appropriateness of therapeutic and rehabilitative services?

34.02.01 Scope & Description of Available Services.

There is a written program description which includes, but is not limited to:

1. The scope of services provided specific to inpatient, partial day, residential and outpatient and aftercare programs.
2. How these programs relate to each other.
3. Admission criteria, including limitations
4. Assessment / evaluation process
5. Treatment planning processes
6. Therapeutic modalities utilized
7. Provisions for children,

The plan for the provision of psychiatric care and services is a component of the facility-wide written plan.

DOCUMENT REVIEW

Review the plan for the provision of services.

Verify the plan addresses:

1. **The required elements.**
2. The ages of patients and the conditions accepted for service.

- 1 = Compliant
 2 = Not Compliant

This standard is not met as evidenced by:

PROSPECTIVE PAYMENT SYSTEM EXCLUDED (PPS EXCLUDED UNIT) & DISTINCT PART UNIT - PSYCHIATRIC UNIT

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adolescents, young adults, adults
geriatric and mentally /
developmentally disabled patients

- 8. Staffing, including the roles, responsibilities and supervisory relationships of professional staff as part of the treatment team
- 9. The quality assessment and improvement program.

34.02.02 Physical Facilities.

The physical facilities for psychiatric patients provide, to the extent possible, an attractive environment.

The environment provides for patient privacy for sleeping, bathing, toileting and other activities of a personal nature without compromising the safety of the therapeutic milieu.

To the extent possible, the dignity of each patient is preserved and enhanced in the physical space provided for psychiatric and/or substance abuse patient care areas.

Shatterproof materials are used for windows, fixture covers, mirrors, etc. Showerheads and other fixtures are designed to reduce the potential of patient injury.

OBSERVATION

Observe the physical setting for the elements listed.

- 1. Does it promote reasonable privacy and the dignity of the patient population?
- 2. Is a sense of safety and security present?

- 1 = Compliant
- 2 = Not Compliant

This standard is not met as evidenced by:

PROSPECTIVE PAYMENT SYSTEM EXCLUDED (PPS EXCLUDED UNIT) & DISTINCT PART UNIT - PSYCHIATRIC UNIT

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>34.02.03 Patient Bedrooms: Safety & Security.</p> <ul style="list-style-type: none"> • Patient bedrooms have closable doors, door locks and other structural restraints are kept to a minimum. • Doors are constructed to prevent barricading and allow staff to enter patient rooms, baths, toilet, and shower rooms. • Mirrors are as distortion free as possible. 	<p>Privacy for sleeping and personal activities is afforded to the extent possible while maintaining access by staff to protect patients who may accidentally or intentionally be involved in harmful behaviors.</p>	<p align="center"><u>OBSERVATION</u></p> <p>Observe doors in the unit. Determine the staff has access patients.</p> <p>Determine if the environment has been assessed for potentially hazardous items that could be used for homicidal or suicidal purposes:</p> <ol style="list-style-type: none"> 1. Doors for rooms where patients at high risk for self-harm are housed may be specially fitted (piano hinge or other devices) to reduce risk of suicidal hanging gestures. 2. Are barricading possibilities considered and mechanisms to reduce or deal with such behavior in place? 3. Are mirrors and light fixtures shatter-resistant? 4. Are light fixtures secured from tampering? 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>
<p>34.02.04 Patient Hygiene Needs.</p> <ul style="list-style-type: none"> • Patients are provided with clean bath and bed linens on a regularly scheduled basis, and as required to meet basic hygienic needs. • Linen inventories are stored in secured closets; reasonable access by patients is provided. 	<p>Self-explanatory.</p>	<p align="center"><u>OBSERVATION</u></p> <p>Observe linen inventories and schedules for issuing same to patients.</p> <ol style="list-style-type: none"> 1. Does staff assist patients who need help in changing bed linen? 2. Are “housekeeping” activities promoted as participating in normal activities of daily living behavior? 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

PROSPECTIVE PAYMENT SYSTEM EXCLUDED (PPS EXCLUDED UNIT) & DISTINCT PART UNIT - PSYCHIATRIC UNIT

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<ul style="list-style-type: none"> Patients may be encouraged to take responsibility for maintaining their own living quarters including daily housekeeping activities appropriate with their abilities. Patients shall be oriented to the unit's expectations concerning housekeeping. Access to hazardous cleaning chemicals is minimal and constantly supervised. 		<ol style="list-style-type: none"> Are patients oriented to these expectations? Are such duties assigned as discipline or in a punitive fashion? Observe that reasonable care is taken by staff to limit (or directly supervise) patient access to hazardous chemicals. 	
<p>34.02.05 Handicapped Accessibility. The facility shall be barrier-free to permit handicapped individuals to gain access for visiting and therapy.</p> <p>All toilets are equipped with seats, handicapped grab bars, and patient operated call devices without compromising privacy or safety.</p>	<p>The facility shall be barrier-free consistent with the current provisions of the Americans with Disabilities Act (ADA).</p>	<p align="center"><u>OBSERVATION</u> During tour of the unit, determine the area is barrier-free.</p>	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>
<p>34.02.06 Confidentiality of Information. There shall be policies and practices to protect clinical data and information, which may be described as "unusually sensitive" for psychiatric patients.</p>	<p>The facility has written policies regarding the release of information. Policies address specific components that may require additional patient consent.</p> <p>In filing closed records the facility may adhere to unit record principles with parallel files; one for psychiatric / substance abuse and another for general medical-</p>	<p align="center"><u>OBSERVATION</u></p> <ol style="list-style-type: none"> Review policies to determine the required security and confidentiality of patient information are addressed. Observe clinical areas for breeches in security and confidentiality of patient information. 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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surgical records with a file notation that **indicates** “other file(s) exist and may be accessed by persons with appropriate need, within the health information service area.”

Upon subsequent readmission to the facility for non-behavioral treatment, the behavioral records is not routinely forwarded, but is made available on a “need to know” basis.

If a patient is admitted **to the inpatient psychiatric unit** from a medical-surgical unit in the hospital, the patient **must first** be discharged from the acute unit and readmitted **to the psychiatric unit**.

APPENDIX A: OSTEOPATHIC TERMINOLOGY FOR BILLING SERVICES TO PATIENT

A. The terminology most commonly required for requesting payment of third-party carriers for osteopathic procedures is outlined below. *

There are three coding classification systems currently required by third party payors for reimbursement. These are:

- ICD-9 CM: The International Classification of Diseases: 9th Revision; Clinical Modification.
- HCPCS: Healthcare Common Procedural Coding System.
- CPT: Current Procedural Terminology, 2006, Professional Edition

With these coding systems, there is terminology of particular relevance to osteopathic medicine.

The osteopathic terminology in ICD-9 CM was worked out with a committee of the American Academy of Osteopathy and the American Osteopathic Association. The committee agreed on the following general points:

1. A relatively uniform method for recording distinctive diagnostic and therapeutic procedures used by osteopathic physicians requires the use of standard anatomic, physiologic, kinesiologic, and pathologic terms.
2. The term “somatic dysfunction” is used to designate an impaired or altered function of related components of the somatic (body framework) system; skeletal, arthrodial and myofascial structures, and related vascular, lymphatic, and neural elements. The term may then be amplified to indicate specific areas of the body that are involved. The term is further amplified to denote the specific dysfunction by using such terms as myositis, neuralgia, or limited arthrodial motion. The term can be further amplified to indicate associated visceral pathology, such as colitis or pneumonitis. Thus an osteopathic physician could indicate on a specific patient for instance, the diagnosis of lumbar and sacral somatic dysfunction with lumbar myositis and right sciatic neuralgia and colitis.
3. The term “osteopathic manipulative treatment” is defined as a form of manual treatment applied by a physician to eliminate or alleviate somatic dysfunction and related disorders. The term may be amplified to include the area treated and specific type of treatment under this classification of treatment. Thus, one could indicate osteopathic manipulative treatment, soft tissue, to entire cervical area.
4. The above may also be explained by the following example: Somatic dysfunction is a malfunction of a segment or segments of the spinal column, pelvis, or extremities which may produce limited motion in an area, muscle spasm, pain, tenderness and even remote symptoms. The osteopathic manipulative treatment could be described in lay terms as a manipulative treatment provided by physician administered to alleviate or eliminate the result of somatic dysfunction and related disorders.

*Reference: The International Classification of Diseases, U.S. National Center for Health and Statistics.

APPENDIX A: OSTEOPATHIC TERMINOLOGY FOR BILLING SERVICES TO PATIENT

B. ICD-9-CM

Volume 1: Tabular list:

- 739 Nonallopathic lesions, not elsewhere classified. Includes: segmental dysfunction and somatic dysfunction.
- 739.0 Head region; occipitocervical **region**.
- 739.1 Cervical region; cervicothoracic **region**.
- 739.2 Thoracic region; thoracolumbar **region**.
- 739.3 Lumbar region; lumbosacral **region**.
- 739.4 Sacral region; sacrococcygeal sacroiliac **region**.
- 739.5 Pelvic region; hip, pubic **region**.
- 739.6 Lower extremities.
- 739.7 Upper extremities; acromioclavicular, sternoclavicular **region**.
- 739.8 Rib cage; costochondral, costovertebral, sternochondral **region**.
- 739.9 Abdomen and other.

Volume 2: Index to diseases: Dysfunction somatic (various regions listed with appropriate numbers).

Volume 3: Tabular List:

- 93.6 Osteopathic manipulative treatment.
- 93.61 Osteopathic manipulative treatment for general mobilization. General articular treatment.

APPENDIX A: OSTEOPATHIC TERMINOLOGY FOR BILLING SERVICES TO PATIENT

- 93.62 Osteopathic manipulative treatment using high-velocity, low-amplitude forces. Thrusting forces.
- 93.63 Osteopathic manipulative treatment using low-velocity, high-amplitude forces. Springing forces.
- 93.64 Osteopathic manipulative treatment using isotonic, isometric forces.
- 93.65 Osteopathic manipulative treatment using indirect forces.
- 93.66 Osteopathic manipulative treatment to move tissue fluids. Lymphatic pump.
- 93.67 Other specified osteopathic manipulative treatment.

C. HCPCS

This alphanumeric classification system is used to report the use of drugs, supplies and durable medical equipment as well as some procedures. Example: L0180 Cervical, multiple post collar, occipital / mandibular supports, adjustable.

D. CPT

Physicians to report services and procedures use this 5-digit classification system. In 1994, the CPT Editorial Panel voted to accept the proposal of the AOA to move the osteopathic manipulative treatment codes from the HCPCS alphanumeric system into CPT. The CPT publication includes definitions of OMT as well as definitions of specific body regions. The OMT codes (98925-98929) are structured by the number of body regions treated, not the body site or the technique(s) employed. These codes should be used for both inpatient and outpatient treatment. Example: 98925 Osteopathic manipulative treatment (OMT); one to two body regions involved.

In addition, there are two-digit modifiers, which may be attached to the 5-digit procedure code to indicate that a service or procedure that has been performed has been altered in some way from the code descriptor. NOTE: For Medicare, the -25 modifier shall be attached to the E/M code reported in conjunction with OMT.

Procedures:

- 98925 OMT one to two body regions involved.
- 98926 OMT three or four body regions involved.

APPENDIX A: OSTEOPATHIC TERMINOLOGY FOR BILLING SERVICES TO PATIENT

98927	Five to six body regions involved.
98928	Seven to eight body regions involved.
98929	Nine to ten body regions involved.

NOTE: There is also a listing for manipulation under anesthesia as needed.

E. Evaluation and Management

In 1992, the entire coding system for evaluation and management (E/M) was changed. The new E/M codes range from 99201 to 99499 and are organized according to site of service, new vs. established patient and the level of care provided. The appropriate code to report is based on key components: history; examination; medical decision making; counseling; coordination of care; nature of presenting problem; and time. The first three components (history, examination and medical decision making) are considered the key components in selecting a level of E/M service.

Evaluation and Management services may be reported separately if the patient's condition requires a significant separately identifiable E/M service, above and beyond the usual pre-service and post-service work associated with the procedure

F. Definitions (Condensed):

1. New Patient:

A new patient is one who has not received any professional services from the physician or another physician of the same specialty who belongs to the same group practice, within the last three years.

2. Established Patient:

An established patient is one who has received professional services from the physician or another physician of the same specialty who belongs to the same group practice, within the past three years.

G. Appropriate Use of OMT Codes

After the physician evaluates the patient and arrives at a diagnosis, it is allowable to use an evaluation and management (E/M) code in addition to the appropriate OMT code (98925-98929) provided the physician has documented in the patient's record the E/M service provided using the SOAP format. SOAP is an acronym for: Subjective complaints and histories from the patient; Objective findings of the physician's examination and any diagnostic tests

APPENDIX A: OSTEOPATHIC TERMINOLOGY FOR BILLING SERVICES TO PATIENT

performed; Assessment or differential diagnosis based on the first two items; and Plan, which is the recommended course of treatment developed by the physician.

Coding Publications:

All coding systems are updated on an annual basis and should be purchased on an annual basis to ensure that you are reporting with the most current, accurate codes and utilizing the most current guidelines.

APPENDIX B: OSTEOPATHIC MUSCULOSKELETAL EXAMINATION

OSTEOPATHIC MUSCULOSKELETAL EXAMINATION OF THE HOSPITALIZED PATIENT

The osteopathic structural examination provides distinctive and valuable diagnostic clues important in differential diagnosis. Additionally, these findings provide a basis for treatment strategies to improve structure-function relationships and to enhance homeostatic mechanisms vital to the healing process. Documentation of somatic dysfunction, biomechanical risk factors and viscerosomatic / somatovisceral reflexes is mandatory for the osteopathic physician to fully understand and properly record the total health status and function of the hospitalized patient.

Documentation of the osteopathic musculoskeletal examination of a hospitalized patient may be accomplished by either:

1. A standardized form (example recommended) which includes the following elements:
 - a. Postural evaluation evaluating AP & lateral curves noting position(s) of examination.
 - b. Regional evaluations for somatic dysfunction of head and neck, spine, pelvis, and extremities along with specification of those TART elements upon which the evaluation was based.
 - c. Specification of dysfunction severity in each region using standardized 0-3 descriptors.
 - d. Evaluator's best assessment of major somatic and visceral correlations.
 - e. If the spine is not examined, this should be noted along with the reason.

2. A narrative report which includes the following elements:
 - a. Description of examination performed in 2 or more positions unless precluded by the patient's condition.
 - b. Is based on inspection, palpation, segmental motion testing, and overall motion testing of major areas of the spine and pelvis. Major findings of the extremities should be included.
 - c. Should mention AP and lateral spinal curves; gross changes of areas of tenderness; muscle tension or spasm; and limitation of motion.
 - d. If the spine is not examined, this should be noted along with the reason.

Either documentation format may include optional diagrammatic worksheets for recording findings, which are meaningful to the evaluating physician.

The following standardized format is an example recommended as satisfying the elements listed in #1 above. It has been approved as a recommended form by the AACOM Educational Council on Osteopathic Principles (ECOP), the American Academy of Osteopathy's Hospital Assistance and Louisa Burns Osteopathic Clinical Research Committees, the AOA Bureau of Research, the AOA Bureau of Health Care Facilities Accreditation, and the AOA Board of Trustees. This form permits computerized scanning for research purposes and adopts an ECOP standardized scale for somatic dysfunction severity. The assessment of somatic dysfunction (including severity) has been field tested (AOA grant #96-26-436) on an outpatient basis and is documented to provide more consistent physician recording of osteopathic findings than the "gold standard" SOAP note.

APPENDIX B: OSTEOPATHIC MUSCULOSKELETAL EXAMINATION

Adoption of the recommended standardized form (#1 above) will support the vertical integration of OPP/OMT in the hospital environment. ECOP agreed, beginning in 1997-98 that all osteopathic students in colleges of osteopathic medicine would be instructed in specific completion of this form. As of 1999, all osteopathic students newly entering AOA-accredited hospitals are trained and capable of completing the recommended form. Also as of 1999, full implementation of Osteopathic Postdoctoral Training Institutions (OPTI) provides a mechanism for integrating this specific patient evaluation record for all osteopathic house staff (externs, interns and residents) in AOA-accredited programs. AS of year 2000, all three parts of the National Board of Osteopathic Medical Examiners accept this format as an efficient and acceptable means of conveying specifics of the osteopathic structural examination in case histories for testing purposes. Ongoing Continuing Medical Education (CME) at local, state and national meetings supported further by AOA publications continue the training of osteopathic physicians-in-practice in order to advance the vertical integration process.

The recommended form also contains a recommended optional worksheet diagram section adaptable to a number of meaningful osteopathic models (including documentation of segmental tissue texture changes, Chapman's viscerosomatic reflexes, Zink's fascial patterns, key craniosacral sites of dysfunction, Counterstrain tender points and collateral ganglion involvement) if desired. The worksheet permits the evaluator to record those TART elements used in assessing somatic dysfunction and any major correlates. The suggested worksheet portion may be substituted as desired.

COMPLETION OF RECOMMENDED STANDARDIZED OSTEOPATHIC MUSCULOSKELETAL EXAMINATION FORM

Overview

Use of a standardized form with profession-wide characteristics offers a number of benefits. These include elements of educational continuity, research opportunities, and clinical advancement for the benefit of patient care.

The emphasis placed by the osteopathic profession on the continuum of osteopathic education was supported by AOA Board of Trustees action (Feb 97), which mandated that a standardized form should be derived from the state-of-the-art consensus text, Foundations for Osteopathic Medicine. The recommended form in these Accreditation Documents was laid out by 2 of the 4 sub-editors responsible for that section of the text. It supports the majority of the current models taught in osteopathic colleges of osteopathic medicine and has been approved by the Educational Council on Osteopathic Principles (ECOP) to be taught to all osteopathic students prior to their entry into clinical training rotations. Institution of Osteopathic Postdoctoral Training Institutions (OPTIs) and the profession's proactive Continuing Medical Education (CME) system provides educational opportunities to extend osteopathic documentation into internship and residency training as well as into the general clinical arena.

Clinical osteopathic research (especially large, multicenter studies) requires consistent nomenclature and measurements, standardized among participating physicians. The primary feature of the form recommended in these Accreditation Guidelines is the assessment of somatic dysfunction, which is, structured around regional somatic dysfunction CPT codes 739.0 (head) through 739.9 (abdominal/other). This form also supports the 1997-98 changes made in documentation rules for Evaluation & Management (E&M) comprehensive levels for both the General Multi-System and Musculoskeletal Single System Examinations. Structuring the form in this manner will facilitate appropriate hospital diagnostic coding of the physician's findings and is consistent with all

APPENDIX B: OSTEOPATHIC MUSCULOSKELETAL EXAMINATION

coding used in national computerized databases – inpatient and outpatient alike. Furthermore, the adopted severity standardization is based on the universally accepted TART diagnostic elements, which will permit longitudinal monitoring of the severity of somatic dysfunction throughout and after the patient’s hospital stay. Severity standardization based on TART is simply classified as follows:

- (0) No somatic dysfunction; all TART elements are minimal, background findings
- (1) Minor TART elements, more than background levels
- (2) TART elements obvious (especially Restricted Motion and Tissue Texture Abnormalities); symptoms may or may not be evident
- (3) Symptomatic, very easily identified Restricted Motion and Tissue Texture Abnormalities elements; a “key lesion”

The recommended form matches an outpatient form developed and tested for use in outpatient outcomes studies (AOA outcomes grant #96-26-436).

Clinical benefits of a standardized form include instant recognition of the location and relative severity of somatic dysfunction in the hospitalized patient. Viscerosomatic clues provide assistance in differential diagnosis; recognition to structural restriction to homeostatic functions such as respiration, lymphaticovenous return and autonomic tone provide treatment insights.

REQUIRED SECTIONS

Headings & Identification

The upper right hand corner is reserved for the patient’s name, hospital number, and other patient identification items. It may be written or imprinted using the hospital stamp. The upper left hand corner of the form should include the chief complaint as well as the printed name of the examining physician, resident, or house staff member. Signature(s) and date(s) should be recorded at the bottom of the form.

Spinal Curvatures & Examination Position

Record the position(s) in which the patient was examined. Note type of kyphotic and lordotic curves. Note presence of any scoliosis; if present, classify by severity and denote if the scoliosis is functional. If there is asymmetry of iliac crests and/or greater trochanters, mark the low side. Additional notations including a mapping of the scoliosis and its crossover sites may be placed as is meaningful on this diagram.

Evaluation, Severity & Somatic Dysfunction Correlations

Specifically summarize pertinent regional palpatory (TART) findings from the osteopathic musculoskeletal examination of the hospitalized patient by indicating the highest “Severity” associated with each region by filling in the appropriate rectangle based on Criteria in the “Severity Key”. An optional blank is provided to write any specific level or major diagnostic characteristics pertinent for the region. Record which TART elements were used (“Assessment Tools”) in the evaluation process and formulate an impression of clinical correlations for the somatic findings based upon the total history and physical examination of the patient. Denote these impressions of “Major Correlations” by filling in as many rectangles as are consistent with your best judgment.

APPENDIX B: OSTEOPATHIC MUSCULOSKELETAL EXAMINATION

OPTIONAL WORKSHEET DIAGRAMS

There are no specific requirements for completing this section. In fact, this entire section may be replaced if there are more meaningful diagrams for individual physicians or for the institution. Alternatively, this area may be redesigned to gather specific research data. In the absence of specific requirements for any of the above reasons, we suggest the diagrams recommended in this Accreditation Document be retained. The diagrams recommended for this section has been designed to support a number of models described in the *Foundations for Osteopathic Medicine* and are taught in the colleges of osteopathic medicine. These diagrams can be used to record those TART elements, which are most meaningful to the individual clinician in diagnosing significant somatic dysfunction. Computer scanning can capture those areas specified by the rectangles or circles for research or other purposes. Additionally, specific meaningful notations can be made anywhere else on the worksheet area.

It should be recognized that this section supports documentation of a number of viscerosomatic clues including paraspinal changes associated with facilitated segments, Chapman’s reflexes, collateral ganglia tension, and abdominal rigidity. It also supports documentation and localization of a number of tender points, segmental spinal and rib somatic dysfunctions, and selected craniosacral somatic dysfunctions. Areas within the diagrams can be used to denote regional motion preference or restriction at transition zones including fascial patterning. Knowledge of different models is not necessary to use the form to identify TART elements, nor are specific levels of dysfunction required unless the clinician feels such specificity is important in the diagnostic and subsequent treatment of the patient.

Osteopathic Musculoskeletal Examination

Examiner: _____

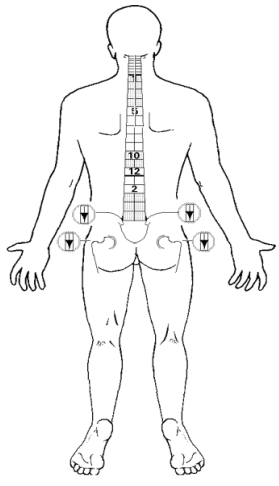
Chief Complaint: _____

Required			
Ant./Post. Spinal Curves	I	N	D
Cervical lordosis	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Thoracic Kyphosis	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Lumbar Lordosis	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

I = increased; N = normal; D = decreased

Scoliosis (Lateral Spinal Curves)			
<input type="checkbox"/>	None	Sitting	<input type="checkbox"/>
<input type="checkbox"/>	Functional	standing	<input type="checkbox"/>
<input type="checkbox"/>	Mild	Prone/ supine	<input type="checkbox"/>
<input type="checkbox"/>	Moderate	Lat. Recumbant.	<input type="checkbox"/>
<input type="checkbox"/>	Severe	Unable to examine	<input type="checkbox"/>

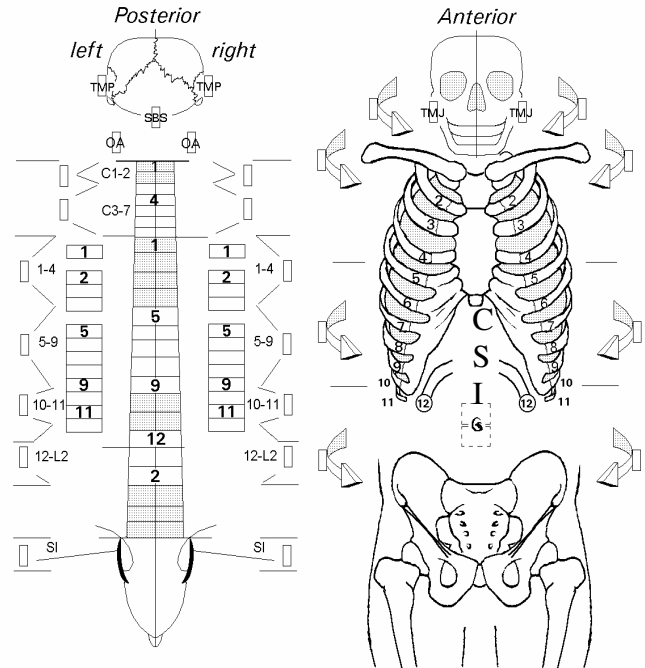
For Coding Purposes Only



- Assessment Tools:**
- T = tenderness
 - A = Asymmetry
 - R = restricted motion
 - No SD
 - No SD
 - T = Tissue texture change

- Severity Key:**
- 0 = No SD
 - 1 = Minor TART \\
more than BG levels
 - 2 = TART obvious (R & T esp.)
+/- symptoms
 - 3 = Symptomatic, R and T
very easily found,
"key lesion"

Optional Worksheet



- Key to Abbreviations**
- OA = Occipitoatlantal joint
 - TMJ = Temporomandibular joint
 - Sympathetic Ganglia :
 - C = Celiac ganglion
 - S = Superior mesenteric ganglion
 - I = Inferior mesenteric ganglion
 - TMP = Temporal Bone
 - SBS = Sphenobasilar joint

Region Evaluated	Severity				Specific of Major Somatic Dysfunctions	Major Correlations with:	
	0	1	2	3			
Head	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/> Traumatic	<input type="checkbox"/> Rheumatological
Neck	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/> Orthopedic	<input type="checkbox"/> EENT
Thoracic T1-4	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/> Neurological	<input type="checkbox"/> Cardiovascular
T5-9	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/> Viscerosomatic	<input type="checkbox"/> Pulmonary
T10-12	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/> Primarily MS	<input type="checkbox"/> Gastrointestinal
Lumbar	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/> Activities of DL	<input type="checkbox"/> Genitourinary
Pelvis / Sacrum	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/> Other _____	<input type="checkbox"/> Congenital
Pelvis/ Innominate	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			
Extremity (lower)	R	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		Other:	
	L	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		_____	
Extremity (upper)	R	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		_____	
	L	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		_____	
Ribs	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		_____	
Other / Abdomen	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		_____	

Signature of the examiner: _____
 Signature of the examiners: _____

Date of Examination: _____
 Date of Examination: _____

GLOSSARY

This glossary of terms and abbreviations has been compiled to furnish users of the document, Healthcare Facilities Accreditation Program's (HFAP) Accreditation Requirements for Acute Care Healthcare Facilities, with a common terminology. The availability of the glossary, it is hoped, will lead to a clearer understanding of the intent of these requirements and guidelines.

It is recognized that the meaning of terms varies regionally in the United States and that the accepted terminology may differ. The requirements are those of a national program, which is applied nationwide without regard to geographical variations in practices or laws.

AABB	American Association of Blood Banks
AAO	American Academy of Osteopathy
ABMS	American Board of Medical Specialties
ABPN	American Board of Psychiatry and Neurology
ACLS	Advanced Cardiac Life Support
ADA	American Dietetic Association
Allied Health Practitioner	This outdated and often confusing term has been removed from this manual; see "non-physician practitioner".
AMT	American Medical Technologist
Anesthesia	Definition of General Anesthesia and Levels of Sedation/Analgesia (adopted from the American Society of Anesthesiology - October 27, 2004) <u>Minimal Sedation (Anxiolysis)</u> is a drug-induced state during which patients respond normally to verbal commands. Although cognitive function and coordination may be impaired, ventilatory and cardiovascular functions are unaffected.

GLOSSARY

Moderate Sedation/ Analgesia (“Conscious Sedation”) is a drug-induced depression of consciousness during which patients respond purposefully** to verbal commands, either alone or accompanied by light tactile stimulation. No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is usually maintained.

Deep Sedation/ Analgesia is a drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully** following repeated or painful stimulation. The ability to independently maintain ventilatory function may be impaired. Patients may require assistance in maintaining a patent airway, and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained.

General Anesthesia is a drug-induced loss of consciousness during which patients are not arousable, even by painful stimulation. The ability to independently maintain ventilatory function is often impaired. Patients often require assistance in maintaining a patent airway, and positive pressure ventilation may be required because of depressed spontaneous ventilation or drug-induced depression of neuromuscular function. Cardiovascular function may be impaired.

- Because sedation is a continuum, it is not always possible to predict how an individual patient will respond. Hence practitioners intending to produce a given level of sedation should be able to rescue*** patients whose level of sedation becomes deeper than initially intended. Individuals administering Moderate Sedation/ Analgesia (“Conscious Sedation”) should be able to rescue*** patients who enter a state of Deep Sedation/ Analgesia, while those administering Deep Sedation/Analgesia should be able to rescue*** patients who enter a state of General Anesthesia.

** Reflex withdrawal from a painful stimulus is NOT considered a purposeful response.

*** Rescue of a patient from a deeper level of sedation than intended is an intervention by a practitioner proficient in airway management and advanced life support. The qualified practitioner corrects adverse physiologic consequences of the deeper-than-intended level of sedation (such as hypoventilation, hypoxia and hypotension) and returns the patient to the

GLOSSARY

	originally intended level of sedation.
Anesthesiologists	Physician who specializes in the administration of local or general anesthesia before and during surgery, performs cardiac and respiratory resuscitation, and alleviates chronic pain through anesthesia.
Anesthetist	A licensed physician not certified in anesthesiology who practices anesthesiology; a full-time resident in training; certified registered nurse anesthetist; registered nurse anesthetist.
AOA	American Osteopathic Association
AOBNP	American Osteopathic Board of Neurology and Psychiatry
AOBP	American Osteopathic Board of Pathology
AOCP	American Osteopathic College of Pathology
APMA	American Podiatric Medical Association
ARRT	American Registry of Radiologic Technologists
ASCP	American Society of Clinical Pathologists
Audiologist	A person who: (a) Meets the education and experience requirements for a Certificate of Clinical Competence in audiology granted by the American Speech-Language-Hearing Association; or (b) Meets the educational requirements for certification and is in the process of accumulating the supervised experience required for certification.
Authenticate	To prove authorship by legible signature, or identifiable initials.

GLOSSARY

APGAR	American Pediatric Gross Assessment Record
Blood Borne Pathogens	Pathogenic microorganisms that are present in human blood and can cause disease in humans. These pathogens include, but are not limited to hepatitis B virus (HBV) and human immunodeficiency virus (HIV).
BLS	Basic Life Support
CDC	Centers for Disease Control and Prevention
CDS	Controlled Dangerous Substance
CFR	Code of Federal Regulations (usually cited by part and chapter, as 21 CFR 211)
Chemotherapy Waste	Cytotoxic drugs or antineoplastic agents. These drugs selectively inhibit the growth of cancerous tissue through nutritional interference, hormonal imbalance, or by inhibition of DNA replication or protein synthesis. To help health care facilities minimize exposure to these compounds, both the National Study Commission on Cytotoxic Exposure (NSCCE) and the Occupational Safety and Health Administration (OSHA) have issued guidelines that provide procedures and practices for the safe handling of cytotoxic drugs.
Chief Executive Officer	The individual appointed by the hospital's governing body to act in its behalf and who direct the overall management of the hospital.
CLIA	Clinical Laboratory Improvement Amendments
Clinical Pathways	The process of interventions by healthcare professionals for a specific diagnosis or procedure designed to maximize the quality of care for the patient.
Clinical Privileges	The right granted to a licensed physician by a hospital's governing body to render medical care commensurate with professional qualifications and demonstrated professional ability.

GLOSSARY

Clinical Review	The review of clinical work of the facility. This should include case review and the presentation of reports of various committees or problems that deal with patient care in the hospital departments and/or staff meetings.
CMS	Centers for Medicare and Medicaid Services
COHA	Committee on Hospital Accreditation
Competency	The ability to adequately perform an assigned task or function.
Complication	Broadly defined, a clinical condition coexisting with the patient's chief complaint that may require investigation and/or treatment. Less broadly defined, a condition arising during the patient's hospital stay that alters the physician's plan of treatment.
Condition of Participation (CoP)	The requirements providers shall meet to participate in the Medicare program.
Consultant	A second physician called by an attending physician to examine a patient and discuss a case.
Continuous(ly)	Available at all times without cessation, break, or interruption.
Continuous Quality Improvement (CQI)	Ongoing interdisciplinary commitment to strive for improvement in systems in order to provide quality healthcare that meets or exceeds patient/customer expectations.
Coverage of	Healthcare worker either physically present or available to render care when required.
Coverage on	Healthcare worker is physically present on a specific unit during entire tour of duty.
CNO	Chief Nursing Officer
CPR	Cardiopulmonary resuscitation

GLOSSARY

CRNA	Certified Registered Nurse Anesthetist
CRTT	Certified Respiratory Therapy Technician
DEA	Drug Enforcement Administration
Deep Sedation/Analgesia	See “Anesthesia”
Dentist	An individual holding a DDS degree or an equivalent degree, who is licensed to practice dentistry.
Department	An organizational entity of the hospital or its medical staff.
Diagnosis	A physician's technical description of the disease afflicting a patient.
DHHS	United States Department of Health and Human Services
Primary Diagnosis (Principal)	The physician's description of the disease or illness chiefly responsible for the patient seeking medical care or for being hospitalized.
Discharge Diagnosis (Final)	The physician's final, recorded diagnosis.
Direction	Authoritative policy or procedural guidance for the accomplishment of a function or activity.
DRG	Diagnosis Related Groups
EKG	Electrocardiogram
ESRD	End Stage Renal Disease
Ex Officio	A position occupied by a person by virtue of this office or function.

GLOSSARY

Extern	A medical or dental student, under professional supervision performs stipulated clinical duties.
Facilities	Identifies buildings, specialized sections of a physical plant, or the equipment necessary to render medical care.
Family	“Family” includes, but is not limited to, an individual’s “spouse”
FACIS	Fraud and Abuse Control Information System
FDA	Food and Drug Administration
FSMB	Federation of State Medical Boards
General Anesthesia	See, “Anesthesia”
Governing Body (Authority)	The individual agency, group or corporation, appointed, elected, or otherwise designated, in which is vested the ultimate responsibility and authority for the conduct of the institution.
Hazardous Chemical Waste	Chemicals which are highly volatile, reactive caustic acids or alkaline, corrosive. Defined and regulated by the U.S. Environmental Protection Agency (EPA) under regulations contained in Title 40 of the Code of Federal Regulations (40 CFR). Primary sources of chemical waste include the medical research laboratory, the clinical laboratory, pharmacy, housekeeping, engineering, and maintenance operations.
Health Care Facility	An organization that directly provides or supplies health care service for which Medicare/Medicaid payment may be made in whole or in part.
Health-Related Services	Services, other than medical, performed by qualified personnel that pertain to protective, preventive, personal, and social services.

GLOSSARY

HFAP	Healthcare Facilities Accreditation Program
HHS	Health and Human Services
HICD	Hospital Adaptation of ICDA (International Classification of Disease, Adapted for Use in the United States)
HIV	Human Immunodeficiency Virus
Home Health Services	Organized health services provided in a patient's place of residence.
Hospital	An establishment with an organized professional staff, with permanent facilities that include inpatient beds, and with medical services including physician services and continuous nursing services, to provide diagnosis and treatment for patients.
Hospital Inpatient	A hospital patient who is provided with room, board, and continuous general nursing service.
Hospital Patient	An individual receiving hospital-based or coordinated medical services for which the hospital is responsible.
House Staff	Interns and residents participating in organized training programs in institutions approved by the AOA and participating in patient care under the direction and supervision of the medical staff.
H&P	History and Physical
HVAC	Heating, Ventilating, and Air Conditioning
ICD	International Classification of Diseases
ICO	Infection Control Officer

GLOSSARY

ICU	Intensive Care Unit
Infectious Waste	<p>Waste capable of producing an infectious disease. This definition requires a consideration of certain factors necessary for induction of disease. These factors include:</p> <ul style="list-style-type: none">a) Presence of a pathogen of sufficient virulence,b) dose,c) portal of entry, andd) resistance of host. <p>Therefore, for a waste to be infectious, it shall contain pathogens with sufficient virulence and quantity so that exposure to the waste by a susceptible host could result in an infectious disease.</p> <p>- U.S Environmental Protection Agency.</p>
Infectious Waste	Contaminated needles, cultures and stocks of infectious agents, blood and blood products, and pathological (Categories) wastes - Center for Disease Control.
Jurisdiction	Designated as having the responsibility of and being the ultimate authority for a specific function, activity, group, or individual.
LGN	Licensed Graduate Nurse
LPN	Licensed Practical Nurse
LSC	Life Safety Code
LVN	Licensed Vocational Nurse
Marriage	“Marriage” means a marriage lawful where it was entered into, including a lawful same-sex marriage, regardless of whether the jurisdiction where the provider or supplier providing health care services to the individual is located, or in which the spouse lives, permits such marriages to occur or recognizes such marriages.

GLOSSARY

MAP	Medical Admissions Profile
MEC	Medical Executive Committee
Medical	A term used to identify physicians (medical staff), distinguishing them from other health workers; used to identify services (medical care) rendered to patients by physicians and other health workers; and used to denote the practice of medicine, surgery, and other physician-oriented specialties (medical practice).
Medical Director	A physician who is formally delegated with the responsibility and authority to maintain proper standards of medical care and to plan for continuance and improvement of medical care.
Medical Services	Services performed at the direction of a physician on behalf of patients by physicians, dentists, nurses, and other professional personnel.
Medical Staff	A formal organization of physicians delegated with the authority and responsibility to maintain proper standards of medical care and to plan for continuance and improvement of medical care.
Medicare Condition	Any condition of participation.
Mid-Level Practitioner (MLP)	This outdated and often confusing term has been deleted from this manual; see “non-physician practitioner”.
Minimal Sedation (Anxiolysis)	See, “Anesthesia”
Moderate Sedation/Analgesia (Conscious Sedation)	See, “Anesthesia”
MPI	Master Patient Index

GLOSSARY

NCQA	National Committee for Quality Assurance
NFPA	National Fire Protection Agency
Non-physician Practitioner	<p>Licensed practice healthcare professionals with advanced education, training, and skills who may be granted medical staff privileges consistent with State law and scope of practice and the medical staff bylaws, rules and regulations. These non-physician practitioners are described in Section 1842(b)(18)(C) of the Act as any of the following:</p> <ul style="list-style-type: none">• Physician assistant• Nurse practitioner• Clinical nurse specialist• Certified registered nurse anesthetist• Certified nurse-midwife• Clinical social worker• Clinical psychologist <p>Other types of licensed healthcare professionals who might be eligible for medical staff privileges, depending on State law, and medical staff bylaws, rules and regulations include, but are not limited to:</p> <ul style="list-style-type: none">• Anesthesiologist's Assistant• Physical Therapist• Occupational Therapist• Speech Language Therapist• Licensed Pharmacists

GLOSSARY

All practitioners who require privileges in order to furnish care to hospital patients must be evaluated under the hospital's medical staff privileging system before the hospital's governing body may grant them privileges.

All practitioners granted medical staff privileges must function under the bylaws, regulations and rules of the hospital's medical staff. The privileges granted to an individual practitioner must be consistent with State scope-of-practice laws. The medical staff and the governing body must enforce its medical staff requirements and take appropriate actions when practitioners with privileges do not adhere to the medical staff bylaws, rules or regulations.

Nosocomial

Pertaining to or originating in a hospital, as nosocomial disease.

NPDB

National Practitioner Data Bank

Nuclear Medicine

The clinical use of radionuclides for investigation, diagnosis, and therapy. Also the term used to identify this medical subspecialty.

Nursing Care

The process of assessing, planning, evaluating, and reevaluating the care of a patient/client's physical, social, mental, and emotional condition to achieve the optimum state of their health in accordance with the physician's orders.

Nursing Care Unit

An organized subdivision of nursing service where continuous care is provided.

Nursing Department

The organized nursing staff that provides nursing care to patients.

Nursing Services

Service providing curative, rehabilitative, and preventative aspects of nursing care to patients.

Occupational Therapist

A person who:

(a) Is a graduate of an occupational therapy curriculum accredited jointly by the Committee on

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- Allied Health Education and Accreditation of the American Medical Association and the American Occupational Therapy Association; or
- (b) Is eligible for the National Registration Examination of the American Occupational Therapy Association; or
 - (c) Has 2 years of appropriate experience as an occupational therapist, and has achieved a satisfactory grade on a proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service, except that such determinations of proficiency do not apply with respect to persons initially licensed by the State or seeking initial qualification as an occupational therapist after December 31, 1977.

OPO

Organ Procurement Organization

OPTN

Organ Procurement and Transplantation Network

OR

Operating Room

Oral Surgeon

Qualified to perform histories and physicals - An individual who has successfully completed a postgraduate program in oral surgery accredited by a nationally recognized accrediting body approved by the U.S. Office of Education. As determined by the medical staff, the individual is also currently competent to perform a complete history and physical examination to determine the ability of each of his patients to undergo the oral surgical procedure the oral surgeon proposes to perform. A practitioner of dentistry who deals with the diagnosis and surgical adjunctive treatment of the diseases, injuries, and defects of the human jaw and associated structures.

Organ procurement organization (OPO)

An organization that performs or coordinates the performance of retrieving, preserving, and transporting organs and maintains a system of locating prospective recipients for available organs.

Organ procurement &
Transportation Network

An organization that provides for the transportation of donated organs to transplant centers arrange (OPTN) to cooperate with tissue banks for the retrieval, processing,

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preservation, storage, and distribution of tissues may be appropriate to assure that all usable tissues are obtained from potential donors.

Osteopathic Medical Student

Pre-doctoral (third or fourth-year) medical student who is continuing their education in an AOA-approved (Clinical Clerk) hospital, and who performs assigned clinical duties under the supervision of a qualified physician.

PACU

Post Anesthesia Care Unit

PAS

Professional Activity Study

Patient

A person who receives health care service from a health care provider.

Peer Review (Appropriate)

Concurrent or retrospective review by practicing physicians or other health professionals of the quality and efficiency of patient care practices or services ordered or performed by other physicians or other health professionals.

Personal Protective Equipment (PPE)

Specialized clothing or equipment worn by an employee for protection against a hazard.

PHS

Public Health Service

Physician

A graduate of an accredited and appropriately recognized osteopathic or allopathic college of medicine (DO/MD) and is licensed in the state to practice.

Physical Therapist

A person who is licensed as a physical therapist by the State in which practicing, and:

(a) Has graduated from a physical therapy curriculum approved by:

- 1) The American Physical Therapy Association; or
- 2) The committee on Allied Health Education and Accreditation of the American Association; or
- 3) The Council on Medical Education of the American Medical Association and the American Physical Therapy Association.

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Physical Therapist Assistant	<p>A person who is licensed as a physical therapy assistant if applicable by the State in which practicing, and;</p> <ul style="list-style-type: none">(a) Has graduated from a 2-year college level program approved by the American Physical Therapy Association; or(b) Has 2 years of appropriate experience as physical therapy assistant and has achieved a satisfactory grade on a proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service, except that these determinations of proficiency do not apply with respect to person initially licensed by a State or seeking initial qualification as a physical therapy assistant after December 31, 1977.
POC	Plan of Correction
Podiatrist	A podiatrist is a physician and surgeon who has graduated from a college of podiatric medicine accredited by the Council on Podiatric Medical Education of the American Podiatric Medical Association and/or approved by state licensing boards.
Podiatry Medicine	Podiatric medicine is that profession of the health sciences which deals with the examination, diagnosis, treatment, and prevention of diseases, conditions, and malfunctions affecting the human foot and its related or governing structures, by employment of medical, surgical, or other means.
Podiatric Service	Designates an area of podiatric practice such as surgery or identifies podiatric staff function.
Podiatric Staff	Podiatrists with privileges to practice in the hospital and functions under bylaws, rules and regulations governing podiatric services approved by the medical staff and the governing body.
Practitioner	An individual credentialed within a recognized health care discipline and involved in providing the services of that discipline to patients.

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Professional Staff	A formal organization of professional health personnel that includes one or more physicians which is delegated with the authority and responsibility to maintain proper standards of medical care and/or health-related care and to plan for continuance and improvement of that medical care.
Quality Assessment/Improvement	A multidisciplinary approach to measuring, assessing and improving outcomes.
Radiologist	A physician who is qualified by education and experience in radiology.
Radioactive Waste	Radioactive materials that are used in the health care facilities for radiotherapeutic, diagnostic, and research purposes produce radioactive wastes that are generally classified as low-level radioactive wastes. Disposal of these wastes may require compliance with federal, state, and local regulations. The U.S. Nuclear Regulatory Commission (NRC) is responsible for regulatory oversight on the use, handling, and disposal of radiological materials (see "Standards for Protection Against Radiation, U.S. Code of Federal Regulations, Title 10").
RHIA	Registered Health Information Administrator
RHIT	Registered Health Information Technician
RN	Registered Nurse
Relative	"Relative," when used as a noun, includes, but is not limited to, an individual's "spouse"
SCU	Special Care Units
Secondary Diagnosis (additional)	The physician's description of a clinical condition in the patient that exists at the time of admission or develops subsequently that affects the treatment received and/or length of stay.

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Sedation	See “Anesthesia”
Signatures	The use of rubber stamp signatures, mechanically or electronically affixed signatures on medical records, are permissible unless prohibited by law. It is the responsibility of the hospital and the individual physician to assure the appropriate use of such signatures.
Speech Language Pathologist	A person who: (a) Meets the education and experience requirements for a Certificate or Clinical Competence (in speech pathology or audiology) granted by the American Speech-Language-Hearing Association; or (b) Meets the educational requirements for certification and is in the process of accumulating the supervised experienced required for certification.
SSA	Social Security Act
Spouse	“Spouse” means an individual who is married to another individual as a result of marriage lawful where it was entered into, including a lawful same-sex marriage, regardless of whether the jurisdiction where the provider or supplier providing health care services to the individual is located, or in which the spouse lives, permits such marriages to occur or recognizes such marriages.
Supervision	Direct oversight and inspection of the act of accomplishing function or activity.
TART	Tenderness/Asymmetry/Restricted Motion/Tissue texture change
Universal Precautions	An approach to infection control. According to the concept of Universal Precautions, all human blood and certain body fluids are treated as if known to be infectious for HIV, HBV, and other Blood borne pathogens.
UOMC	Utilization of Osteopathic Methods & Concepts Activity

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UNOS	United Network for Organ Sharing
UR	Utilization Review

GLOSSARY

Bibliography

Yablonsky, Teri, MA. Total Quality Management in the Laboratory - From under the Microscope into Practice. Laboratory Medicine, Volume 26, Number 4, April 1995.

Kenimer, Elizabeth, MS, MT (ASCP) SBB. Critical Pathways Add Value, Save Time. Advance, February 1997.

Kiger, Anne Fox. Hospital Administration Terminology, American Hospital Association, 1982.

McLaughlin, Curtis P. and Arnold D. Kaluzny. Continuous Quality Improvement in Health Care Theory, Implementation, and Application. Gaithersburg, Maryland: Aspen Publication, 1994.

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CFR Number	Medicare Standard	AOA/HFAP Equivalent Number	AOA/HFAP Standards
§482.11	<p>Condition of participation: <i>The hospital must ensure that all applicable Federal, State, and local law requirements are met.</i></p>	01.00.00	<p><u>Condition of Participation: Compliance with federal, state, and local laws</u> <i>The hospital must ensure that all applicable Federal, State and local law requirements are met.</i></p>
§482.11(a)	<p><i>The hospital must be in compliance with applicable federal laws related to the health and safety of patients.</i></p>	01.00.02	<p><u>Compliance with Laws</u> <i>The hospital must be in compliance with applicable federal laws related to the health and safety of patients.</i></p>
§482.11(b)(1) §482.11(b) (2)	<p><i>The hospital must be licensed or approved as meeting standards for licensing established by the agency of the state or locality responsible for licensing hospitals.</i></p>	01.00.03	<p><u>Hospital Licensure</u> <i>The hospital must be licensed or approved as meeting standards for licensing established by the agency of the state or locality responsible for licensing hospitals.</i></p>
§482.11(c)	<p><i>The hospital must assure that personnel are licensed or meet other applicable standards that are required by State or local laws.</i></p>	01.00.04	<p><u>Licensure of Personnel</u> <i>The hospital must assure that personnel are licensed or meet other applicable standards that are required by State or local laws.</i></p>
§482.12	<p>Condition of participation: Governing Body <i>There must be an effective governing body that is legally responsible for the conduct of the hospital as an institution.</i></p> <p><i>If a hospital does not have an organized governing body, the persons legally responsible for the conduct of the hospital must carry out the functions specified in this part that pertain to the governing body.</i></p>	01.01.00	<p><u>Condition of Participation: Governing Body</u> <i>There must be an effective governing body that is legally responsible for the conduct of the hospital as an institution.</i></p> <p><i>If a hospital does not have an organized governing body, the persons legally responsible for the conduct of the hospital must carry out the functions specified in this part that pertain to the governing body.</i></p>

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<p>§482.12(a) §482.12(a)(1)</p>	<p>Standard: Medical staff. The governing body must: (1) Determine, in accordance with State law, which categories of practitioners are eligible candidates for appointment to the medical staff;</p>	<p>01.01.01</p>	<p><u>Categories Eligible for Appointment</u> The governing body must:</p> <ul style="list-style-type: none"> Determine, in accordance with State law, which categories of practitioners are eligible candidates for appointment to the medical staff.
<p>§482.12(a)(2)</p>	<p>(2) Appoint members of the medical staff after considering the recommendations of the existing members of the medical staff;</p>	<p>01.01.02</p>	<p><u>Medical Staff Appointment</u> The governing body must:</p> <ul style="list-style-type: none"> Appoint members of the medical staff after considering the recommendations of the existing members of the medical staff.
<p>§482.12(a)(3)</p>	<p>(3) Assure that the medical staff has bylaws;</p>	<p>01.01.03</p>	<p><u>Provision of Medical Staff Bylaws</u> The governing body must:</p> <ul style="list-style-type: none"> Assure that the medical staff has bylaws.
<p>§482.12(a)(4)</p>	<p>(4) Approve medical staff bylaws and other medical staff rules and regulations;</p>	<p>01.01.04</p>	<p><u>Approval of Medical Staff Bylaws</u> The governing body must:</p> <ul style="list-style-type: none"> Approve medical staff bylaws and other medical staff rules and regulations.
<p>§482.12(a)(5)</p>	<p>(5) Ensure that the medical staff is accountable to the governing body for the quality of care provided to patients;</p>	<p>01.01.05</p>	<p><u>Medical Staff Quality of Care</u> The governing body must:</p> <ul style="list-style-type: none"> Ensure that the medical staff is accountable to the governing body for the quality of care provided to patients.
<p>§482.12(a)(6)</p>	<p>(6) Ensure the criteria for selection are individual character, competence, training, experience, and judgment;</p>	<p>01.01.06</p>	<p><u>Selection Criteria for Appointment to the Staff</u> The governing body must:</p> <ul style="list-style-type: none"> Ensure the criteria for selection are individual character, competence, training, experience, and judgment.

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<p>§482.12(a)(7)</p>	<p>(7) <i>Ensure that under no circumstances is the accordance of staff membership or professional privileges in the hospital dependent solely upon certification, fellowship, or membership in a specialty body or society.</i></p>	<p>01.01.07</p>	<p><u>Required Criteria for Appointment</u> <i>The governing body must:</i></p> <ul style="list-style-type: none"> • <i>Ensure that under no circumstances is the accordance of staff membership or professional privileges in the hospital dependent solely upon certification, fellowship or membership in a specialty body or society.</i>
<p>§482.12(a)(8) §482.12(a)(9)</p>	<p><i>The governing body must:</i></p> <ul style="list-style-type: none"> • <i>Ensure that, when telemedicine services are furnished to the hospital's patients through an agreement with a distant-site hospital, the agreement is written and that it specifies that it is the responsibility of the governing body of the distant-site hospital to meet the requirements in paragraphs (a)(1) through (a)(7) of this section with regard to the distant-site hospital's physicians and practitioners providing telemedicine services. The governing body of the hospital whose patients are receiving the telemedicine services may, in accordance with §482.22(a)(3) of this part, grant privileges based on its medical staff recommendations that rely on information provided by the distant-site hospital.</i> • <i>Ensure that when telemedicine services are furnished to the hospital's patients through an agreement with a distant-site telemedicine entity, the written agreement specifies that the distant-site telemedicine entity is a contractor of services to the hospital and as such, in accordance with §482.12(e), furnishes the contracted services in a manner that permits the hospital to comply with all applicable conditions of participation for the contracted services, including, but not limited to, the requirements in paragraphs (a)(1) through (a)(7) of this section with regard to the distant-site telemedicine entity's physicians and practitioners providing</i> 	<p>01.01.08</p>	<p><u>Telemedicine Agreements with Distant-Site Hospital or Distant-Site Telemedicine Entity.</u> <i>The governing body must:</i></p> <ul style="list-style-type: none"> • <i>Ensure that, when telemedicine services are furnished to the hospital's patients <u>through an agreement with a distant-site hospital</u>, the agreement is written and that it specifies that it is the responsibility of the governing body of the distant-site hospital to meet the requirements in accordance with paragraphs (a)(1) through (a)(7) of 42 CFR 482.12 with regard to the distant-site hospital's physicians and practitioners providing telemedicine services. The governing body of the hospital whose patients are receiving the telemedicine services may, in accordance with §482.22(a)(3) of 42 CFR 482.12, grant privileges based on its medical staff recommendations that rely on information provided by the distant-site hospital.</i> • <i>Ensure that, when telemedicine services are furnished to the hospital's patients through an agreement with a distant-site telemedicine entity, the written agreement specifies that the distant-site telemedicine entity is a contractor of services to the hospital and as such, in accordance with §482.12(e), furnishes the contracted services in a manner that permits the hospital to comply with all applicable conditions of participation for the contracted services, including, but not limited to, the requirements in paragraphs (a)(1) through (a)(7) of 42 CFR 482.12 with regard to the distant-site telemedicine entity's physicians and practitioners providing telemedicine services. The</i>

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	<p><i>telemedicine services. The governing body of the hospital whose patients are receiving the telemedicine services may, in accordance with §482.22(a)(4) of this part, grant privileges to physicians and practitioners employed by the distant-site telemedicine entity based on such hospital's medical staff recommendations; such staff recommendations may rely on information provided by the distant-site telemedicine entity.</i></p>		<p><i>governing body of the hospital whose patients are receiving the telemedicine services may, in accordance with §482.22(a)(4) of 42 CFR 482.22, grant privileges to physicians and practitioners employed by the distant-site telemedicine entity based on such hospital's medical staff recommendations; such staff recommendations may rely on information provided by the distant-site telemedicine entity.</i></p>
§482.12(a)(10)	<p><i>The governing body must:</i></p> <p><i>Consult directly with the individual assigned the responsibility for the organization and conduct of the hospital's medical staff, or his or her designee. At a minimum, this direct consultation must occur periodically throughout the fiscal or calendar year and include discussion of matters related to the quality of medical care provided to patients of the hospital.</i></p> <p><i>For a multi-hospital system using a single governing body, the single multi-hospital system governing body must consult directly with the individual responsible for the organized medical staff (or his or her designee) of each hospital within its system in addition to the other requirements of this paragraph (a).</i></p>	01.01.10	<p><u>Governing Body Periodically Consults with the Medical Staff.</u></p> <p><i>The governing body must:</i></p> <ul style="list-style-type: none"> • <i>Consult directly with the individual assigned the responsibility for the organization and conduct of the hospital's medical staff, or his or her designee.</i> • <i>At a minimum, this direct consultation must occur periodically throughout the fiscal or calendar year and include discussion of matters related to the quality of medical care provided to patients of the hospital.</i> • <i>For a multi-hospital system using a single governing body, the single multi-hospital system governing body must consult directly with the individual responsible for the organized medical staff (or his or her designee) of each hospital within its system in addition to the other requirements of this paragraph (a) in 42 CFR 482.12.</i>
§482.12(b)	<p><i>Standard: Chief executive officer.</i></p> <p><i>The governing body must appoint a chief executive officer who is responsible for managing the hospital.</i></p>	01.01.11	<p><u>CEO Appointment</u></p> <p><i>The governing body must:</i></p> <ul style="list-style-type: none"> • <i>Appoint a chief executive officer who is responsible for managing the hospital.</i>

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<p>§482.12(c) §482.12(c)(1) §482.12(c)(1)(i) §482.12(c)(1)(ii) §482.12(c)(1)(iii) §482.12(c)(1)(iv) §482.12(c)(1)(v) §482.12(c)(1)(vi)</p>	<p><i>Standard: Care of patients.</i> <i>In accordance with hospital policy, the governing body must ensure that the following requirements are met:</i></p> <p><i>(1) Every Medicare patient is under the care of:</i></p> <ul style="list-style-type: none"> <i>(i) A doctor of medicine or osteopathy (This provision is not to be construed to limit the authority of a doctor of medicine or osteopathy to delegate tasks to other qualified healthcare personnel to the extent recognized under State law or a State’s regulatory mechanism.);</i> <i>(ii) A doctor of dental surgery or dental medicine who is legally authorized to practice dentistry by the State and who is acting within the scope of his or her license;</i> <i>(iii) A doctor of podiatric medicine, but only with respect to functions which he or she is legally authorized by the State to perform;</i> <i>(iv) A doctor of optometry who is legally authorized to practice optometry by the State in which he or she practices;</i> <i>(v) A chiropractor who is licensed by the State or legally authorized to perform the services of a chiropractor, but only with respect to treatment by means of manual manipulation of the spine to correct a subluxation demonstrated by x-ray to exist; and</i> <i>(vi) A clinical psychologist as defined in § 410.71 of this chapter, but only with respect to clinical psychologist services as defined in § 410.71 of this chapter and only to the extent permitted by State law.</i> 	<p>01.01.12</p>	<p>Care of Patients <i>In accordance with hospital policy, the governing body must ensure that the following requirements are met.</i></p> <p><i>Every Medicare patient is under the care of:</i></p> <ul style="list-style-type: none"> <i>(i) A doctor of medicine or osteopathic medicine. (This provision is not to be construed to limit the authority of a doctor of medicine or osteopathy to delegate tasks to other qualified health care personnel to the extent recognized under State law or a state’s regulatory mechanism.);</i> <i>(ii) A doctor of dental surgery or dental medicine who is legally authorized to practice dentistry by the State and who is acting within the scope of his or her license;</i> <i>(iii) A doctor of podiatric medicine, but only with respect to functions which he or she is legally authorized by the State to perform;</i> <i>(iv) A doctor of optometry who is legally authorized to practice optometry by the State in which he or she practices;</i> <i>(v) A chiropractor who is licensed by the State or legally authorized to perform the services of a chiropractor, but only with respect to treatment by means of manual manipulation of the spine to correct a subluxation demonstrated by x-ray to exist; and</i> <i>(vi) A clinical psychologist as defined in §410.71 of 42 CFR 410.71, but only with respect to clinical psychologist services as defined in §410.71 of 42 CFR 410.71 and only to the extent permitted by State law.</i>
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<p>§482.12(c)(2)</p>	<p><i>In accordance with hospital policy, the governing body must ensure that the following requirements are met:</i></p> <p>(2) <i>Patients are admitted to the hospital only on the recommendation of a licensed practitioner permitted by the State to admit patients to a hospital. If a Medicare patient is admitted by a practitioner not specified in paragraph (c)(1) of this section, that patient is under the care of a doctor of medicine or osteopathy.</i></p>	<p>01.01.13</p>	<p><u>State Privilege Requirements</u> <i>In accordance with hospital policy, the governing body must ensure that the following requirements are met:</i></p> <ul style="list-style-type: none"> • <i>Patients are admitted to the hospital only on the recommendation of a licensed practitioner permitted by the State to admit patients to a hospital.</i> • <i>If a Medicare patient is admitted by a practitioner not specified in paragraph (c)(1) [standards 01.01.15] of 42 CFR 482.12, that patient is under the care of a doctor of medicine or osteopathic medicine.</i>
<p>§482.12(c)(3)</p>	<p>(3) <i>A doctor of medicine or osteopathy is on duty or on call at all times.</i></p>	<p>01.01.14</p>	<p><u>Physician Availability</u> <i>The governing body must ensure that the following requirements are met:</i></p> <ul style="list-style-type: none"> • <i>A doctor of medicine or osteopathic medicine is on duty or on call at all times.</i>
<p>§482.12(c)(4) §482.12(c)(4)(i) §482.12(c)(4)(ii) §482.12(c)(4)(ii)(A) §482.12(c)(4)(ii)(B) §482.12(c)(4)(ii)(C)</p>	<p>(4) <i>A doctor of medicine or osteopathy is responsible for the care of each Medicare patient with respect to any medical or psychiatric problem that—</i></p> <p><i>(i) is present on admission or develops during hospitalization; and</i></p> <p><i>(ii) Is not specifically within the scope of practice of a doctor of dental surgery, dental medicine, podiatric medicine, or optometry; a chiropractor; or clinical psychologist, as that scope is—</i></p> <p><i>(A) Defined by the medical staff;</i></p> <p><i>(B) Permitted by State law; and</i></p> <p><i>(C) Limited, under paragraph (c)(1)(v) of this section, with respect to chiropractors.</i></p>	<p>01.01.15</p>	<p><u>Medical Staff Oversight</u> <i>The governing body must ensure that the following requirements are met:</i></p> <p><i>A doctor of medicine or osteopathic medicine is responsible for the care of each Medicare patient with respect to any medical or psychiatric problem that—</i></p> <p><i>(1) Is present on admission or develops during hospitalization; and</i></p> <p><i>(2) Is not specifically within the scope of practice of a doctor of dental surgery, dental medicine, podiatric medicine, or optometry; a chiropractor; or clinical psychologist, as that scope is—</i></p> <p><i>(A) Defined by the medical staff;</i></p> <p><i>(B) Permitted by State law; and</i></p>

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			<p>(C) Limited, under paragraph (c)(1)(v) of 42 CFR 482.12, with respect to chiropractors.</p>
<p>§482.12(d) §482.12(d)(1) §482.12(d)(2) §482.12(d)(3) §482.12(d)(4) §482.12(d)(4)(i) §482.12(d)(4)(ii) §482.12(d)(4)(iii)</p>	<p><i>Standard: Institutional plan and budget.</i> <i>The institution must have an overall institutional plan that meets the following conditions:</i></p> <p>(1) <i>The plan must include an annual operating budget that is prepared according to generally accepted accounting principles.</i></p> <p>(2) <i>The budget must include all anticipated income and expenses. This provision does not require that the budget identify item by item the components of each anticipated income or expense.</i></p> <p>(3) <i>The plan must provide for capital expenditures for at least a 3-year period, including the year in which the operating budget specified in paragraph (d)(2) of this section is applicable.</i></p> <p>(4) <i>The plan must include and identify in detail the objective of, and the anticipated sources of financing for, each anticipated capital expenditure in excess of \$600,000 (or a lesser amount that is established, in accordance with section 1122(g)(1) of the Act, by the State in which the hospital is located) that relates to any of the following:</i></p> <p style="margin-left: 40px;">(i) <i>Acquisition of land;</i></p> <p style="margin-left: 40px;">(ii) <i>Improvement of land, buildings, and equipment; or</i></p> <p style="margin-left: 40px;">(iii) <i>The replacement, modernization, and expansion of buildings and equipment.</i></p>	<p style="text-align: center;">01.01.16</p>	<p><u>Institutional Plan & Budget</u> <i>The institution must have an overall institutional plan that meets the following conditions:</i></p> <p>(1) <i>The plan must include an annual operating budget that is prepared according to generally accepted accounting principles.</i></p> <p>(2) <i>The budget must include all anticipated income and expenses. This provision does not require that the budget identify item by item the components of each anticipated income or expense.</i></p> <p>(3) <i>The plan must provide for capital expenditures for at least a 3-year period, including the year in which the operating budget specified in paragraph (d)(2) of 42 CFR 482.12 is applicable.</i></p> <p>(4) <i>The plan must include and identify in detail the objective of, and the anticipated sources of financing for, each anticipated capital expenditure in excess of \$600,000 (or a lesser amount that is established, in accordance with section 1122(g)(1) of the Act (Social Security Act), by the State in which the hospital is located) that relates to any of the following:</i></p> <p style="margin-left: 40px;">(i) <i>Acquisition of land.</i></p> <p style="margin-left: 40px;">(ii) <i>Improvement of land, building, and equipment.</i></p> <p style="margin-left: 40px;">(iii) <i>The replacement, modernization, and expansion of the buildings and equipment.</i></p>

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<p>§482.12(d)(5) §482.12(d)(5)(i) §482.12(d)(5)(ii) §482.12(d)(5)(iii) §482.12(d)(5)(iv) §482.12(d)(5)(v)</p>	<p>(5) <i>The plan must be submitted for review to the planning agency designated in accordance with section 1122(b) of the Act, or if an agency is not designated, to the appropriate health planning agency in the State. (See part 100 of this title.) A capital expenditure is not subject to section 1122 review if 75 percent of the health care facility's patients who are expected to use the service for which the capital expenditure is made are individuals enrolled in a health maintenance organization (HMO) or competitive medical plan (CMP) that meets the requirements of section 1876(b) of the Act, and if the Department determines that the capital expenditure is for services and facilities that are needed by the HMO or CMP in order to operate efficiently and economically and that are not otherwise readily accessible to the HMO or CMP because—</i></p> <p>(i) <i>The facilities do not provide common services at the same site;</i> (ii) <i>The facilities are not available under a contract of reasonable duration;</i> (iiii) <i>Full and equal medical staff privileges in the facilities are not available;</i> (iv) <i>Arrangements with these facilities are not administratively feasible; or</i> (v) <i>The purchase of these services is more costly than if the HMO or CMP provided the services directly.</i></p>	<p style="text-align: center;">01.01.17</p>	<p>Plan Submission <i>The plan must be submitted for review to the planning agency designated in accordance with section 1122(b) of the Social Security Act (the Act), or if an agency is not designated, to the appropriate health planning agency in the state (See part 100 of this title.)</i></p> <p><i>A capital expenditure is not subject to section 1122 review (of the Social Security Act) if 75 percent of the healthcare facility's patients who are expected to use the service for which the capital expenditure is made are individuals enrolled in a health maintenance organization (HMO) or competitive medical plan (CMP) that meets the requirements of section 1876(b) of the Act (Social Security Act), and if the department determines that the capital expenditure is for services and facilities that are needed by the HMO or CMP in order to operate efficiently and economically and that are not otherwise readily accessible to the HMO or CMP because-</i></p> <p>(i) <i>The facilities do not provide common services at the same site.</i> (ii) <i>The facilities are not available under a contract of reasonable duration.</i> (iiii) <i>Full and equal medical staff privileges in the facilities are not available.</i> (iv) <i>Arrangements with these facilities are not administratively feasible.</i> (v) <i>The purchase of these services is more costly than if the HMO or CMP provided the services directly.</i></p>
<p>§482.12(d)(6)</p>	<p>(6) <i>The plan must be reviewed and updated annually.</i></p>	<p style="text-align: center;">01.01.18</p>	<p>Plan Review & Update <i>The plan must be reviewed and updated annually.</i></p>
<p>§482.12(d)(7) §482.12(d)(7)(i) §482.12(d)(7)(ii)</p>	<p>(7) <i>The plan must be prepared—</i> (i) <i>Under the direction of the governing body; and</i> (ii) <i>By a committee consisting of representatives of the governing body, the administrative staff, and the medical staff of the institution.</i></p>	<p style="text-align: center;">01.01.19</p>	<p>Plan Preparation <i>The plan must be prepared—</i> (i) <i>Under the direction of the governing body; and</i> (ii) <i>By a committee consisting of representatives of the governing body, the administrative staff, and the</i></p>

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			<i>medical staff of the institution.</i>
§482.12(e)	<i>Standard: Contracted services. The governing body must be responsible for services furnished in the hospital whether or not they are furnished under contracts. The governing body must ensure that a contractor of services (including one for shared services and joint ventures) furnishes services that permit the hospital to comply with all applicable conditions of participation and standards for the contracted services.</i>	01.01.22	<u>Contracted Services</u> <i>The governing body must be responsible for services furnished in the hospital whether or not they are furnished under contracts. The governing body must ensure that a contractor of services (including one for shared services and joint ventures) furnishes services that permit the hospital to comply with all applicable conditions of participation and standards for the contracted services.</i>
§482.12(e)(1)	(1) <i>The governing body must ensure that the services performed under a contract are provided in a safe and effective manner.</i>	01.01.23	<u>Contractor Quality Monitoring</u> <i>The governing body must ensure that the services performed under a contract are provided in a safe and effective manner.</i>
§482.12(e)(2)	(2) <i>The hospital must maintain a list of all contracted services, including the scope and nature of the services provided.</i>	01.01.24	<u>List of Contracted Services</u> <i>The hospital must maintain a list of all contracted services, including the scope and nature of the services provided.</i>
§482.12(f)	<i>Standard: Emergency services.</i>	01.02.01	<u>Emergency Services</u> <i>The hospital must ensure the emergency services requirements are met.</i>
§482.12(f)(1)	(1) <i>If emergency services are provided at the hospital, the hospital must comply with the requirements of § 482.55.</i>	01.02.02	<u>Emergency Services Compliance with Federal Laws</u> <i>If emergency services are provided at the hospital, the hospital must comply with the requirements of §482.55.</i>
§482.12(f)(2)	(2) <i>If emergency services are not provided at the hospital, the governing body must assure that the medical staff has written policies and procedures for appraisal of emergencies, initial treatment, and referral when appropriate.</i>	01.02.03	<u>Policies Regarding Emergency Care When Services Are not Provided</u> <i>If emergency services are not provided at the hospital, the governing body must assure that the medical staff has written policies and procedures for appraisal of emergencies, initial treatment, and referral when appropriate.</i>

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§482.12(f)(3)	(3) <i>If emergency services are provided at the hospital but are not provided at one or more off-campus departments of the hospital, the governing body of the hospital must assure that the medical staff has written policies and procedures in effect with respect to the off-campus department(s) for appraisal of emergencies and referral when appropriate.</i>	01.02.04	<p><u>Off-Site Emergency Care</u> <i>If emergency services are provided at the hospital but are not provided at one or more off-campus departments of the hospital, the governing body of the hospital must assure that the medical staff has written policies and procedures in effect with respect to the off-campus department(s) for appraisal of emergencies and referral when appropriate.</i></p>
§482.13	<p>Condition of participation: Patient’s rights. <i>A hospital must protect and promote each patient’s rights.</i></p>	15.00.00	<p><u>Condition of Participation: Patient’s Rights</u> <i>A hospital must protect and promote each patient’s rights.</i></p>
§482.13(a)(1)	<p><i>Standard: Notice of rights—</i> <i>(1) A hospital must inform each patient, or when appropriate, the patient’s representative (as allowed under State law), of the patient’s rights, in advance of furnishing or discontinuing patient care whenever possible.</i></p>	15.01.02	<p><u>Notice of Patient Rights</u> <i>A hospital must inform each patient, or when appropriate, the patient’s representative (as allowed under State law), of the patient’s rights in advance of furnishing or discontinuing patient care whenever possible.</i></p>
§482.13(a)(2)	<p><i>(2) The hospital must establish a process for prompt resolution of patient grievances and must inform each patient whom to contact to file a grievance.</i></p> <p><i>The hospital’s governing body must approve and be responsible for the effective operation of the grievance process and must review and resolve grievances, unless it delegates the responsibility in writing to a grievance committee.</i></p> <p><i>The grievance process must include a mechanism for timely referral of patient concerns regarding quality of care or premature discharge to the appropriate Utilization and Quality Control Quality Improvement Organization.</i></p>	15.01.03	<p><u>Patient Grievances</u> <i>The hospital must establish a process for prompt resolution of patient grievances and must inform each patient whom to contact to file a grievance.</i></p>
		15.01.04	<p><u>Governing Body Responsibility for the Grievance Process</u> <i>[The hospital must establish a process for prompt resolution of patient grievances and must inform each patient whom to contact to file a grievance.]</i></p> <p><i>The hospital’s governing body must approve and be responsible for the effective operation of the grievance process and must review and resolve grievances, unless it delegates the responsibility in writing to a grievance committee.</i></p>
		15.01.05	<p><u>Timely Referrals</u> <i>[The hospital must establish a process for prompt resolution of patient grievances and must inform each patient whom to contact to file a grievance.]</i></p>

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			<i>The grievance process must include a mechanism for timely referral of patient concerns regarding quality of care or premature discharge to the appropriate Utilization and Quality Control, Quality Improvement Organization (QIO).</i>
§482.13(a)(2)(i)	<i>At a minimum: (2)(i) The hospital must establish a clearly explained procedure for the submission of a patient’s written or verbal grievance to the hospital.</i>	15.01.06	<u>Grievance Process</u> <i>At a minimum: The hospital must establish a clearly explained procedure for the submission of a patient’s written or verbal grievance to the hospital.</i>
§482.13(a)(2)(ii)	<i>(2)(ii) The grievance process must specify time frames for review of the grievance and the provision of a response.</i>	15.01.07	<u>Grievance Process Response Time Frames</u> <i>At a minimum: The grievance process must specify time frames for review of the grievance and the provision of a response.</i>
§482.13(a)(2)(iii)	<i>(2)(iii) In its resolution of the grievance, the hospital must provide the patient with written notice of its decision that contains the name of the hospital contact person, the steps taken on behalf of the patient to investigate the grievance, the results of the grievance process, and the date of completion.</i>	15.01.08	<u>Patient Notification of the Grievance Process</u> <i>At a minimum: In its resolution of the grievance, the hospital must provide the patient with a written notice of its decision that contains the name of the hospital contact person, the steps taken on behalf of the patient to investigate the grievance, the results of the grievance process, and the date of completion.</i>
§482.13(b)	<i>Standard: Exercise of rights. (1) The patient has the right to participate in the development and implementation of his or her plan of care. (2) The patient or his or her representative (as allowed under State law) has the right to make informed decisions regarding his or her care. The patient’s rights include being informed of his or her health status, being involved in care planning and treatment, and being able to request or refuse treatment. This right must not be construed as a mechanism to demand the provision of</i>	15.01.09	<u>Exercise of Patient Rights</u> <i>The Patient’s Rights document includes, at a minimum, that the patient has: A. The right to participate in the development and implementation of his or her plan of care; B. Or his or her representative (as allowed under state law) has the right to make informed decisions regarding his or her care. The patient’s rights include being informed of his or her health status, being involved in care planning and treatment, and being able to request or refuse treatment. This right must not be construed as a mechanism to demand the provision of treatment or services</i>

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	<p><i>treatment or services deemed medically unnecessary or inappropriate.</i></p> <p>(3) <i>The patient has the right to formulate advance directives and to have hospital staff and practitioners who provide care in the hospital comply with these directives, in accordance with § 489.100 of this part (Definition), § 489.102 of this part (Requirements for providers), and § 489.104 of this part (Effective dates).</i></p> <p>(4) <i>The patient has the right to have a family member or representative of his or her choice and his or her own physician notified promptly of his or her admission to the hospital.</i></p>		<p><i>deemed medically unnecessary or inappropriate;</i></p> <p>C. <i>The right to formulate advance directives and to have hospital staff and practitioners who provide care in the hospital comply with these directives, in accordance with 489.100 of this part, 489.102 of this part, and 489.104 of this part;</i></p> <p>D. <i>The right to have a family member or representative of his or her choice and his or her own physician notified promptly of his or her admission to the hospital;</i></p> <p>E. <i>The right to personal privacy;</i></p> <p>F. <i>The right to receive care in a safe setting;</i></p> <p>G. <i>The right to be free from all forms of abuse or harassment;</i></p> <p>H. <i>The right to the confidentiality of his or her clinical records;</i></p> <p>I. <i>The right to access information contained in his or her clinical records within a reasonable time frame. The hospital must not frustrate the legitimate efforts of individuals to gain access to their own medical records and must actively seek to meet these requests as quickly as its record keeping system permits.</i></p> <p>J. <i>The right to be free from restraints of any form that are not medically necessary or are used as a means of coercion, discipline, convenience, or retaliation by staff;</i></p> <p>K. <i>The right to be fully informed of and to consent or refuse to participate in any unusual, experimental or research project without compromising his / her access to services;</i></p> <p>L. <i>The right to know the professional status of any person providing his / her care / services;</i></p> <p>M. <i>The right to know the reasons for any proposed change in the Professional Staff responsible for his / her care;</i></p> <p>N. <i>The right to know the reasons for his / her transfer either within or outside the hospital;</i></p> <p>O. <i>The relationship(s) of the hospital to other persons or organizations participating in the provision of his / her care;</i></p> <p>P. <i>The right of access to the cost, itemized when possible, of services rendered within a reasonable period of time;</i></p> <p>Q. <i>The right to be informed of the source of the hospital's reimbursement for his / her services, and of any limitations which may be placed upon his / her care;</i></p> <p>R. <i>Informed of the right to have pain treated as effectively as</i></p>
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			<p>possible.</p> <p>5. A hospital must have written policies and procedures regarding the visitation rights of patients, including those setting forth any clinically necessary or reasonable restriction or limitation that the hospital may need to place on such rights and the reason for the clinical restriction or limitation. A hospital must meet the following requirements:</p> <ul style="list-style-type: none"> • Inform each patient (or support person, where appropriate) of his or her visitation rights, including any clinical restriction or limitation on such rights, when he or she is informed of his or her other rights under this section. • Inform each patient (or support person, where appropriate) of the right, subject to his or her consent, to receive the visitors whom he or she designates, including, but not limited to, a spouse, a domestic partner (including a same sex domestic partner), another family member, or a friend, and his or her right to withdraw or deny such consent at any time. • Not restrict, limit or otherwise deny visitation privileges on the basis of race, color, national origin, religion, sex, gender identity, sexual orientation, or disability. • Ensure that all visitors enjoy full and equal visitation privileges consistent with patient preferences. <p>482.13(h) (1)(2)(3)(4)(Revised January 18, 2011; effective January 18, 2011)</p> <p>7. The patient's family has the right of informed consent for donation of organs and tissues.</p>
§482.13(b)(1)	(1) <i>The patient has the right to participate in the development and implementation of his or her plan of care.</i>	15.01.10	<p>Participation in the Plan of Care <i>The patient has the right to participate in the development and implementation of his or her plan of care.</i></p>
§482.13(b)(2)	(2) <i>The patient or his or her representative (as allowed under State law) has the right to make informed decisions regarding his or her care. The patient's rights include being informed of his or her health status, being</i>	15.01.11	<p>Participation in Decision Making <i>The patient or his or her representative (as allowed under State law) has the right to make informed decisions regarding his or her care. The patient's rights include being informed of his or her health status,</i></p>

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	<i>involved in care planning and treatment, and being able to request or refuse treatment. This right must not be construed as a mechanism to demand the provision of treatment or services deemed medically unnecessary or inappropriate.</i>		<i>being involved in care planning and treatment, and being able to request or refuse treatment. This right must not be construed as a mechanism to demand the provision of treatment or services deemed medically unnecessary or inappropriate.</i>
§482.13(b)(3)	(3) <i>The patient has the right to formulate advance directives and to have hospital staff and practitioners who provide care in the hospital comply with these directives, in accordance with § 489.100 of this part (Definition), § 489.102 of this part (Requirements for providers), and § 489.104 of this part (Effective dates).</i>	15.01.12	<u>Advance Directives</u> <i>The patient has the right to formulate advance directives and to have hospital staff and practitioners who provide care in the hospital comply with these directives, in accordance with 489.100 of this part, 489.102 of this part and 489.104 of this part.</i>
§482.13(b)(4)	(4) <i>The patient has the right to have a family member or representative of his or her choice and his or her own physician notified promptly of his or her admission to the hospital.</i>	15.01.14	<u>Admission Notification</u> <i>The patient has the right to have a family member or representative of his or her choice and his or her own physician notified promptly of his or her admission to the hospital.</i>
§482.13(c) §482.13(c)(1)	(1) <i>The patient has the right to personal privacy.</i>	15.01.16	<u>Privacy & Safety: Personal Privacy</u> <i>The patient has the right to personal privacy.</i>
§482.13(c)(2)	(2) <i>The patient has the right to receive care in a safe setting.</i>	15.01.17	<u>Privacy & Safety: Safe Setting</u> <i>The patient has the right to receive care in a safe setting.</i>
§482.13(c)(3)	(3) <i>The patient has the right to be free from all forms of abuse or harassment.</i>	15.01.18	<u>Privacy & Safety: Free From Abuse</u> <i>The patient has the right to be free from all forms of abuse or harassment.</i>
§482.13(d) §482.13(d)(1)	(1) <i>The patient has the right to the confidentiality of his or her clinical records.</i>	15.01.21	<u>Confidentiality of Patient Records: Confidentiality of Medical Records</u> <i>The patient has the right to the confidentiality of his or her clinical records.</i>
§482.13(d)(2)	(2) <i>The patient has the right to access information contained in his or her clinical records within a reasonable time frame.</i>	15.01.22	<u>Access to Medical Records</u> <i>The patient has the right to access information contained in his or her clinical records within a reasonable time frame. The hospital must not frustrate the legitimate efforts of individuals to gain access to their</i>

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	<p>(3) <i>The hospital must not frustrate the legitimate efforts of individuals to gain access to their own medical records and must actively seek to meet these requests as quickly as its record keeping system permits.</i></p>		<p><i>own medical records and must actively seek to meet these requests as quickly as its record keeping system permits.</i></p>
<p>§482.13(e)</p>	<p><i>Standard: Restraint or seclusion.</i></p> <p><i>All patients have the right to be free from physical or mental abuse, and corporal punishment. All patients have the right to be free from restraint or seclusion, of any form, imposed as a means of coercion, discipline, convenience, or retaliation by staff. Restraint or seclusion may only be imposed to ensure the immediate physical safety of the patient, a staff member, or others and must be discontinued at the earliest possible time.</i></p>	<p>15.01.09</p>	<p>Exercise of Patient Rights <i>The Patient's Rights document includes, at a minimum, that the patient has:</i></p> <ul style="list-style-type: none"> <i>A. The right to participate in the development and implementation of his or her plan of care;</i> <i>B. Or his or her representative (as allowed under state law) has the right to make informed decisions regarding his or her care. The patient's rights include being informed of his or her health status, being involved in care planning and treatment, and being able to request or refuse treatment. This right must not be construed as a mechanism to demand the provision of treatment or services deemed medically unnecessary to inappropriate;</i> <i>C. The right to formulate advance directives and to have hospital staff and practitioners who provide care in the hospital comply with these directives, in accordance with 489.100 of this part, 489.102 of this part, and 489.104 of this part;</i> <i>D. The right to have a family member or representative of his or her choice and his or her own physician notified promptly of his or her admission to the hospital;</i> <i>E. The right to personal privacy;</i> <i>F. The right to receive care in a safe setting;</i> <i>G. The right to be free from all forms of abuse or harassment;</i> <i>H. The right to the confidentiality of his or her clinical records;</i> <i>I. The right to access information contained in his or her clinical records within a reasonable time frame. The hospital must not frustrate the legitimate efforts of individuals to gain access to their own medical records and must actively seek to meet these requests as quickly as its record keeping system permits.</i> <i>J. The right to be free from restraints of any form that are not medically necessary or are used as a means of coercion,</i>

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		<p><i>discipline, convenience, or retaliation by staff;</i></p> <p>K. The right to be fully informed of and to consent or refuse to participate in any unusual, experimental or research project without compromising his / her access to services;</p> <p>L. The right to know the professional status of any person providing his / her care / services;</p> <p>M. The right to know the reasons for any proposed change in the Professional Staff responsible for his / her care;</p> <p>N. The right to know the reasons for his / her transfer either within or outside the hospital;</p> <p>O. The relationship(s) of the hospital to other persons or organizations participating in the provision of his / her care;</p> <p>P. The right of access to the cost, itemized when possible, of services rendered within a reasonable period of time;</p> <p>Q. The right to be informed of the source of the hospital's reimbursement for his / her services, and of any limitations which may be placed upon his / her care;</p> <p>R. Informed of the right to have pain treated as effectively as possible.</p> <p>S. A hospital must have written policies and procedures regarding the visitation rights of patients, including those setting forth any clinically necessary or reasonable restriction or limitation that the hospital may need to place on such rights and the reason for the clinical restriction or limitation. A hospital must meet the following requirements:</p> <ul style="list-style-type: none"> • Inform each patient (or support person, where appropriate) of his or her visitation rights, including any clinical restriction or limitation on such rights, when he or she is informed of his or her other rights under this section. • Inform each patient (or support person, where appropriate) of the right, subject to his or her consent, to receive the visitors whom he or she designates, including, but not limited to, a spouse, a domestic partner (including a same sex domestic partner), another family member, or a friend, and his or her right
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			<p>to withdraw or deny such consent at any time.</p> <ul style="list-style-type: none"> • Not restrict, limit or otherwise deny visitation privileges on the basis of race, color, national origin, religion, sex, gender identity, sexual orientation, or disability. • Ensure that all visitors enjoy full and equal visitation privileges consistent with patient preferences. <p>§482.13(h) (1)(2)(3)(4) (Revised January 18, 2011; effective January 18, 2011)</p> <p>T. The patient's family has the right of informed consent for donation of organs and tissues.</p>
		15.02.00	<p><u>Restraint or Seclusion</u> <i>All patients have the right to be free from physical or mental abuse, and corporal punishment. All patients have the right to be free from restraint or seclusion, of any form, imposed as a means of coercion, discipline, convenience, or retaliation by staff. Restraint or seclusion may only be imposed to ensure the immediate physical safety of the patient, a staff member, or others and must be discontinued at the earliest possible time.</i></p>
§482.13(e)(1)(i)(A)	<i>(1)(i)(A) Any manual method, physical or mechanical device, material, or equipment that immobilizes or reduces the ability of a patient to move his or her arms, legs, body, or head freely; or</i>	15.02.01	<p><u>Restraint Definitions</u> <i>A restraint is—</i></p> <ul style="list-style-type: none"> • <i>Any manual method, physical or mechanical device, material, or equipment that immobilizes or reduces the ability of a patient to move his or her arms, legs, body, or head freely;</i>
§482.13(e)(1)(i)(B)	<i>(1)(i)(B) A drug or medication when it is used as a restriction to manage the patient's behavior or restrict the patient's freedom of movement and is not a standard treatment or dosage for the patient's condition.</i>	15.02.02	<p><u>Medication as a Restraint</u> <i>A restraint is—</i></p> <ul style="list-style-type: none"> • <i>A drug or medication when it is used as a restriction to manage the patient's behavior or restrict the patient's freedom of movement and is not a standard treatment or dosage for the patient's condition.</i>

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§482.13(e)(1)(i)(C)	(1)(i)(C) A restraint does not include devices, such as orthopedically prescribed devices, surgical dressings or bandages, protective helmets, or other methods that involve the physical holding of a patient for the purpose of conducting routine physical examinations or tests, or to protect the patient from falling out of bed, or to permit the patient to participate in activities without the risk of physical harm (this does not include a physical escort).	15.02.03	<p>Non-Restraints A restraint does not include –</p> <ul style="list-style-type: none"> Devices, such as orthopedically prescribed devices, surgical dressings or bandages, protective helmets, or other methods that involve the physical holding of a patient for the purpose of conducting routine physical examinations or tests, or to protect the patient from falling out of bed, or to permit the patient to participate in activities without the risk of physical harm (this does not include a physical escort).
§482.13(e)(1)(ii)	(1)(ii) Seclusion is the involuntary confinement of a patient alone in a room or area from which the patient is physically prevented from leaving. Seclusion may only be used for the management of violent or self-destructive behavior.	15.02.04	<p>Definition of Seclusion Seclusion is the involuntary confinement of a patient alone in a room or area from which the patient is physically prevented from leaving. Seclusion may only be used for the management of violent or self-destructive behavior.</p>
§482.13(e)(2)	(2) Restraint or seclusion may only be used when less restrictive interventions have been determined to be ineffective to protect the patient a staff member or others from harm.	15.02.05	<p>Least Restrictive Interventions Restraint or seclusion may only be used when less restrictive interventions have been determined to be ineffective to protect the patient, a staff member, or others from harm.</p>
§482.13(e)(3)	(3) The type or technique of restraint or seclusion used must be the least restrictive intervention that will be effective to protect the patient, a staff member, or others from harm.	15.02.07	<p>Effective Restraints The type or technique of restraint or seclusion used must be the least restrictive intervention that will be effective to protect the patient, a staff member, or others from harm.</p>
§482.13(e)(4) §482.13(e)(4)(i)	(4) The use of restraint or seclusion must be— (i) In accordance with a written modification to the patient’s plan of care;	15.02.08	<p>Modification of the Plan of Care – Restraint or Seclusion The use of restraint or seclusion must be –</p> <ul style="list-style-type: none"> In accordance with a written modification to the patient’s plan of care.
§482.13(e)(4)(ii)	(4) The use of restraint or seclusion must be— (ii) Implemented in accordance with safe and appropriate restraint and seclusion techniques as determined by hospital policy in accordance with	15.02.09	<p>Safe Application The use of restraint or seclusion must be-</p> <ul style="list-style-type: none"> Implemented in accordance with safe and appropriate restraint

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	<i>State law.</i>		<i>and seclusion techniques as determined by hospital policy in accordance with State law.</i>
§482.13(e)(5)	(5) <i>The use of restraint or seclusion must be in accordance with the order of a physician or other licensed independent practitioner who is responsible for the care of the patient as specified under § 482.12(c) and authorized to order restraint or seclusion by hospital policy in accordance with State law.</i>	15.02.10	<p><u>Orders for Restraint or Seclusion</u> <i>The use of restraint or seclusion must be –</i></p> <ul style="list-style-type: none"> • <i>In accordance with the order of a physician or other licensed independent practitioner who is responsible for the care of the patient as specified under 482.12 (c) and authorized to order restraint or seclusion by hospital policy in accordance with State law.</i>
§482.13(e)(6)	(6) <i>Orders for the use of restraint or seclusion must never be written as a standing order or on an as needed basis (PRN).</i>	15.02.11	<p><u>Use of Standing or PRN Orders</u> <i>Orders for the use of restraint or seclusion must never be written as a standing order or on an as needed basis (PRN).</i></p>
§482.13(e)(7)	(7) <i>The attending physician must be consulted as soon as possible if the attending physician did not order the restraint or seclusion.</i>	15.02.12	<p><u>Physician Notification of Restraint Use</u> <i>The attending physician must be consulted as soon as possible if the attending physician did not order the restraint or seclusion.</i></p>
§482.13(e)(8)(i) §482.13(e)(8)(i)(A) §482.13(e)(8)(i)(B) §482.13(e)(8)(i)(C)	(8) <i>Unless superseded by State law that is more restrictive—</i> (i) <i>Each order for restraint or seclusion used for the management of violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others may only be renewed in accordance with the following limits for up to a total of 24 hours:</i> (A) <i>4 hours for adults 18 years of age or older;</i> (B) <i>2 hours for children and adolescents 9 to 17 years of age; or</i> (C) <i>1 hour for children under 9 years of age;</i>	15.02.13	<p><u>Restraint Orders for Management of Violent Behavior</u> <i>Unless superseded by State law that is more restrictive –</i> (i) <i>Each order for restraint or seclusion used for the management of violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others may only be renewed in accordance with the following limits for up to a total of 24 hours:</i> (A) <i>4 hours for adults 18 years of age or older;</i> (B) <i>2 hours for children and adolescents 9 to 17 years of age; or</i> (C) <i>1 hour for children under 9 years of age;</i></p>
§482.13(e)(8)(ii)	(8) <i>Unless superseded by State law that is more restrictive—</i> (ii) <i>After 24 hours, before writing a new order for the use of restraint or seclusion for the management of violent or self-destructive behavior, a physician or other licensed independent practitioner who is</i>	15.02.14	<p><u>Physician Assessment</u> <i>Unless superseded by State law that is more restrictive,</i></p> <ul style="list-style-type: none"> • <i>After 24 hours, before writing a new order for the use of restraint or seclusion for the management of violent or self-destructive</i>

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	<i>responsible for the care of the patient as specified under § 482.12(c) of this part and authorized to order restraint or seclusion by hospital policy in accordance with State law must see and assess the patient.</i>		<i>behavior, a physician or other licensed independent practitioner who is responsible for the care of the patient as specified under §482.12(c) of 42 CFR 482.12 and authorized to order restraint or seclusion by hospital policy in accordance with State law must see and assess the patient.</i>
§482.13(e)(8)(iii)	(8) Unless superseded by State law that is more restrictive— (iii) Each order for restraint used to ensure the physical safety of the nonviolent or non-self-destructive patient may be renewed as authorized by hospital policy.	15.02.15	Renewal of Restraint Orders <i>Unless superseded by State law that is more restrictive,</i> <ul style="list-style-type: none">• Each order for restraint used to ensure the physical safety of the non-violent or non-self-destructive patient may be renewed as authorized by hospital policy.
§482.13(e)(9)	(9) <i>Restraint or seclusion must be discontinued at the earliest possible time, regardless of the length of time identified in the order.</i>	15.02.16	Discontinuation of Restraints <i>Restraint or seclusion must be discontinued at the earliest possible time, regardless of the length of time identified in the order.</i>
§482.13(e)(10)	(10) <i>The condition of the patient who is restrained or secluded must be monitored by a physician, other licensed independent practitioner or trained staff that have completed the training criteria specified in paragraph (f) of this section at an interval determined by hospital policy.</i>	15.02.17	Monitoring of the Patient <i>The condition of the patient who is restrained or secluded must be monitored by a physician, other licensed independent practitioner or trained staff that have completed the training criteria specified in paragraph (f) of 42 CFR 482.13 at an interval determined by hospital policy.</i>
§482.13(e)(11)	(11) <i>Physician and other licensed independent practitioner training requirements must be specified in hospital policy. At a minimum, physicians and other licensed independent practitioners authorized to order restraint or seclusion by hospital policy in accordance with State law must have a working knowledge of hospital policy regarding the use of restraint or seclusion.</i>	15.02.18	Physician Training <i>Physician and other licensed independent practitioner training requirements must be specified in hospital policy. At a minimum, physicians and other licensed independent practitioners authorized to order restraint or seclusion by hospital policy in accordance with State law must have a working knowledge of hospital policy regarding the use of restraint or seclusion.</i>
§482.13(e)(12) §482.13(e)(12)(i) §482.13(e)(12)(i)(A) §482.13(e)(12)(i)(B)	(12) <i>When restraint or seclusion is used for the management of violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others, the patient must be seen face-to-face</i>	15.02.19	One Hour Face-to-Face <i>When restraint or seclusion is used for the management of violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others, the patient must be</i>

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	<p><i>within 1 hour after the initiation of the intervention—</i></p> <p>(1) <i>By a—</i></p> <p>(A) <i>Physician or other licensed independent practitioner; or</i></p> <p>(B) <i>Registered nurse or physician assistant who has been trained in accordance with the requirements specified in paragraph (f) of this section.</i></p>		<p><i>seen face-to-face within 1 hour after the initiation of the intervention</i></p> <p>–</p> <p>(i) <i>By a –</i></p> <p>(A) <i>Physician or other licensed independent practitioner; or</i></p> <p>(B) <i>Registered nurse or physician assistant who has been trained in accordance with the requirements specified in paragraph (f) of 42 CFR 482.13.</i></p>
<p>§482.13(e)(12)(ii) §482.13(e)(12)(ii)(A)) §482.13(e)(12)(ii)(B) §482.13(e)(12)(ii)(C) §482.13(e)(12)(ii)(D))</p>	<p>(12) <i>When restraint or seclusion is used for the management of violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others, the patient must be seen face-to-face within 1 hour after the initiation of the intervention—</i></p> <p>(ii) <i>To evaluate—</i></p> <p>(A) <i>The patient’s immediate situation;</i></p> <p>(B) <i>The patient’s reaction to the intervention;</i></p> <p>(C) <i>The patient’s medical and behavioral condition; and</i></p> <p>(D) <i>The need to continue or terminate the restraint or seclusion.</i></p>	15.02.20	<p>Physician Assessment Requirements</p> <p><i>When restraint or seclusion is used for the management of violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others, the patient must be seen face-to-face within 1 hour after the initiation of the intervention to evaluate –</i></p> <p>(A) <i>The patient’s immediate situation;</i></p> <p>(B) <i>The patient’s reaction to the intervention;</i></p> <p>(C) <i>The patient’s medical and behavioral condition; and</i></p> <p>(D) <i>The need to continue or terminate the restraint or seclusion.</i></p>
§482.13(e)(13)	<p>(13) <i>States are free to have requirements by statute or regulation that are more restrictive than those contained in paragraph (e)(12)(i) of this section.</i></p>	15.02.21	<p>State Requirements</p> <p><i>States are free to have requirements by statute or regulation that are more restrictive than those contained in paragraph (e)(12)(i) of 42 CFR 482.13.</i></p>
§482.13(e)(14)	<p>(14) <i>If the face-to-face evaluation specified in paragraph (e)(12) of this section is conducted by a trained registered nurse or physician assistant, the trained registered nurse or physician assistant must consult the attending physician or other licensed independent practitioner who is responsible for the care of the patient as specified under § 482.12(c) as soon as possible after the completion of the 1-hour face to-face evaluation.</i></p>	15.02.22	<p>Physician Notification</p> <p><i>If the face-to-face evaluation specified in paragraph (e)(12) of 42 CFR 482.13 is conducted by a trained registered nurse or physician assistant, the trained registered nurse or physician assistant must consult the attending physician or other licensed independent practitioner who is responsible for the care of the patient as specified under §482.12(c) as soon as possible after the completion of the 1 hour face-to-face evaluation.</i></p>

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<p>§482.13(e)(15)(i) §482.13(e)(15)(ii)</p>	<p>(15) All requirements specified under this paragraph are applicable to the simultaneous use of restraint and seclusion. Simultaneous restraint and seclusion use is only permitted if the patient is continually monitored—</p> <ul style="list-style-type: none"> (i) Face-to-face by an assigned, trained staff member; or (ii) By trained staff using both video and audio equipment. This monitoring must be in close proximity to the patient. 	<p>15.02.23</p>	<p>Simultaneous Use of Restraint and Seclusion All requirements specified under this paragraph are applicable to the simultaneous use of restraint and seclusion. Simultaneous restraint and seclusion use is only permitted if the patient is continually monitored:</p> <ul style="list-style-type: none"> (i) Face-to-face by an assigned, trained staff member; or (ii) By trained staff using both video and audio equipment. This monitoring must be in close proximity to the patient.
<p>§482.13(e)(16)(i)</p>	<p>(16) When restraint or seclusion is used, there must be documentation in the patient’s medical record of the following:</p> <ul style="list-style-type: none"> (i) The 1-hour face-to-face medical and behavioral evaluation if restraint or seclusion is used to manage violent or self-destructive behavior; 	<p>15.02.24</p>	<p>Requirements for Documentation When restraint or seclusion is used, there must be documentation in the patient’s medical record of the following:</p> <ul style="list-style-type: none"> (i) The 1-hour face-to-face medical and behavioral evaluation if restraint or seclusion is used to manage violent or self-destructive behavior;
<p>§482.13(e)(16)(ii)</p>	<p>(16) When restraint or seclusion is used, there must be documentation in the patient’s medical record of the following:</p> <ul style="list-style-type: none"> (ii) A description of the patient’s behavior and the intervention used; 	<p>15.02.25</p>	<p>Requirements for Documentation When restraint or seclusion is used, there must be documentation in the patient’s medical record of the following:</p> <ul style="list-style-type: none"> (ii) A description of the patient’s behavior and the intervention used;
<p>§482.13(e)(16)(iii)</p>	<p>(16) When restraint or seclusion is used, there must be documentation in the patient’s medical record of the following:</p> <ul style="list-style-type: none"> (iii) Alternatives or other less restrictive interventions attempted (as applicable); 	<p>15.02.26</p>	<p>Requirements for Documentation When restraint or seclusion is used, there must be documentation in the patient’s medical record of the following:</p> <ul style="list-style-type: none"> (iii) Alternatives or other less restrictive interventions attempted (as applicable);
<p>§482.13(e)(16)(iv)</p>	<p>(16) When restraint or seclusion is used, there must be documentation in the patient’s medical record of the following:</p> <ul style="list-style-type: none"> (iv) The patient’s condition or symptom(s) that warranted the use of the restraint or seclusion; and 	<p>15.02.27</p>	<p>Requirements for Documentation When restraint or seclusion is used, there must be documentation in the patient’s medical record of the following:</p> <ul style="list-style-type: none"> (iv) The patient’s condition or symptom(s) that warranted the use of the restraint or seclusion; and

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<p>§482.13(e)(16)(v)</p>	<p>(16) When restraint or seclusion is used, there must be documentation in the patient’s medical record of the following: (v) The patient’s response to the intervention(s) used, including the rationale for continued use of the intervention.</p>	<p>15.02.28</p>	<p>Requirements for Documentation When restraint or seclusion is used, there must be documentation in the patient’s medical record of: (v) The patient’s response to the interventions(s) used, including the rationale for continued use of the intervention.</p>
<p>§482.13(f)</p>	<p>Standard: Restraint or seclusion: Staff training requirements. The patient has the right to safe implementation of restraint or seclusion by trained staff.</p>	<p>15.02.29</p>	<p>Staff Training Requirements – Use of Restraints or Seclusion The patient has the right to safe implementation of restraint or seclusion by trained staff.</p>
<p>§482.13(f)(1) §482.13(f)(1)(i) §482.13(f)(1)(ii) §482.13(f)(1)(iii)</p>	<p>(1) Training intervals. Staff must be trained and able to demonstrate competency in the application of restraints, implementation of seclusion, monitoring, assessment, and providing care for a patient in restraint or seclusion— (i) Before performing any of the actions specified in this paragraph; (ii) As part of orientation; and (iii) Subsequently on a periodic basis consistent with hospital policy.</p>	<p>15.02.30</p>	<p>Training Intervals Training Intervals – Staff must be trained and able to demonstrate competency in the application of restraints, implementation of seclusion, monitoring, assessment, and providing care for a patient in restraint or seclusion – (i) Before performing any of the actions specified in this paragraph; (ii) As part of orientation; and (iii) Subsequently on a periodic basis consistent with hospital policy.</p>
<p>§482.13(f)(2)(i)</p>	<p>(2) Training content. The hospital must require appropriate staff to have education, training, and demonstrated knowledge based on the specific needs of the patient population in at least the following: (i) Techniques to identify staff and patient behaviors, events, and environmental factors that may trigger circumstances that require the use of a restraint or seclusion.</p>	<p>15.02.31</p>	<p>Training Content Training Content – The hospital must require appropriate staff to have education, training, and demonstrated knowledge based on the specific needs of the patient population in at least the following: (i) Techniques to identify staff and patient behaviors, events, and environmental factors that may trigger circumstances that require the use of a restraint or seclusion.</p>

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§482.13(f)(2)(ii)	(2) <i>Training content. The hospital must require appropriate staff to have education, training, and demonstrated knowledge based on the specific needs of the patient population in at least the following:</i> (ii) <i>The use of nonphysical intervention skills.</i>	15.02.32	<u>Training Requirements: Nonphysical Intervention</u> <i>Training Content –</i> <i>The hospital must require appropriate staff to have education, training, and demonstrated knowledge based on the specific needs of the patient population in at least the following:</i> (ii) <i>The use of nonphysical intervention skills.</i>
§482.13(f)(2)(iii)	(2) <i>Training content. The hospital must require appropriate staff to have education, training, and demonstrated knowledge based on the specific needs of the patient population in at least the following:</i> (iii) <i>Choosing the least restrictive intervention based on an individualized assessment of the patient’s medical, or behavioral status or condition.</i>	15.02.33	<u>Training Requirements: Least Restrictive Intervention</u> <i>Training Content –</i> <i>The hospital must require appropriate staff to have education, training, and demonstrated knowledge based on the specific needs of the patient population in at least the following:</i> (iii) <i>Choosing the least restrictive intervention based on an individualized assessment of the patient’s medical, or behavioral status or condition.</i>
§482.13(f)(2)(iv)	(2) <i>Training content. The hospital must require appropriate staff to have education, training, and demonstrated knowledge based on the specific needs of the patient population in at least the following:</i> (iv) <i>The safe application and use of all types of restraint or seclusion used in the hospital, including training in how to recognize and respond to signs of physical and psychological distress (for example, positional asphyxia);</i>	15.02.34	<u>Training Requirements: Safe Application</u> <i>Training Content –</i> <i>The hospital must require appropriate staff to have education, training, and demonstrated knowledge based on the specific needs of the patient population in at least the following:</i> (iv) <i>The safe application and use of all types of restraint or seclusion used in the hospital, including training in how to recognize and respond to signs of physical and psychological distress (for example, positional asphyxia).</i>
§482.13(f)(2)(v)	(2) <i>Training content. The hospital must require appropriate staff to have education, training, and demonstrated knowledge based on the specific needs of the patient population in at least the following:</i> (v) <i>Clinical identification of specific behavioral changes that indicate that restraint or seclusion is no longer necessary.</i>	15.02.35	<u>Training Requirements: Restraint Removal</u> <i>Training Content –</i> <i>The hospital must require appropriate staff to have education, training, and demonstrated knowledge based on the specific needs of the patient population in at least the following:</i> (v) <i>Clinical identification of specific behavioral changes that indicate that restraint or seclusion is no longer necessary.</i>

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§482.13(f)(2)(vi)	<p>(2) Training content. The hospital must require appropriate staff to have education, training, and demonstrated knowledge based on the specific needs of the patient population in at least the following:</p> <p>(vi) Monitoring the physical and psychological well-being of the patient who is restrained or secluded, including but not limited to, respiratory and circulatory status, skin integrity, vital signs, and any special requirements specified by hospital policy associated with the 1-hour face-to-face evaluation.</p>	15.02.36	<p><u>Training Requirements: Patient Monitoring</u> <i>Training Content –</i></p> <p><i>The hospital must require appropriate staff to have education, training, and demonstrated knowledge based on the specific needs of the patient population in at least the following:</i></p> <p><i>(vi) Monitoring the physical and psychological well-being of the patient who is restrained or secluded, including but not limited to, respiratory and circulatory status, skin integrity, vital signs, and any special requirements specified by hospital policy associated with the 1-hour face-to-face evaluation.</i></p>
§482.13(f)(2)(vii)	<p>(2) Training content. The hospital must require appropriate staff to have education, training, and demonstrated knowledge based on the specific needs of the patient population in at least the following:</p> <p>(vii) The use of first aid techniques and certification in the use of cardiopulmonary resuscitation, including required periodic recertification</p>	15.02.37	<p><u>Training Requirements: CPR Training</u> <i>Training Content –</i></p> <p><i>The hospital must require appropriate staff to have education, training, and demonstrated knowledge based on the specific needs of the patient population in at least the following:</i></p> <p><i>(vii) The use of first aid techniques and certification in the use of cardiopulmonary resuscitation, including required periodic recertification.</i></p>
§482.13(f)(3)	<p>(3) Trainer requirements. Individuals providing staff training must be qualified as evidenced by education, training, and experience in techniques used to address patients' behaviors.</p>	15.02.38	<p><u>Trainer Requirements</u> <i>Trainer Requirements.</i></p> <ul style="list-style-type: none"> • <i>Individuals providing staff training must be qualified as evidenced by education, training, and experience in techniques used to address patients' behaviors.</i>
§482.13(f)(4)	<p>(4) Training documentation. The hospital must document in the staff personnel records that the training and demonstration of competency were successfully completed.</p>	15.02.39	<p><u>Training Documentation</u> <i>Training Documentation.</i></p> <ul style="list-style-type: none"> • <i>The hospital must document in the staff personnel records that the training and demonstration of competency were successfully completed.</i>

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<p>§482.13(g) §482.13(g)(1)(i-iii) §482.13(g)(1)(i) §482.13(g)(1)(ii) §482.13(g)(1)(iii) §482.13(g)(2) §482.13(g)(2)(i) §482.13(g)(2)(ii) §482.13(g)(3) §482.13(g)(3)(i) §482.13(g)(3)(ii) §482.13(g)(4) §482.13(g)(4)(i) §482.13(g)(4)(ii) §482.13(g)(4)(iii)</p>	<p><i>Standard: Death reporting requirements: Hospitals must report deaths associated with the use of seclusion or restraint.</i></p> <p><i>(1) With the exception of deaths described under paragraph (g)(2) of this section, the hospital must report the following information to CMS by telephone, facsimile, or electronically, as determined by CMS, no later than the close of business on the next business day following knowledge of the patient's death:</i></p> <p><i>(i) Each death that occurs while a patient is in restraint or seclusion.</i></p> <p><i>(ii) Each death that occurs within 24 hours after the patient has been removed from restraint or seclusion.</i></p> <p><i>(iii) Each death known to the hospital that occurs within 1 week after restraint or seclusion where it is reasonable to assume that use of restraint or placement in seclusion contributed directly or indirectly to a patient's death, regardless of the type(s) of restraint used on the patient during this time. "Reasonable to assume" in this context includes, but is not limited to, deaths related to restrictions of movement for prolonged periods of time, or death related to chest compression, restriction of breathing, or asphyxiation.</i></p> <p><i>(2) When no seclusion has been used and when the only restraints used on the patient are those applied exclusively to the patient's wrist(s), and which are composed solely of soft, non-rigid, cloth-like materials, the hospital staff must record in an internal log or other system, the following information:</i></p> <p><i>(1) Any death that occurs while a patient is in such restraints.</i></p>	<p>15.02.41</p>	<p><u>Death Related to Restraint or Seclusion – Reporting Requirements.</u></p> <p><i>Hospitals must report deaths associated with the use of seclusion or restraint.</i></p> <p><i>1) With the exception of deaths described under paragraph(g)(2) of 42 CFR 482.13, the hospital must report the following information to CMS by telephone, facsimile, or electronically, as determined by CMS, no later than the close of business on the next business day following knowledge of the patient's death:</i></p> <p><i>i) Each death that occurs while a patient is in restraint or seclusion.</i></p> <p><i>ii) Each death that occurs within 24 hours after the patient has been removed from restraint or seclusion.</i></p> <p><i>iii) Each death known to the hospital that occurs within one (1) week after restraint or seclusion where it is reasonable to assume that use of restraint or placement in seclusion contributed directly or indirectly to a patient's death, regardless of the type(s) of restraint used on the patient during this time. "Reasonable to assume" in this context includes, but is not limited to, deaths related to restrictions of movement for prolonged periods of time, or death related to chest compression, restriction of breathing or asphyxiation.</i></p> <p><i>2) When no seclusion has been used and when the only restraints used on the patient are those applied exclusively to the patient's wrist(s), and which are composed solely of soft, non-rigid, cloth-like materials, the hospital staff must record in an internal log or other system, the following information:</i></p> <p><i>i) Any death that occurs while a patient is in such restraints</i></p> <p><i>ii) Any death that occurs within 24 hours after a patient has been removed from such restraints.</i></p> <p><i>3) Staff must document in the patient's medical record the date</i></p>
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	<p>(2) Any death that occurs within 24 hours after a patient has been removed from such restraints.</p> <p>(3) The staff must document in the patient's medical record the date and time the death was:</p> <p>(i) Reported to CMS for deaths described in paragraph (g)(1) of this section; or</p> <p>(ii) Recorded in the internal log or other system for deaths described in paragraph (g)(2) of this section.</p> <p>(4) For deaths described in paragraph (g)(2) of this section, entries into the internal log or other system must be documented as follows:</p> <p>(i) Each entry must be made not later than seven days after the date of death of the patient.</p> <p>(ii) Each entry must document the patient's name, date of birth, date of death, name of attending physician or other licensed independent practitioner who is responsible for the care of the patient as specified under §482.12(c), medical record number, and primary diagnosis(es).</p> <p>(iii) The information must be made available in either written or electronic form to CMS immediately upon request.</p>		<p>and time the death was:</p> <p>i) Reported to CMS for deaths described in paragraph (g)(1) of 42 CFR 482.13; or</p> <p>ii) Recorded in the internal log or other system for deaths described in item 2 of 42 CFR 482.13</p> <p>4) For deaths described in paragraph (g)(2) of 42 CFR 482.13, entries into the internal log or other system must be documented as follows:</p> <p>i) Each entry must be made not later than seven days after the date of death of the patient</p> <p>ii) Each entry must document the patient's name, date of birth, date of death, name of attending physician or other licensed independent practitioner who is responsible for the care of the patient as specified in §482.12(c), medical record number, and primary diagnosis(es).</p> <p>iii) The information must be made available in either written or electronic form to CMS immediately upon request.</p>
<p>§482.13(h)</p>	<p>A hospital must have written policies and procedures regarding the visitation rights of patients, including those setting forth any clinically necessary or reasonable restriction or limitation that the hospital may need to place on such rights and the reasons for the clinical restriction or limitation.</p>	<p>15.01.25</p>	<p><u>Visitation Rights</u> A hospital must have written policies and procedures regarding the visitation rights of patients, including those setting forth any clinically necessary or reasonable restriction or limitation that the hospital may need to place on such rights and the reasons for the clinical restriction or limitation.</p>
<p>§482.13(h)(1) §482.13(h)(2)</p>	<p>A hospital must have written policies and procedures regarding the visitation rights of patients, including those setting forth any clinically necessary or reasonable restriction or limitation that the hospital may need to place on such</p>	<p>15.01.26</p>	<p><u>Patient Visitation Rights</u> A hospital must have written policies and procedures regarding the visitation rights of patients, including those setting forth any clinically necessary or reasonable restriction or limitation that the hospital may</p>

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	<p><i>rights and the reasons for the clinical restriction or limitation.</i></p> <p><i>A hospital must meet the following requirements:</i></p> <p><i>(1) Inform each patient (or support person, where appropriate) of his or her visitation rights, including any clinical restriction or limitation on such rights, when he or she is informed of his or her other rights under this section.</i></p> <p><i>(2) Inform each patient (or support person, where appropriate) of the right, subject to his or her consent, to receive the visitors whom he or she designates, including, but not limited to, a spouse, a domestic partner (including a same sex domestic partner), another family member, or a friend, and his or her right to withdraw or deny such consent at any time.</i></p>		<p><i>need to place on such rights and the reason for the clinical restriction or limitation.</i></p> <p><i>A hospital must meet the following requirements:</i></p> <p><i>(1) Inform each patient (or support person, where appropriate) of his or her visitation rights, including any clinical restriction or limitation on such rights, when he or she is informed of his or her other rights under this section.</i></p> <p><i>(2) Inform each patient (or support person, where appropriate) of the right, subject to his or her consent, to receive the visitors whom he or she designates, including, but not limited to, a spouse, a domestic partner (including a same sex domestic partner), another family member, or a friend, and his or her right to withdraw or deny such consent at any time.</i></p>
<p>§482.13(h)(3) §482.13(h)(4)</p>	<p><i>A hospital must have written policies and procedures regarding the visitation rights of patients, including those setting forth any clinically necessary or reasonable restriction or limitation that the hospital may need to place on such rights and the reasons for the clinical restriction or limitation.</i></p> <p><i>A hospital must meet the following requirements:</i></p> <p><i>(3) Not restrict, limit, or otherwise deny visitation privileges on the basis of race, color, national origin, religion, sex, gender identity, sexual orientation, or disability.</i></p> <p><i>(4) Ensure that all visitors enjoy full and equal visitation privileges consistent with patient preferences.</i></p>	<p>15.01.28</p>	<p><u>Visitation Rights - Discrimination</u></p> <p><i>A hospital must have written policies and procedures regarding the visitation rights of patients, including those setting forth any clinically necessary or reasonable restriction or limitation that the hospital may need to place on such rights and the reason for the clinical restriction or limitation. A hospital must meet the following requirements:</i></p> <p><i>(iii) Not restrict, limit or otherwise deny visitation privileges on the basis of race, color, national origin, religion, sex, gender identity, sexual orientation, or disability.</i></p> <p><i>(iv) Ensure that all visitors enjoy full and equal visitation privileges consistent with patient preferences.</i></p>
<p>§482.13(h) §482.13(h)(1) §482.13(h)(2) §482.13(h)(3) §482.13(h)(4)</p>	<p><i>Standard: Patient visitation rights.</i></p> <p><i>A hospital must have written policies and procedures regarding the visitation rights of patients, including those setting forth any clinically necessary or reasonable restriction or limitation that the hospital may need to place on such rights and the reasons for the clinical restriction or limitation.</i></p>	<p>15.01.09</p>	<p><u>Exercise of Patient Rights</u></p> <p><i>The Patient's Rights document includes, at a minimum, that the patient has:</i></p> <p>A. <i>The right to participate in the development and implementation of his or her plan of care;</i></p> <p>B. <i>Or his or her representative (as allowed under state law) has the right to make informed decisions regarding his or her care. The</i></p>

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	<p><i>A hospital must meet the following requirements:</i></p> <ul style="list-style-type: none"> <i>(1) Inform each patient (or support person, where appropriate) of his or her visitation rights, including any clinical restriction or limitation on such rights, when he or she is informed of his or her other rights under this section.</i> <i>(2) Inform each patient (or support person, where appropriate) of the right, subject to his or her consent, to receive the visitors whom he or she designates, including, but not limited to, a spouse, a domestic partner (including a same sex domestic partner), another family member, or a friend, and his or her right to withdraw or deny such consent at any time.</i> <i>(3) Not restrict, limit, or otherwise deny visitation privileges on the basis of race, color, national origin, religion, sex, gender identity, sexual orientation, or disability.</i> <i>(4) Ensure that all visitors enjoy full and equal visitation privileges consistent with patient preferences.</i> 		<p><i>patient's rights include being informed of his or her health status, being involved in care planning and treatment, and being able to request or refuse treatment. This right must not be construed as a mechanism to demand the provision of treatment or services deemed medically unnecessary to inappropriate;</i></p> <ul style="list-style-type: none"> <i>C. The right to formulate advance directives and to have hospital staff and practitioners who provide care in the hospital comply with these directives, in accordance with 489.100 of this part, 489.102 of this part, and 489.104 of this part;</i> <i>D. The right to have a family member or representative of his or her choice and his or her own physician notified promptly of his or her admission to the hospital;</i> <i>E. The right to personal privacy;</i> <i>F. The right to receive care in a safe setting;</i> <i>G. The right to be free from all forms of abuse or harassment;</i> <i>H. The right to the confidentiality of his or her clinical records;</i> <i>I. The right to access information contained in his or her clinical records within a reasonable time frame. The hospital must not frustrate the legitimate efforts of individuals to gain access to their own medical records and must actively seek to meet these requests as quickly as its record keeping system permits.</i> <i>J. The right to be free from restraints of any form that are not medically necessary or are used as a means of coercion, discipline, convenience, or retaliation by staff;</i> <i>K. The right to be fully informed of and to consent or refuse to participate in any unusual, experimental or research project without compromising his / her access to services;</i> <i>L. The right to know the professional status of any person providing his / her care / services;</i> <i>M. The right to know the reasons for any proposed change in the Professional Staff responsible for his / her care;</i> <i>N. The right to know the reasons for his / her transfer either within or outside the hospital;</i> <i>O. The relationship(s) of the hospital to other persons or organizations participating in the provision of his / her care;</i> <i>P. The right of access to the cost, itemized when possible, of services rendered within a reasonable period of time;</i>
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			<p>Q. The right to be informed of the source of the hospital's reimbursement for his / her services, and of any limitations which may be placed upon his / her care;</p> <p>R. Informed of the right to have pain treated as effectively as possible.</p> <p>S. <i>A hospital must have written policies and procedures regarding the visitation rights of patients, including those setting forth any clinically necessary or reasonable restriction or limitation that the hospital may need to place on such rights and the reason for the clinical restriction or limitation. A hospital must meet the following requirements:</i></p> <ul style="list-style-type: none"> • <i>Inform each patient (or support person, where appropriate) of his or her visitation rights, including any clinical restriction or limitation on such rights, when he or she is informed of his or her other rights under this section.</i> • <i>Inform each patient (or support person, where appropriate) of the right, subject to his or her consent, to receive the visitors whom he or she designates, including, but not limited to, a spouse, a domestic partner (including a same sex domestic partner), another family member, or a friend, and his or her right to withdraw or deny such consent at any time.</i> • <i>Not restrict, limit or otherwise deny visitation privileges on the basis of race, color, national origin, religion, sex, gender identity, sexual orientation, or disability.</i> • <i>Ensure that all visitors enjoy full and equal visitation privileges consistent with patient preferences.</i> <p>482.13(h) (1)(2)(3)(4) (Revised January 18, 2011; effective January 18, 2011)</p> <p>T. The patient's family has the right of informed consent for donation of organs and tissues.</p>
<p>§482.21</p>	<p>Condition of participation: Quality assessment and performance improvement program. The hospital must develop, implement, and maintain an effective, ongoing, hospital-wide, data-driven quality</p>	<p>12.00.00</p>	<p><u>Condition of Participation: Quality Assessment Performance Improvement</u> <i>The hospital must develop, implement, and maintain an effective, ongoing, hospital-wide, data-driven quality assessment and</i></p>

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	<p>assessment and performance improvement program. The hospital's governing body must ensure that the program reflects the complexity of the hospital's organization and services; involves all hospital departments and services (including those services furnished under contract or arrangement); and focuses on indicators related to improved health outcomes and the prevention and reduction of medical errors. The hospital must maintain and demonstrate evidence of its QAPI program for review by CMS.</p>		<p><i>performance improvement program. The hospital's governing body must ensure that the program reflects the complexity of the hospital's organization and services; involves all hospital departments and services (including those services furnished under contract or arrangement); and focuses on indicators related to improved health outcomes and the prevention and reduction of medical errors. The hospital must maintain and demonstrate evidence of its QAPI program for review by CMS.</i></p>
		12.00.07	<p>STANDARD: Quality Assessment Performance Improvement. <i>The hospital's governing body must ensure that the program reflects the complexity of the hospital's organization and services; involves all hospital departments and services (including those services furnished under contract or arrangement); and focuses on indicators related to improved health outcomes and the prevention and reduction of medical errors.</i></p> <p><i>The hospital must maintain and demonstrate evidence of its QAPI program for review by CMS.</i></p>
<p>§482.21(a) §482.21(a)(1) §482.21(a)(2)</p>	<p>Standard: Program scope.</p> <p>(1) The program must include, but not be limited to, an ongoing program that shows measurable improvement in indicators for which there is evidence that it will improve health outcomes...</p> <p>(2) The hospital must measure, analyze, and track quality indicators...and other aspects of performance that assess processes of care, hospital service and operations.</p>	12.00.01	<p>Data Collection & Analysis: Program Scope.</p> <ul style="list-style-type: none"> • <i>The program must include, but not be limited to, an ongoing program that shows measurable improvement in indicators for which there is evidence that it will improve health outcomes and identify and reduce medical errors.</i> • <i>The hospital must measure, analyze, and track quality indicators, including adverse patient events, and other aspects of performance that assess processes of care, hospital service and operations.</i> • <i>The program must incorporate quality indicator data including patient care data, and other relevant data, for example, information submitted to, or received from, the hospital's Quality Improvement Organization (QIO).</i>

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			<ul style="list-style-type: none"> • <i>The hospital must use the data collected to monitor the effectiveness and safety of services and quality of care.</i> • <i>The frequency and detail of data collection must be specified by the hospital's governing body.</i>
		12.00.03	<p><u>Patient Safety, Medical Errors & Adverse Events.</u></p> <ul style="list-style-type: none"> • <i>The program must include, but not be limited to, an ongoing program that shows measurable improvement in indicators for which there is evidence that it will improve health outcomes and identify and reduce medical errors.</i> • <i>The hospital must measure, analyze, and track quality indicators, including adverse patient events, and other aspects of performance that assess processes of care, hospital service and operations.</i> <p><i>Performance improvement activities must:</i></p> <ul style="list-style-type: none"> • <i>track medical errors and adverse patient events,</i> • <i>analyze their causes, and</i> • <i>implement preventive actions and mechanisms that include feedback and learning throughout the hospital.</i> <p><i>The hospital's governing body (organized group or individual who assumes full legal authority and responsibility for operations of the hospital), medical staff, and administrative officials are responsible and accountable for ensuring the following:</i></p> <ul style="list-style-type: none"> • <i>That clear expectations for safety are established.</i>

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<p>§482.21(b) §482.21(b)(1) §482.21(b)(1)(i)</p> <p>§482.21(b)(2) §482.21(b)(2)(i) §482.21(b)(3)</p>	<p>(1) The program must incorporate quality indicator data including patient care data, and other relevant data, for example, information submitted to, or received from, the hospital's Quality Improvement Organization.</p> <p>(2) The hospital must use the data collected to--</p> <p style="padding-left: 40px;">(i) Monitor the effectiveness and safety of services and quality of care; and...</p> <p>(3) The frequency and detail of data collection must be specified by the hospital's governing body.</p>	<p style="text-align: center;">12.00.01</p>	<p>Data Collection & Analysis: Program Scope.</p> <ul style="list-style-type: none"> • <i>The program must include, but not be limited to, an ongoing program that shows measurable improvement in indicators for which there is evidence that it will improve health outcomes and identify and reduce medical errors.</i> • <i>The hospital must measure, analyze, and track quality indicators, including adverse patient events, and other aspects of performance that assess processes of care, hospital service and operations.</i> • <i>The program must incorporate quality indicator data including patient care data, and other relevant data, for example, information submitted to, or received from, the hospital's Quality Improvement Organization (QIO).</i> • <i>The hospital must use the data collected to monitor the effectiveness and safety of services and quality of care.</i> • <i>The frequency and detail of data collection must be specified by the hospital's governing body.</i>
<p>§482.21(b)(2)(ii)</p>	<p>(2) The hospital must use the data collected to—</p> <p style="padding-left: 40px;">(ii) Identify opportunities for improvement and changes that will lead to improvement.</p>	<p style="text-align: center;">12.00.02</p>	<p>Quality Improvement Program Activities.</p> <ul style="list-style-type: none"> • <i>The hospital must use the data collected to identify opportunities for improvement and changes that will lead to improvement.</i> • <i>The hospital must set priorities for its performance improvement activities that:</i> <ul style="list-style-type: none"> (i) <i>Focus on high-risk, high-volume, or problem-prone areas;</i> (ii) <i>Consider the incidence, prevalence, and severity of problems in those areas; and</i>

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			<p>(iii) <i>Affect health outcomes, patient safety and quality of care.</i></p> <ul style="list-style-type: none"> • <i>The hospital must take actions aimed at performance improvement and, after implementing those actions, the hospital must measure its success, and track performance to ensure that improvements are sustained.</i>
<p>§482.21(c) §482.21(c)(1) §482.21(c)(1)(i) §482.21(c)(1)(ii) §482.21(c)(1)(iii)</p>	<p>Standard: Program activities. (1) The hospital must set priorities for its performance improvement activities that—</p> <p>(i) Focus on high-risk, high-volume, or problem-prone areas;</p> <p>(ii) Consider the incidence, prevalence, and severity of problems in those areas; and</p> <p>(iii) Affect health outcomes, patient safety, and quality of care.</p>	<p>12.00.02</p>	<p>Quality Improvement Program Activities.</p> <ul style="list-style-type: none"> • <i>The hospital must use the data collected to identify opportunities for improvement and changes that will lead to improvement.</i> • <i>The hospital must set priorities for its performance improvement activities that:</i> <ul style="list-style-type: none"> (i) <i>Focus on high-risk, high-volume, or problem-prone areas;</i> (ii) <i>Consider the incidence, prevalence, and severity of problems in those areas; and</i> (iii) <i>Affect health outcomes, patient safety and quality of care.</i> • <i>The hospital must take actions aimed at performance improvement and, after implementing those actions, the hospital must measure its success, and track performance to ensure that improvements are sustained.</i>

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<p>§482.21(c)(2)</p>	<p>(2) Performance improvement activities must track medical errors and adverse patient events, analyze their causes, and implement preventive actions and mechanisms that include feedback and learning throughout the hospital.</p>	<p>12.00.03</p>	<p><u>Patient Safety, Medical Errors & Adverse Events.</u></p> <ul style="list-style-type: none"> • <i>The program must include, but not be limited to, an ongoing program that shows measurable improvement in indicators for which there is evidence that it will improve health outcomes and identify and reduce medical errors.</i> • <i>The hospital must measure, analyze, and track quality indicators, including adverse patient events, and other aspects of performance that assess processes of care, hospital service and operations.</i> <p><i>Performance improvement activities must:</i></p> <ul style="list-style-type: none"> • <i>track medical errors and adverse patient events,</i> • <i>analyze their causes, and</i> • <i>implement preventive actions and mechanisms that include feedback and learning throughout the hospital.</i> <p><i>The hospital's governing body (organized group or individual who assumes full legal authority and responsibility for operations of the hospital), medical staff, and administrative officials are responsible and accountable for ensuring the following:</i></p> <ul style="list-style-type: none"> • <i>That clear expectations for safety are established.</i>
<p>§482.21(c)(3)</p>	<p>(3) The hospital must take actions aimed at performance improvement and, after implementing those actions, the hospital must measure its success, and track performance to ensure that improvements are sustained.</p>	<p>12.00.02</p>	<p><u>Quality Improvement Program Activities.</u></p> <ul style="list-style-type: none"> • <i>The hospital must use the data collected to identify opportunities for improvement and changes that will lead to improvement.</i>

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			<ul style="list-style-type: none"> • <i>The hospital must set priorities for its performance improvement activities that:</i> <ul style="list-style-type: none"> (iv) <i>Focus on high-risk, high-volume, or problem-prone areas;</i> (v) <i>Consider the incidence, prevalence, and severity of problems in those areas; and</i> (vi) <i>Affect health outcomes, patient safety and quality of care.</i> • <i>The hospital must take actions aimed at performance improvement and, after implementing those actions, the hospital must measure its success, and track performance to ensure that improvements are sustained.</i>
<p>§482.21(d) §482.21(d)(1) §482.21(d)(2) §482.21(d)(3) §482.21(d)(4)</p>	<p>Standard: Performance improvement projects. As part of its quality assessment and performance improvement program, the hospital must conduct performance improvement projects.</p> <p>(1) The number and scope of distinct improvement projects conducted annually must be proportional to the scope and complexity of the hospital’s services and operations.</p> <p>(2) A hospital may, as one of its projects, develop and implement an information technology system explicitly designed to improve patient safety and quality of care. This project, in its initial stage of development, does not need to demonstrate measurable improvement in indicators related to health outcomes.</p> <p>(3) The hospital must document what quality improvement projects are being conducted, the reasons for conducting these projects, and the measurable progress achieved on</p>	<p style="text-align: center;">12.00.04</p>	<p>Performance Improvement Projects. <i>As part of its quality assessment and performance improvement program, the hospital must conduct performance improvement projects.</i></p> <p>(1) <i>The number and scope of distinct improvement projects conducted annually must be proportional to the scope and complexity of the hospital’s services and operations.</i></p> <p>(2) <i>A hospital may, as one of its projects, develop and implement an information technology system explicitly designed to improve patient safety and quality of care. This project, in its initial stage of development, does not need to demonstrate measurable improvement in indicators related to health outcomes.</i></p> <p>(3) <i>The hospital must document:</i></p> <ul style="list-style-type: none"> • <i>what quality assessment & performance improvement</i>

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	<p>these projects.</p> <p>(4) A hospital is not required to participate in a QIO cooperative project, but its own projects are required to be of comparable effort.</p>		<p><i>projects are being conducted,</i></p> <ul style="list-style-type: none"> • <i>the reasons for conducting these projects, and</i> • <i>the measurable progress achieved on these projects.</i> <p>(4) <i>A hospital is not required to participate in a QIO cooperative project but its own projects are required to be of comparable effort.</i></p>
<p>§482.21(e) §482.21(e)(1) §482.21(e)(2) §482.21(e)(5)</p>	<p><i>Standard: Executive responsibilities.</i> <i>The hospital's governing body (or organized group or individual who assumes full legal authority and responsibility for operations of the hospital), medical staff, and administrative officials are responsible and accountable for ensuring the following:</i></p> <p>(1) <i>That an ongoing program for quality improvement and patient safety, including the reduction of medical errors, is defined, implemented, and maintained.</i></p> <p>(2) <i>That the hospital-wide quality assessment and performance improvement efforts address priorities for improved quality of care and patient safety; and that all improvement actions are evaluated.</i></p> <p>(5) <i>That the determination of the number of distinct improvement projects is conducted annually.</i></p>	<p style="text-align: center;">12.00.05</p>	<p>12.00.05 Executive Responsibilities. <i>The hospital's governing body (organized group or individual who assumes full legal authority and responsibility for operations of the hospital), medical staff, and administrative officials are responsible and accountable for ensuring the following:</i></p> <p>(1) <i>That an ongoing program for quality improvement and patient safety, including the reduction of medical errors, is defined, implemented, and maintained;</i></p> <p>(2) <i>That the hospital-wide quality assessment and performance improvement efforts address priorities for improved quality of care and patient safety, and that all improvement actions are evaluated;</i></p> <p>(5) <i>That the determination of the number of distinct improvement projects is conducted annually.</i></p>

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<p>§482.21(e)(3)</p>	<p><i>The hospital's governing body (organized group or individual who assumes full legal authority and responsibility for operations of the hospital), medical staff, and administrative officials are responsible and accountable for ensuring the following:</i></p> <ul style="list-style-type: none"> • <i>That clear expectations for safety are established.</i> 	<p style="text-align: center;">12.00.03</p>	<p><u>Patient Safety, Medical Errors & Adverse Events.</u></p> <ul style="list-style-type: none"> • <i>The program must include, but not be limited to, an ongoing program that shows measurable improvement in indicators for which there is evidence that it will improve health outcomes and identify and reduce medical errors.</i> • <i>The hospital must measure, analyze, and track quality indicators, including adverse patient events, and other aspects of performance that assess processes of care, hospital service and operations.</i> <p><i>Performance improvement activities must:</i></p> <ul style="list-style-type: none"> • <i>track medical errors and adverse patient events,</i> • <i>analyze their causes, and</i> • <i>implement preventive actions and mechanisms that include feedback and learning throughout the hospital.</i> <p><i>The hospital's governing body (organized group or individual who assumes full legal authority and responsibility for operations of the hospital), medical staff, and administrative officials are responsible and accountable for ensuring the following:</i></p> <ul style="list-style-type: none"> • <i>That clear expectations for safety are established.</i>
<p>§482.21(e)(4)</p>	<p><i>The hospital's governing body (organized group or individual who assumes full legal authority and responsibility for operations of the hospital), medical staff, and administrative officials are responsible and accountable for ensuring the following:</i></p> <p>(3) <i>That adequate resources are allocated for measuring, assessing, improving, and sustaining the hospital's performance and reducing risk to patients.</i></p>	<p style="text-align: center;">12.00.06</p>	<p><u>Adequate Resources.</u></p> <p><i>The hospital's governing body (or organized group or individual who assumes full legal authority and responsibility for operations of the hospital), medical staff, and administrative officials are responsible and accountable for ensuring the following:</i></p> <ul style="list-style-type: none"> • <i>That adequate resources are allocated for measuring, assessing, improving, and sustaining the hospital's performance and reducing risk to patients.</i>

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§482.22	<p>Condition of participation: Medical staff. <i>The hospital must have an organized medical staff that operates under bylaws approved by the governing body and is responsible for the quality of medical care provided to patients by the hospital.</i></p>	03.00.00	<p>Condition of Participation: Medical Staff <i>The hospital must have an organized medical staff that operates under bylaws approved by the governing body, and which is responsible for the quality of medical care provided to patients by the hospital.</i></p>
§482.22(a)	<p><i>Standard: Eligibility and process for appointment to medical staff.</i> <i>The medical staff must be composed of doctors of medicine or osteopathy. In accordance with State law, including scope-of-practice laws, the medical staff may also include other categories of physicians (as listed at §482.12(c)(1)) and non-physician practitioners who are determined to be eligible for appointment by the governing body.</i></p>	03.00.01	<p>Composition of the Medical Staff <i>The medical staff must be composed of doctors of medicine or osteopathy. In accordance with State law, including scope-of-practice laws, the medical staff may also include other categories of physicians (as listed at §482.12(c)(1)) and non-physician practitioners who are determined to be eligible for appointment by the governing body.</i></p>
§482.22(a)(1)	<p>(1) <i>The medical staff must periodically conduct appraisals of its members.</i></p>	03.00.02	<p>Periodic Appraisal of Members <i>The Medical Staff must periodically conduct appraisals of its members.</i></p>
§482.22(a)(2)	<p>(2) <i>The medical staff must examine the credentials of all eligible candidates for medical staff membership and make recommendations to the governing body on the appointment of these candidates in accordance with State law, including scope-of-practice laws, and the medical staff bylaws, rules, and regulations. A candidate who has been recommended by the medical staff and who has been appointed by the governing body is subject to all medical staff bylaws, rules, and regulations, in addition to the requirements contained in this section.</i></p>	03.00.06	<p>Recommendation of Appointment to Governance. <i>The medical staff must examine the credentials of all eligible candidates for medical staff membership and make recommendations to the governing body on the appointment of these candidates in accordance with State law, including scope-of-practice laws, and the medical staff bylaws, rules, and regulations.</i></p> <p><i>A candidate who has been recommended by the medical staff and who has been appointed by the governing body is subject to all medical staff bylaws, rules, and regulations, in addition to the requirements contained in 42 CFR 482.22.</i></p>
§482.22(a)(3) §482.22(a)(3)(i) §482.22(a)(3)(ii)	<p>(3) <i>When telemedicine services are furnished to the hospital's patients through an agreement with a distant site hospital, the governing body of the hospital whose</i></p>	03.00.08	<p>Telemedicine Privileging Provisions Through Distant-Site Hospital Agreement <i>When telemedicine services are furnished to the hospital's patients</i></p>

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<p>§482.22(a)(3)(iii) §482.22(a)(3)(iv)</p>	<p>patients are receiving the telemedicine services may choose, in lieu of the requirements in paragraphs (a)(1) and (a)(2) of this section, to have its medical staff rely upon the credentialing and privileging decisions made by the distant-site hospital when making recommendations on privileges for the individual distant-site physicians and practitioners providing such services, if the hospital's governing body ensures, through its written agreement with the distant-site hospital, that all of the following provisions are met:</p> <ul style="list-style-type: none"> (i) The distant-site hospital providing the telemedicine services is a Medicare-participating hospital. (ii) The individual distant-site physician or practitioner is privileged at the distant-site hospital providing the telemedicine services, which provides a current list of the distant-site physician's or practitioner's privileges at the distant-site hospital. (iii) The individual distant-site physician or practitioner holds a license issued or recognized by the State in which the hospital whose patients are receiving the telemedicine services is located. (iv) With respect to a distant-site physician or practitioner, who holds current privileges at the hospital whose patients are receiving the telemedicine services, the hospital has evidence of an internal review of the distant-site physician's or practitioner's performance of these privileges and sends the distant-site hospital such performance information for use in the periodic appraisal of the distant-site physician or practitioner. At a minimum, this information must include all adverse events that result from the telemedicine services provided by the distant-site physician or practitioner to the hospital's patients and all complaints the hospital has received about the distant-site physician or practitioner. 	<p>through an agreement with a distant-site hospital, the governing body of the hospital whose patients are receiving the telemedicine services may choose, in lieu of the requirements in paragraphs (a)(1) and (a)(2) of 42 CFR 482.22, to have its medical staff rely upon the credentialing and privileging decisions made by the distant-site hospital when making recommendations on privileges for the individual distant-site physicians and practitioners providing such services, if the hospital's governing body ensures, through its written agreement with the distant-site hospital, that all of the following provisions are met:</p> <ul style="list-style-type: none"> (i) The distant-site hospital providing the telemedicine services is a Medicare participating hospital. (ii) The individual distant-site physician or practitioner is privileged at the distant-site hospital providing the telemedicine services, which provides a current list of the distant-site physician's or practitioner's privileges at the distant-site hospital. (iii) The individual distant-site physician or practitioner holds a license issued or recognized by the State in which the hospital whose patients are receiving the telemedicine services is located. (iv) With respect to a distant-site physician or practitioner, who holds current privileges at the hospital whose patients are receiving the telemedicine services, the hospital has evidence of an internal review of the distant-site physician's or practitioner's performance of these privileges and sends the distant-site hospital such performance information for use in the periodic appraisal of the distant-site physician or practitioner. At a minimum, this information must include all adverse events that result from the telemedicine services provided by the distant-site physician or practitioner to the hospital's patients and all complaints the hospital has received about the distant-site physician or practitioner.
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<p>§482.22(a)(4) §482.22(a)(4)(i) §482.22(a)(4)(ii) §482.22(a)(4)(iii) §482.22(a)(4)(iv)</p>	<p>(4) <i>When telemedicine services are furnished to the hospital’s patients through an agreement with a distant-site telemedicine entity, the governing body of the hospital whose patients are receiving the telemedicine services may choose, in lieu of the requirements in paragraphs (a)(1) and (a)(2) of this section, to have its medical staff rely upon the credentialing and privileging decisions made by the distant-site telemedicine entity when making recommendations on privileges for the individual distant-site physicians and practitioners providing such services, if the hospital’s governing body ensures, through its written agreement with the distant-site telemedicine entity, that the distant-site telemedicine entity furnishes services that, in accordance with § 482.12(e), permit the hospital to comply with all applicable conditions of participation for the contracted services. The hospital’s governing body must also ensure, through its written agreement with the distant-site telemedicine entity, that all of the following provisions are met:</i></p> <ul style="list-style-type: none"> (i) <i>The distant-site telemedicine entity’s medical staff credentialing and privileging process and standards at least meet the standards at §482.12(a)(1) through (a)(7) and § 482.22(a)(1) through (a)(2).</i> (ii) <i>The individual distant-site physician or practitioner is privileged at the distant-site telemedicine entity providing the telemedicine services, which provides the hospital with a current list of the distant-site physician’s or practitioner’s privileges at the distant-site telemedicine entity.</i> (iii) <i>The individual distant-site physician or practitioner holds a license issued or recognized by the State in which the hospital whose patients are receiving such telemedicine services is located.</i> (iv) <i>With respect to a distant-site physician or practitioner, who holds current privileges at the hospital whose patients are receiving the</i> 	<p>03.00.09</p>	<p><u>Telemedicine Privileging Provisions Through Distant-Site Telemedicine Entity Agreement</u> <i>When telemedicine services are furnished to the hospital’s patients through an agreement with a distant-site telemedicine entity, the governing body of the hospital whose patients are receiving the telemedicine services may choose, in accordance with the requirements at §482.22(a)(1) and §482.22(a)(2) of 42 CFR 482.22, to have its medical staff rely upon the credentialing and privileging decisions made by the distant-site telemedicine entity when making recommendations on privileges for the individual distant-site physicians and practitioners providing such services, if the hospital’s governing body ensures, through its written agreement with the distant-site telemedicine entity, that the distant-site telemedicine entity furnishes services that, in accordance with § 482.12(e), permit the hospital to comply with all applicable conditions of participation for the contracted services.</i></p> <p><i>The hospital’s governing body must also ensure, through its written agreement with the distant-site telemedicine entity, that all of the following provisions are met:</i></p> <ul style="list-style-type: none"> (i) <i>The distant-site telemedicine entity’s medical staff credentialing and privileging process and standards at least meet the standards at § 482.12(a)(1) through (a)(7) and § 482.22(a)(1) through (a)(2).</i> (ii) <i>The individual distant-site physician or practitioner is privileged at the distant-site telemedicine entity providing the telemedicine services, which provides the hospital with a current list of the distant-site physician’s or practitioner’s privileges at the distant-site telemedicine entity.</i> (iii) <i>The individual distant-site physician or practitioner holds a license issued or recognized by the state in which the hospital whose patients are receiving such telemedicine services is located.</i> (iv) <i>With respect to a distant-site physician or practitioner, who holds current privileges at the hospital whose patients are receiving the telemedicine services, the hospital has evidence of an internal review of the distant-site physician’s or</i>
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	<p><i>telemedicine services, the hospital has evidence of an internal review of the distant-site physician’s or practitioner’s performance of these privileges and sends the distant-site telemedicine entity such performance information for use in the periodic appraisal of the distant-site physician or practitioner. At a minimum, this information must include all adverse events that result from the telemedicine services provided by the distant-site physician or practitioner to the hospital’s patients, and all complaints the hospital has received about the distant-site physician or practitioner.</i></p>		<p><i>practitioner’s performance of these privileges and sends the distant-site telemedicine entity such performance information for use in the periodic appraisal of the distant-site physician or practitioner. At a minimum, this information must include all adverse events that result from the telemedicine services provided by the distant-site physician or practitioner to the hospital’s patients, and all complaints the hospital has received about the distant-site physician or practitioner.</i></p>
<p>§482.22(b) §482.22(b)(1) §482.22(b)(2) §482.22(b)(3) §482.22(b)(3)(i) §482.22(b)(3)(ii) §482.22(b)(3)(iii)</p>	<p><i>(b) Standard: Medical staff organization and accountability.</i></p> <p><i>The medical staff must be well organized and accountable to the governing body for the quality of the medical care provided to patients.</i></p> <p>(1) <i>The medical staff must be organized in a manner approved by the governing body.</i></p> <p>(2) <i>If the medical staff has an executive committee, a majority of the members of the committee must be doctors of medicine or osteopathy.</i></p> <p>(3) <i>The responsibility for organization and conduct of the medical staff must be assigned only to one of the following:</i></p> <p>(i) <i>An individual doctor of medicine or osteopathy.</i></p> <p>(ii) <i>A doctor of dental surgery or dental medicine, when permitted by State law of the State in which the hospital is located.</i></p> <p>(iii) <i>A doctor of podiatric medicine, when permitted by State law of the State in which the hospital is located.</i></p>	<p style="text-align: center;">03.00.10</p>	<p>Medical Staff Responsibilities to the Governing Body.</p> <p>(1) <i>The Medical Staff must be well organized and accountable to the governing body for the quality of the medical care provided to the patients. The medical staff must be organized in a manner approved by the governing body.</i></p> <p>(2) <i>If the medical staff has an executive committee, a majority of the members of the committee must be doctors of medicine or osteopathy.</i></p> <p>(3) <i>The responsibility for organization and conduct of the medical staff must be assigned only to one of the following:</i></p> <p>(i) <i>An individual doctor of medicine or osteopathy.</i></p> <p>(ii) <i>A doctor of dental surgery or dental medicine, when permitted by State law of the State in which the hospital is located.</i></p> <p>(iii) <i>A doctor of podiatric medicine, when permitted by State law of the State in which the hospital is located.</i></p>

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<p>§482.22(b)(4)</p>	<p><i>If a hospital is part of a hospital system consisting of multiple separately certified hospitals and the system elects to have a unified and integrated medical staff for its member hospitals, after determining that such a decision is in accordance with all applicable State and local laws, each separately certified hospital must demonstrate that:</i></p>	<p>03.00.11</p>	<p><u>Multiple-Hospital Systems: Unified and Integrated Medical Staff.</u> <i>If a hospital is part of a hospital system consisting of multiple separately certified hospitals and the system elects to have a unified and integrated medical staff for its member hospitals, after determining that such a decision is in accordance with all applicable State and local laws, each separately certified hospital must demonstrate that...</i></p>
<p>§482.22(b)(4) §482.22(b)(4)(i)</p>	<p>(i) <i>The medical staff members of each separately certified hospital in the system (that is, all medical staff members who hold specific privileges to practice at that hospital) have voted by majority, in accordance with medical staff bylaws, either to accept a unified and integrated medical staff structure or to opt out of such a structure and to maintain a separate and distinct medical staff for their respective hospital;</i></p>	<p>03.00.12</p>	<p><u>Voting Requirements for Separately Certified Hospitals.</u> <i>If a hospital is part of a hospital system consisting of multiple separately certified hospitals and the system elects to have a unified and integrated medical staff for its member hospitals, after determining that such a decision is in accordance with all applicable State and local laws, each separately certified hospital must demonstrate that:</i></p> <p>(i) <i>The medical staff members of each separately certified hospital in the system (that is, all medical staff members who hold specific privileges to practice at that hospital) have voted by majority, in accordance with medical staff bylaws, either to accept a unified and integrated medical staff structure or to opt out of such a structure and to maintain a separate and distinct medical staff for their respective hospital.</i></p>
<p>§482.22(b)(4) §482.22(b)(4)(ii)</p>	<p>(ii) <i>The unified and integrated medical staff has bylaws, rules, and requirements that describe its processes for self-governance, appointment, credentialing, privileging, and oversight, as well as its peer review policies and due process rights guarantees, and which include a process for the members of the medical staff of each separately certified hospital (that is, all medical staff members who hold specific privileges to practice at that hospital) to be advised of their rights to opt out of the unified and integrated medical staff structure after a majority vote by the</i></p>	<p>03.00.13</p>	<p><u>Medical Staff: Bylaws of the Unified Medical Staff.</u> <i>If a hospital is part of a hospital system consisting of multiple separately certified hospitals and the system elects to have a unified and integrated medical staff for its member hospitals, after determining that such a decision is in accordance with all applicable State and local laws, each separately certified hospital must demonstrate that:</i></p> <p>(ii) <i>The unified and integrated medical staff has bylaws, rules, and requirements that describe its processes for self-governance, appointment, credentialing, privileging, and oversight, as well as its peer review policies and due process rights guarantees, and</i></p>

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	<p><i>members to maintain a separate and distinct medical staff for their hospital;</i></p>		<p><i>which include a process for the members of the medical staff of each separately certified hospital (that is, all medical staff members who hold specific privileges to practice at that hospital) to be advised of their rights to opt out of the unified and integrated medical staff structure after a majority vote by the members to maintain a separate and distinct medical staff for their hospital.</i></p>
<p>§482.22(b)(4) §482.22(b)(4)(iii)</p>	<p>(iii) <i>The unified and integrated medical staff is established in a manner that takes into account each member hospital's unique circumstances and any significant differences in patient populations and services offered in each hospital; and</i></p>	<p>03.00.14</p>	<p>Multiple-Hospital Systems: Unique Circumstances. <i>If a hospital is part of a hospital system consisting of multiple separately certified hospitals and the system elects to have a unified and integrated medical staff for its member hospitals, after determining that such a decision is in accordance with all applicable State and local laws, each separately certified hospital must demonstrate that:</i></p> <p>(iii) <i>The unified and integrated medical staff is established in a manner that takes into account each member hospital's unique circumstances and any significant differences in patient populations and service.</i></p>
<p>§482.22(b)(4) §482.22(b)(4)(iv)</p>	<p>(iv) <i>The unified and integrated medical staff establishes and implements policies and procedures to ensure that the needs and concerns expressed by members of the medical staff, at each of its separately certified hospitals, regardless of practice or location, are given due consideration, and that the unified and integrated medical staff has mechanisms in place to ensure that issues localized to particular hospitals are duly considered and addressed.</i></p>	<p>03.00.15</p>	<p>Medical Staff: Policies of the Unified Medical Staff. <i>If a hospital is part of a hospital system consisting of multiple separately certified hospitals and the system elects to have a unified and integrated medical staff for its member hospitals, after determining that such a decision is in accordance with all applicable State and local laws, each separately certified hospital must demonstrate that:</i></p> <p>(iv) <i>The unified and integrated medical staff establishes and implements policies and procedures to ensure that the needs and concerns expressed by members of the medical staff, at each of its separately certified hospitals, regardless of practice or location, are given due consideration, and that the unified and integrated medical staff has mechanisms in place to ensure that issues localized to particular hospitals are duly considered and addressed.</i></p>

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§482.22(c)	<p><i>Standard: Medical staff bylaws.</i> <i>The medical staff must adopt and enforce bylaws to carry out its responsibilities.</i></p>	03.01.01	<p><u>Medical Staff Bylaws</u> <i>The medical staff must adopt and enforce bylaws to carry out its responsibilities.</i></p>
§482.22(c)(1)	<p><i>The bylaws must:</i> (1) <i>Be approved by the governing body.</i></p>	03.01.02	<p><u>Medical Staff Bylaws: Approval by Governance.</u> <i>The bylaws must:</i></p> <ul style="list-style-type: none"> • <i>Be approved by the governing body.</i>
§482.22(c)(2)	<p><i>The bylaws must:</i> (2) <i>Include a statement of the duties and privileges of each category of medical staff (e.g., active, courtesy, etc.)</i></p>	03.01.03	<p><u>Medical Staff Bylaws: Categories, Duties, & Responsibilities of the Medical Staff.</u> <i>The bylaws must:</i></p> <ul style="list-style-type: none"> • <i>Include a statement of the duties and privileges of each category of medical staff (e.g., active, courtesy, etc.).</i>
§482.22(c)(3)	<p><i>The bylaws must:</i> (3) <i>Describe the organization of the medical staff.</i></p>	03.01.04	<p><u>Medical Staff Bylaws: Organization of the Medical Staff.</u> <i>The bylaws must:</i></p> <ul style="list-style-type: none"> • <i>Describe the organization of the medical staff.</i>
§482.22(c)(4)	<p><i>The bylaws must:</i> (4) <i>Describe the qualifications to be met by a candidate in order for the medical staff to recommend that the candidate be appointed by the governing body.</i></p>	03.01.06	<p><u>Medical Staff Bylaws: Process for Application, Reapplication, & Criteria for Membership.</u> <i>The bylaws must:</i></p> <ul style="list-style-type: none"> • <i>Describe the qualifications to be met by a candidate in order for the medical staff to recommend that the candidate be appointed by the governing body.</i>
§482.22(c)(5)(i)	<p><i>The bylaws must:</i> (5) <i>Include a requirement that—</i> (i) <i>A medical history and physical examination be completed and documented for each patient no more than 30 days before or 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia services. The medical history and physical examination must be completed and documented by a physician</i></p>	03.01.07	<p><u>Bylaws - History & Physical Requirement.</u> <i>The bylaws must include:</i></p> <ul style="list-style-type: none"> (i) <i>A medical history and physical be completed and documented for each patient no more than 30 days before or 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia services. The medical history and physical examination must be completed and documented by a physician (as defined in section 1861 (r) of</i>

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	<i>(as defined in section 1861(r) of the Act), an oromaxillofacial surgeon, or other qualified licensed individual in accordance with State law and hospital policy.</i>		<i>the Act) (Social Security Act), an oromaxillofacial surgeon, or other qualified licensed individual in accordance with state law and hospital policy.</i>
§482.22(c)(5)(ii)	<p>The bylaws must:</p> <p>(5) Include a requirement that—</p> <p>(ii) An updated examination of the patient, including any changes in the patient’s condition, be completed and documented within 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia services, when the medical history and physical examination are completed within 30 days before admission or registration. The updated examination of the patient, including any changes in the patient’s condition, must be completed and documented by a physician (as defined in section 1861(r) of the Act), an oromaxillofacial surgeon, or other qualified licensed individual in accordance with State law and hospital policy.</p>	03.01.08	<p>History and Physical prior to admission.</p> <p>The bylaws must include a requirement that:</p> <p>(ii) An updated examination of the patient, including any changes in the patient’s condition, be completed and documented within 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia services, when the medical history and physical examination are completed within 30 days before admission or registration. The updated examination of the patient, including any changes in the patient’s condition, must be completed and documented by a physician (as defined in section 1861 (r) of the Act) (Social Security Act), an oromaxillofacial surgeon, or other qualified licensed individual in accordance with state law and hospital policy.</p>
§482.22(c)(6)	<p>The bylaws must:</p> <p>(6) Include criteria for determining the privileges to be granted to individual practitioners and a procedure for applying the criteria to individuals requesting privileges.</p> <p>For distant-site physicians and practitioners requesting privileges to furnish telemedicine services under an agreement with the hospital, the criteria for determining privileges and the procedure for applying the criteria are also subject to the requirements in § 482.12(a)(8) and (a)(9), and § 482.22(a)(3) and (a)(4).</p>	03.01.09	<p>Bylaws - Granting of Privileges</p> <p>The bylaws must:</p> <p>Include criteria for determining the privileges to be granted to individual practitioners and a procedure for applying the criteria to individuals requesting privileges.</p> <p>For distant-site physicians and practitioners requesting privileges to furnish telemedicine services under an agreement with the hospital, the criteria for determining privileges and the procedure for applying the criteria are also subject to the requirements in §482.12(a)(8) and (a)(9), and §482.22(a)(3) and (a)(4).</p>

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§482.22(d)	<p><i>Standard: Autopsies.</i> <i>The medical staff should attempt to secure autopsies in all cases of unusual deaths and of medical-legal and educational interest. The mechanism for documenting permission to perform an autopsy must be defined. There must be a system for notifying the medical staff, and specifically the attending practitioner, when an autopsy is being performed.</i></p>	03.02.01	<p><u>Autopsies</u> <i>The medical staff should attempt to secure autopsies in all cases of unusual deaths and of medical-legal and educational interest. The mechanism for documenting permission to perform an autopsy must be defined. There must be a system for notifying the medical staff, and specifically the attending practitioner, when an autopsy is being performed.</i></p>
§482.23	<p><i>Condition of participation: Nursing services.</i> <i>The hospital must have an organized nursing service that provides 24-hour nursing services. The nursing services must be furnished or supervised by a registered nurse.</i></p>	16.00.00	<p><u>Condition of Participation: Nursing Services</u> <i>The hospital must have an organized Nursing Service that provides 24-hour Nursing services. The nursing services must be furnished or supervised by a registered nurse.</i></p>
§482.23(a)	<p><i>Standard: Organization.</i> <i>The hospital must have a well-organized service with a plan of administrative authority and delineation of responsibilities for patient care.</i></p> <p><i>The director of the nursing service must be a licensed registered nurse. He or she is responsible for the operation of the service, including determining the types and numbers of nursing personnel and staff necessary to provide nursing care for all areas of the hospital.</i></p>	16.00.03	<p><u>Nursing Organization</u> <i>The hospital must have a well-organized service with a plan of administrative authority and delineation of responsibilities for patient care.</i></p> <p><i>The director of the nursing service must be a licensed registered nurse. He or she is responsible for the operation of the service, including determining the types and numbers of nursing personnel and staff necessary to provide nursing care for all areas of the hospital.</i></p>
§482.23(b)	<p><i>Standard: Staffing and delivery of care.</i> <i>The nursing service must have adequate numbers of licensed registered nurses, licensed practical (vocational) nurses, and other personnel to provide nursing care to all patients as needed. There must be supervisory and staff personnel for each department or nursing unit to ensure, when needed, the immediate availability of a registered nurse for bedside care of any patient.</i></p>	16.00.04	<p><u>Staffing and Delivery of Care.</u> <i>The nursing service must have an adequate number of licensed registered nurses, licensed practical (vocational) nurses, and other personnel to provide nursing care to all patients as needed. There must be supervisory and staff personnel for each department or nursing unit to ensure, when needed, the immediate availability of a registered nurse for bedside care of any patient.</i></p>

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§482.23(b)(1)	(1) <i>The hospital must provide 24-hour nursing services furnished or supervised by a registered nurse, and have a licensed practical nurse or registered nurse on duty at all times, except for rural hospitals that have in effect a 24-hour nursing waiver granted under § 488.54(c) of this chapter.</i>	16.00.05	<u>24-Hour Provision of Services</u> <i>The hospital must provide 24-hour nursing services furnished or supervised by a registered nurse, and have a licensed practical nurse or registered nurse on duty at all times, except for rural hospitals that have in effect a 24 –hour nursing waiver granted under 488.54(c) of 42 CFR 482.54 .</i>
§482.23(b)(2)	(2) <i>The nursing service must have a procedure to ensure that hospital nursing personnel for whom licensure is required have valid and current licensure.</i>	16.00.06	<u>Licensure</u> <i>The nursing service must have a procedure to ensure that the hospital nursing personnel for whom licensure is required have valid and current licensure.</i>
§482.23(b)(3)	(3) <i>A registered nurse must supervise and evaluate the nursing care for each patient.</i>	16.00.09	<u>Supervision of Care</u> <i>A registered nurse must supervise and evaluate the nursing care for each patient.</i>
§482.23(b)(4)	(4) <i>The hospital must ensure that the nursing staff develops, and keeps current, a nursing care plan for each patient. The nursing care plan may be part of an interdisciplinary care plan.</i>	16.00.10	<u>Plan of Care</u> <i>The hospital must ensure that the nursing staff develops, and keeps current, a nursing care plan for each patient. The nursing care plan may be part of an interdisciplinary care plan.</i>
§482.23(b)(5)	(5) <i>A registered nurse must assign the nursing care of each patient to other nursing personnel in accordance with the patient’s needs and the specialized qualifications and competence of the nursing staff available.</i>	16.00.11	<u>Care Assignments</u> <i>A registered nurse must assign the nursing care of each patient to nursing personnel in accordance with the patient’s needs and the specialized qualifications and competence of the nursing staff available.</i>
§482.23(b)(6)	(6) <i>Non-employee licensed nurses who are working in the hospital must adhere to the policies and procedures of the hospital. The director of nursing service must provide for the adequate supervision and evaluation of the clinical activities of non-employee nursing personnel which occur within the responsibility of the nursing service.</i>	16.00.13	<u>Supervision of Non-Employee Staff</u> <i>Non-employee licensed nurses who are working in the hospital must adhere to the policies and procedures of the hospital. The director of nursing service must provide for the adequate supervision and evaluation of the clinical activities of non-employee nursing personnel that occur within the responsibility of the nursing services.</i>
§482.23(c) §482.23(c)(1) §482.23(c)(1)(i)	(c) <i>Standard: Preparation and administration of drugs.</i> (1) <i>Drugs and biologicals must be prepared and administered in accordance with Federal and State laws,</i>	16.01.01	<u>Preparation and Administration of Drugs</u> (1) <i>Drugs and biologicals must be prepared and administered in accordance with Federal and State laws, the orders of the</i>

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	<p><i>the orders of the practitioner or practitioners responsible for the patient's care as specified under §482.12(c), and accepted standards of practice.</i></p> <p><i>(i) Drugs and biologicals may be prepared and administered on the orders of other practitioners not specified under §482.12(c) only if such practitioners are acting in accordance with State law, including scope-of-practice laws, hospital policies, and medical staff bylaws, rules, and regulations.</i></p>		<p><i>practitioner or practitioners responsible for the patient's care as specified under §482.12(c), and accepted standards of practice.</i></p> <p><i>(i) Drugs and biological may be prepared and administered on the orders of other practitioners not specified under 482.12(c) only if such practitioners are acting in accordance with State law, including scope-of-practice laws, hospital policies, and medical staff bylaws, rules and regulations.</i></p>
§482.23(c)(1)(ii)	<p><i>(ii) Drugs and biologicals may be prepared and administered on the orders contained within pre-printed and electronic standing orders, order sets, and protocols for patient orders only if such orders meet the requirements of §482.24(c)(3).</i></p>	16.01.03	<p><u>Medication Orders.</u> <i>Drugs and biologicals may be prepared and administered on the orders contained within pre-printed and electronic standing orders, order sets, and protocols for patient orders only if such orders meet the requirements of §482.12(c)(3).</i></p>
§482.23(c)(2)	<p><i>(2) All drugs and biologicals must be administered by, or under supervision of, nursing or other personnel in accordance with Federal and State laws and regulations, including applicable licensing requirements, and in accordance with the approved medical staff policies and procedures.</i></p>	16.01.01	<p><u>Medication Administration Oversight</u> <i>All drugs and biologicals must be administered by, or under supervision of, nursing or other personnel in accordance with Federal and State laws and regulations, including applicable licensing requirements, and in accordance with the approved medical staff policies and procedures.</i></p>
§482.23(c)(3)	<p><i>(3) With the exception of influenza and pneumococcal vaccines, which may be administered per physician-approved hospital policy after an assessment of contraindications, orders for drugs and biologicals must be documented and signed by a practitioner who is authorized to write orders in accordance with State law and hospital policy, and who is responsible for the care of the patient as specified under §482.12(c).</i></p>	16.01.03	<p><u>Medication Orders</u> <i>With the exception of influenza and pneumococcal vaccines, which may be administered per physician-approved hospital policy after an assessment of contraindications, orders for drugs and biologicals must be documented and signed by a practitioner who is authorized to write orders by hospital policy and in accordance with State law, and who is responsible for the care of the patient as specified under §482.12(c).</i></p>
§482.23(c)(3)(i)	<p><i>(i) If verbal orders are used, they are to be used infrequently.</i></p>	16.01.04	<p><u>Verbal Orders</u> <i>If verbal orders are used, they are to be used infrequently.</i></p>

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§482.23(c)(3)(ii)	(ii) <i>When verbal orders are used, they must only be accepted by persons who are authorized to do so by hospital policy and procedures consistent with Federal and State law.</i>	16.01.05	<p><u>Accepting Verbal Orders</u> <i>When verbal orders are used, they must only be accepted by persons who are authorized to do so by hospital policy and procedures consistent with Federal and State law.</i></p>
§482.23(c)(3)(iii)	(iii) <i>Orders for drugs and biologicals may be documented and signed by other practitioners not specified under §482.12(c) only if such practitioners are acting in accordance with State law, including scope-of-practice laws, hospital policies, and medical staff bylaws, rules, and regulations.</i>	16.01.03	<p><u>Medication Orders</u> <i>Orders for drugs and biologicals may be documented and signed by other practitioners not specified under 482.12(c) only if such practitioners are acting in accordance with State law, including scope-of-practice laws, hospital policies, and medical staff bylaws, rules, and regulations.</i></p>
§482.23(c)(4)	(4) <i>Blood transfusions and intravenous medications must be administered in accordance with State law and approved medical staff policies and procedures.</i>	16.01.06	<p><u>Administration of Blood Products & IV Medications</u> <i>Blood transfusions and intravenous medications must be administered in accordance with state law and approved medical staff policies and procedures.</i></p>
§482.23(c)(5)	(5) <i>There must be a hospital procedure for reporting transfusion reactions, adverse drug reactions, and errors in administration of drugs.</i>	16.01.07	<p><u>Adverse Drug Reactions, Transfusion Reactions & Medical Error Reporting</u> <i>There must be a hospital procedure for reporting transfusion reactions, adverse drug reactions, and errors in administration of drugs.</i></p>
§482.23(c)(6)(i) §482.23(c)(6)(i)(A) §482.23(c)(6)(i)(B) §482.23(c)(6)(i)(C) §482.23(c)(6)(i)(D) §482.23(c)(6)(i)(E)	(6) <i>The hospital may allow a patient (or his or her caregiver/support person where appropriate) to self-administer both hospital-issued medications and the patient's own medications brought into the hospital, as defined and specified in the hospital's policies and procedures.</i> (i) <i>If the hospital allows a patient to self-administer specific hospital-issued medications, then the hospital must have policies and procedures in place to:</i> (A) <i>Ensure that a practitioner responsible for the care of the patient has issued an order, consistent with hospital policy, permitting self-administration.</i> (B) <i>Assess the capacity of the patient (or the patient's</i>	16.01.09	<p><u>Self-Administration of Medications: Hospital-Issued Medications</u> <i>The hospital may allow a patient (or his or her caregiver/support person where appropriate) to self-administer both hospital-issued medications and the patient's own medications brought into the hospital, as defined and specified in the hospital's policies and procedures.</i> <i>If the hospital allows a patient to self-administer specific hospital-issued medications, then the hospital must have policies and procedures in place to:</i> (A) <i>Ensure that a practitioner responsible for the care of the patient has issued an order, consistent with hospital policy, permitting self-administration.</i></p>

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	<p><i>caregiver/support person where appropriate) to self-administer the specified medication(s).</i></p> <p>(C) <i>Instruct the patient (or the patient's caregiver/support person where appropriate) in the safe and accurate administration of the specified medication(s).</i></p> <p>(D) <i>Address the security of the medication(s) for each patient.</i></p> <p>(E) <i>Document the administration of each medication, as reported by the patient (or the patient's caregiver/support person where appropriate), in the patient's medical record.</i></p>		<p>(B) <i>Assess the capacity of the patient (or the patient's caregiver/support person where appropriate) to self-administer the specified medication(s).</i></p> <p>(C) <i>Instruct the patient (or the patient's support person where appropriate) in the safe and accurate administration of the specified medication(s).</i></p> <p>(D) <i>Address the security of the medication(s) for each patient.</i></p> <p>(E) <i>Document the administration of each medication, as reported by the patient (or the patient's caregiver/support person where appropriate), in the patient's medical record.</i></p>
<p>§482.23(c)(6)(ii) §482.23(c)(6)(iii)(A) §482.23(c)(6)(ii)(B) §482.23(c)(6)(ii)(C) §482.23(c)(6)(ii)(D) §482.23(c)(6)(ii)(E)</p>	<p>(6) <i>The hospital may allow a patient (or his or her caregiver/support person where appropriate) to self-administer both hospital-issued medications and the patient's own medications brought into the hospital, as defined and specified in the hospital's policies and procedures.</i></p> <p>(ii) <i>If the hospital allows a patient to self-administer his or her own specific medications brought into the hospital, then the hospital must have policies and procedures in place to:</i></p> <p>(A) <i>Ensure that a practitioner responsible for the care of the patient has issued an order, consistent with hospital policy, permitting self-administration of medications the patient brought into the hospital.</i></p> <p>(B) <i>Assess the capacity of the patient (or the patient's caregiver/support person where appropriate) to self-administer the specified medication(s), and also determine if the patient (or the patient's caregiver/support person where appropriate) needs instruction in the safe and accurate administration of the specified</i></p>	<p style="text-align: center;">16.01.10</p>	<p><u>Self-Administration of Medications: Medications Brought into the Hospital.</u></p> <p><i>If the hospital allows a patient to self-administer his or her own specific medications brought into the hospital, then the hospital must have policies and procedures in place to:</i></p> <p>(A) <i>Ensure that a practitioner responsible for the care of the patient has issued an order, consistent with hospital policy, permitting self-administration of medications the patient brought into the hospital.</i></p> <p>(B) <i>Assess the capacity of the patient (or the patient's caregiver/support person where appropriate) to self-administer the specified medication(s) and also determine if the patient (or the patient's caregiver/support person where appropriate) needs instruction in the safe and accurate administration of the specified medication(s).</i></p> <p>(C) <i>Identify the specified medication(s) and visually evaluate the medication(s) for integrity.</i></p> <p>(D) <i>Address the security of the medication(s) for each patient.</i></p> <p>(E) <i>Document the administration of each medication, as reported by the patient (or the patient's caregiver/support person where</i></p>

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	<p>medication(s).</p> <p>(C) Identify the specified medication(s) and visually evaluate the medication(s) for integrity.</p> <p>(D) Address the security of the medication(s) for each patient.</p> <p>(E) Document the administration of each medication, as reported by the patient (or the patient's caregiver/support person where appropriate), in the patient's medical record.</p>		<p>appropriate), in the patient's medical record.</p>
§482.24	<p>Condition of participation: Medical record services. The hospital must have a medical record service that has administrative responsibility for medical records. A medical record must be maintained for every individual evaluated or treated in the hospital.</p>	10.00.00	<p>Condition of Participation: Medical Record Services The hospital must have a medical record service that has administrative responsibility for medical records. A medical record must be maintained for every individual evaluated or treated in the hospital.</p>
§482.24(a)	<p>Standard: Organization and staffing. The organization of the medical record service must be appropriate to the scope and complexity of the services performed. The hospital must employ adequate personnel to ensure prompt completion, filing, and retrieval of records.</p>	10.00.02	<p>Organization & Staffing The organization of the medical record service must be appropriate to the scope and complexity of the service performed. The hospital must employ adequate personnel to ensure prompt completion, filing, and retrieval of records.</p>
§482.24(b)	<p>Standard: Form and retention of record. The hospital must maintain a medical record for each inpatient and outpatient. Medical records must be accurately written, promptly completed, properly filed and retained, and accessible. The hospital must use a system of author identification and record maintenance that ensures the integrity of the authentication and protects the security of all record entries.</p>	10.00.03	<p>Retention of Medical Records The hospital must maintain a medical record for each inpatient and outpatient. Medical records must be accurately written, promptly completed, properly filed and retained, and accessible. The hospital must use a system of author identification and record maintenance that ensures the integrity of the authentication and protects the security of all record entries.</p>
§482.24(b)(1)	<p>(1) Medical records must be retained in their original or legally reproduced form for a period of at least 5 years.</p>	10.00.04	<p>Record Security & Retention Requirements Medical records must be secured and retained in their original or legally reproduced form for a period of at least 5 years.</p>

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§482.24(b)(2)	(2) <i>The hospital must have a system of coding and indexing medical records. The system must allow for timely retrieval by diagnosis and procedure, in order to support medical care evaluation studies.</i>	10.00.05	<p><u>Coding & Indexing</u> <i>The hospital must have a system of coding and indexing medical records. The system must allow for timely retrieval by diagnosis and procedure, in order to support medical care evaluation studies.</i></p>
§482.24(b)(3)	(3) <i>The hospital must have a procedure for ensuring the confidentiality of patient records. Information from or copies of records may be released only to authorized individuals, and the hospital must ensure that unauthorized individuals cannot gain access to or alter patient records. Original medical records must be released by the hospital only in accordance with Federal or State laws, court orders, or subpoenas.</i>	10.00.06	<p><u>Security of Medical Information</u> <i>The hospital must have a procedure for ensuring the confidentiality of patient records. Information from or copies of records may be released only to authorized individuals and the hospital must ensure that unauthorized individuals cannot gain access to or alter patient records. Original medical records must be released by the hospital only in accordance with Federal or State laws, court orders, or subpoenas.</i></p>
		14.00.11	<p><u>Confidentiality of Patient Records</u> <i>Hospitals and OPOs must have procedures for ensuring the confidentiality of patient records.</i></p>
§482.24(c)	<p><i>Standard: Content of record.</i> <i>The medical record must contain information to justify admission and continued hospitalization, support the diagnosis, and describe the patient’s progress and response to medications and services.</i></p>	10.01.01	<p><u>Content of the Record</u> <i>The medical record must contain information to justify admission and continued hospitalization, support the diagnosis, and describe the patient’s progress and response to medications and services.</i></p>
§482.24(c)(1)	(1) <i>All patient medical record entries must be legible, complete, dated, timed, and authenticated in written or electronic form by the person responsible for providing or evaluating the service provided, consistent with hospital policies and procedures.</i>	10.01.03	<p><u>Legible & Complete</u> <i>All patient medical record entries must be legible, complete, dated, timed, and authenticated in written or electronic form by the person responsible for providing or evaluating the service provided, consistent with hospital policies and procedures.</i></p>
§482.24(c)(2)	(2) <i>All orders, including verbal orders, must be dated, timed, and authenticated promptly by the ordering practitioner or by another practitioner who is responsible for the care of the patient only if such a practitioner is acting in accordance with State law, including scope-of-practice laws, hospital policies, and medical staff bylaws, rules, and regulations.</i>	10.01.04	<p><u>Dating, Timing & Authentication of Orders</u> <i>All orders, including verbal orders, must be dated, timed, and authenticated promptly by the ordering practitioner or by another practitioner who is responsible for the care of the patient only if such a practitioner is acting in accordance with State law, including scope-of-practice laws, hospital policies, and medical staff bylaws, rules and regulations.</i></p>

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<p>§482.24(c)(3) §482.24(c)(3)(i) §482.24(c)(3)(ii) §482.24(c)(3)(iii) §482.24(c)(3)(iv)</p>	<p>(3) <i>Hospitals may use pre-printed and electronic standing orders, order sets, and protocols for patient orders only if the hospital:</i></p> <p>(i) <i>Establishes that such orders and protocols have been reviewed and approved by the medical staff and the hospital's nursing and pharmacy leadership;</i></p> <p>(ii) <i>Demonstrates that such orders and protocols are consistent with nationally recognized and evidence-based guidelines;</i></p> <p>(iii) <i>Ensures that the periodic and regular review of such orders and protocols is conducted by the medical staff and the hospital's nursing and pharmacy leadership to determine the continuing usefulness and safety of the orders and protocols; and</i></p> <p>(iv) <i>Ensures that such orders and protocols are dated, timed, and authenticated promptly in the patient's medical record by the ordering practitioner or by another practitioner responsible for the care of the patient only if such a practitioner is acting in accordance with State law, including scope-of-practice laws, hospital policies, and medical staff bylaws, rules, and regulations.</i></p>	<p style="text-align: center;">10.01.05</p>	<p>Pre-printed Orders, Order Sets & Protocols <i>Hospitals may use pre-printed and electronic standing orders, order sets, and protocols for patient orders only if the hospital:</i></p> <p>(i) <i>Establishes that such orders and protocols have been reviewed and approved by the medical staff and the hospital's nursing and pharmacy leadership;</i></p> <p>(ii) <i>Demonstrates that such orders and protocols are consistent with nationally recognized and evidence-based guidelines;</i></p> <p>(iii) <i>Ensures that the periodic and regular review of such orders and protocols is conducted by the medical staff and the hospital's nursing and pharmacy leadership to determine the continuing usefulness and safety of the orders and protocols; and</i></p> <p>(iv) <i>Ensures that such orders and protocols are dated, timed, and authenticated promptly in the patient's medical record by the ordering practitioner or by another practitioner responsible for the care of the patient only if such a practitioner is acting in accordance with State law, including scope-of-practice laws, hospital policies, and medical staff bylaws, rules, and regulations.</i></p>
<p>§482.24(c)(4)(i)(A)</p>	<p>(4) <i>All records must document the following, as appropriate:</i></p> <p>(i) <i>Evidence of—</i></p> <p>(A) <i>A medical history and physical examination completed and documented no more than 30 days before or 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia services. The medical history and physical examination must be placed in the patient's medical record within 24 hours after admission or registration, but prior to surgery or a procedure requiring</i></p>	<p style="text-align: center;">10.01.07</p>	<p>History & Physical Requirements <i>All medical records must document the following, as appropriate:</i></p> <p>Evidence of-</p> <ul style="list-style-type: none"> • <i>A medical history and physical examination completed and documented no more than 30 days before or 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia services. The medical history and physical examination must be placed in the patient's medical record within 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia services.</i>

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	<i>anesthesia services.</i>		
§482.24(c)(4)(i)(B)	<p>(4) All records must document the following, as appropriate:</p> <p>(i) Evidence of—</p> <p>(B) An updated examination of the patient, including any changes in the patient's condition, when the medical history and physical examination are completed within 30 days before admission or registration. Documentation of the updated examination must be placed in the patient's medical record within 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia services.</p>	10.01.08	<p><u>History and Physical Update Requirements</u></p> <p>All records must document the following as appropriate:</p> <p>Evidence of—</p> <ul style="list-style-type: none"> • An updated examination of the patient, including any changes in the patient's condition, when the medical history and physical examination are completed within 30 days before admission or registration. Documentation of the updated examination must be placed in the patient's medical record within 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia services.
§482.24(c)(4)(ii)	<p>(4) All records must document the following, as appropriate:</p> <p>(ii) Admitting diagnosis.</p>	10.01.09	<p><u>Admitting Diagnosis</u></p> <p>All records must document the following, as appropriate:</p> <ul style="list-style-type: none"> • The medical records must contain the admitting diagnosis.
§482.24(c)(4)(iii)	<p>(4) All records must document the following, as appropriate:</p> <p>(iii) Results of all consultative evaluations of the patient and appropriate findings by clinical and other staff involved in the care of the patient.</p>	10.01.10	<p><u>Consultative Reports</u></p> <p>All records must document the following, as appropriate:</p> <ul style="list-style-type: none"> • Results of all consultative evaluations of the patient and appropriate findings by clinical and other staff involved in the care of the patient.
§482.24(c)(4)(iv)	<p>(4) All records must document the following, as appropriate:</p> <p>(iv) Documentation of complications, hospital acquired infections, and unfavorable reactions to drugs and anesthesia.</p>	10.01.15	<p><u>Documentation of Complications</u></p> <p>All records must document the following, as appropriate:</p> <ul style="list-style-type: none"> • Documentation of complications, hospital acquired infections, and unfavorable reactions to drugs and anesthesia.

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§482.24(c)(4)(v)	(4) All records must document the following, as appropriate: (v) Properly executed informed consent forms for procedures and treatments specified by the medical staff, or by Federal or State law if applicable, to require written patient consent.	10.01.16	<p><u>Informed Consent</u> All records must document the following, as appropriate:</p> <ul style="list-style-type: none"> Properly executed informed consent forms for procedures and treatments specified by the medical staff, or by Federal or State law if applicable, to require written patient consent.
§482.24(c)(4)(vi)	(4) All records must document the following, as appropriate: (vi) All practitioners' orders, nursing notes, reports of treatment, medication records, radiology, and laboratory reports, and vital signs and other information necessary to monitor the patient's condition.	10.01.17	<p><u>Adequacy of Available Information</u> All records must document the following, as appropriate:</p> <ul style="list-style-type: none"> All practitioners' orders, nursing notes, reports of treatment, medication records, radiology, and laboratory reports, and vital signs and other information necessary to monitor the patient's condition.
§482.24(c)(4)(vii)	(4) All records must document the following, as appropriate: (vii) Discharge summary with outcome of hospitalization, disposition of case, and provisions for follow-up care.	10.01.18	<p><u>Discharge Summary</u> The records must document the following, as appropriate:</p> <ul style="list-style-type: none"> Discharge summary with outcome of hospitalization, disposition of case and provisions for follow-up care.
§482.24(c)(4)(viii)	(4) All records must document the following, as appropriate: (viii) Final diagnosis with completion of medical records within 30 days following discharge	10.01.19	<p><u>Medical Record Delinquency</u> All records must document the following, as appropriate:</p> <ul style="list-style-type: none"> Final diagnosis with completion of medical records within 30 days following discharge.
§482.25	<p><u>Condition of participation: Pharmaceutical services.</u> The hospital must have pharmaceutical services that meet the needs of the patients. The institution must have a pharmacy directed by a registered pharmacist or a drug storage area under competent supervision. The medical staff is responsible for developing policies and procedures that minimize drug errors. This function may be delegated to the hospital's organized pharmaceutical service.</p>	25.00.00	<p><u>Condition of Participation: Pharmaceutical Services.</u> The hospital must have pharmaceutical services that meet the needs of the patients. The institution must have a pharmacy directed by a registered pharmacist or a drug storage area under competent supervision. The medical staff is responsible for developing policies and procedures that minimize drug errors. This function may be delegated to the hospital's organized pharmaceutical service.</p>

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§482.25(a)	Standard: Pharmacy management and administration. The pharmacy or drug storage area must be administered in accordance with accepted professional principles.	25.00.04	Pharmacy Management and Administration The pharmacy or drug storage area must be administered in accordance with accepted professional principles.
§482.25(a)(1)	(1) A full-time, part-time, or consulting pharmacist must be responsible for developing, supervising, and coordinating all the activities of the pharmacy services.	25.00.05	Management A full time, part time, or consulting pharmacist must be responsible for developing, supervising, and coordinating all of the activities of the pharmacy services.
§482.25(a)(2)	(2) The pharmaceutical service must have an adequate number of personnel to ensure quality pharmaceutical services, including emergency services.	25.00.06	Staffing The pharmaceutical service must have an adequate number of personnel to ensure quality pharmaceutical services, including emergency services.
§482.25(a)(3)	(3) Current and accurate records must be kept of the receipt and disposition of all scheduled drugs.	25.00.07	Scheduled Drugs Current and accurate records must be kept of the receipt and disposition of all scheduled drugs.
§482.25(b)	Standard: Delivery of services. In order to provide patient safety, drugs and biologicals must be controlled and distributed in accordance with applicable standards of practice, consistent with Federal and State law.	25.01.01	Medication Control & Distribution. In order to provide patient safety, drugs and biologicals must be controlled and distributed in accordance with applicable standards of practice consistent with Federal and State law.
§482.25(b)(1)	(1) All compounding, packaging, and dispensing of drugs and biological must be under the supervision of a pharmacist and performed consistent with State and Federal laws.	25.01.02	Supervision of Pharmacy Activities. All compounding, packaging and dispensing of drugs and biologicals must be under the supervision of a pharmacist and performed consistent with Federal and State laws.
§482.25(b)(2)(i)	(2) (i) All drugs and biologicals must be kept in a secure area, and locked when appropriate.	25.01.03	Security of Medications. Consistent with State and Federal requirements, in the pharmacy and throughout the facility: <ul style="list-style-type: none"> • All drugs and biologicals must be kept in a secure area, and locked when appropriate.
§482.25(b)(2)(ii)	(2) (ii) Drugs listed in Schedules II, III, IV, and V of the	25.01.04	Controlled Substances Drugs listed in Schedules II, III, IV, and V of the Comprehensive Drug

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	Comprehensive Drug Abuse Prevention and Control Act of 1970 must be kept locked within a secure area.		<i>Abuse Prevention and Control Act of 1970 must be kept locked within a secure area.</i>
§482.25(b)(2)(iii)	(2) (iii) Only authorized personnel may have access to locked areas.	25.01.05	<u>Access To Controlled Substances</u> <i>Only authorized personnel may have access to locked areas.</i>
§482.25(b)(3)	(3) <i>Outdated, mislabeled, or otherwise unusable drugs and biological must not be available for patient use.</i>	25.01.07	<u>Inventory Management System</u> <i>Outdated, mislabeled, or otherwise unusable drugs and biologicals must not be available for patient use.</i>
§482.25(b)(4)	(4) <i>When a pharmacist is not available, drugs and biologicals must be removed from the pharmacy or storage area only by personnel designated in the policies of the medical staff and pharmaceutical service, in accordance with Federal and State law.</i>	25.01.08	<u>Pharmacy Access.</u> <i>When a pharmacist is not available, drugs and biologicals must be removed from the pharmacy or storage area only by personnel designated in the policies of the medical staff and pharmaceutical service, in accordance with Federal and State law.</i>
§482.25(b)(5)	(5) <i>Drugs and biologicals not specifically prescribed as to time or number of doses must automatically be stopped after a reasonable time that is predetermined by the medical staff.</i>	25.01.09	<u>Automatic Stop Medication Orders.</u> <i>Drugs and biologicals not specifically prescribed as to time and/or number of doses must automatically be stopped after a reasonable time that is predetermined by the medical staff.</i>
§482.25(b)(6)	(6) <i>Drug administration errors, adverse drug reactions, and incompatibilities must be immediately reported to the attending physician and, if appropriate, to the hospital's quality assessment and performance improvement program.</i>	25.01.10	<u>Drug Reactions & Administration Errors & Incompatibilities.</u> <i>Drug administration errors, adverse drug reactions and incompatibilities must be immediately reported to the attending physician and if appropriate, to the hospital's quality assurance and performance improvement program.</i>
§482.25(b)(7)	(7) <i>Abuses and losses of controlled substances must be reported, in accordance with applicable Federal and State laws, to the individual responsible for the pharmaceutical service, and to the chief executive officer, as appropriate.</i>	25.01.11	<u>Reporting of Controlled Drug Loss and/or Abuse.</u> <i>Abuses and losses of controlled substances must be reported, in accordance with applicable Federal and State laws, to the individual responsible for the pharmaceutical service, and to the chief executive officer, as appropriate.</i>
§482.25(b)(8)	(8) <i>Information relating to drug interactions and information of drug therapy, side effects, toxicology, dosage, indications for use, and routes of administration</i>	25.01.12	<u>Informational Resources</u> <i>Information relating to drug interactions and information of drug therapy, side effects, toxicology, dosage, indications for use, and</i>

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	<i>must be available to the professional staff.</i>		<i>routes of administration must be available to the professional staff.</i>
§482.25(b)(9)	(9) <i>A formulary system must be established by the medical staff to assure quality pharmaceuticals at reasonable costs.</i>	25.01.13	<u>Formulary System.</u> <i>A formulary system must be established by the medical staff to assure quality pharmaceuticals at reasonable costs.</i>
§482.26	<i>Condition of participation: Radiologic services.</i> <i>The hospital must maintain, or have available, diagnostic radiologic services. If therapeutic services are also provided, they, as well as the diagnostic services, must meet professionally approved standards for safety and personnel qualifications.</i>	19.00.00	<u>Condition of Participation: Radiological Services</u> <i>The hospital must maintain, or have available, diagnostic radiological services. If therapeutic services are also provided, they, as well as the diagnostic services, must meet the professionally approved standards for safety and personnel qualifications.</i>
§482.26(a)	<i>Standard: Radiologic services.</i> <i>The hospital must maintain, or have available, radiologic services according to needs of the patients.</i>	19.00.01	<u>Scope of Service</u> <i>The hospital must maintain, or have available, radiology services according to the needs of the patients.</i>
§482.26(b)	<i>Standard: Safety for patients and personnel.</i> <i>The radiologic services, particularly ionizing radiology procedures, must be free from hazards for patients and personnel.</i>	19.00.02	<u>Safety of Services</u> <i>Radiological services, particularly ionizing radiology, must be free from hazards for patients and personnel.</i>
§482.26(b)(1)	(1) <i>Proper safety precautions must be maintained against radiation hazards. This includes adequate shielding for patients, personnel, and facilities, as well as appropriate storage, use, and disposal of radioactive materials.</i>	19.00.03	<u>Shielding</u> <i>Proper safety precautions must be maintained against radiation hazards. This includes adequate shielding for patients, personnel, and facilities, as well as appropriate storage, use and disposal of radioactive materials;</i>
§482.26(b)(2)	(2) <i>Periodic inspection of equipment must be made and hazards identified must be promptly corrected.</i>	19.00.04	<u>Equipment Inspections</u> <i>Periodic inspection of equipment must be made and hazards identified must be promptly corrected;</i>
§482.26(b)(3)	(3) <i>Radiation workers must be checked periodically, by the use of exposure meters or badge tests, for amount of radiation exposure.</i>	19.00.05	<u>Exposure Meters</u> <i>Radiation workers must be checked periodically, by the use of exposure meters or badge tests, for amount of radiation exposure;</i>

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§482.26(b)(4)	(4) <i>Radiologic services must be provided only on the order of practitioners with clinical privileges or, consistent with State law, of other practitioners authorized by the medical staff and the governing body to order the services.</i>	19.00.06	<p><u>Orders</u> <i>Radiologic services must be provided only on the order of practitioners with clinical privileges or, consistent with State law, of other practitioners authorized by the medical staff and the governing body to order the services.</i></p>
§482.26(c)	<i>Standard: Personnel.</i>	19.00.10	<p><u>Personnel</u></p>
§482.26(c)(1)	(1) <i>A qualified full-time, part-time, or consulting radiologist must supervise the ionizing radiology services and must interpret only those radiologic tests that are determined by the medical staff to require a radiologist's specialized knowledge. For purposes of this section, a radiologist is a doctor of medicine or osteopathy who is qualified by education and experience in radiology.</i>	19.00.11	<p><u>Medical Supervision</u> <i>A qualified full-time, part-time, or consulting radiologist must supervise the ionizing radiology services and must interpret only those radiologic tests that are determined by the medical staff to require a radiologist's specialized knowledge.</i></p> <p><i>For purposes of this section, a radiologist is a doctor of medicine or osteopathy who is qualified by education and experience in radiology.</i></p>
§482.26(c)(2)	(2) <i>Only personnel designated as qualified by the medical staff may use the radiologic equipment and administer procedures.</i>	19.00.13	<p><u>Qualified Personnel</u> <i>Only personnel designated as qualified by the medical staff may use the radiological equipment and administer procedures.</i></p>
§482.26(d)	<i>Standard: Records. Records of radiologic services must be maintained.</i>	19.00.15	<p><u>Record Maintenance</u> <i>Records of radiologic services must be maintained.</i></p>
§482.26(d)(1)	(1) <i>The radiologist or other practitioner who performs radiology services must sign reports of his or her interpretations.</i>	19.00.16	<p><u>Report Authentication</u> <i>The radiologist or other practitioner who performs radiology services must sign reports of his or her interpretations.</i></p>
§482.26(d)(2)(i) §482.26(d)(2)(ii)	(2) <i>The hospital must maintain the following for at least 5 years:</i> <i>(i) Copies of reports and printouts.</i> <i>(ii) Films, scans, and other image records, as appropriate.</i>	19.00.19	<p><u>Retention of Records</u> <i>The hospital must maintain the following for at least 5 years:</i> <i>(i) Copies of reports and printouts,</i> <i>(ii) Films, scans and other image records, as appropriate.</i></p>

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§482.27	<p>Condition of participation: Laboratory services. <i>The hospital must maintain, or have available, adequate laboratory services to meet the needs of its patients. The hospital must ensure that all laboratory services provided to its patients are performed in a facility certified in accordance with part 493 of this chapter.</i></p>	22.00.00	<p>Condition of Participation: Laboratory Services – Scope of Services <i>The hospital must maintain, or have available, adequate laboratory services to meet the needs of its patients. The hospital must ensure that all laboratory services provided to its patient are performed in a facility certified in accordance with part 493 of 42 CFR 493.</i></p>
§482.27(a)	<p>Standard: Adequacy of laboratory services. <i>The hospital must have laboratory services available, either directly or through a contractual agreement with a certified laboratory that meets requirements of part 493 of this chapter.</i></p>	22.00.02	<p>Accreditation/Certification of Laboratory Services <i>The hospital must have laboratory services available, either directly or through a contractual agreement with a certified laboratory that meets requirements of 42 CFR 493 (CLIA).</i></p>
§482.27(a)(1)	<p>(1) <i>Emergency laboratory services must be available 24 hours a day.</i></p>	22.00.03	<p>Emergency Service Availability <i>Emergency laboratory services must be available 24 hours a day.</i></p>
§482.27(a)(2)	<p>(2) <i>A written description of services provided must be available to the medical staff.</i></p>	22.00.04	<p>Laboratory Services Description <i>A written description of services provided must be available to the medical staff and other staff as appropriate.</i></p>
§482.27(a)(3)	<p>(3) <i>The laboratory must make provision for proper receipt and reporting of tissue specimens.</i></p>	22.00.05	<p>Tissue Specimens <i>The laboratory must make provision for proper receipt and reporting of tissue specimens.</i></p>
§482.27(a)(4)	<p>(4) <i>The medical staff and a pathologist must determine which tissue specimens require a macroscopic (gross) examination and which require both macroscopic and microscopic examinations.</i></p>	22.00.06	<p>Required Tissue Examination <i>The medical staff and a pathologist must determine which tissue specimens require a macroscopic (gross) examination and which require both macroscopic and microscopic examinations.</i></p>
§482.27(b)	<p>Standard: Potentially infectious blood and blood components— (1) <i>Potentially human immunodeficiency virus (HIV) infectious blood and blood components. Potentially HIV infectious blood and blood components are prior collections from a donor—</i> (i) <i>Who tested negative at the time of donation but tests reactive for evidence of HIV infection on a later</i></p>	22.01.01	<p>Potentially Infectious Blood and Blood Components. (1) <i>Potentially human immunodeficiency virus (HIV) infectious blood and blood components. Potentially HIV infectious blood and blood components are prior collections from a donor –</i> (i) <i>Who tested negative at the time of donation but tests reactive for evidence of HIV infection on a later donation;</i> (ii) <i>Who tests positive on the supplemental (additional, more specific) test or other follow-up testing required by FDA; and</i></p>

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<p>donation;</p> <p>(ii) Who tests positive on the supplemental (additional, more specific) test or other follow-up testing required by FDA; and</p> <p>(iii) For whom the timing of seroconversion cannot be precisely estimated.</p> <p>(2) Potentially hepatitis C virus (HCV) infectious blood and blood components. Potentially HCV infectious blood and blood components are the blood and blood components identified in 21 CFR 610.47.</p> <p>(3) Services furnished by an outside blood collecting establishment. If a hospital regularly uses the services of an outside blood collecting establishment, it must have an agreement with the blood collecting establishment that governs the procurement, transfer, and availability of blood and blood components. The agreement must require that the blood collecting establishment notify the hospital—</p> <p>(i) Within 3 calendar days if the blood collecting establishment supplied blood and blood components collected from a donor who tested negative at the time of donation but tests reactive for evidence of HIV or HCV infection on a later donation or who is determined to be at increased risk for transmitting HIV or HCV infection;</p> <p>(ii) Within 45 days of the test, of the results of the supplemental (additional, more specific) test for HIV or HCV, as relevant, or other follow-up testing required by FDA; and</p> <p>(iii) Within 3 calendar days after the blood collecting establishment supplied blood and blood components collected from an infectious donor, whenever records are available, as set forth at 21 CFR 610.48(b)(3).</p> <p>(4) Quarantine and disposition of blood and blood</p>	<p>(iii) For whom the timing of seroconversion cannot be precisely estimated.</p> <p>(2) Potentially hepatitis C virus (HCV) infectious blood and blood components. Potentially HCV infectious blood and blood components are the blood and blood components identified in 21 CFR 610.47.</p> <p>(3) Services furnished by an outside blood collecting establishment. If a hospital regularly uses the services of an outside blood collecting establishment, it must have an agreement with the blood collecting establishment that governs the procurement, transfer, and availability of blood and blood components. The agreement must require that the blood collecting establishment notify the hospital --</p> <p>(i) Within 3 calendar days if the blood collecting establishment supplied blood and blood components collected from a donor who tested negative at the time of donation but tests reactive for evidence of HIV or HCV infection on a later donation or who is determined to be at increased risk for transmitting HIV or HCV infection;</p> <p>(ii) Within 45 days of the test, of the results of the supplemental (additional, more specific) test for HIV or HCV, as relevant, or other follow-up testing required by FDA;</p> <p>(iii) Within 3 calendar days after the blood collecting establishment supplied blood and blood components collected from an infectious donor, whenever records are available, as set forth at 21 CFR 610.48(b)(3).</p> <p>(4) Quarantine of blood and blood components pending completion of testing. If the blood collecting establishment (either internal or under an agreement) notifies the hospital of the reactive HIV or HCV screening test results, the hospital must determine the disposition of the blood or blood component and quarantine all blood and blood components from previous donations in inventory.</p> <p>(i) If the blood collecting establishment notifies the hospital that</p>
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	<p><i>components pending completion of testing. If the blood collecting establishment (either internal or under an agreement) notifies the hospital of the reactive HIV or HCV screening test results, the hospital must determine the disposition of the blood or blood product and quarantine all blood and blood components from previous donations in inventory.</i></p> <p><i>(i) If the blood collecting establishment notifies the hospital that the result of the supplemental (additional, more specific) test or other follow-up testing required by FDA is negative, absent other informative test results, the hospital may release the blood and blood components from quarantine.</i></p> <p><i>(ii) If the blood collecting establishment notifies the hospital that the result of the supplemental, (additional, more specific) test or other follow-up testing required by FDA is positive, the hospital must—</i></p> <p style="padding-left: 40px;"><i>(A) Dispose of the blood and blood components; and</i></p> <p style="padding-left: 40px;"><i>(B) Notify the transfusion recipients as set forth in paragraph (b)(6) of this section.</i></p> <p><i>(iii) If the blood collecting establishment notifies the hospital that the result of the supplemental, (additional, more specific) test or other follow-up testing required by FDA is indeterminate, the hospital must destroy or label prior collections of blood or blood components held in quarantine as set forth at 21 CFR 610.46(b)(2), 610.47(b)(2), and 610.48(c)(2).</i></p> <p><i>(5) Recordkeeping by the hospital. The hospital must maintain—</i></p> <p style="padding-left: 20px;"><i>(i) Records of the source and disposition of all units of blood and blood components for at least 10 years from the date of disposition in a manner that</i></p>	<p><i>the result of the supplemental (additional, more specific) test or other follow-up testing required by FDA is negative, absent other informative test results, the hospital may release the blood and blood components from quarantine.</i></p> <p><i>(ii) If the blood collecting establishment notifies the hospital that the result of the supplemental (additional, more specific) test or other follow-up testing required by FDA is positive, the hospital must—</i></p> <p style="padding-left: 40px;"><i>(A) Dispose of the blood and blood components; and</i></p> <p style="padding-left: 40px;"><i>(B) Notify the transfusion recipients as set forth in paragraph (b)(6) of 42 CFR 482.27 .</i></p> <p><i>(iii) If the blood collecting establishment notifies the hospital that the result of the supplemental (additional, more specific) test or other follow-up testing required by FDA is indeterminate, the hospital must destroy or label prior collections of blood or blood components held in quarantine as set forth at 21 CFR 610.46(b)(2), 610.47(b)(2), and 610.48(c)(2).</i></p> <p><i>(5) Recordkeeping by the hospital. The hospital must maintain --</i></p> <p style="padding-left: 20px;"><i>(i) Records of the source and disposition of all units of blood and blood components for at least 10 years from the date of disposition in a manner that permits prompt retrieval; and</i></p> <p style="padding-left: 20px;"><i>(ii) A fully funded plan to transfer these records to another hospital or other entity if such hospital ceases operation for any reason.</i></p> <p><i>(6) Patient notification. If the hospital has administered potentially HIV or HCV infectious blood or blood components (either directly through its own blood collecting establishment or under an agreement) or released such blood or blood components to another entity or appropriate individual, the hospital must take the following actions:</i></p> <p style="padding-left: 20px;"><i>(i) Make reasonable attempts to notify the patient, or to notify the attending physician, or the physician who ordered the blood or blood component and ask the physician to notify the</i></p>
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	<p><i>permits prompt retrieval; and</i></p> <p>(ii) <i>A fully funded plan to transfer these records to another hospital or other entity if such hospital ceases operation for any reason.</i></p> <p>(6) <i>Patient notification. If the hospital has administered potentially HIV or HCV infectious blood or blood components (either directly through its own blood collecting establishment or under an agreement) or released such blood or blood components to another entity or individual, the hospital must take the following actions:</i></p> <p>(i) <i>Make reasonable attempts to notify the patient, or to notify the attending physician or the physician who ordered the blood or blood component and ask the physician to notify the patient, or other individual as permitted under paragraph (b)(10) of this section, that potentially HIV or HCV infectious blood or blood components were transfused to the patient and that there may be a need for HIV or HCV testing and counseling.</i></p> <p>(ii) <i>If the physician is unavailable or declines to make the notification, make reasonable attempts to give this notification to the patient, legal guardian, or relative.</i></p> <p>(iii) <i>Document in the patient’s medical record the notification or attempts to give the required notification.</i></p> <p>(7) <i>Timeframe for notification—</i></p> <p>(i) <i>For donors tested on or after February 20, 2008. For notifications resulting from donors tested on or after February 20, 2008 as set forth at 21 CFR 610.46 and 21 CFR 610.47 the notification effort begins when the blood collecting establishment notifies the hospital that it received potentially HIV or HCV infectious blood and blood components. The</i></p>		<p><i>patient, or other individual as permitted under paragraph (b)(10) of 42 Code of Federal Regulation, that potentially HIV or HCV infectious blood or blood components were transfused to the patient and that there may be a need for HIV or HCV testing and counseling.</i></p> <p>(ii) <i>If the physician is unavailable or declines to make the notification, make reasonable attempts to give this notification to the patient, legal guardian or relative.</i></p> <p>(iii) <i>Document in the patient’s medical record the notification or attempts to give the required notification.</i></p> <p>(7) <i>Time frame for notification.</i></p> <p>(i) <i>For donors tested on or after February 20, 2008. For notifications resulting from donors tested on or after February 20, 2008 as set forth at 21 CFR 610.46 and 21 CFR 610.47 the notification effort begins when the blood collecting establishment notifies the hospital that it received potentially HIV or HCV infectious blood and blood components. The hospital must make reasonable attempts to give notification over a period of 12 weeks unless--</i></p> <p style="padding-left: 20px;">(A) <i>The patient is located and notified; or</i></p> <p style="padding-left: 20px;">(B) <i>The hospital is unable to locate the patient and documents in the patient’s medical record the extenuating circumstances beyond the hospital’s control that caused the notification timeframe to exceed 12 weeks.</i></p> <p>(ii) <i>For donors tested before February 20, 2008. For notifications from donors tested before February 20, 2008 as set forth at 21 CFR 610.48(b) and (c), the notification effort begins when the blood collecting establishment notifies the hospital that it received potentially HCV infectious blood and blood components. The hospital must make reasonable attempts to give notification and must complete the actions within 1 year of the date on which the hospital received notification from the outside blood collecting establishment.</i></p>
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<p><i>hospital must make reasonable attempts to give notification over a period of 12 weeks unless—</i></p> <ul style="list-style-type: none"> <i>(A) The patient is located and notified; or</i> <i>(B) The hospital is unable to locate the patient and documents in the patient’s medical record the extenuating circumstances beyond the hospital’s control that caused the notification timeframe to exceed 12 weeks.</i> <p><i>(ii) For donors tested before February 20, 2008. For notifications resulting from donors tested before February 20, 2008 as set forth at 21 CFR 610.48(b) and (c), the notification effort begins when the blood collecting establishment notifies the hospital that it received potentially HCV infectious blood and blood components. The hospital must make reasonable attempts to give notification and must complete the actions within 1 year of the date on which the hospital received notification from the outside blood collecting establishment.</i></p> <p><i>(8) Content of notification. The notification must include the following information:</i></p> <ul style="list-style-type: none"> <i>(i) A basic explanation of the need for HIV or HCV testing and counseling;</i> <i>(ii) Enough oral or written information so that an informed decision can be made about whether to obtain HIV or HCV testing and counseling; and</i> <i>(iii) A list of programs or places where the person can obtain HIV or HCV testing and counseling, including any requirements or restrictions the program may impose.</i> <p><i>(9) Policies and procedures. The hospital must establish policies and procedures for notification and documentation that conform to Federal, State, and local</i></p>	<p><i>(8) Content of notification. The notification must include the following information:</i></p> <ul style="list-style-type: none"> <i>(i) A basic explanation of the need for HIV or HCV testing and counseling.</i> <i>(ii) Enough oral or written information so that an informed decision can be made about whether to obtain HIV or HCV testing and counseling.</i> <i>(iii) A list of programs or places where the person can obtain HIV or HCV testing and counseling, including any requirements or restrictions the program may impose.</i> <p><i>(9) Policies and procedures. The hospital must establish policies and procedures for notification and documentation that conform to Federal, State, and local laws, including requirements for the confidentiality of medical records and other patient information.</i></p> <p><i>(10) Notification to legal representative or relative. If the patient has been adjudged incompetent by a State court, the physician or hospital must notify a legal representative designated in accordance with State law. If the patient is competent, but State law permits a legal representative or relative to receive the information on the patient’s behalf, the physician or hospital must notify the patient or his or her legal representative or relative. For possible HIV infectious transfusion recipients that are deceased, the physician or hospital must inform the deceased patient’s legal representative or relative. If the patient is a minor, the parents or legal guardian must be notified.</i></p> <p><i>(11) Applicability. HCV notification requirements resulting from donors tested before February 20, 2008, as set forth at 21 CFR 610.48 will expire on August 24, 2015.</i></p> <ul style="list-style-type: none"> <i>(i) Appropriate testing and quarantining of infectious blood and blood components.</i> <i>(ii) Notification and counseling of beneficiaries that may have received infectious blood and blood components.</i> 	
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	<p><i>laws, including requirements for the confidentiality of medical records and other patient information.</i></p> <p>(10) <i>Notification to legal representative or relative. If the patient has been adjudged incompetent by a State court, the physician or hospital must notify a legal representative designated in accordance with State law. If the patient is competent, but State law permits a legal representative or relative to receive the information on the patient’s behalf, the physician or hospital must notify the patient or his or her legal representative or relative. For possible HIV infectious transfusion recipients that are deceased, the physician or hospital must inform the deceased patient’s legal representative or relative. If the patient is a minor, the parents or legal guardian must be notified.</i></p> <p>(11) <i>Applicability. HCV notification requirements resulting from donors tested before February 20, 2008 as set forth at 21 CFR 610.48 will expire on August 24, 2015.</i></p> <p>(i) <i>Appropriate testing and quarantining of infectious blood and blood components.</i></p> <p>(ii) <i>Notification and counseling of beneficiaries that may have received infectious blood and blood components.</i></p>		
<p>§482.27(c)</p>	<p><i>General blood safety issues. For look-back activities only related to new blood safety issues that are identified after August 24, 2007, hospitals must comply with FDA regulations as they pertain to blood safety issues in the following areas:</i></p> <p>(1) <i>Appropriate testing and quarantining of infectious blood and blood components.</i></p>	<p>22.01.03</p>	<p><u>General Blood Safety Issues</u></p> <p><i>For look-back activities only related to new blood safety issues that are identified after August 24, 2007, hospitals must comply with FDA regulations as they pertain to blood safety issues in the following areas:</i></p> <p>(1) <i>Appropriate testing and quarantining of infectious blood and blood components.</i></p>

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	(2) <i>Notification and counseling of recipients that may have received infectious blood and blood components.</i>		(2) <i>Notification and counseling of recipients that may have received infectious blood and blood components.</i>
§482.28	Condition of participation: Food and dietetic services. <i>The hospital must have organized dietary services that are directed and staffed by adequate qualified personnel. However, a hospital that has a contract with an outside food management company may be found to meet this Condition of participation if the company has a dietitian who serves the hospital on a full-time, part-time, or consultant basis, and if the company maintains at least the minimum standards specified in this section and provides for constant liaison with the hospital medical staff for recommendations on dietetic policies affecting patient treatment.</i>	24.00.00	Condition of Participation: Food & Dietetic Services <i>The hospital must have organized dietary services that are directed and staffed by adequate qualified personnel. However, a hospital that has a contract with an outside food management company may be found to meet this Condition of Participation if the company has a dietitian who serves the hospital on a full-time, part-time, or consultant basis, and if the company maintains at least the minimum standards specified in this section and provides for constant liaison with the hospital medical staff for recommendations on dietetic policies affecting patient treatment.</i>
§482.28(a)	<i>Standard: Organization.</i>	24.00.01	<i>Organization.</i>
§482.28(a)(1) §482.28(a)(1)(i) §482.28(a)(1)(ii) §482.28(a)(1)(iii)	(1) <i>The hospital must have a full-time employee who—</i> <i>(i) Serves as director of the food and dietetic service;</i> <i>(ii) Is responsible for the daily management of the dietary services; and</i> <i>(iii) Is qualified by experience or training.</i>	24.00.02	Food & Dietetic Services <i>The hospital must have a full-time employee who:</i> <i>(i) Serves as director of the food and dietetic services,</i> <i>(ii) Is responsible for daily management of the dietary services, and</i> <i>(iii) Is qualified by experience or training.</i>
§482.28(a)(2)	(2) <i>There must be a qualified dietitian, full-time, part-time, or on a consultant basis.</i>	24.00.03	Dietitian Services <i>There must be a qualified dietitian,</i> <ul style="list-style-type: none">• <i>full-time,</i>• <i>part-time or</i>• <i>on a consultant basis.</i>
§482.28(a)(3)	(3) <i>There must be administrative and technical personnel competent in their respective duties.</i>	24.00.04	Staffing Qualifications <i>There must be administrative and technical personnel competent in their respective duties.</i>

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<p>§482.28(b) §482.28(b)(1)</p>	<p><i>Standard: Diets.</i> <i>Menus must meet the needs of the patients.</i> (1) <i>Individual patient nutritional needs must be met in accordance with recognized dietary practices.</i></p>	<p>24.00.06</p>	<p>Diets: Menus Must Meet the Needs of Patients. <i>Individual patient nutritional needs must be met in accordance with recognized dietary practices.</i></p>
<p>§482.28(b)(2)</p>	<p>(2) <i>All patient diets, including therapeutic diets, must be ordered by a practitioner responsible for the care of the patient, or by a qualified dietitian or qualified nutrition professional as authorized by the medical staff and in accordance with State law governing dietitians and nutrition professionals.</i></p>	<p>24.00.07</p>	<p>Diet Orders <i>All patient diets, including therapeutic diets, must be ordered by a practitioner responsible for the care of the patient, or by a qualified dietitian or qualified nutrition professional as authorized by the medical staff and in accordance with State law governing dietitians and nutrition professionals.</i></p>
<p>§482.28(b)(3)</p>	<p>(3) <i>A current therapeutic diet manual approved by the dietitian and medical staff must be readily available to all medical, nursing, and food service personnel.</i></p>	<p>24.00.08</p>	<p>Diet Manual <i>A current therapeutic diet manual approved by the dietitian and medical staff must be readily available to all medical, nursing and food service personnel.</i></p>
<p>§482.30</p>	<p>Condition of participation: Utilization review. <i>The hospital must have in effect a utilization review (UR) plan that provides for review of services furnished by the institution and by members of the medical staff to patients entitled to benefits under the Medicare and Medicaid programs.</i></p>	<p>03.04.00</p>	<p>Condition of Participation: Utilization Review <i>The hospital must have in effect a utilization review (UR) plan that provides for review of services furnished by the institution and by members of the Medical Staff to patients entitled to benefits under the Medicare and Medicaid program.</i></p>
<p>§482.30(a) §482.30(a)(1) §482.30(a)(2)</p>	<p><i>Applicability.</i> <i>The provisions of this section apply except in either of the following circumstances:</i> (1) <i>A Utilization and Quality Control Quality Improvement Organization (QIO) has assumed binding review for the hospital.</i> (2) <i>CMS has determined that the UR procedures established by the State under title XIX of the Act are superior to the procedures required in this section, and has required hospitals in that State to meet the UR plan requirements under §§ 456.50 through 456.245 of this chapter.</i></p>	<p>03.04.01</p>	<p>Applicability <i>The provisions of 42 CFR 482.30 apply <u>except</u> in either of the following circumstances:</i> 1) <i>A Utilization and Quality Control Quality Improvement Organization (QIO) has assumed binding review for the hospital.</i> 2) <i>CMS has determined that the UR procedures established by the State under title XIX of the Act (Social Security Act) are superior to the procedures required in this section, and has required hospitals in that State to meet the UR plan requirements under 456.50 through 456.245 of 42 CFR 456.</i></p>

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<p>§482.30(b) §482.30(b)(1) §482.30(b)(1)(i) §482.30(b)(1)(ii) §482.30(b)(1)(ii)(A) §482.30(b)(1)(ii)(B) §482.30(b)(2) §482.30(b)(3) §482.30(b)(3)(i) §482.30(b)(3)(ii)</p>	<p><i>Standard: Composition of utilization review committee.</i> A UR committee consisting of two or more practitioners must carry out the UR function. At least two of the members of the committee must be doctors of medicine or osteopathy. The other members may be any of the other types of practitioners specified in § 482.12(c)(1).</p> <p>(1) Except as specified in paragraphs (b) (2) and (3) of this section, the UR committee must be one of the following:</p> <p>(i) A staff committee of the institution; (ii) A group outside the institution—</p> <p>(A) Established by the local medical society and some or all of the hospitals in the locality; or (B) Established in a manner approved by CMS.</p> <p>(2) If, because of the small size of the institution, it is impracticable to have a properly functioning staff committee, the UR committee must be established as specified in paragraph (b)(1)(ii) of this section.</p> <p>(3) The committee’s or group’s reviews may not be conducted by any individual who—</p> <p>(i) Has a direct financial interest (for example, an ownership interest) in that hospital; or (ii) Was professionally involved in the care of the patient whose case is being reviewed.</p>	<p style="text-align: center;">03.04.02</p>	<p><u>Composition of the UR Committee</u> (A) UR committee consisting of two or more practitioners must carry out the UR function. At least two of the members of the committee must be doctors of medicine or osteopathy. The other members may be any of the other types of practitioners specified in §482.12(c)(1).</p> <p>(1) Except as specified in paragraphs (b)(2) and (3) of 42 CFR 482.30, the UR committee must be one of the following:</p> <p>(i) A staff committee of the institution; (ii) A group outside the institution—</p> <p>(A) Established by the local medical society and some or all of the hospitals in the locality; or (B) Established in a manner approved by CMS.</p> <p>(2) If, because of the small size of the institution, it is impracticable to have a properly functioning staff committee, the UR committee must be established as specified in paragraph (b)(1)(ii) of 42 CFR 482.30.</p> <p>(3) The committee or group’s reviews may not be conducted by any individual who—</p> <p>(i) Has a direct financial interest (for example, an ownership interest) in that hospital; or (ii) Was professionally involved in the care of the patient whose case is being reviewed.</p>
<p>§482.30(c)(1) §482.30(c)(1)(i) §482.30(c)(1)(ii) §482.30(c)(1)(iii) §482.30(c)(2) §482.30(c)(3) §482.30(c)(4) §482.30(c)(4)(i) §482.30(c)(4)(ii)</p>	<p><i>Standard: Scope and frequency of review.</i></p> <p>(1) The UR plan must provide for review for Medicare and Medicaid patients with respect to the medical necessity of—</p> <p>(i) Admissions to the institution; (ii) The duration of stays; and (iii) Professional services furnished, including drugs and biologicals.</p> <p>(2) Review of admissions may be performed before, at, or after hospital admission.</p> <p>(3) Except as specified in paragraph (e) of this section,</p>	<p style="text-align: center;">03.04.03</p>	<p><u>UR Review Requirements</u></p> <p>(1) The UR plan must provide for review for Medicare and Medicaid patients with respect to the medical necessity of:</p> <p>(i) Admissions to the institution; (ii) The duration of stays; (iii) Professional services furnished including, drugs and biologicals.</p> <p>(2) Review of admissions may be performed before, at, or after hospital admission.</p> <p>(3) Except as specified in paragraph (e) of 42 CFR 482.30, reviews</p>

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	<p>reviews may be conducted on a sample basis.</p> <p>(4) Hospitals that are paid for inpatient hospital services under the prospective payment system set forth in Part 412 of this chapter must conduct review of duration of stays and review of professional services as follows:</p> <ul style="list-style-type: none"> (i) For duration of stays, these hospitals need review only cases that they reasonably assume to be outlier cases based on extended length of stay, as described in § 412.80(a)(1)(i) of this chapter; and (ii) For professional services, these hospitals need review only cases that they reasonably assume to be outlier cases based on extraordinarily high costs, as described in § 412.80(a)(1)(ii) of this chapter. 		<p>may be conducted on a sample basis.</p> <p>(4) Hospitals that are paid for inpatient hospital services under the prospective payment system set forth in Part 412 of 42 CFR 412 must conduct review of duration of stays and review of professional services as follows:</p> <ul style="list-style-type: none"> (i) for duration of stays, these hospitals need review only cases that they reasonably assume to be outlier cases based on extended length of stay, as described in §412.80(a)(1)(i) of 42 CFR 482.80; and (ii) for professional services, these hospitals need review only cases that they reasonably assume to be outlier cases based on extraordinarily high costs as described in §412.80(a)(1)(ii) of 42 CFR 482.80.
<p>§482.30(d) §482.30(d)(1) §482.30(d)(1)(i) §482.30(d)(1)(ii) §482.30(d)(2) §482.30(d)(3)</p>	<p>Standard: Determination regarding admissions or continued stays.</p> <p>(1) The determination that an admission or continued stay is not medically necessary—</p> <ul style="list-style-type: none"> (i) May be made by one member of the UR committee if the practitioner or practitioners responsible for the care of the patient, as specified of §482.12(c), concur with the determination or fail to present their views when afforded the opportunity; and (ii) Must be made by at least two members of the UR committee in all other cases. <p>(2) Before making a determination that an admission or continued stay is not medically necessary, the UR committee must consult the practitioner or practitioners responsible for the care of the patient, as specified in §482.12(c), and afford the practitioner or practitioners the opportunity to present their views.</p> <p>(3) If the committee decides that admission to or continued stay in the hospital is not medically necessary, written notification must be given, no later than 2 days after the determination, to the hospital, the patient, and the practitioner or practitioners responsible for the care of</p>	<p style="text-align: center;">03.04.04</p>	<p>Determination Regarding Admissions or Continued Stays</p> <p>(1) The determination that an admission or continued stay is not medically necessary –</p> <ul style="list-style-type: none"> (i) May be made by one member of the UR committee, if the practitioner or practitioners responsible for the care of the patient as specified of 482.12(c) concur with the determination or fail to present their views when afforded the opportunity; and (ii) Must be made by at least two members of the UR Committee in all other cases. <p>(2) Before making a determination that an admission or continued stay is not medically necessary, the URC must consult the practitioner or practitioners responsible for the care of the patient as specified in 482.12(c), and afford the practitioner or practitioners the opportunity to present their views.</p> <p>(3) If the committee decides that admission to or continued stay in the hospital is not medically necessary, written notification must be given, no later than 2 days after the determination, to the hospital, the patient, and the practitioner or practitioners responsible for the care of the patient.</p>

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	<i>the patient, as specified in § 482.12(c);</i>		
<p>§482.30(e) §482.30(e)(1) §482.30(e)(1)(i) §482.30(e)(1)(ii) §482.30(e)(2) §482.30(e)(3)</p>	<p><i>Standard: Extended stay review.</i></p> <p>(1) <i>In hospitals that are not paid under the prospective payment system, the UR committee must make a periodic review, as specified in the UR plan, of each current inpatient receiving hospital services during a continuous period of extended duration. The scheduling of the periodic reviews may—</i></p> <p style="margin-left: 20px;"><i>(i) Be the same for all cases; or</i></p> <p style="margin-left: 20px;"><i>(ii) Differ for different classes of cases.</i></p> <p>(2) <i>In hospitals paid under the prospective payment system, the UR committee must review all cases reasonably assumed by the hospital to be outlier cases because the extended length of stay exceeds the threshold criteria for the diagnosis, as described in § 412.80(a)(1)(i). The hospital is not required to review an extended stay that does not exceed the outlier threshold for the diagnosis.</i></p> <p>(3) <i>The UR committee must make the periodic review no later than 7 days after the day required in the UR plan.</i></p>	03.04.05	<p><u>Utilization Review Scope in Non-PPS Hospitals – Extended Stay Review.</u></p> <p>(1) <i>In hospitals that are not paid under the prospective payment system, the UR committee must make a periodic review, as specified in the UR plan, of each current inpatient receiving hospital services during a continuous period of extended duration. The scheduling of the periodic reviews may:</i></p> <p style="margin-left: 20px;"><i>(a) Be the same for all cases or</i></p> <p style="margin-left: 20px;"><i>(b) Differ for different classes of cases.</i></p> <p>(2) <i>In hospitals paid under the prospective payment system, the UR committee must review all cases reasonably assumed by the hospital to be outlier cases because of the extended length of stay exceeding the threshold criteria for diagnosis. The hospital is not required to review an extended stay that does not exceed the outlier threshold for the diagnosis..</i></p> <p>(3) <i>The Utilization Review committee must make the periodic review no later than 7 days after the day required in the UR plan</i></p>
§482.30(f)	<p><i>Standard: Review of professional services.</i></p> <p><i>The committee must review professional services provided, to determine medical necessity and to promote the most efficient use of available health facilities and services.</i></p>	03.04.06	<p><u>Review of Professional Services</u></p> <p><i>The committee must review professional services provided, to determine medical necessity and to promote the most efficient use of available health facilities and services.</i></p>
§482.41	<p><u>Condition of participation: Physical environment.</u></p> <p><i>The hospital must be constructed, arranged, and maintained to ensure the safety of the patient, and to provide facilities for diagnosis and treatment and for special hospital services appropriate to the needs of the community.</i></p>	11.00.01	<p><u>Physical Environment</u></p> <p><i>The hospital must be constructed, arranged, and maintained to ensure the safety of the patient, and to provide facilities for diagnosis and treatment, and for special hospital services appropriate to the needs of the community.</i></p>

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<p>§482.41(a)</p>	<p><i>Standard: Buildings.</i> <i>The condition of the physical plant and the overall hospital environment must be developed and maintained in such a manner that the safety and well-being of patients are assured.</i></p>	<p>11.01.02</p>	<p><u>Building Safety</u></p> <p><i>The condition of the physical plant and the overall hospital environment must be developed and maintained in such a manner that the safety and well-being of patients, visitors, and staff is assured.</i></p>
<p>§482.41(a)(1)</p>	<p>(1) <i>There must be emergency power and lighting in at least the operating, recovery, intensive care, and emergency rooms, and stairwells. In all other areas not serviced by the emergency supply source, battery lamps and flashlights must be available.</i></p>	<p>11.06.01</p>	<p><u>Emergency Power & Lighting</u></p> <p><i>There must be emergency power and lighting in at least the operating, recovery, intensive care, emergency rooms, and stairwells. In all other areas not serviced by the emergency supply source, battery lamps and flashlights shall be available.</i></p>
<p>§482.41(a)(2)</p>	<p>(2) <i>There must be facilities for emergency gas and water supply.</i></p>	<p>09.01.03</p>	<p><u>Emergency Utilities</u></p> <p>The Emergency Operations Plan provides for the continuation of emergency power, fuel, medical air, gas, and vacuum, and potable water during an emergency event.</p> <p><i>There must be facilities for emergency gas and water supply.</i></p>
<p>§482.41(b) §482.41(b)(1) §482.41(b)(1)(i) §482.41(b)(1)(ii)</p>	<p><i>Standard: Life safety from fire.</i></p> <p>(1) <i>Except as otherwise provided in this section—</i></p> <p style="padding-left: 20px;">(i) <i>The hospital must meet the applicable provisions and must proceed in accordance with the Life Safety Code (NFPA 101 and Tentative Interim Amendments TIA 12-1, TIA 12-2, TIA 12-3, and TIA 12-4.) Outpatient surgical departments must meet the provisions applicable to Ambulatory Health Care Occupancies, regardless of the number of patients served.</i></p> <p style="padding-left: 20px;">(ii) <i>Notwithstanding paragraph (b)(1)(i) of this section, corridor doors and doors to rooms containing</i></p>	<p>13.00.01</p>	<p><u>Life Safety Code Compliance</u></p> <p><i>Except as otherwise provided in this section—</i></p> <p><i>The hospital must meet the applicable provisions and must proceed in accordance with the Life Safety Code (NFPA 101 and Tentative Interim Amendments TIA 12-1, TIA 12-2, TIA 12-3, and TIA 12-4.) Outpatient surgical departments must meet the provisions applicable to Ambulatory Health Care Occupancies, regardless of the number of patients served. §482.41(b)(1)(i)</i></p>

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	<p><i>flammable or combustible materials must be provided with positive latching hardware. Roller latches are prohibited on such doors.</i></p>		<p><i>Notwithstanding paragraph (b)(1)(i) of this section, corridor doors and doors to rooms containing flammable or combustible materials must be provided with positive latching hardware. Roller latches are prohibited on such doors. §482.41(b)(1)(ii)</i></p> <p><i>The provisions of the Life Safety Code do not apply in a State where CMS finds that a fire and safety code imposed by State law adequately protects patients in hospitals. §482.41(b)(3)</i></p>
		<p>13.01.01</p>	<p><u>Doors.</u></p> <p>Corridor doors and doors to hazardous rooms shall be provided with positive latching hardware.</p> <p>Roller latches are not permitted on corridor doors that are required to latch.</p> <p>Corridor doors shall be capable of resisting the passage of smoke.</p> <p>Doors in the path of egress must be side-hinged or pivot-swing type.</p>
<p>§482.41(b)(2)</p>	<p>(2) <i>In consideration of a recommendation by the State survey agency or Accrediting Organization or at the discretion of the Secretary, may waive, for periods deemed appropriate, specific provisions of the Life Safety Code, which would result in unreasonable hardship upon a hospital, but only if the waiver will not adversely affect the health and safety of the patients.</i></p>	<p>Chapter 13; page 3 Introduction</p>	<p><u>Waivers</u></p> <p>Requests for waivers are permitted but only after the Life Safety Code deficiency has been cited during an HFAP survey. As part of the organization’s Plan of Correction, a waiver request may be presented to HFAP, who will consider the request and pass it on to the respective CMS Regional Office for approval. The waiver must explain the unreasonable hardship the healthcare organization has in meeting the Life Safety Code requirement and that it does not present a safety risk to the patient or staff.</p> <p>When making a waiver request, the hospital should identify the deficiency, how the hospital deviates from the code, and steps taken by the hospital to ensure the equivalent level of safety. The hospital has the option of requesting a time-limited waiver if the intent is to ‘bridge’ a period of time until a feature of safety is installed or</p>

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			<p>modified, such as the installation of sprinklers.</p> <p>Waivers approved by CMS are only valid until the next survey cycle.</p> <p>§482.41(b)(2)</p>
§482.41(b)(3)	(3) <i>The provisions of the Life Safety Code do not apply in a State where CMS finds that a fire and safety code imposed by State law adequately protects patients in hospitals.</i>	13.00.01	<p><u>Life Safety Code Compliance</u></p> <p><i>Except as otherwise provided in this section—</i></p> <p><i>The hospital must meet the applicable provisions and must proceed in accordance with the Life Safety Code (NFPA 101 and Tentative Interim Amendments TIA 12-1, TIA 12-2, TIA 12-3, and TIA 12-4.) Outpatient surgical departments must meet the provisions applicable to Ambulatory Health Care Occupancies, regardless of the number of patients served. §482.41(b)(1)(i)</i></p> <p><i>Notwithstanding paragraph (b)(1)(i) of this section, corridor doors and doors to rooms containing flammable or combustible materials must be provided with positive latching hardware. Roller latches are prohibited on such doors. §482.41(b)(1)(ii)</i></p> <p><i>The provisions of the Life Safety Code do not apply in a State where CMS finds that a fire and safety code imposed by State law adequately protects patients in hospitals. §482.41(b)(3)</i></p>
§482.41(b)(4)	(4) <i>The hospital must have procedures for the proper routine storage and prompt disposal of trash.</i>	11.03.02	<p><u>11.03.01 Storage & Disposal Of Trash.</u></p> <p><i>The hospital must have procedures for the proper routine storage and prompt disposal of trash.</i></p> <p>§482.41(b)(4)</p>
		13.05.03	<p><u>Trash & Linen Chutes</u></p> <p>All trash and linen chute inlet and discharge door assemblies are</p>

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			<p>properly fire rated, are self-closing, and positive latching. Chute door assemblies have not been modified in the field.</p> <p>Trash chutes discharge into a collection room that is not used for any other purpose.</p> <p>An approved automatic sprinkler system is installed inside the chute at the top and at the lowest service level, and on alternating floors levels.</p> <p>Trash and linen discharge rooms are separated from the corridor and other areas with 1-hour fire rated barriers.</p>
§482.41(b)(5)	(5) <i>The hospital must have written fire control plans that contain provisions for prompt reporting of fires; extinguishing fires; protection of patients, personnel and guests; evacuation; and cooperation with fire fighting authorities.</i>	11.04.01	<p><u>Written Fire Control Plans.</u></p> <p><i>The hospital must have written fire control plans that contain provisions for:</i></p> <ul style="list-style-type: none"> • <i>Prompt reporting of fires</i> • <i>Extinguishing fires</i> • <i>Protection for patients, personnel and guests</i> • <i>Evacuation</i> • <i>Cooperation with fire-fighting authorities</i>
§482.41(b)(6)	(6) <i>The hospital must maintain written evidence of regular inspection and approval by State or local fire control agencies.</i>	11.04.04	<p><u>Approval by State & Local Fire Agencies.</u></p> <p><i>The hospital must maintain written evidence of regular inspection and approval by state or local fire control agencies.</i></p>
§482.41(b)(7)	(7) <i>A hospital may install alcohol-based hand rub dispensers in its facility if the dispensers are installed in a manner that adequately protects against inappropriate access.</i>	13.06.05	<p><u>Alcohol Based Hand-Rub Dispensers.</u></p> <p>Alcohol based hand-rub (ABHR) dispensers are permitted to be installed in exit access corridors of healthcare occupancies, and ambulatory health care occupancies.</p>

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			§482.41(b)(7)
§482.41(b)(8) §482.41(b)(8)(i) §482.41(b)(8)(ii)	(8) <i>When a sprinkler system is shut down for more than 10 hours, the hospital must:</i> (i) <i>Evacuate the building or portion of the building affected by the system outage until the system is back in service, or</i> (ii) <i>Establish a fire watch until the system is back in service</i>	13.00.04	<p><u>Notification of Emergency Response Forces.</u></p> <p>The hospital notifies the local emergency response force (fire department) when a fire alarm system, or parts thereof, is out of service more than four (4) hours in a 24-hour period, and either evacuates the building or portions of the building affected by the outage or implements a fire watch in all affected areas.</p> <p>The hospital notifies the local emergency response force (fire department) when an automatic sprinkler system, or parts thereof, is out of service more than ten (10) hours in a 24-hour period, and either evacuates the building or portions of the building affected by the outage or implements a fire watch in all affected areas.</p> <p>The fire watch and the notification of the local emergency response force are documented.</p> <p>§482.41(b)(8) §482.41(b)(8)(i) §482.41(b)(8)(ii)</p>
		13.00.09	<p><u>Fire Watch.</u></p> <p>A fire watch consists of dedicated, trained individual(s) with no other duties constantly circulating throughout the portion of the facility affected by the deficiency or impairment looking for a fire, fire hazards, or hazardous conditions that may affect the fire safety of the facility.</p>

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<p>§482.41(b)(9) §482.41(b)(9)(i) §482.41(b)(9)(ii)</p>	<p>(9) <i>Buildings must have an outside window or outside door in every sleeping room, and for any building constructed after July 5, 2016 the sill height must not exceed 36 inches above the floor. Windows in atrium walls are considered outside windows for the purposes of this requirement.</i></p> <p>(i) <i>The sill height requirement does not apply to newborn nurseries and rooms intended for occupancy for less than 24 hours.</i></p> <p>(ii) <i>The sill height in special nursing care areas of new occupancies must not exceed 60 inches.</i></p>	<p>11.07.01</p>	<p><u>Adequate Facilities and Supplies.</u> <i>The hospital must maintain adequate facilities for its services.</i></p> <p><i>Facilities, supplies, and equipment must be maintained to ensure an acceptable level of safety and quality.</i></p> <p><i>The extent and complexity of facilities shall be determined by the services offered.</i></p> <p><i>Diagnostic and therapeutic facilities must be located for the safety of patients.</i></p> <p><i>Buildings must have an outside window or outside door in every sleeping room, and for any building constructed after July 5, 2016 the sill height must not exceed 36 inches above the floor. Windows in atrium walls are considered outside windows for the purposes of this requirement.</i></p> <p><i>The sill height requirement does not apply to newborn nurseries and rooms intended for occupancy for less than 24 hours.</i></p> <p><i>The sill height in special nursing care areas of new occupancies must not exceed 60 inches.</i></p>
<p>§482.41(c) §482.41(c)(1) §482.41(c)(2)</p>	<p><i>Standard: Building safety.</i></p> <p><i>Except as otherwise provided in this section, the hospital must meet the applicable provisions and must proceed in accordance with the Health Care Facilities Code (NFPA 99 and Tentative Interim Amendments TIA 12-2, TIA 12-3, TIA 12-4, TIA 12-5 and TIA 12-6).</i></p> <p><i>Chapters 7, 8, 12, and 13 of the adopted Health Care Facilities Code do not apply to a hospital.</i></p> <p><i>If application of the Health Care Facilities Code required under paragraph (c) of this section would result in unreasonable hardship for the hospital, CMS may waive</i></p>	<p>13.05.12</p>	<p><u>Health Care Facilities Code.</u></p> <p>Except as otherwise provided in this section, the hospital must meet the applicable provision and must proceed in accordance with the Health Care Facilities Code (NFPA 99-2012 edition, and Tentative Interim Amendments TIA-12-2, TIA 12-3, TIA 12-4, TIA 12-5 and TIA 12-6.</p> <p>Chapters 7, 8, 12 and 13 of the adopted Health Care Facilities Code do not apply to a hospital.</p> <p>If application of the Health Care Facilities Code required under this section would result in an unreasonable hardship for the hospital,</p>

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	<i>specific provisions of the Health Care Facilities Code, but only if the waiver does not adversely affect the health and safety of patients.</i>		CMS may waive specific provisions of the Health Care Facilities Code, but only if the waiver does not adversely affect the health and safety of the patients.
<p>§482.41(d) §482.41(d)(1) §482.41(d)(2) §482.41(d)(3)</p>	<p><i>Standard: Facilities.</i> <i>The hospital must maintain adequate facilities for its services.</i> (1) <i>Diagnostic and therapeutic facilities must be located for the safety of patients.</i> (2) <i>Facilities, supplies, and equipment must be maintained to ensure an acceptable level of safety and quality.</i> (3) <i>The extent and complexity of facilities must be determined by the services offered.</i></p>	11.07.01	<p><u>Adequate Facilities and Supplies.</u> <i>The hospital must maintain adequate facilities for its services.</i></p> <p><i>Facilities, supplies, and equipment must be maintained to ensure an acceptable level of safety and quality.</i></p> <p><i>The extent and complexity of facilities shall be determined by the services offered.</i></p> <p><i>Diagnostic and therapeutic facilities must be located for the safety of patients.</i></p> <p><i>Buildings must have an outside window or outside door in every sleeping room, and for any building constructed after July 5, 2016 the sill height must not exceed 36 inches above the floor. Windows in atrium walls are considered outside windows for the purposes of this requirement.</i></p> <p><i>The sill height requirement does not apply to newborn nurseries and rooms intended for occupancy for less than 24 hours.</i></p> <p><i>The sill height in special nursing care areas of new occupancies must not exceed 60 inches.</i></p> <p>§482.41(b)(9); §482.41(b)(9)(i); §482.41(b)(9)(ii)</p>
§482.41(d)(4)	(4) <i>There must be proper ventilation, light, and temperature controls in pharmaceutical, food preparation, and other appropriate areas.</i>	11.07.03	<p><u>Ventilation, Light, & Temperature Controls.</u> <i>There must be proper ventilation, light, and temperature controls in</i></p>

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			<p><i>pharmaceutical, food preparation, and other appropriate areas.</i></p> <p>§482.41(d)(4)</p>
<p>§482.41(e)</p>	<p><i>(e) The standards incorporated by reference in this section are approved for incorporation by reference by the Director of the Office of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may inspect a copy at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to:</i></p> <p><i>http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html. If any changes in this edition of the Code are incorporated by reference, CMS will publish a document in the FEDERAL REGISTER to announce the changes.</i></p> <p><i>(1) National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02169, www.nfpa.org, 1.617.770.3000.</i></p> <p><i>(i) NFPA 99, Standards for Health Care Facilities Code of the National Fire Protection Association 99, 2012 edition, issued August 11, 2011.</i></p> <p><i>(ii) TIA 12-2 to NFPA 99, issued August 11, 2011.</i></p> <p><i>(iii) TIA 12-3 to NFPA 99, issued August 9, 2012.</i></p> <p><i>(iv) TIA 12-4 to NFPA 99, issued March 7, 2013.</i></p> <p><i>(v) TIA 12-5 to NFPA 99, issued August 1, 2013.</i></p> <p><i>(vi) TIA 12-6 to NFPA 99, issued March 3, 2014.</i></p> <p><i>(vii) NFPA 101, Life Safety Code, 2012 edition, issued August 11, 2011;</i></p> <p><i>(viii) TIA 12-1 to NFPA 101, issued August 11, 2011.</i></p> <p><i>(ix) TIA 12-2 to NFPA 101, issued October 30, 2012.</i></p> <p><i>(x) TIA 12-3 to NFPA 101, issued October 22, 2013.</i></p>	<p>Chapter 13</p> <p>Page 62</p>	<p>CMS Resources:</p> <p>482.41(e) The standards incorporated by reference in this section are approved for incorporation by reference by the Director of the Office of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may inspect a copy at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to:</p> <p><i>http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html. If any changes in this edition of the Code are incorporated by reference, CMS will publish a document in the FEDERAL REGISTER to announce the changes.</i></p> <p>482.41(e)(1) National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02169, www.nfpa.org, 1.617.770.3000.</p> <p>(i) NFPA 99, Standards for Health Care Facilities Code of the National Fire Protection Association 99, 2012 edition, issued August 11, 2011.</p> <p>(ii) TIA 12-2 to NFPA 99, issued August 11, 2011.</p> <p>(iii) TIA 12-3 to NFPA 99, issued August 9, 2012.</p> <p>(iv) TIA 12-4 to NFPA 99, issued March 7, 2013.</p> <p>(v) TIA 12-5 to NFPA 99, issued August 1, 2013.</p> <p>(vi) TIA 12-6 to NFPA 99, issued March 3, 2014.</p> <p>(vii) NFPA 101, Life Safety Code, 2012 edition, issued August 11, 2011;</p> <p>(viii) TIA 12-1 to NFPA 101, issued August 11, 2011.</p> <p>(ix) TIA 12-2 to NFPA 101, issued October 30, 2012.</p> <p>(x) TIA 12-3 to NFPA 101, issued October 22, 2013.</p> <p>(xi) TIA 12-4 to NFPA 101, issued October 22, 2013.</p>

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	(xi) TIA 12-4 to NFPA 101, issued October 22, 2013. (2) [Reserved]		
§482.42	Condition of participation: Infection control. <i>The hospital must provide a sanitary environment to avoid sources and transmission of infections and communicable diseases. There must be an active program for the prevention, control, and investigation of infections and communicable diseases.</i>	07.00.00	Condition of Participation: Infection Control <i>The hospital must provide a sanitary environment to avoid sources and transmission of infections and communicable diseases. There must be an active program for the prevention, control, and investigation of infections and communicable diseases.</i>
§482.42(a)	(a) <i>Standard: Organization and policies.</i> <i>A person or persons must be designated as infection control officer or officers to develop and implement policies governing control of infections and communicable diseases.</i>	07.01.01	Infection Control Officer (ICO) <i>A person or persons must be designated as Infection Control Officer (ICO) or officers to develop and implement policies governing control of infections and communicable diseases.</i>
§482.42(a)	<i>The infection control officer or officers must develop a system for identifying, reporting, investigating, and controlling infections and communicable diseases of patients and personnel.</i>	07.01.02	Infection Prevention <i>The infection control officer or officers must develop a system for identifying, investigating, reporting and preventing spread of infections among patients and personnel.</i>
§482.42(b) §482.42(b)(1) §482.42(b)(2)	(b) <i>Standard: Responsibilities of chief executive officer, medical staff, and director of nursing services.</i> <i>The chief executive officer, the medical staff, and the director of nursing services must—</i> (1) <i>Ensure that the hospital-wide quality assessment and performance improvement (QAPI) program and training programs address problems identified by the infection control officer or officers; and</i> (2) <i>Be responsible for the implementation of successful corrective action plans in affected problem areas.</i>	07.01.04	Responsibilities of Chief Executive Officer, Medical Staff, & Director of Nursing Services <i>The hospital's chief executive officer, the medical staff, and the director of nursing services must:</i> (1) <i>Ensure that the hospital-wide quality assessment and performance improvement (QAPI) program and training programs address problems identified by the infection control officer(s).</i> (2) <i>Be responsible for the implementation of successful corrective action plans in affected problem areas.</i>
§482.43	Condition of participation: Discharge planning. <i>The hospital must have in effect a discharge planning process that applies to all patients. The hospital's policies and</i>	15.03.00	Condition of Participation: Discharge Planning <i>The hospital must have an effective discharge planning process that applies to all patients. The hospital's policies and procedures must be</i>

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	<i>procedures must be specified in writing.</i>		<i>specified in writing.</i>
§482.43(a)	<i>Standard: Identification of patients in need of discharge planning. The hospital must identify at an early stage of hospitalization all patients who are likely to suffer adverse health consequences upon discharge if there is no adequate discharge planning.</i>	15.03.01	<u>Discharge Planning – Identification of Patients in Need</u> <i>The hospital must identify at an early stage of hospitalization all patients who are likely to suffer adverse health consequences upon discharge if there is no adequate discharge planning.</i>
§482.43(b) §482.43(b)(1)	<i>Standard: Discharge planning evaluation. (1) The hospital must provide a discharge planning evaluation to the patients identified in paragraph (a) of this section, and to other patients upon the patient’s request, the request of a person acting on the patient’s behalf, or the request of the physician.</i>	15.03.02	<u>Discharge Planning Evaluation</u> <i>(1) The hospital must provide a discharge planning evaluation to the patients identified in paragraph (a) of 42 CFR 482.43 , and to other patients upon the patient’s request, the request of a person acting on the patient’s behalf, or the request of the physician. (3) The discharge planning evaluation must include an evaluation of the likelihood of a patient needing post-hospital services and of the availability of the services. (4) The discharge planning evaluation must include an evaluation of the likelihood of a patient’s capacity for self-care or of the possibility of the patient being cared for in the environment from which he or she entered the hospital.</i>
§482.43(b)(2)	<i>(2) A registered nurse, social worker, or other appropriately qualified personnel must develop, or supervise the development of, the evaluation.</i>	15.03.03	<u>Discharge Planning – Staff Qualifications</u> <i>A registered nurse, social worker, or other appropriately qualified personnel must develop or supervise the development of, the evaluation.</i>
§482.43(b)(3)	<i>(3) The discharge planning evaluation must include an evaluation of the likelihood of a patient needing post-hospital services and of the availability of the services.</i>	15.03.02	<u>Discharge Planning Evaluation</u> <i>(1) The hospital must provide a discharge planning evaluation to the patients identified in paragraph (a) of 42 CFR 482.43, and to other patients upon the patient’s request, the request of a person acting on the patient’s behalf, or the request of the</i>

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			<p>physician.</p> <p>(3) <i>The discharge planning evaluation must include an evaluation of the likelihood of a patient needing post-hospital services and of the availability of the services.</i></p> <p>(4) <i>The discharge planning evaluation must include an evaluation of the likelihood of a patient’s capacity for self-care or of the possibility of the patient being cared for in the environment from which he or she entered the hospital.</i></p>
§482.43(b)(4)	(4) <i>The discharge planning evaluation must include an evaluation of the likelihood of a patient’s capacity for self-care or of the possibility of the patient being cared for in the environment from which he or she entered the hospital.</i>	15.03.02	<p><u>Discharge Planning Evaluation</u></p> <p>(1) <i>The hospital must provide a discharge planning evaluation to the patients identified in paragraph (a) of 42 CFR 482.43, and to other patients upon the patient’s request, the request of a person acting on the patient’s behalf, or the request of the physician.</i></p> <p>(4) <i>The discharge planning evaluation must include an evaluation of the likelihood of a patient needing post-hospital services and of the availability of the services.</i></p> <p>(4) <i>The discharge planning evaluation must include an evaluation of the likelihood of a patient’s capacity for self-care or of the possibility of the patient being cared for in the environment from which he or she entered the hospital.</i></p>
§482.43(b)(5)	(5) <i>The hospital personnel must complete the evaluation on a timely basis so that appropriate arrangements for post-hospital care are made before discharge, and to avoid unnecessary delays in discharge.</i>	15.03.06	<p><u>Timeliness of Assessment</u></p> <p><i>The hospital personnel must complete the evaluation on a timely basis so that appropriate arrangements for post-hospital care are made before discharge, and to avoid unnecessary delays in discharge.</i></p>
§482.43(b)(6)	(6) <i>The hospital must include the discharge planning evaluation in the patient’s medical record for use in</i>	15.03.07	<p><u>Patient Involvement & Documentation Requirements</u></p> <p><i>The hospital must:</i></p>

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	<i>establishing an appropriate discharge plan and must discuss the results of the evaluation with the patient or individual acting on his or her behalf.</i>		<ul style="list-style-type: none"> • <i>Include the discharge planning evaluation in the patient's medical record for use in establishing an appropriate discharge plan and</i> • <i>Must discuss the results of the evaluation with the patient or individual acting on his/her behalf.</i>
§482.43(c)(1)	<p><i>Standard: Discharge plan.</i></p> <p>(1) <i>A registered nurse, social worker, or other appropriately qualified personnel must develop, or supervise the development of, a discharge plan if the discharge planning evaluation indicates a need for a discharge plan.</i></p>	15.03.09	<p><u>Discharge Planning: Required Supervision</u></p> <p><i>A registered nurse, social worker, or other appropriately qualified personnel must develop, or supervise the development of, a discharge plan if the discharge planning evaluation indicates a need for a discharge plan</i></p>
§482.43(c)(2)	(2) <i>In the absence of a finding by the hospital that a patient needs a discharge plan, the patient's physician may request a discharge plan. In such a case, the hospital must develop a discharge plan for the patient.</i>	15.03.10	<p><u>Discharge Plan – Physician Request</u></p> <p><i>In the absence of a finding by the hospital that a patient needs a discharge plan, the patient's physician may request a discharge plan. In such case, the hospital must develop a discharge plan for the patient.</i></p>
§482.43(c)(3)	(3) <i>The hospital must arrange for the initial implementation of the patient's discharge plan.</i>	15.03.11	<p><u>Implementation of the Discharge Plan</u></p> <p><i>The hospital must arrange for the initial implementation of the patient's discharge plan.</i></p> <p><i>As needed, the patient and family members or interested persons must be counseled to prepare them for post hospital care.</i></p>
§482.43(c)(4)	(4) <i>The hospital must reassess the patient's discharge plan if there are factors that may affect continuing care needs or the appropriateness of the discharge plan.</i>	15.03.12	<p><u>Plan Reassessment</u></p> <p><i>The hospital must reassess the patient's discharge plan if there are factors that may affect continuing care needs or the appropriateness of the discharge plan.</i></p>
§482.43(c)(5)	(5) <i>As needed, the patient and family members or interested persons must be counseled to prepare them for post-hospital care.</i>	15.03.11	<p><u>Implementation of the Discharge Plan</u></p> <p><i>The hospital must arrange for the initial implementation of the patient's discharge plan.</i></p>

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			<p><i>As needed, the patient and family members or interested persons must be counseled to prepare them for post hospital care.</i></p>
<p>§482.43(c)(6) §482.43(c)(6)(i) §482.43(c)(6)(ii) §482.43(c)(6)(iii) §482.43(c)(7) §482.43(c)(8)</p>	<p>(6) <i>The hospital must include in the discharge plan a list of HHAs or SNFs that are available to the patient, that are participating in the Medicare program, and that serve the geographic area (as defined by the HHA) in which the patient resides, or in the case of a SNF, in the geographic area requested by the patient. HHAs must request to be listed by the hospital as available.</i></p> <p>(i) <i>This list must only be presented to patients for who home health care or post-hospital extended care services are indicated and appropriate as determined by the discharge planning evaluation.</i></p> <p>(ii) <i>For patients enrolled in managed care organizations, the hospital must indicate the availability of home health and posthospital extended care services through individuals and entities that have a contract with the managed care organizations.</i></p> <p>(iii) <i>The hospital must document in the patient’s medical record that the list was presented to the patient or to the individual acting on the patient’s behalf.</i></p> <p>(7) <i>The hospital, as part of the discharge planning process, must inform the patient or the patient’s family of their freedom to choose among participating Medicare providers of posthospital care services and must, when possible, respect patient and family preferences when they are expressed. The hospital must not specify or otherwise limit the qualified providers that are available to the patient.</i></p> <p>(8) <i>The discharge plan must identify any HHA or SNF to which the patient is referred in which the hospital has a</i></p>	<p style="text-align: center;">15.03.14</p>	<p><u>Selection of Discharge Care Providers</u> <i>The hospital must include in the discharge plan a list of home health agencies (HHA) or skilled nursing facilities (SNF) that are available to the patient, that are participating in the Medicare program, and that serve the geographic area (as defined by the HHA) in which the patient resides, or in the case of the SNF, in the geographic area requested by the patient. HHAs must request to be listed by the hospital as available.</i></p> <p>(i) <i>This list must only be presented to patients for whom home health care or post hospital extended care services are indicated and appropriate as determined by the discharge planning evaluation.</i></p> <p>(ii) <i>For patients enrolled in managed care organizations, the hospital must indicate the availability of home health and post hospital extended care services through individuals and entities that have a contract with the managed care organizations.</i></p> <p>(iii) <i>The hospital must document in the patient’s medical record that the list was presented to the patient or to the individual acting on the patient’s behalf.</i></p> <p><i>The hospital, as part of the discharge planning process, must inform the patient or the patient’s family of their freedom to choose among participating Medicare providers of post-hospital care services and must, when possible, respect patient and family preferences when they are expressed. The hospital must not specify or otherwise limit the qualified providers that are available to the patient.</i></p> <p><i>The discharge plan must identify any HHA or SNF to which the patient is referred in which the hospital has a disclosable financial interest, as</i></p>

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	<p><i>disclosable financial interest, as specified by the Secretary, and any HHA or SNF that has a disclosable financial interest in a hospital under Medicare. Financial interests that are disclosable under Medicare are determined in accordance with the provisions of Part 420, Subpart C, of this chapter.</i></p>		<p><i>specified by the Secretary, and any HHA or SNF that has a disclosable financial interest in a hospital under Medicare. Financial interests that are disclosable under Medicare are determined in accordance with the provisions of Part 420, Subpart C, of 42 CFR 420.</i></p>
§482.43(d)	<p><i>Standard: Transfer or referral. The hospital must transfer or refer patients, along with necessary medical information, to appropriate facilities, agencies, or outpatient services, as needed, for follow-up or ancillary care.</i></p>	15.03.23	<p><u>Transfer or Referral</u> <i>The hospital must transfer or refer patients, along with necessary medical information, to appropriate facilities, agencies, or outpatient services, as needed, for follow-up or ancillary care.</i></p>
§482.43(e)	<p><i>Standard: Reassessment. The hospital must reassess its discharge planning process on an on-going basis. The reassessment must include a review of discharge plans to ensure that they are responsive to discharge needs.</i></p>	15.03.24	<p><u>Discharge Plan Reassessment</u> <i>The hospital must reassess the discharge planning process on an ongoing basis. The reassessment must include a review of discharge plans to ensure that they are responsive to the patient's discharge needs.</i></p>
§482.45	<p>Condition of participation: Organ, tissue, and eye procurement</p>	14.00.01	<p><u>Condition of Participation:</u> Organ, Tissue, and Eye Procurement</p>
§482.45(a) §482.45(a)(1)	<p><i>Standard: Organ procurement responsibilities. The hospital must have and implement written protocols that:</i></p> <p>(1) <i>Incorporate an agreement with an OPO designated under part 486 of this chapter, under which it must notify, in a timely manner, the OPO or a third party designated by the OPO of individuals whose death is imminent or who have died in the hospital. The OPO determines medical suitability for organ donation and, in the absence of alternative arrangements by the hospital, the OPO determines medical suitability for tissue and eye donation, using the definition of potential tissue and eye donor and the notification protocol developed in</i></p>	14.00.02	<p><u>Organ/Tissue Donation & Transplantation</u> <i>The hospital must have and implement written protocols that:</i></p> <ul style="list-style-type: none"> • <i>Incorporate an agreement with an Organ Procurement Organization (OPO), under part 486 of 42 CFR 486.322, under which it must notify, in a timely manner, the OPO or a third party designated by the OPO of individuals whose death is imminent or who have died in the hospital.</i> • <i>The OPO determines medical suitability for organ donation and, in the absence of alternative arrangements by the hospital, the OPO determines medical suitability for tissue and eye donation, using the definition of potential tissue and eye donor and the</i>

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	<i>consultation with the tissue and eye banks identified by the hospital for this purpose;</i>		<i>notification protocol developed in consultation with the tissue and eye banks identified by the hospital for this purpose.</i>
§482.45(a)(2)	<p><i>The hospital must have and implement written protocols that:</i></p> <p>(2) <i>Incorporate an agreement with at least one tissue bank and at least one eye bank to cooperate in the retrieval, processing, preservation, storage and distribution of tissues and eyes, as may be appropriate to assure that all usable tissues and eyes are obtained from potential donors, insofar as such an agreement does not interfere with organ procurement;</i></p>	14.00.03	<p><u>Tissue & Eye Bank Agreements</u></p> <p><i>The hospital must have and implement written protocols that:</i></p> <ul style="list-style-type: none"> • <i>Incorporates an agreement with at least one tissue bank and at least one eye bank to cooperate in the retrieval, processing, preservation, storage, and distribution of tissues and eyes, as may be appropriate to assure that all usable tissues and eyes are obtained from potential donors, insofar as such agreement does not interfere with organ procurement.</i>
§482.45(a)(3)	<p><i>The hospital must have and implement written protocols that:</i></p> <p>(3) <i>Ensure, in collaboration with the designated OPO, that the family of each potential donor is informed of its options to donate organs, tissues, or eyes or to decline to donate. The individual designated by the hospital to initiate the request to the family must be an organ procurement representative or a designated requestor. A designated requestor is an individual who has completed a course offered or approved by the OPO and designed in conjunction with the tissue and eye bank community in the methodology for approaching potential donor families and requesting organ or tissue donation;</i></p>	14.00.04	<p><u>Informed Consent Requirements</u></p> <p><i>The hospital must have and implement a written protocols that:</i></p> <ul style="list-style-type: none"> • <i>Ensure, in collaboration with the designated OPO, that the family of each potential donor is informed of its option to donate organs, tissues, or eyes, or to decline to donate.</i>
		14.00.05	<p><u>Designated Requestors</u></p> <p><i>The individual designated by the hospital to initiate the request to the family must be an organ procurement representative or a designated requestor.</i></p> <p><i>A designated requestor is an individual who has completed a course offered or approved by the OPO and designed in conjunction with the tissue and eye bank community in the methodology for approaching potential donor families and requesting organ or tissue donation.</i></p>
§482.45(a)(4)	<p><i>The hospital must have and implement written protocols that:</i></p> <p>(4) <i>Encourage discretion and sensitivity with respect to the circumstances, views, and beliefs of the families of potential donors;</i></p>	14.00.06	<p><u>Sensitivity Training</u></p> <p><i>The hospital must have and implement written protocols that:</i></p> <ul style="list-style-type: none"> • <i>Encourage discretion and sensitivity with respect to the circumstances, views, and beliefs of the families of potential donors.</i>

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<p>§482.45(a)(5)</p>	<p><i>The hospital must have and implement written protocols that:</i></p> <p>(5) <i>Ensure that the hospital works cooperatively with the designated OPO, tissue bank and eye bank in educating staff on donation issues, reviewing death records to improve identification of potential donors, and maintaining potential donors while necessary testing and placement of potential donated organs, tissues, and eyes take place.</i></p>	<p>14.00.07</p>	<p><u>OPO Responsibilities</u></p> <p><i>The hospital must have and implement protocols that:</i></p> <p><i>Ensure that the hospital works cooperatively with the designated OPO, tissue bank and eye bank in:</i></p> <p>(1) <i>Educating staff on donation issues;</i></p> <p>(2) <i>Reviewing death records to improve identification of potential donors; and</i></p> <p>(3) <i>Maintaining potential donors while necessary testing and placement of potential donated organs, tissues, and eyes take place.</i></p>
<p>§482.45(b) §482.45(b)(1) §482.45(b)(2)</p>	<p><i>Standard: Organ transplantation responsibilities.</i></p> <p>(1) <i>A hospital in which organ transplants are performed must be a member of the Organ Procurement and Transplantation Network (OPTN) established and operated in accordance with section 372 of the Public Health Service (PHS) Act (42 U.S.C. 274) and abide by its rules. The term “rules of the OPTN” means those rules provided for in regulations issued by the Secretary in accordance with section 372 of the PHS Act which are enforceable under 42 CFR 121.10. No hospital is considered to be out of compliance with section 1138(a)(1)(B) of the Act, or with the requirements of this paragraph, unless the Secretary has given the OPTN formal notice that he or she approves the decision to exclude the hospital from the OPTN and has notified the hospital in writing.</i></p> <p>(2) <i>For purposes of these standards, the term “organ” means a human kidney, liver, heart, lung, or pancreas.</i></p>	<p>14.00.08</p>	<p><u>Organ Transplant Facilities</u></p> <p><i>A hospital in which organ transplants are performed must be a member of the Organ Procurement and Transplantation Network (OPTN) established and operated in accordance with section 372 of the Public Health Service (PHS) Act (42 U.S.C. 274) and abide by its rules.</i></p> <p><i>The term “rules of the OPTN” means those rules provided for in regulations issued by the Secretary in accordance with section 372 of the PHS Act which are enforceable under 42 CFR 121.10. No hospital is considered to be out of compliance with section 1138(a)(1)(B) of the Act (Social Security Act), or with the requirements of this paragraph, unless the Secretary has given the OPTN formal notice that he or she approves the decision to exclude the hospital from the OPTN and has notified the hospital in writing.</i></p> <p><i>For the purpose of these standards, the term “organ” means a human kidney, liver, heart, lung, or pancreas.</i></p>

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§482.45(b)(3)	(3) <i>If a hospital performs any type of transplants, it must provide organ transplant-related data, as requested by the OPTN, the Scientific Registry, and the OPOs. The hospital must also provide such data directly to the Department when requested by the Secretary.</i>	14.00.09	<p><u>Data Collection & Reporting</u> <i>If a hospital performs any type of transplants, it must provide organ-transplant-related data, as requested by the OPTN, the Scientific Registry, and the OPOs. The hospital must also provide data directly to the Department of Health and Human Services when requested by the Secretary.</i></p>
§482.51	<p><u>Condition of participation: Surgical services.</u> <i>If the hospital provides surgical services, the services must be well organized and provided in accordance with acceptable standards of practice. If outpatient surgical services are offered the services must be consistent in quality with inpatient care in accordance with the complexity of services offered.</i></p>	30.00.00	<p><u>Condition of Participation: Surgical Services</u> <i>If the hospital provides surgical services, the services must be well organized and provided in accordance with acceptable Standards of Practice.</i></p> <p><i>If outpatient surgical services are offered, the services must be consistent in quality with inpatient care in accordance with the complexity of services offered.</i></p>
§482.51(a)	<p><u>Standard: Organization and staffing.</u> <i>The organization of the surgical services must be appropriate to the scope of the services offered.</i></p>	30.00.01	<p><u>Organizational Structure</u> <i>The organization of the surgical services must be appropriate to the scope of the services offered.</i></p>
§482.51(a)(1)	(1) <i>The operating rooms must be supervised by an experienced registered nurse or a doctor of medicine or osteopathy.</i>	30.00.02	<p><u>Leadership</u> <i>The operating rooms must be supervised by an experienced registered nurse or a doctor of medicine or Doctor of Osteopathic Medicine.</i></p>
§482.51(a)(2)	(2) <i>Licensed practical nurses (LPNs) and surgical technologists (operating room technicians) may serve as “scrub nurses” under the supervision of a registered nurse.</i>	30.00.03	<p><u>Scrub Nurses</u> A Registered Nurse plans and supervises the care of each operative patient.</p> <p><i>Licensed Practical Nurses (LPNs) and surgical technologists (operating room technicians) may serve as "scrub" nurses under the supervision of a registered nurse.</i></p>
§482.51(a)(3)	(3) <i>Qualified registered nurses may perform circulating duties in the operating room. In accordance with applicable State laws and approved medical staff policies and procedures, LPNs and surgical technologists may assist in circulatory duties under the supervision of a</i>	30.00.04	<p><u>Circulating Nurse.</u> <i>Qualified registered nurses may perform circulating duties in the operating room. In accordance with applicable state laws and approved medical staff policies and procedures, LPNs and surgical technologists may assist in circulatory duties under the supervision of</i></p>

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	<i>qualified registered nurse who is immediately available to respond to emergencies.</i>		<i>a qualified registered nurse who is immediately available to respond to emergencies.</i>
§482.51(a)(4)	(4) <i>Surgical privileges must be delineated for all practitioners performing surgery in accordance with the competencies of each practitioner. The surgical service must maintain a roster of practitioners specifying the surgical privileges of each practitioner.</i>	30.00.05	<u>Surgical Privileges</u> <i>Surgical privileges must be delineated for all practitioners performing surgery in accordance with the competencies of each practitioner. The surgical service must maintain a roster of practitioners specifying the surgical privileges of each practitioner.</i>
§482.51(b)	<i>Standard: Delivery of service. Surgical services must be consistent with needs and resources. Policies governing surgical care must be designed to assure the achievement and maintenance of high standards of medical practice and patient care.</i>	30.00.09	<u>Standards of Practice.</u> <i>Surgical Service must be consistent with needs and resources. Policies governing surgical care must be designed to assure the achievement and maintenance of high standards of medical practice and patient care.</i>
§482.51(b)(1) §482.51(b)(1)(i) §482.51(b)(1)(ii)	(1) <i>Prior to surgery or a procedure requiring anesthesia services and except in the case of emergencies:</i> (i) <i>A medical history and physical examination must be completed and documented no more than 30 days before or 24 hours after admission or registration.</i> (ii) <i>An updated examination of the patient, including any changes in the patient's condition, must be completed and documented within 24 hours after admission or registration when the medical history and physical examination are completed within 30 days before admission or registration.</i>	30.00.10	<u>History & Physical.</u> <i>Prior to surgery or a procedure requiring anesthesia services and except in the case of emergencies:</i> (i) <i>A medical history and physical examination must be completed and documented no more than 30 days before or 24 hours after admission or registration.</i> (ii) <i>An updated examination of the patient, including any changes in the patient's condition, must be completed and documented within 24 hours after admission or registration when the medical history and physical examination are completed within 30 days before admission or registration.</i>
§482.51(b)(2)	(2) <i>A properly executed informed consent form for the operation must be in the patient's chart before surgery, except in emergencies.</i>	30.00.11	<u>Informed Consent.</u> <i>A properly executed Informed Consent Form for the operative procedure must be in the patient's chart prior to the procedure, except in emergencies.</i> <i>The medical record must contain properly executed informed consent forms for procedures and treatments specified by the medical staff, or by federal or state law if applicable, to require written patient</i>

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			<i>consent.</i>
§482.51(b)(3)	(3) <i>The following equipment must be available to the operating room suites: call-in-system, cardiac monitor, resuscitator, defibrillator, aspirator, and tracheotomy set.</i>	30.00.12	<p>Required Equipment The Surgical Services maintains an adequate inventory of instrumentation, supplies and equipment. <i>The following equipment must be available to the operating room suites:</i></p> <ul style="list-style-type: none"> • <i>Call-in-system (intercom or equivalent)</i> • <i>Cardiac monitor</i> • <i>Defibrillator</i> • <i>Aspirator (suction equipment/vacuum)</i> • <i>Resuscitator (ventilator)</i> • <i>Tracheotomy set</i>
§482.51(b)(4)	(4) <i>There must be adequate provisions for immediate post-operative care.</i>	30.00.17	<p>Postoperative Care <i>There must be adequate provisions for immediate postoperative care.</i></p>
§482.51(b)(5)	(5) <i>The operating room register must be complete and up-to-date.</i>	30.00.18	<p>Operating Room Register <i>The operating room register(s) must be complete and up-to-date.</i></p>
§482.51(b)(6)	(6) <i>An operative report describing techniques, findings, and tissues removed or altered must be written or dictated immediately following surgery and signed by the surgeon.</i>	30.00.19	<p>Operative Report. <i>An operative report describing-</i></p> <ul style="list-style-type: none"> • <i>Techniques,</i> • <i>Findings, and</i> • <i>Tissues removed or altered must be written or dictated immediately following surgery and signed by the surgeon.</i>
§482.52	<p>Condition of participation: Anesthesia services. <i>If the hospital furnishes anesthesia services, they must be provided in a well-organized manner under the direction of a qualified doctor of medicine or osteopathy. The service is responsible for all anesthesia administered in the hospital.</i></p>	30.01.00	<p>Medical Leadership – Anesthesia Services-Condition of Participation <i>If the hospital furnishes anesthesia services, they must be provided in a well-organized manner under the direction of a qualified doctor of medicine or Doctor of Osteopathic Medicine.</i></p> <p><i>The service is responsible for all anesthesia administered in the hospital.</i></p>

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<p>§482.52(a)</p>	<p><i>Standard: Organization and staffing.</i> <i>The organization of anesthesia services must be appropriate to the scope of the services offered.</i></p>	<p>30.01.01</p>	<p><u>Scope of Service: Anesthesia</u> <i>The organization of anesthesia services must be appropriate to the scope of the services offered.</i></p>
<p>§482.52(a) §482.52(a)(1) §482.52(a)(2) §482.52(a)(3) §482.52(a)(4) §482.52(a)(5)</p> <p>§482.52(c)(1) §482.52(c)(2)</p>	<p><i>Anesthesia must be administered only by—</i></p> <ol style="list-style-type: none"> (1) <i>A qualified anesthesiologist;</i> (2) <i>A doctor of medicine or osteopathy (other than an anesthesiologist);</i> (3) <i>A dentist, oral surgeon, or podiatrist who is qualified to administer anesthesia under State law;</i> (4) <i>A certified registered nurse anesthetist (CRNA), as defined in § 410.69(b) of this chapter, who, unless exempted in accordance with paragraph (c) of this section, is under the supervision of the operating practitioner or of an anesthesiologist who is immediately available if needed; or</i> (5) <i>An anesthesiologist's assistant, as defined in § 410.69(b) of this chapter, who is under the supervision of an anesthesiologist who is immediately available if needed.</i> <p><i>Standard: State exemption.</i></p> <ol style="list-style-type: none"> (1) <i>A hospital may be exempted from the requirement for physician supervision of CRNAs as described in paragraph (a)(4) of this section, if the State in which the hospital is located submits a letter to CMS signed by the Governor, following consultation with the State's Boards of Medicine and Nursing, requesting exemption from physician supervision of CRNAs. The letter from the Governor must attest that he or she has consulted with State Boards of Medicine and Nursing about issues related to access to and the quality of anesthesia services in the State and has concluded that it is in the best interests of the State's citizens to optout of the current physician supervision requirement, and that the optout is consistent with State law.</i> 	<p>30.01.02</p>	<p><u>Anesthesia Providers</u> <i>Anesthesia must be administered only by:</i></p> <ol style="list-style-type: none"> (1) <i>A qualified anesthesiologist</i> (2) <i>A doctor of medicine or osteopathy (other than an anesthesiologist)</i> (3) <i>A dentist, oral surgeon, or podiatrist who is qualified to administer anesthesia under State law;</i> (4) <i>A certified registered nurse anesthetist (CRNA), as defined by §410.69 (b) of 42 CFR 410.69, who, unless exempted in accordance with paragraph (c) of 42 CFR 482.52, is under the supervision of the operating practitioner or of an anesthesiologist who is immediately available if needed; or</i> (5) <i>An anesthesiologist's assistant, as defined in Sec. 410.69 (b) of 42 CFR 410.69, who is under the supervision of an anesthesiologist who is immediately available if needed.</i> <p><i>State exemption:</i></p> <ol style="list-style-type: none"> (6) <i>A hospital may be exempted from the requirement for Doctor of Medicine/Doctor of Osteopathic Medicine supervision of CRNAs as described in paragraph (a)(4) of 42 CFR 482.52, if the State in which the hospital is located submits a letter to CMS signed by the Governor, following consultation with the State's Boards of Medicine and Nursing, requesting exemption from MD/DO supervision for CRNAs. The letter from the Governor must attest that he or she has consulted with the State Boards of Medicine and Nursing about issues related to access to and the quality of anesthesia services in the State and has concluded that it is in the best interests of the State's citizens to opt-out of the current MD/DO supervision requirement, and that the opt-out is consistent with State law.</i> (7) <i>The request for exemption and recognition of state laws and the</i>

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	(2) <i>The request for exemption and recognition of State laws and the withdrawal of the request may be submitted at any time, and are effective upon submission.</i>		<i>withdrawal of the request may be submitted at any time, and are effective upon submission.</i>
§482.52(b)	<i>Standard: Delivery of services. Anesthesia services must be consistent with needs and resources. Policies on anesthesia procedures must include the delineation of preanesthesia and postanesthesia responsibilities.</i>	30.01.04	Required Policies <i>Anesthesia services must be consistent with needs and resources. Policies on anesthesia procedures must include the delineation of preanesthesia and postanesthesia responsibilities.</i>
§482.52(b) §482.52(b)(1)	<i>The policies must ensure that the following are provided for each patient:</i> (1) <i>A preanesthesia evaluation completed and documented by an individual qualified to administer anesthesia, as specified in paragraph (a) of this section, performed within 48 hours prior to surgery or a procedure requiring anesthesia services.</i>	30.01.05	Pre-anesthesia Evaluation. <i>The policies must ensure that the following are provided for each patient:</i> • <i>A pre-anesthesia evaluation completed and documented by an individual qualified to administer anesthesia, as specified in paragraph (a) of 42 CFR 482.52, performed within 48 hours prior to surgery or a procedure requiring anesthesia services.</i>
§482.52(b)(2)	(2) <i>An intraoperative anesthesia record.</i>	30.01.06	Intraoperative Anesthesia Record <i>The policies must ensure that the following are provided for each patient:</i> • <i>An Intra-operative Anesthesia record.</i>
§482.52(b)(3)	(3) <i>A postanesthesia evaluation completed and documented by an individual qualified to administer anesthesia, as specified in paragraph (a) of this section, no later than 48 hours after surgery or a procedure requiring anesthesia services. The postanesthesia evaluation for anesthesia recovery must be completed in accordance with State law and with hospital policies and procedures that have been approved by the medical staff and that reflect current standards of anesthesia care.</i>	30.01.07	Postanesthesia Assessment. <i>The policies must ensure that the following are provided for each patient:</i> • <i>A postanesthesia evaluation completed and documented by an individual qualified to administer anesthesia, as specified in paragraph (a) of 42 CFR 482.52, no later than 48 hours after surgery or a procedure requiring anesthesia services. The postanesthesia evaluation for anesthesia recovery must be completed in accordance with State law and with hospital policies and procedures that have been approved by the medical</i>

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			<i>staff and that reflect current standards of anesthesia care.</i>
§482.53	Condition of participation: Nuclear medicine services. <i>If the hospital provides nuclear medicine services, those services must meet the needs of the patients in accordance with acceptable standards of practice.</i>	23.00.00	Condition of Participation: Nuclear Medicine Services <i>If the hospital provides nuclear medicine services, those services must meet the needs of the patients in accordance with acceptable standards of practice.</i>
§482.53(a)	<i>Standard: Organization and staffing.</i> <i>The organization of the nuclear medicine service must be appropriate to the scope and complexity of the services offered.</i>	23.00.01	Organization and Staffing <i>The organization of the nuclear medicine service must be appropriate to the scope and complexity of the services offered.</i>
§482.53(a)(1)	(1) <i>There must be a director who is a doctor of medicine or osteopathy qualified in nuclear medicine.</i>	23.00.02	Medical Director <i>There must be a director who is a doctor of medicine or osteopathic medicine qualified in nuclear medicine.</i>
§482.53(a)(2)	(2) <i>The qualifications, training, functions, and responsibilities of nuclear medicine personnel must be specified by the service director and approved by the medical staff.</i>	23.00.03	Personnel Requirements <i>The qualifications, training, functions, and responsibilities of nuclear medicine personnel must be specified by the service director and approved by the Professional Medical Staff.</i>
§482.53(b)	<i>Standard: Delivery of service.</i> <i>Radioactive materials must be prepared, labeled, used, transported, stored, and disposed of in accordance with acceptable standards of practice.</i>	23.00.04	Policy & Procedure Requirements <i>Radioactive materials must be prepared, labeled, used, transported, stored, and disposed of in accordance with acceptable standards of practice.</i>
§482.53(b)(1)	(1) <i>In-house preparation of radiopharmaceuticals is by, or under the supervision of, an appropriately trained registered pharmacist or a doctor of medicine or osteopathy.</i>	23.00.05	In-House Preparation of Radiopharmaceuticals <i>In-house preparation of radiopharmaceuticals is by, or under, the direct supervision of an appropriately trained registered pharmacist or doctor of medicine or osteopathic medicine.</i>
§482.53(b)(2)	(2) <i>There is proper storage and disposal of radioactive material.</i>	23.00.06	Storage & Disposal of Waste <i>There is proper storage and disposal of radioactive material.</i>

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§482.53(b)(3)	(3) <i>If laboratory tests are performed in the nuclear medicine service, the service must meet the applicable requirement for laboratory services specified in §482.27.</i>	23.00.10	<u>Laboratory Testing</u> <i>If laboratory tests are performed in the nuclear medicine service, the service must meet the applicable requirement for laboratory services specified in 482.27.</i>
§482.53(c)	<i>Standard: Facilities. Equipment and supplies must be appropriate for the types of nuclear medicine services offered and must be maintained for safe and efficient performance.</i>	23.00.11	<u>Safe Handling of Reagents & Equipment Maintenance</u> <i>Equipment and supplies must be appropriate for the types of nuclear medicine services offered and must be maintained for safe and efficient performance.</i>
§482.53(c)(1) §482.53(c)(2)	<i>The equipment must be— (1) Maintained in safe operating condition; and (2) Inspected, tested, and calibrated at least annually by qualified personnel.</i>	23.00.12	<u>Equipment Safety</u> <i>The equipment must be— (1) Maintained in safe operating condition; and (2) Inspected, tested and calibrated at least annually by qualified personnel.</i>
§482.53(d)	<i>Standard: Records. The hospital must maintain signed and dated reports of nuclear medicine interpretations, consultations, and procedures.</i>	23.00.16	<u>Medical Record Requirements</u> <i>The hospital must maintain signed and dated reports of nuclear medicine interpretations, consultations and procedures.</i>
§482.53(d)(1)	(1) <i>The hospital must maintain copies of nuclear medicine reports for at least 5 years.</i>	23.00.17	<u>Record Retention Requirements</u> <i>The hospital must maintain copies of nuclear medicine reports for at least 5 years.</i>
§482.53(d)(2)	(2) <i>The practitioner approved by the medical staff to interpret diagnostic procedures must sign and date the interpretation of these tests.</i>	23.00.18	<u>Qualified Practitioners</u> <i>The practitioner approved by the medical staff to interpret diagnostic procedures must sign and date the interpretation of these tests.</i>
§482.53(d)(3)	(3) <i>The hospital must maintain records of the receipt and disposition of radiopharmaceuticals.</i>	23.00.19	<u>Documentation Requirements</u> <i>The hospital must maintain records of the receipt and distribution of radiopharmaceuticals.</i>
§482.53(d)(4)	(4) <i>Nuclear medicine services must be ordered only by practitioner whose scope of Federal or State licensure and whose defined staff privileges allow such referrals.</i>	23.00.20	<u>Qualified Ordering Practitioners</u> <i>Nuclear medicine services must be ordered by practitioners whose scope of Federal or State licensure and whose defined privileges allow such referrals.</i>

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§482.54	<p>Condition of participation: Outpatient services. <i>If the hospital provides outpatient services, the services must meet the needs of the patients in accordance with acceptable standards of practice.</i></p>	31.00.00	<p>Outpatient Services: Condition of Participation <i>If the hospital provides outpatient services, the services must meet the needs of the patients in accordance with acceptable standards of practice.</i></p>
§482.54(a)	<p><i>Standard: Organization.</i> <i>Outpatient services must be appropriately organized and integrated with inpatient services.</i></p>	31.00.01	<p>Integration of Services <i>Outpatient services must be appropriately organized and integrated with inpatient services.</i></p>
§482.54(b)(1) §482.54(b)(2)	<p><i>(b) Standard: Personnel. The hospital must—</i> <i>(1) Assign one or more individuals to be responsible for outpatient services.</i> <i>(2) Have appropriate professional and nonprofessional personnel available at each location where outpatient services are offered, based on the scope and complexity of outpatient services.</i></p>	31.00.02	<p>Personnel <i>(1) The hospital must assign one or more individuals to be responsible for outpatient services.</i> <i>(2) The hospital must have appropriate professional and nonprofessional personnel available at each location where outpatient services are offered, based on the scope and complexity of outpatient services.</i></p>
§482.54(c) §482.54(c)(1) §482.54(c)(2) §482.54(c)(3) §482.54(c)(4) §482.54(c)(4)(i) §482.54(c)(4)(ii)	<p><i>(c) Standard: Orders for outpatient services. Outpatient services must be ordered by a practitioner who meets the following conditions:</i></p> <p><i>(1) Is responsible for the care of the patient.</i></p> <p><i>(2) Is licensed in the State where he or she provides care to the patient.</i></p> <p><i>(3) Is acting within his or her scope of practice under State law.</i></p> <p><i>(4) Is authorized in accordance with State law and policies adopted by the medical staff, and approved by the governing body, to order the applicable outpatient services. This applies to the following:</i></p>	31.00.11	<p>Orders for Outpatient Services. <i>Outpatient services must be ordered by a practitioner who meets the following conditions:</i></p> <p><i>(1) Is responsible for the care of the patient.</i></p> <p><i>(2) Is licensed in the State where he or she provides care to the patient.</i></p> <p><i>(3) Is acting within his or her scope of practice under State law.</i></p> <p><i>(4) Is authorized in accordance with State law and policies adopted by the medical staff, and approved by the governing body, to order the applicable outpatient services. This applies to the following:</i></p> <p><i>(i) All practitioners who are appointed to the hospital's medical staff and who have been granted privileges to order the applicable outpatient services.</i></p>

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	<p>(i) All practitioners who are appointed to the hospital's medical staff and who have been granted privileges to order the applicable outpatient services.</p> <p>(ii) All practitioners not appointed to the medical staff, but who satisfy the above criteria for authorization by the medical staff and the hospital for ordering the applicable outpatient services for their patients.</p>		<p>(ii) All practitioners not appointed to the medical staff, but who satisfy the above criteria for authorization by the medical staff and the hospital for ordering the applicable outpatient services for their patients.</p>
§482.55	<p>Condition of participation: Emergency services. The hospital must meet the emergency needs of patients in accordance with acceptable standards of practice.</p>	20.00.00	<p>Condition of Participation: Emergency Services The hospital must meet the emergency needs of patients in accordance with acceptable standards of practice.</p>
§482.55(a)(1)	<p>Standard: Organization and direction. If emergency services are provided at the hospital— (1) The services must be organized under the direction of a qualified member of the medical staff;</p>	20.00.01	<p>Medical Staff Leadership If emergency services are provided at the hospital,</p> <ul style="list-style-type: none"> The services must be organized under the direction of a qualified member of the Medical Staff.
§482.55(a)(2)	<p>If emergency services are provided at the hospital— (2) The services must be integrated with other departments of the hospital;</p>	20.00.02	<p>Integration If emergency services are provided at the hospital,</p> <ul style="list-style-type: none"> The services must be integrated with other departments of the hospital.
§482.55(a)(3)	<p>If emergency services are provided at the hospital— (3) The policies and procedures governing medical care provided in the emergency service or department are established by and are a continuing responsibility of the medical staff.</p>	20.00.03	<p>Policies & Procedures If emergency services are provided at the hospital,</p> <ul style="list-style-type: none"> Policies and procedures governing medical care provided in the Emergency Service are established by and are a continuing responsibility of the Medical Staff.
§482.55(b) §482.55(b)(1)	<p>Standard: Personnel. (1) The emergency services must be supervised by a qualified member of the medical staff.</p>	20.00.05	<p>Personnel The hospital must ensure the emergency services personnel requirements are met.</p>

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			<i>The emergency services must be supervised by a qualified member of the medical staff.</i>
§482.55(b)(2)	<p><i>Standard: Personnel.</i></p> <p>(2) <i>There must be adequate medical and nursing personnel qualified in emergency care to meet the written emergency procedures and needs anticipated by the facility.</i></p>	20.00.06	<p><u>Personnel: Staffing & Staff Qualifications</u></p> <p><i>There must be adequate medical and nursing personnel qualified in emergency care to meet the written emergency procedures and needs anticipated by the facility.</i></p>
§482.56	<p><u>Condition of participation: Rehabilitation services.</u></p> <p><i>If the hospital provides rehabilitation, physical therapy, occupational therapy, audiology, or speech pathology services, the services must be organized and staffed to ensure the health and safety of patients.</i></p>	26.00.00	<p><u>Condition of Participation: Rehabilitation Services</u></p> <p><i>If the hospital provides rehabilitation, physical therapy, occupational therapy, audiology, or speech pathology services, the services must be organized and staffed to ensure the health and safety of patients.</i></p>
§482.56(a)	<p><i>Standard: Organization and staffing.</i></p> <p><i>The organization of the service must be appropriate to the scope of the services offered.</i></p>	26.00.01	<p><u>Organization and Staffing</u></p> <p><i>The organization of the service must be appropriate to the scope of the services offered</i></p>
§482.56(a)(1)	<p>(1) <i>The director of the services must have the necessary knowledge, experience, and capabilities to properly supervise and administer the services.</i></p>	26.00.02	<p><u>Leadership</u></p> <p><i>The director of services must have the necessary knowledge, experience and capabilities to properly supervise and administer the services.</i></p>
§482.56(a)(2)	<p>(2) <i>Physical therapy, occupational therapy, speech-language pathology or audiology services, if provided, must be provided by qualified physical therapists, physical therapist assistants, occupational therapists, occupational therapy assistants, speech-language pathologists, or audiologists as defined in part 484 of this chapter.</i></p>	26.00.03	<p><u>Staff Qualifications</u></p> <p><i>Physical therapy, occupational therapy, or speech-language pathology or audiology services, if provided, must be provided by qualified physical therapists, physical therapist assistants, occupational therapists, occupational therapy assistants, speech-language pathologists, or audiologists as defined in part 484 of 42 CFR 484.4 .</i></p>
§482.56(b)	<p><i>Standard: Delivery of services.</i></p> <p><i>Services must only be provided under the orders of a qualified and licensed practitioner who is responsible for the care of the patient, acting within his or her scope of practice under State law, and who is authorized by the hospital's medical</i></p>	26.00.06	<p><u>Delivery of Services</u></p> <p><i>Services must only be provided under the orders of a qualified and licensed practitioner who is responsible for the care of the patient, acting within his or her scope of practice under State law, and who is authorized by the hospital's medical staff to order the services in</i></p>

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	<i>staff to order the services in accordance with hospital policies and procedures and State laws.</i>		<i>accordance with hospital policies and procedures and State laws.</i>
§482.56(b)(1)	(1) <i>All rehabilitation services orders must be documented in the patient's medical record in accordance with the requirements at §482.24.</i>	26.00.07	Rehabilitation Orders <i>All rehabilitation services orders must be documented in the patient's medical record in accordance with the requirements at §482.24.</i>
§482.56(b)(2)	(2) <i>The provision of care and the personnel qualifications must be in accordance with national acceptable standards of practice and must also meet the requirements of §409.17 of this chapter.</i>	26.01.08	Standards of Practice <i>The provision of care and the personnel qualifications must be in accordance with national acceptable standards of practice and must also meet the requirements of §409.17 of 42 CFR 409.17.</i>
§482.57	Condition of participation: Respiratory care services. <i>The hospital must meet the needs of the patients in accordance with acceptable standards of practice. The following requirements apply if the hospital provides respiratory care service.</i>	17.00.00	Condition of Participation - Respiratory Services <i>The hospital must meet the needs of the patients in accordance with acceptable standards of practice. The following requirements apply if the hospital provides respiratory care services.</i>
§482.57(a)	<i>Standard: Organization and Staffing.</i> <i>The organization of the respiratory care services must be appropriate to the scope and complexity of the services offered.</i>	17.00.01	Organization & Staffing <i>The organization of the respiratory care services must be appropriate to the scope and complexity of the services offered.</i>
§482.57(a)(1)	(1) <i>There must be a director of respiratory care services who is a doctor of medicine or osteopathy with the knowledge, experience, and capabilities to supervise and administer the service properly. The director may serve on either a full-time or part-time basis.</i>	17.00.02	Medical Director <i>There must be a director of respiratory care services who is a doctor of medicine or osteopathic medicine with the knowledge, experience and capabilities to supervise and administer the service properly.</i> <i>The director may serve on either a full time or part time basis.</i>
§482.57(a)(2)	(2) <i>There must be adequate numbers of respiratory therapists, respiratory therapy technicians, and other personnel who meet the qualifications specified by the medical staff, consistent with State law.</i>	17.00.03	Staffing & Qualifications <i>There must be adequate numbers of respiratory therapists, respiratory therapy technicians, and other personnel who meet the qualifications specified by the medical staff, consistent with state law.</i>

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§482.57(b)	<i>Standard: Delivery of Services. Services must be delivered in accordance with medical staff directives.</i>	17.00.04	<u>Policies & Procedures</u> <i>Services must be delivered in accordance with medical staff directives.</i>
§482.57(b)(1)	(1) <i>Personnel qualified to perform specific procedures and the amount of supervision required for personnel to carry out specific procedures must be designated in writing.</i>	17.00.05	<u>Qualified Staff</u> <i>Personnel qualified to perform specific procedures and the amount of supervision required for personnel to carry out specific procedures shall be designated in writing.</i>
§482.57(b)(2)	(2) <i>If blood gases or other laboratory tests are performed in the respiratory care unit, the unit must meet the applicable requirements for laboratory services specified in § 482.27.</i>	17.00.06	<u>Clinical Laboratory Testing</u> <i>If blood gases or other clinical laboratory tests are performed in the respiratory care unit, the unit must meet the applicable requirements for laboratory services specified in §482.27.</i>
§482.57(b)(3)	(3) <i>Services must only be provided under the orders of a qualified and licensed practitioner who is responsible for the care of the patient, acting within his or her scope of practice under State law, and who is authorized by the hospital's medical staff to order the services in accordance with hospital policies and procedures and State laws.</i>	17.00.07	<u>Services Provided</u> <i>Services must only be provided under the orders of a qualified and licensed practitioner who is responsible for the care of the patient, acting within his or her scope of practice under state law, and who is authorized by the hospital's medical staff to order the services in accordance with hospital policies and procedures and state laws.</i>
§482.57(b)(4)	(4) <i>All respiratory care services orders must be documented in the patient's medical record in accordance with the requirements at § 482.24.</i>	17.00.08	<u>Respiratory Care Services Orders</u> <i>All respiratory care services orders must be documented in the patient's medical record in accordance with the requirements at §482.24.</i>
§482.58	<u>Special requirements for hospital providers of long-term care services ("swing-beds").</u> <i>A hospital that has a Medicare provider agreement must meet the following requirements in order to be granted an approval from CMS to provide post-hospital extended care services, as specified in § 409.30 of this chapter, and be reimbursed as a swing-bed hospital, as specified in § 413.114 of this chapter:</i>	32.00.00	<u>Special Requirements for Hospital Providers of Long-Term Care Services ("Swing-Beds").</u> <i>A hospital that has a Medicare provider agreement must meet the following requirements in order to be granted an approval from CMS to provide post-hospital extended care services, as specified in <u>§409.30</u> of 42 CFR 409.30, and be reimbursed as a swing-bed hospital, as specified in <u>§413.114</u> of 42 CFR 413.114.</i>

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<p>§482.58(a) §482.58(a)(1) §482.58(a)(2) §482.58(a)(3) §482.58(a)(4)</p>	<p>Eligibility. A hospital must meet the following eligibility requirements:</p> <ol style="list-style-type: none"> (1) <i>The facility has fewer than 100 hospital beds, excluding beds for newborns and beds in intensive care type inpatient units (for eligibility of hospitals with distinct parts electing the optional reimbursement method, see § 413.24(d)(5) of this chapter).</i> (2) <i>The hospital is located in a rural area. This includes all areas not delineated as “urbanized” areas by the Census Bureau, based on the most recent census.</i> (3) <i>The hospital does not have in effect a 24-hour nursing waiver granted under § 488.54(c) of this chapter.</i> (4) <i>The hospital has not had a swing-bed approval terminated within the two years previous to application.</i> 	<p style="text-align: center;">32.00.01</p>	<p>Eligibility A hospital must meet the following eligibility requirements:</p> <ol style="list-style-type: none"> (1) The facility has fewer than 100 hospital beds, excluding beds for newborns and beds in intensive care type inpatient units (for eligibility of hospitals with distinct parts electing the optional reimbursement method, see §413.24(d)(5) of 42 CFR 413.24). (2) The hospital is located in a rural area. This includes all areas not delineated as “urbanized” areas by the Census Bureau, based on the most recent census. (3) The hospital does not have in effect a 24-hour nursing waiver granted under §488.54(c) of 42 CFR 488.54. (4) The hospital has not had a swing-bed approval terminated within the two years previous to application.
<p>§482.58(b)</p>	<p><i>Skilled nursing facility services. The facility is substantially in compliance with the following skilled nursing facility requirements contained in subpart B of part 483 of this chapter.</i></p> <ol style="list-style-type: none"> (1) <i>Resident rights (§ 483.10 (b)(3), (b)(4), (b)(5), (b)(6), (d), (e), (h), (i), (j)(1)(vii), (j)(1)(viii), (l), and (m)).</i> (2) <i>Admission, transfer, and discharge rights (§483.12 (a)(1), (a)(2), (a)(3), (a)(4), (a)(5), (a)(6), and (a)(7)).</i> (3) <i>Resident behavior and facility practices (§483.13).</i> (4) <i>Patient activities (§483.15(f)).</i> (5) <i>Social services (§483.15(g)).</i> 	<p style="text-align: center;">32.00.06</p>	<p>Skilled Nursing Facility Services. The facility must be in substantial compliance with the following skilled nursing facility requirements which are scored individually.</p> <ol style="list-style-type: none"> (1) <u>Resident rights</u> (§483.10 (b)(3), (b)(4),(b)(5), (b)(6), (d), (e), (h), (i), (j)(1)(vii), (j)(1)(viii), (l), and (m), (2) <u>Admission, transfer, and discharge rights</u> (§483.12 (a)(1), (a)(2), (a)(3), (a)(4), (a)(5), (a)(6) and (a)(7), (3) <u>Resident behavior and facility practices</u> (§483.13), (4) <u>Patient activities</u> (§483.15 (f) , (5) <u>Social services</u> (§483.15(g),

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	<p>(6) <i>Discharge planning</i> (§483.20(l)).</p> <p>(7) <i>Specialized rehabilitative services</i> (§483.45).</p> <p>(8) <i>Dental services</i> (§483.55).</p>		<p>(6) <u>Discharge Planning</u>. (§483.20(l))</p> <p>(7) <u>Specialized rehabilitative services</u> (§483.45),</p> <p>(8) <u>Dental services</u> (§483.55),</p>
§412.25	Excluded hospital units: Common requirements.	33.00.00	<u>Distinct Part Rehabilitation Unit/Prospective payment system excluded unit.</u>
		34.00.00	<u>Distinct Part Psychiatric Unit/Prospective payment system excluded unit.</u>
<p>§412.25(a)</p> <p>§412.25(a)(1)</p> <p>§412.25(a)(1)(i)</p> <p>§412.25(a)(1)(ii)</p> <p>§412.25(a)(1)(iii)</p>	<p>(1) <i>Basis for exclusion. In order to be excluded from the prospective payment systems as specified in</i></p> <ul style="list-style-type: none"> • § 412.1(a)(1) and be paid under the inpatient psychiatric facility prospective payment system as specified in • § 412.1(a)(2) or the inpatient rehabilitation facility prospective payment system as specified in • § 412.1(a)(3), a psychiatric or rehabilitation unit must meet the following requirements. <p>(1) <i>Be part of an institution that—</i></p> <ul style="list-style-type: none"> (i) <i>Has in effect an agreement under part 489 of this chapter to participate as a hospital;</i> (ii) <i>Is not excluded in its entirety from the prospective payment systems; and</i> (iii) <i>Has enough beds that are not excluded from the inpatient prospective payment systems to permit the provision of adequate cost information, as required</i> 	<p>33.00.01</p>	<p><u>PPS Excluded Hospital Units: Basis for Exclusion</u></p> <p><i>In order to be excluded from the Prospective Payment Systems (PPS) specified in §412.1(a)(1), a rehabilitation unit must meet the following requirements in addition to all criteria under subpart B of part 412 of 42 CFR 412:</i></p> <p><i>Be part of an institution that-</i></p> <ul style="list-style-type: none"> • <i>Has in effect an agreement under part 489 (42 CFR 489) to participate as a hospital and</i> • <i>Is not excluded in its entirety from the prospective payment systems and</i> • <i>Has enough beds that are not excluded from the inpatient prospective payment systems to permit the provision of adequate cost information, as required by §413.24(c) of 42 CFR 413.24.</i>

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	<i>by § 413.24(c) of this chapter.</i>	34.00.01	<p>PPS Excluded Hospital Units: Basis for Exclusion <i>In order to be excluded from the Prospective Payment Systems (PPS) specified in §412.1(a)(1), a rehabilitation unit must meet the following requirements in addition to all criteria under subpart B of part 412 of 42 CFR 412:</i></p> <p><i>Be part of an institution that-</i></p> <ul style="list-style-type: none"> • <i>Has in effect an agreement under part 489 (42 CFR 489) to participate as a hospital and</i> • <i>Is not excluded in its entirety from the prospective payment systems and</i> • <i>Has enough beds that are not excluded from the inpatient prospective payment systems to permit the provision of adequate cost information, as required by §413.24(c) of 42 CFR 413.24.</i>
§412.25(a)(2)	(2) <i>Have written admission criteria that are applied uniformly to both Medicare and non-Medicare patients.</i>	33.00.02	<p>PPS Excluded Hospital Units: Admission Criteria <i>In order to be excluded for the Medicare PPS System, the unit must meet the following criteria:</i></p> <ul style="list-style-type: none"> • <i>Have written admission criteria that are applied uniformly to both Medicare and non-Medicare patients.</i>
		34.00.02	<p>PPS Excluded Hospital Units: Admission Criteria. <i>In order to be excluded from the Medicare PPS System, the unit must meet the following criteria:</i></p> <ul style="list-style-type: none"> • <i>Have written admission criteria that are applied uniformly to both Medicare and non-Medicare patients.</i>
§412.25(a)(3)	(3) <i>Have admission and discharge records that are separately identified from those of the hospital in which it is located and are readily available.</i>	33.00.03	<p>PPS Excluded Hospital Units: Separate Medical Records. <i>In order to be excluded for the Medicare PPS System, the unit must meet the following criteria:</i></p> <ul style="list-style-type: none"> • <i>Have admission and discharge records that are separately identified from those of the hospital in which it is located and are readily available.</i>

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		34.00.03	<p><u>PPS Excluded Hospital Units: Separate Medical Records.</u> <i>In order to be excluded from the Medicare PPS System, the unit must meet the following criteria:</i></p> <ul style="list-style-type: none"> • <i>Have admission and discharge records that are separately identified from those of the hospital in which it is located and are readily available.</i>
§412.25(a)(4)	(4) <i>Have policies specifying that necessary clinical information is transferred to the unit when a patient of the hospital is transferred to the unit.</i>	33.00.04	<p><u>PPS Excluded Hospital Units: Availability of Clinical Records & Information</u> <i>In order to be excluded for the Medicare PPS System, the unit must meet the following criteria:</i></p> <ul style="list-style-type: none"> • <i>Have policies specifying that necessary clinical information is transferred to the unit when a patient of the hospital is transferred to the unit.</i>
		34.00.04	<p><u>PPS Excluded Hospital Units: Availability of Clinical Records & Information.</u> <i>In order to be excluded from the Medicare PPS System, the unit must meet the following criteria:</i></p> <ul style="list-style-type: none"> • <i>Have policies specifying that necessary clinical information is transferred to the unit when a patient of the hospital is transferred to the unit.</i>
§412.25(a)(5)	(5) <i>Meet applicable State licensure laws.</i>	33.00.05	<p><u>PPS Excluded Hospital Units: State Licensure Requirements</u> <i>In order to be excluded for the Medicare PPS System, the unit must meet the following criteria:</i></p> <ul style="list-style-type: none"> • <i>Meet applicable State licensure laws.</i>
		34.00.05	<p><u>PPS Excluded Hospital Units: State Licensure Requirements.</u> <i>In order to be excluded from the Medicare PPS System, the unit must</i></p>

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			<p><i>meet the following criteria:</i></p> <ul style="list-style-type: none"> • <i>Meet applicable State licensure laws.</i>
§412.25(a)(6)	(6) <i>Have utilization review standards applicable for the type of care offered in the unit.</i>	33.00.06	<p>PPS Excluded Hospital Units: Utilization Review Requirements In order to be excluded for the Medicare PPS System, the unit must meet the following criteria:</p> <ul style="list-style-type: none"> • <i>Have utilization review standards applicable for the type of care offered in the unit.</i>
		34.00.06	<p>PPS Excluded Hospital Units: Utilization Review Requirements. In order to be excluded from the Medicare PPS System, the unit must meet the following criteria:</p> <ul style="list-style-type: none"> • <i>Have utilization review standards applicable for the type of care offered in the unit.</i>
§412.25(a)(7)	(7) <i>Have beds physically separate from (that is, not commingled with) the hospital's other beds.</i>	33.00.07	<p>PPS Excluded Hospital Units: Distinct Unit Structure In order to be excluded for the Medicare PPS System, the unit must meet the following criteria:</p> <ul style="list-style-type: none"> • <i>Have beds physically separate from (that is, not commingled with) the hospitals other beds.</i>
		34.00.07	<p>PPS Excluded Hospital Units: Distinct Unit Structure. In order to be excluded from the Medicare PPS System, the unit must meet the following criteria:</p> <ul style="list-style-type: none"> • <i>Have beds physically separate from (that is, not commingled with) the hospital's other beds.</i>
§412.25(a)(8)	(8) <i>Be serviced by the same fiscal intermediary as the hospital.</i>	33.00.08	<p>PPS Excluded Hospital Units: Fiscal Intermediary. In order to be excluded from the Medicare PPS System, the unit must meet the following criteria:</p> <ul style="list-style-type: none"> • <i>Be serviced by the same fiscal intermediary as the hospital.</i>

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		34.00.08	<p>PPS Excluded Hospital Units: Fiscal Intermediary. <i>In order to be excluded from the Medicare PPS System, the unit must meet the following criteria:</i></p> <ul style="list-style-type: none"> • <i>Be serviced by the same fiscal intermediary as the hospital.</i>
§412.25(a)(9)	(9) <i>Be treated as a separate cost center for cost finding and apportionment purposes.</i>	33.00.09	<p>PPS Excluded Hospital Units: Separate Cost Center <i>In order to be excluded from the Medicare PPS System, the unit must meet the following criteria:</i></p> <ul style="list-style-type: none"> • <i>Be treated as a separate cost center for cost finding and apportionment purposes.</i>
		34.00.09	<p>PPS Excluded Hospital Units: Separate Cost Center. <i>In order to be excluded from the Medicare PPS System, the unit must meet the following criteria:</i></p> <ul style="list-style-type: none"> • <i>Be treated as a separate cost center for cost finding and apportionment purposes.</i>
§412.25(a)(10)	(10) <i>Use an accounting system that properly allocates costs.</i>	33.00.10	<p>PPS Excluded Hospital Units: Allocate Costs <i>In order to be excluded from the Medicare PPS System, the unit must meet the following criteria:</i></p> <ul style="list-style-type: none"> • <i>Use an accounting system that properly allocates costs.</i>
		34.00.10	<p>PPS Excluded Hospital Units: Allocate Costs. <i>In order to be excluded from the Medicare PPS System, the unit must meet the following criteria:</i></p> <ul style="list-style-type: none"> • <i>Use an accounting system that properly allocates costs.</i>

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§412.25(a)(11)	(11) <i>Maintain adequate statistical data to support the basis of allocation.</i>	33.00.11	<p><u>PPS Excluded Hospital Units: Statistical Data</u> <i>In order to be excluded from the Medicare PPS System, the unit must meet the following criteria:</i></p> <ul style="list-style-type: none"> • <i>Maintain adequate statistical data to support the basis of allocation.</i>
		34.00.11	<p><u>PPS Excluded Hospital Units: Statistical Data.</u> <i>In order to be excluded from the Medicare PPS System, the unit must meet the following criteria:</i></p> <ul style="list-style-type: none"> • <i>Maintain adequate statistical data to support the basis of allocation.</i>
§412.25(a)(12)	(12) <i>Report its costs in the hospital's cost report covering the same fiscal period and using the same method of apportionment as the hospital.</i>	33.00.12	<p><u>PPS Excluded Hospital Units: Cost Report</u> <i>In order to be excluded from the Medicare PPS System, the unit must meet the following criteria:</i></p> <ul style="list-style-type: none"> • <i>Report its costs in the hospital's cost report covering the same fiscal period and using the same method of apportionment as the hospital.</i>
		34.00.12	<p><u>PPS Excluded Hospital Units: Cost Report.</u> <i>In order to be excluded from the Medicare PPS System, the unit must meet the following criteria:</i></p> <ul style="list-style-type: none"> • <i>Report its costs in the hospital's cost report covering the same fiscal period and using the same method of apportionment as the hospital.</i>
§412.25(a)(13)	(13) <i>As of the first day of the first cost reporting period for which all other exclusion requirements are met, the unit is fully equipped and staffed and is capable of providing hospital inpatient psychiatric or rehabilitation care regardless of whether there are any inpatients in the unit on that date.</i>	33.00.13	<p><u>PPS Excluded Hospital Units: Requirements on the First Day of the First Cost Reporting Period</u> <i>In order to be excluded from the Medicare PPS System, the unit must meet the following criteria:</i></p> <ul style="list-style-type: none"> • <i>As of the first day of the first cost reporting period for which all other exclusion requirements are met, the unit is fully equipped and staffed and is capable of providing hospital inpatient psychiatric or rehabilitation care regardless of whether there are</i>

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			<p style="text-align: center;"><i>any inpatients in the unit on that date.</i></p>
		34.00.13	<p><u>PPS Excluded Hospital Units: Requirements on the First Day of the First cost Reporting Period.</u> <i>In order to be excluded from the Medicare PPS System, the unit must meet the following criteria:</i></p> <ul style="list-style-type: none"> • <i>As of the first day of the first cost reporting period for which all other exclusion requirements are met, the unit is fully equipped and staffed and is capable of providing hospital inpatient psychiatric or rehabilitation care regardless of whether there are any inpatients in the unit on that date.</i>
§412.25(b)	<p><i>(b) Changes in the size of excluded units. Except in the special cases noted at the end of this paragraph, changes in the number of beds or square footage considered to be part of an excluded unit under this section are allowed one time during a cost reporting period if the hospital notifies its Medicare contractor and the CMS RO in writing of the planned change at least 30 days before the date of the change. The hospital must maintain the information needed to accurately determine costs that are attributable to the excluded unit. A change in bed size or a change in square footage may occur at any time during a cost reporting period and must remain in effect for the rest of that cost reporting period. Changes in bed size or square footage may be made at any time if these changes are made necessary by relocation of a unit to permit construction or renovation necessary for compliance with changes in Federal, State, or local law affecting the physical facility or because of catastrophic events such as fires, floods, earthquakes, or tornadoes.</i></p>	33.00.14	<p><u>PPS Excluded Hospital Units: Change in Size</u> <i>Changes in the size of excluded units. Except in the special cases noted at the end of this paragraph, changes in the number of beds or square footage considered to be part of an excluded unit under this section are allowed one time during a cost reporting period if the hospital notifies its Medicare contractor and the CMS RO in writing of the planned change at least 30 days before the date of the change.</i></p> <p><i>The hospital must maintain the information needed to accurately determine costs that are attributable to the excluded unit. A change in bed size or a change in square footage may occur at any time during a cost reporting period and must remain in effect for the rest of that cost reporting period.</i></p> <p><i>Changes in bed size or square footage may be made at any time if these changes are made necessary by relocation of a unit to permit construction or renovation necessary for compliance with changes in Federal, State, or local law affecting the physical facility or because of catastrophic events such as fires, floods, earthquakes, or tornadoes.</i></p>

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		34.00.14	<p>PPS Excluded Hospital Unit: Change in Size. <i>Changes in the size of excluded units. Except in the special cases noted at the end of this paragraph, changes in the number of beds or square footage considered to be part of an excluded unit under this section are allowed one time during a cost reporting period if the hospital notifies its Medicare contractor and the CMS RO in writing of the planned change at least 30 days before the date of the change.</i></p> <p><i>The hospital must maintain the information needed to accurately determine costs that are attributable to the excluded unit. A change in bed size or a change in square footage may occur at any time during a cost reporting period and must remain in effect for the rest of that cost reporting period. Changes in bed size or square footage may be made at any time if these changes are made necessary by relocation of a unit to permit construction or renovation necessary for compliance with changes in Federal, State, or local law affecting the physical facility or because of catastrophic events such as fires, floods, earthquakes, or tornadoes.</i></p>
<p>§412.25(c)(1) §412.25(c)(2)</p>	<p><i>(c) Changes in the status of hospital units. For purposes of exclusions from the prospective payment systems under this section, the status of each hospital unit (excluded or not excluded) is determined as specified in paragraphs (c)(1) and (c)(2) of this section.</i></p> <p><i>(1) The status of a hospital unit may be changed from not excluded to excluded only at the start of the cost reporting period. If a unit is added to a hospital after the start of a cost reporting period, it cannot be excluded from the prospective payment systems before the start of a hospital's next cost reporting period.</i></p> <p><i>(2) The status of a hospital unit may be changed from excluded to not excluded at any time during a cost reporting period, but only if the hospital notifies the fiscal intermediary and the CMS Regional Office in writing of the change at least 30 days before the date of</i></p>	33.00.15	<p>33.00.10 PPS Excluded Hospital Units: Change in Status <i>Changes in the status of hospital units.</i> <i>For purposes of exclusions from the prospective payment systems under this section, the status of each hospital unit (excluded or not excluded) is determined as specified in paragraphs (c)(1) and (c)(2) of 42 CFR 412.25.</i></p> <p><i>(1) The status of a hospital unit may be changed from not excluded to excluded only at the start of the cost reporting period. If a unit is added to a hospital after the start of a cost reporting period, it cannot be excluded from the prospective payment systems before the start of a hospital's next cost reporting period.</i></p> <p><i>(2) The status of a hospital unit may be changed from excluded to not excluded at any time during a cost reporting period, but only if the hospital notifies the fiscal intermediary and the CMS Regional Office in writing of the change at least 30 days before the date of the change, and maintains the information needed to accurately determine costs that are or are not attributable to the</i></p>

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	<p><i>the change, and maintains the information needed to accurately determine costs that are or are not attributable to the excluded unit. A change in the status of a unit from excluded to not excluded that is made during a cost reporting period must remain in effect for the rest of that cost reporting period.</i></p>		<p><i>excluded unit. A change in the status of a unit from excluded to not excluded that is made during a cost reporting period must remain in effect for the rest of that cost reporting period.</i></p>
		34.00.15	<p>PPS Excluded Hospital Unit: Change in Status: <i>Changes in the status of hospital units. For purposes of exclusions from the prospective payment systems under this section, the status of each hospital unit (excluded or not excluded) is determined as specified in paragraphs (c)(1) and (c)(2) of 42 CFR 412.25.</i></p> <p>(1) <i>The status of a hospital unit may be changed from not excluded to excluded only at the start of the cost reporting period. If a unit is added to a hospital after the start of a cost reporting period, it cannot be excluded from the prospective payment systems before the start of a hospital's next cost reporting period.</i></p> <p>(2) <i>The status of a hospital unit may be changed from excluded to not excluded at any time during a cost reporting period, but only if the hospital notifies the fiscal intermediary and the CMS Regional Office in writing of the change at least 30 days before the date of the change, and maintains the information needed to accurately determine costs that are or are not attributable to the excluded unit. A change in the status of a unit from excluded to not excluded that is made during a cost reporting period must remain in effect for the rest of that cost reporting period.</i></p>
§412.25(d)	<p><i>(d) Number of excluded units. Each hospital may have only one unit of each type (psychiatric or rehabilitation) excluded from the prospective payment systems.</i></p>	33.00.16	<p>PPS Excluded Hospital Units: Number of Excluded Units. <i>Each hospital may have only one unit of each type (psychiatric or rehabilitation) excluded from the prospective payment systems.</i></p>
		34.00.16	<p>PPS Excluded Hospital Unit: Number of Excluded Units.</p>

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			<ul style="list-style-type: none"> Each hospital may have only one unit of each type (psychiatric or rehabilitation) excluded from the prospective payment systems.
<p>§412.25(e); §412.25(e)(1)</p>	<p>(e) <i>Satellite facilities.</i> (1) <i>For purposes of paragraphs (e)(2) through (e)(5) of this section, a satellite facility is a part of a hospital unit that provides inpatient services in a building also used by another hospital, or in one or more entire buildings located on the same campus as buildings used by another hospital.</i></p>	33.00.17	<p>Satellite Facility: Define. <i>For purposes of paragraphs (e)(2) through (e)(5) of 42 CFR 412.25, a satellite facility is:</i></p> <ul style="list-style-type: none"> A part of a hospital unit that provides inpatient services in a building also used by another hospital, or In one or more entire buildings located on the same campus as buildings used by another hospital.
		34.00.17	<p>Satellite Facilities: Define. <i>For purposes of paragraphs (e)(2) through (e)(5) of 42 CFR 412.25, a satellite facility is</i></p> <ul style="list-style-type: none"> A part of a hospital unit that provides inpatient services in a building also used by another hospital, or In one or more entire buildings located on the same campus as buildings used by another hospital.
<p>§412.25(e)(2); §412.25(e)(2)(i); §412.25(e)(2)(ii); §412.25(e)(2)(ii)(A); §412.25(e)(2)(ii)(B)</p>	<p>(2) <i>Except as provided in paragraphs (e)(3) and (e)(6) of this section, effective for cost reporting periods beginning on or after October 1, 1999, a hospital that has a satellite facility must meet the following criteria in order to be excluded from the acute care hospital inpatient prospective payment systems for any period:</i></p> <p>(i) <i>In the case of a unit excluded from the prospective payment systems for the most recent cost reporting period beginning before October 1, 1997, the unit's number of State-licensed and Medicare-certified beds, including those at the satellite facility, does not exceed the unit's number of State-licensed and Medicare-certified beds on the last day of the unit's last cost reporting period beginning before October</i></p>	33.00.18	<p>Satellite Facility: Criteria. <i>Except as provided in paragraphs (e)(3) and (e)(6) of 42 CFR 412.25, effective for cost reporting periods beginning on or after October 1, 1999, a hospital that has a satellite facility must meet the following criteria in order to be excluded from the acute care hospital inpatient prospective payment systems for any period:</i></p> <p>(i) <i>In the case of a unit excluded from the prospective payment systems for the most recent cost reporting period beginning before October 1, 1997, the unit's number of State-licensed and Medicare-certified beds, including those at the satellite facility, does not exceed the unit's number of state-licensed and Medicare-certified beds on the last day of the unit's last cost reporting period beginning before October 1, 1997.</i></p> <p>(ii) <i>The satellite facility independently complies with—</i></p>

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	<p>1, 1997.</p> <p>(ii) The satellite facility independently complies with—</p> <p>(A) For a rehabilitation unit, the requirements under §412.29 of this subpart; or</p> <p>(B) For a psychiatric unit, the requirements under §412.27(a).</p>		<p>(A) For a Rehabilitation Unit, the requirements under §412.29 of 42 CFR 412.29.</p> <p>(B) For a psychiatric unit, the requirements under §412.27(a).</p>
<p>§412.25(e)(2)(iii)(A)</p>	<p>e) Satellite facilities.</p> <p>(ii) The satellite facility independently complies with—</p> <p>(A) Effective for cost reporting periods beginning on or after October 1, 2002, it is not under the control of the governing body or chief executive officer of the</p>	<p>34.00.18</p>	<p>Satellite Facility: Criteria. <i>Except as provided in paragraphs (e)(3) and (e)(6) of 42 CFR 412.25, effective for cost reporting periods beginning on or after October 1, 1999, a hospital that has a satellite facility must meet the following criteria in order to be excluded from the acute care hospital inpatient prospective payment systems for any period:</i></p> <p>(1) <i>In the case of a unit excluded from the prospective payment systems for the most recent cost reporting period beginning before October 1, 1997, the unit’s number of State-licensed and Medicare-certified beds, including those at the satellite facility, does not exceed the unit’s number of state-licensed and Medicare-certified beds on the last day of the unit’s last cost reporting period beginning before October 1, 1997.</i></p> <p>(2) <i>The satellite facility independently complies with—</i></p> <p>(A) <i>For a rehabilitation unit, the requirements under 412.29 of 42 CFR 412.29; or</i></p> <p>(B) <i>For a psychiatric unit, the requirements under §412.27(a).</i></p>
		<p>33.00.19</p>	<p>Satellite Facility: Separate Governing Body. <i>The satellite facility meets all the following requirements:</i></p> <ul style="list-style-type: none"> • <i>Effective for cost reporting periods beginning on or after October 1, 2002, it is not under the control of the governing body or chief executive officer of the hospital in which it is located, and it furnishes inpatient care through the use of medical personnel who are not under the control of the medical staff or chief medical officer of the hospital in which it is located.</i>

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	hospital in which it is located, and it furnishes inpatient care through the use of medical personnel who are not under the control of the medical staff or chief medical officer of the hospital in which it is located.		
		34.00.19	<p>Satellite Facility: Separate Governing Body. The satellite facility meets all the following requirements:</p> <ul style="list-style-type: none"> Effective for cost reporting periods beginning on or after October 1, 2002, it is not under the control of the governing body or chief executive officer of the hospital in which it is located, and it furnishes inpatient care through the use of medical personnel who are not under the control of the medical staff or chief medical officer of the hospital in which it is located.
§412.25(e)(2)(iii)(B)	(B) It maintains admission and discharge records that are separately identified from those of the hospital in which it is located and are readily available.	33.00.20	<p>Satellite Facility: Admission and Discharge Records. The satellite facility meets all the following requirements:</p> <ul style="list-style-type: none"> It maintains admission and discharge records that are separately identified from those of the hospital in which it is located and are readily available.
		34.00.20	<p>Satellite Facility: Admission and Discharge Records. The satellite facility meets all the following requirements:</p> <ul style="list-style-type: none"> It maintains admission and discharge records that are separately identified from those of the hospital in which it is located and are readily available.
§412.25(e)(2)(iii)(C)	(C) It has beds that are physically separate from (that is, not commingled with) the beds of the hospital in which it is located.	33.00.21	<p>Satellite Facility: Beds are Physically Separate. The satellite facility meets all the following requirements:</p> <ul style="list-style-type: none"> It has beds that are physically separate from (that is, not commingled with) the beds of the hospital in which it is located.
		34.00.21	<p>Satellite Facility: Beds Are Physically Separate. The satellite facility meets all the following requirements:</p> <ul style="list-style-type: none"> It has beds that are physically separate from (that is, not commingled with) the beds of the hospital in which it is located.

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§412.25(e)(2)(iii)(D)	(D) <i>It is serviced by the same fiscal intermediary as the hospital unit of which it is a part.</i>	33.00.22	<p><u>Satellite Facility: Fiscal Intermediary.</u> <i>The satellite facility meets all the following requirements:</i></p> <ul style="list-style-type: none"> • <i>It is serviced by the same fiscal intermediary as the hospital unit of which it is a part.</i>
		34.00.22	<p><u>Satellite Facility: Fiscal Intermediary.</u> <i>The satellite facility meets all the following requirements:</i></p> <ul style="list-style-type: none"> • <i>It is serviced by the same fiscal intermediary as the hospital unit of which it is a part.</i>
§412.25(e)(2)(iii)(E)	(E) <i>It is treated as a separate cost center of the hospital unit of which it is a part.</i>	33.00.23	<p><u>Satellite Facility: Separate Cost Center.</u> <i>The satellite facility meets all the following requirements:</i></p> <ul style="list-style-type: none"> • <i>It is treated as a separate cost center of the hospital unit of which it is a part.</i>
		34.00.23	<p><u>Satellite Facility: Separate Cost Center.</u> <i>The satellite facility meets all the following requirements:</i></p> <ul style="list-style-type: none"> • <i>It is treated as a separate cost center of the hospital unit of which it is a part.</i>
§412.25(e)(2)(iii)(F)	(F) <i>For cost reporting and apportionment purposes, it uses an accounting system that properly allocates costs and maintains adequate statistical data to support the basis of allocation.</i>	33.00.24	<p><u>Satellite Facility: Accounting System.</u> <i>The satellite facility meets all the following requirements:</i></p> <ul style="list-style-type: none"> • <i>For cost reporting and apportionment purposes, it uses an accounting system that properly allocates costs and maintains adequate statistical data to support the basis of allocation.</i>
		34.00.24	<p><u>Satellite Facility: Accounting System.</u> <i>The satellite facility meets all the following requirements:</i></p> <ul style="list-style-type: none"> • <i>For cost reporting and apportionment purposes, it uses an</i>

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			<i>accounting system that properly allocates costs and maintains adequate statistical data to support the basis of allocation.</i>
§412.25(e)(2)(iii)(G)	(G) <i>It reports its costs on the cost report of the hospital of which it is a part, covering the same fiscal period and using the same method of apportionment as the hospital of which it is a part.</i>	33.00.25	<p>Satellite Facility: Hospital Cost Report. The satellite facility meets all the following requirements:</p> <ul style="list-style-type: none"> • <i>It reports its costs on the cost report of the hospital of which it is a part, covering the same fiscal period and using the same method of apportionment as the hospital of which it is a part.</i>
		34.00.25	<p>Satellite Facility: Hospital Cost Report. The satellite facility meets all the following requirements:</p> <ul style="list-style-type: none"> • <i>It reports its costs on the cost report of the hospital of which it is a part, covering the same fiscal period and using the same method of apportionment as the hospital of which it is a part.</i>
§412.25(e)(3)	(3) <i>Except as specified in paragraphs (e)(4) and (e)(5) of this section, the provisions of paragraph (e)(2) of this section do not apply to any unit structured as a satellite facility on September 30, 1999, and excluded from the prospective payment systems on that date, to the extent the unit continues operating under the same terms and conditions, including the number of beds and square footage considered to be part of the unit at the satellite facility on September 30, 1999.</i>	33.00.26	<p>Satellite Facility: Exception. <i>Except as specified in paragraphs (e)(4) and (e)(5) of 42 CFR 412.25, the provisions of paragraph (e)(2) of 42 CFR 412.25 do not apply to any unit structured as a satellite facility on September 30, 1999, and excluded from the prospective payment systems on that date, to the extent the unit continues operating under the same terms and conditions, including the number of beds and square footage considered to be part of the unit at the satellite facility on September 30, 1999.</i></p>
		34.00.26	<p>34.00.20 Satellite Facility: Exception. <i>Except as specified in paragraphs (e)(4) and (e)(5) of 42 CFR 412.25, the provisions of paragraph (e)(2) of 42 CFR 412.25 do not apply to any unit structured as a satellite facility on September 30, 1999, and excluded from the prospective payment systems on that date, to the extent the unit continues operating under the same terms and conditions, including the number of beds and square footage considered to be part of the unit at the satellite facility on September</i></p>

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			30, 1999.
<p>§412.25(e)(4), §412.25(e)(4)(i), §412.25(e)(4)(ii)</p>	<p>(4) <i>In applying the provisions of paragraph (e)(3) of this section, any unit structured as a satellite facility on September 30, 1999, may increase or decrease the square footage of the satellite facility or may decrease the number of beds in the satellite facility considered to be part of the satellite facility at any time, if these changes are made by the relocation of a facility—</i></p> <p>(i) <i>To permit construction or renovation necessary for compliance with changes in Federal, State, or local law affecting the physical facility; or</i></p> <p>(ii) <i>Because of catastrophic events such as fires, floods, earthquakes, or tornadoes.</i></p>	33.00.27	<p><u>Satellite Facility: Increase / Decrease the Square Footage or Decrease the Number of Beds.</u> <i>In applying the provisions of paragraph (e)(3) of 42 CFR 412.25 , any unit structured as a satellite facility on September 30, 1999, may increase or decrease the square footage of the satellite facility or may decrease the number of beds in the satellite facility considered to be part of the satellite facility at any time, if these changes are made by the relocation of a facility—</i></p> <p>(i) <i>To permit construction or renovation necessary for compliance with changes in federal, state, or local law affecting the physical facility.</i></p> <p>(ii) <i>Because of catastrophic events such as fires, floods, earthquakes, or tornadoes.</i></p>
		34.00.27	<p><u>Satellite Facility: Increase/Decrease Square Footage or Decrease Beds.</u> <i>In applying the provisions of paragraph (e)(3) of 42 CFR 412.25 , any unit structured as a satellite facility on September 30, 1999, may increase or decrease the square footage of the satellite facility or may decrease the number of beds in the satellite facility considered to be part of the satellite facility at any time, if these changes are made by the relocation of a facility—</i></p> <p>(i) <i>To permit construction or renovation necessary for compliance with changes in federal, state, or local law affecting the physical facility.</i></p> <p>(ii) <i>Because of catastrophic events such as fires, floods, earthquakes, or tornadoes.</i></p>

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<p>§412.25(e)(5), §412.25(e)(5)(i), §412.25(e)(5)(ii)</p>	<p>(5) For cost reporting periods beginning on or after October 1, 2006, in applying the provisions of paragraph (e)(3) of this section—</p> <p style="padding-left: 40px;">(ii) Any unit structured as a satellite facility on September 30, 1999, may increase the square footage of the unit only at the beginning of a cost reporting period or decrease the square footage or number of beds considered to be part of the satellite facility subject to the provisions of paragraph (b)(2) of this section, without affecting the provisions of paragraph (e)(3) of this section; and</p> <p style="padding-left: 40px;">(iii) If the unit structured as a satellite facility decreases its number of beds below the number of beds considered to be part of the satellite facility on September 30, 1999, subject to the provisions of paragraph (b)(2) of this section, it may subsequently increase the number of beds at the beginning or a cost reporting period as long as the resulting total number of beds considered to be part of the satellite facility does not exceed the number of beds at the satellite facility on September 30, 1999.</p>	<p>33.00.28</p>	<p>Satellite Facility: Structure Changes After October 1, 2005. For the cost reporting periods beginning on or after October 1, 2006, in applying the provisions of Medicare paragraph (e)(3) of 42 CFR 412.25 —</p> <p>(i) Any unit structured as a satellite facility on September 30, 1999, may increase the square footage of the unit only at the beginning of a cost reporting period or decrease the square footage or number of beds considered to be part of the satellite facility subject to the provisions of paragraph (b)(2) of 42 CFR 412.25 , without affecting the provisions of paragraph (e)(3) of 42 CFR 412.25 ; and</p> <p>(ii) If the unit structured as a satellite facility decreases its number of beds below the number of beds considered to be part of the satellite facility on September 30, 1999, subject to the provisions of paragraph (b)(2) of 42 CFR 412.25 , it may subsequently increase the number of beds at the beginning or a cost reporting period as long as the resulting total number of beds considered to be part of the satellite facility does not exceed the number of beds at the satellite facility on September 30, 1999.</p>
	<p>(5) For cost reporting periods beginning on or after October 1, 2006, in applying the provisions of paragraph (e)(3) of this section—</p>	<p>34.00.28</p>	<p>Satellite Facility: After October 1, 2006. For the cost reporting periods beginning on or after October 1, 2006, in applying the provisions of Medicare paragraph (e)(3) of 42 CFR 412.25 —</p> <p>(i) Any unit structured as a satellite facility on September 30, 1999, may increase the square footage of the unit only at the beginning of a cost reporting period or decrease the square footage or number of beds considered to be part of the satellite facility subject to the provisions of paragraph (b)(2) of 42 CFR 412.25 , without affecting the provisions of paragraph (e)(3) of 42 CFR 412.25; and</p> <p>(ii) If the unit structured as a satellite facility decreases its number of beds below the number of beds considered to be</p>

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			<p>part of the satellite facility on September 30, 1999, subject to the provisions of paragraph (b)(2) of 42 CFR 412.25, it may subsequently increase the number of beds at the beginning or a cost reporting period as long as the resulting total number of beds considered to be part of the satellite facility does not exceed the number of beds at the satellite facility on September 30, 1999.</p>
§412.25(e)(6)	<p>(6) <i>The provisions of paragraph (e)(2)(i) of this section do not apply to any inpatient rehabilitation facility that is subject to the inpatient rehabilitation facility prospective payment system under subpart P of this part, effective for cost reporting periods beginning on or after October 1, 2003.</i></p>	33.00.29	<p>Satellite Facility: Inpatient Rehabilitation Facility. <i>The provisions of Medicare paragraph (e)(2)(i) of 42 CFR 412.25—</i></p> <ul style="list-style-type: none"> • <i>Do not apply to any inpatient rehabilitation facility that is subject to the inpatient rehabilitation facility prospective payment system under subpart P of 42 CFR 412.25, effective for cost reporting periods beginning on or after October 1, 2003.</i>
		34.00.29	<p>Satellite Facility: Inpatient Psychiatric Unit. <i>The provisions of Medicare paragraph (e)(2)(i) of 42 CFR 412.25—</i></p> <ul style="list-style-type: none"> • <i>Do not apply to any inpatient rehabilitation facility that is subject to the inpatient rehabilitation facility prospective payment system under subpart P of 42 CFR 412.25, effective for cost reporting periods beginning on or after October 1, 2003.</i>
§412.25(f)	<p><i>For purposes of exclusions from the prospective payment system under this section—</i></p> <ul style="list-style-type: none"> • <i>The classification of a hospital unit is effective for the unit’s entire cost reporting period. Any changes in the classification of a hospital unit are made only at the start of a cost reporting period.</i> 	33.00.30	<p>Changes in Classification of Hospital Units. <i>For purposes of exclusions from the prospective payment system under 42 CFR 412.25—</i></p> <ul style="list-style-type: none"> • <i>The classification of a hospital unit is effective for the unit’s entire cost reporting period. Any changes in the classification of a hospital unit are made only at the start of a cost reporting period.</i>
		34.00.30	<p>Changes in Classification of Hospital Units. <i>For purposes of exclusions from the prospective payment system</i></p>

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			<p><i>under 42 CFR 412.25—</i></p> <ul style="list-style-type: none"> <i>The classification of a hospital unit is effective for the unit's entire cost reporting period. Any changes in the classification of a hospital unit are made only at the start of a cost reporting period.</i>
§412.27	<p>Excluded psychiatric units: Additional requirements.</p> <p><i>In order to be excluded from the prospective payment system as specified in § 412.1(a)(1), and paid under the prospective payment system as specified in § 412.1(a)(2), a psychiatric unit must meet the following requirements:</i></p>	34.01.01	<p>PPS Excluded Psychiatric Units: Additional Requirements-Condition of Participation</p> <p>In order to be excluded from the prospective payment systems, a psychiatric unit must meet the requirements in 27.06.09 thru 27.06.43</p>
§412.27(a)	<p>(a) <i>Admit only patients whose admission to the unit is required for active treatment, of an intensity that can be provided appropriately only in an inpatient hospital setting, of a psychiatric principal diagnosis that is listed in the Fourth Edition, Text Revision of the American Psychiatric Association's Diagnostic and Statistical Manual, or in Chapter Five ("Mental Disorders") of the International Classification of Diseases, Ninth Revision, Clinical Modification.</i></p>	34.01.02	<p>PPS Excluded Psychiatric Units: Admission Criteria</p> <p>The psychiatric unit will:</p> <ul style="list-style-type: none"> <i>Admit only patients whose admission to the unit is required for active treatment, of an intensity that can be provided appropriately only in an inpatient hospital setting, of a psychiatric principal diagnosis that is listed in the Fourth Edition, Text Revision of the American Psychiatric Association's Diagnostic and Statistical Manual, or in Chapter Five ("Mental Disorders") of the International Classification of Diseases, Ninth Revision, Clinical Modification.</i>
§412.27(b)	<p>(b) <i>Furnish, through the use of qualified personnel, psychological services, social work services, psychiatric nursing, and therapeutic activities.</i></p>	34.01.03	<p>PPS Excluded Psychiatric Units: Scope of Service</p> <p>The psychiatric unit will:</p> <ul style="list-style-type: none"> <i>Furnish, through the use of qualified personnel, psychological services, social work services, psychiatric nursing, therapeutic activities.</i>
§412.27(c)	<p>(c) <i>Maintain medical records that permit determination of the degree and intensity of the treatment provided to individuals who are furnished services in the unit, and that meet the following requirements:</i></p>	34.01.04	<p>PPS Excluded Psychiatric Units: Treatment Plan</p> <p>The psychiatric unit will:</p> <ul style="list-style-type: none"> <i>Maintain medical records that permit determination of the</i>

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			<i>degree and intensity of the treatment provided to individuals who are furnished services in the unit, and that meet the following requirements.</i>
§412.27(c)(1)	(1) <i>Development of assessment/diagnostic data. Medical records must stress the psychiatric components of the record, including history of findings and treatment provided for the psychiatric condition for which the inpatient is treated in the unit.</i>	34.01.05	PPS Excluded Psychiatric Units: Development of Assessment/Diagnostic Data <i>Medical records must stress the psychiatric components of the record, including history of findings and treatment provided for the psychiatric condition for which the inpatient is treated in the unit.</i>
§412.27(c)(1)(i)	(i) <i>The identification data must include the inpatient's legal status.</i>	34.01.06	PPS Excluded Psychiatric Units: Legal Status <i>The medical records must include:</i> <ul style="list-style-type: none"><i>The identification data of the inpatient's legal status.</i>
§412.27(c)(1)(ii)	(ii) <i>A provisional or admitting diagnosis must be made on every inpatient at the time of admission, and must include the diagnoses of intercurrent diseases as well as the psychiatric diagnoses.</i>	34.01.07	PPS Excluded Psychiatric Units: Admission Diagnosis <i>The medical records must include:</i> <ul style="list-style-type: none"><i>A provisional or admitting diagnosis must be made on every inpatient at the time of admission, and must include the diagnoses of intercurrent diseases as well as the psychiatric diagnoses.</i>
§412.27(c)(1)(iii)	(iii) <i>(iii) The reasons for admission must be clearly documented as stated by the inpatient or others significantly involved, or both.</i>	34.01.08	PPS Excluded Psychiatric Units: Patient Reason for Admission <i>The medical records must include:</i> <ul style="list-style-type: none"><i>The reasons for admission must be clearly documented as stated by the inpatient or others significantly involved, or both.</i>
§412.27(c)(1)(iv)	(iv) <i>The social service records, including reports of interviews with inpatients, family members, and others must provide an assessment of home plans and family attitudes, and community resource contacts as well as a social history.</i>	34.01.09	PPS Excluded Psychiatric Units: Social History & Assessment <i>The medical records must include:</i> <ul style="list-style-type: none"><i>The social service records, including reports of interviews with inpatients, family members, and others must provide an assessment of home plans and family attitudes, and community resource contacts as well as a social history.</i>

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§412.27(c)(1)(v)	(v) <i>When indicated, a complete neurological examination must be recorded at the time of the admission physical examination.</i>	34.01.10	<p><u>PPS Excluded Psychiatric Units: Neurological Examination</u> <i>The medical records must include:</i></p> <ul style="list-style-type: none"> • <i>When indicated, a complete neurological examination must be recorded at the time of the admission physical examination.</i>
§412.27(c)(2)	(2) <i>Psychiatric evaluation. Each inpatient must receive a psychiatric evaluation that must—</i>	34.01.11	<p><u>PPS Excluded Psychiatric Units: Psychiatric Evaluation</u> <i>Each inpatient must receive a psychiatric evaluation that must:</i></p> <ul style="list-style-type: none"> • Comply with requirements found in 34.01.11 – 34.01.17
§412.27(c)(2)(i)	(2) <i>Psychiatric evaluation. Each inpatient must receive a psychiatric evaluation that must—</i> (i) <i>Be completed within 60 hours of admission;</i>	34.01.12	<p><u>PPS Excluded Psychiatric Units: Psychiatric Evaluation Requirements-Timeframe</u> <i>Each inpatient must receive a psychiatric evaluation that must:</i></p> <ul style="list-style-type: none"> • <i>Be completed with 60 hours of admission</i>
§412.27(c)(2)(ii)	(2) <i>Psychiatric evaluation. Each inpatient must receive a psychiatric evaluation that must—</i> (ii) <i>Include a medical history;</i>	34.01.13	<p><u>PPS Excluded Psychiatric Units: Psychiatric Evaluation Requirements-Medical History.</u> <i>Each inpatient must receive a psychiatric evaluation that must:</i></p> <ul style="list-style-type: none"> • <i>Include a medical history.</i>
§412.27(c)(2)(iii)	(2) <i>Psychiatric evaluation. Each inpatient must receive a psychiatric evaluation that must—</i> (iii) <i>Contain a record of mental status;</i>	34.01.14	<p><u>PPS Excluded Psychiatric Units: Psychiatric Evaluation Requirements-Mental status</u> <i>Each inpatient must receive a psychiatric evaluation that must:</i></p> <ul style="list-style-type: none"> • <i>Contain a record of mental status.</i>
§412.27(c)(2)(iv)	(2) <i>Psychiatric evaluation. Each inpatient must receive a psychiatric evaluation that must—</i> (iv) <i>Note the onset of illness and the circumstances leading to admission;</i>	34.01.15	<p><u>PPS Excluded Psychiatric Units: Psychiatric Evaluation Requirements –Onset of Illness</u> <i>Each inpatient must receive a psychiatric evaluation that must:</i></p> <ul style="list-style-type: none"> • <i>Note the onset of illness and the circumstances leading to admission;</i>
§412.27(c)(2)(v)	(2) <i>Psychiatric evaluation. Each inpatient must receive a psychiatric evaluation that must—</i> (v) <i>Describe attitudes and behavior;</i>	34.01.16	<p><u>PPS Excluded Psychiatric Units: Psychiatric Evaluation Requirements-Description of Attitudes and Behaviors</u> <i>Each inpatient must receive a psychiatric evaluation that must:</i></p>

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			<ul style="list-style-type: none"> Describe attitudes and behavior;
§412.27(c)(2)(vi)	(2) <i>Psychiatric evaluation. Each inpatient must receive a psychiatric evaluation that must—</i> (vi) <i>Estimate intellectual functioning, memory functioning, and orientation; and</i>	34.01.17	<p>PPS Excluded Psychiatric Units: Psychiatric Evaluation Requirements –Cognition</p> <p><i>Each inpatient must receive a psychiatric evaluation that must:</i></p> <ul style="list-style-type: none"> <i>Estimate intellectual functioning, memory functioning, and orientation;</i>
§412.27(c)(2)(vii)	(2) <i>Psychiatric evaluation. Each inpatient must receive a psychiatric evaluation that must—</i> (vii) <i>Include an inventory of the inpatient’s assets in descriptive, not interpretative fashion.</i>	34.01.18	<p>PPS Excluded Psychiatric Units: Psychiatric Evaluation Requirements – Assets</p> <p><i>Each inpatient must receive a psychiatric evaluation that must:</i></p> <ul style="list-style-type: none"> <i>Include an inventory of the inpatient’s assets in descriptive, not interpretative fashion.</i>
§412.27(c)(3)(i)	(3) <i>Treatment plan.</i> (i) <i>Each inpatient must have an individual comprehensive treatment plan that must be based on an inventory of the inpatient’s strengths and disabilities. The written plan must include a substantiated diagnosis; short-term and long-term goals; the specific treatment modalities utilized; the responsibilities of each member of the treatment team; and adequate documentation to justify the diagnosis and the treatment and rehabilitation activities carried out; and</i>	34.01.19	<p>PPS Excluded Psychiatric Units: Treatment Plan</p> <p><i>Each inpatient must have an individual comprehensive treatment plan that shall be based on an inventory of the inpatient’s strengths and disabilities.</i></p> <p><i>The written plan must include:</i></p> <ul style="list-style-type: none"> <i>a substantiated diagnosis;</i> <i>short-term, and</i> <i>long term goals;</i> <i>the specific treatment modalities utilized; and</i> <i>responsibilities of each member of the treatment team; and</i> <i>adequate documentation to justify the diagnosis and the treatment and</i> <i>rehabilitation activities carried out.</i>

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§412.27(c)(3)(ii)	<p>(ii) <i>The treatment received by the inpatient must be documented in such a way as to assure that all active therapeutic efforts are included.</i></p>	34.01.20	<p><u>PPS Excluded Psychiatric Units: Documentation of Active Treatment</u> <i>The treatment received by the inpatient must be documented in such a way as to assure that all active therapeutic efforts are included.</i></p>
§412.27(c)(4)	<p>(4) <i>Recording progress. Progress notes must be recorded by the doctor of medicine or osteopathy responsible for the care of the inpatient, a nurse, social worker and, when appropriate, others significantly involved in active treatment modalities. The frequency of progress notes is determined by the condition of the inpatient but must be recorded at least weekly for the first two months and at least once a month thereafter and must contain recommendations for revisions in the treatment plan as indicated as well as precise assessment of the inpatient's progress in accordance with the original or revised treatment plan.</i></p>	34.01.21	<p><u>PPS Excluded Psychiatric Units: Progress Notes Requirements</u> <i>Progress notes must be recorded by the doctor of medicine or osteopathy responsible for the care of the inpatient, a nurse, social worker and, when appropriate others significantly involved in active treatment modalities.</i></p> <p><i>The frequency of progress notes is determined by the condition of the inpatient but must be recorded at least weekly for the first two months and at least once a month thereafter and must contain recommendations for revisions in the treatment plan as indicated as well as precise assessment of the inpatient's progress in accordance with the original or revised treatment plan.</i></p>
§412.27(c)(5)	<p>(5) <i>Discharge planning and discharge summary. The record of each patient who has been discharged must have a discharge summary that includes a recapitulation of the inpatient's hospitalization in the unit and recommendations from appropriate services concerning follow-up or aftercare as well as a brief summary of the patient's condition on discharge.</i></p>	34.01.22	<p><u>PPS Excluded Psychiatric Units: Discharge Planning & Discharge Summary.</u> <i>The record of each patient who has been discharged must have a discharge summary that includes a recapitulation of the inpatient's hospitalization in the unit and recommendations from appropriate services concerning follow-up or after care as well as a brief summary of the patient's condition on discharge.</i></p>
§412.27(d)(1)	<p>(d) <i>Meet special staff requirements in that the unit must have adequate numbers of qualified professional and supportive staff to evaluate inpatients, formulate written, individualized, comprehensive treatment plans, provide active treatment measures and engage in discharge planning, as follows:</i></p> <p>(1) <i>Personnel. The unit must employ or undertake to provide adequate numbers of qualified professional, technical, and consultative personnel to—</i></p> <p style="padding-left: 40px;">(i) <i>Evaluate inpatients;</i></p>	34.01.23	<p><u>PPS Excluded Psychiatric Units: Staffing Requirements</u> <i>The unit must:</i></p> <p><i>Meet special staff requirements in that the unit must have adequate numbers of qualified professional and supportive staff to evaluate inpatients, formulate written, individualized, comprehensive treatment plans, provide active treatment measures and engage in discharge planning.</i></p> <p><i>The unit must employ or undertake to provide adequate numbers of qualified professional, technical, and consultative personnel to—</i></p>

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			<ul style="list-style-type: none"> Evaluate inpatients
§412.27(d)(1)(iii)	(1) <i>Personnel. The unit must employ or undertake to provide adequate numbers of qualified professional, technical, and consultative personnel to—</i> (ii) <i>Formulate written, individualized, comprehensive treatment plans;</i>	34.01.24	<p>PPS Excluded Psychiatric Units: Staffing Requirements The unit must <i>employ or undertake to provide adequate numbers of qualified professional, technical, and consultative personnel to—</i></p> <ul style="list-style-type: none"> Formulate written, individualized comprehensive treatment plans
§412.27(d)(1)(iii)	(1) <i>Personnel. The unit must employ or undertake to provide adequate numbers of qualified professional, technical, and consultative personnel to—</i> (iii) <i>Provide active treatment measures; and</i>	34.01.25	<p>PPS Excluded Psychiatric Units: Staffing Requirements The unit must <i>employ or undertake to provide adequate numbers of qualified professional, technical, and consultative personnel to—</i></p> <ul style="list-style-type: none"> Provide active treatment measures
§412.27(d)(1)(iv)	(1) <i>Personnel. The unit must employ or undertake to provide adequate numbers of qualified professional, technical, and consultative personnel to—</i> (iv) <i>Engage in discharge planning.</i>	34.01.26	<p>PPS Excluded Psychiatric Units: Staffing Requirements The unit must <i>employ or undertake to provide adequate numbers of qualified professional, technical, and consultative personnel to—</i></p> <ul style="list-style-type: none"> Engage in discharge planning.
§412.27(d)(2)	(2) Director of inpatient psychiatric services: Medical staff. <i>Inpatient psychiatric services must be under the supervision of a clinical director, service chief, or equivalent who is qualified to provide the leadership required for an intensive treatment program. The number and qualifications of doctors of medicine and osteopathy must be adequate to provide essential psychiatric services.</i>	34.01.27	<p>PPS Excluded Psychiatric Units: Director of Inpatient Psychiatric Services: Medical Staff <i>Inpatient psychiatric services must be under the supervision of a clinical director, service chief, or equivalent who is qualified to provide the leadership required for an intensive treatment program.</i></p> <p><i>The number and qualifications of doctors of medicine and osteopathy must be adequate to provide essential psychiatric services.</i></p>
§412.27(d)(2)(i)	(i) <i>The clinical director, service chief, or equivalent must meet the training and experience requirements for examination by the American Board of Psychiatry and Neurology or the American Osteopathic Board of Neurology and Psychiatry.</i>	34.01.28	<p>PPS Excluded Psychiatric Units: Medical Director Qualifications <i>The Clinical Director, service chief, or equivalent must meet the training and experience requirements for examination by:</i></p> <ul style="list-style-type: none"> the American Board of Psychiatry and Neurology or the American Osteopathic Board of Neurology and Psychiatry.

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§412.27(d)(2)(ii)	(ii) <i>The director must monitor and evaluate the quality and appropriateness of services and treatment provided by the medical staff.</i>	34.01.29	<p>PPS Excluded Psychiatric Units: Medical Director Responsibilities <i>The director must monitor and evaluate the quality and appropriateness of services and treatment provided by the medical staff.</i></p>
§412.27(d)(3)	(3) <i>Nursing services. The unit must have a qualified director of psychiatric nursing services. In addition to the director of nursing, there must be adequate numbers of registered nurses, licensed practical nurses, and mental health workers to provide nursing care necessary under each inpatient’s active treatment program and to maintain progress notes on each inpatient.</i>	34.01.30	<p>PPS Excluded Psychiatric Units: Nursing Services <i>The unit must have a qualified director of psychiatric nursing services.</i></p> <p><i>In addition to the director of nursing, there must be adequate numbers of registered nurses, licensed practical nurses, and mental health workers to provide nursing care necessary under each inpatient’s active treatment program and to maintain progress notes on each inpatient.</i></p>
§412.27(d)(3)(i)	(3) (i) <i>The director of psychiatric nursing services must be a registered nurse who has a master’s degree in psychiatric or mental health nursing, or its equivalent, from a school of nursing accredited by the National League for Nursing, or be qualified by education and experience in the care of the mentally ill. The director must demonstrate competence to participate in interdisciplinary formulation of individual treatment plans; to give skilled nursing care and therapy; and to direct, monitor, and evaluate the nursing care furnished.</i>	34.01.31	<p>PPS Excluded Psychiatric Units: Nursing Services Leadership <i>The Director of psychiatric nursing services must be:</i></p> <ul style="list-style-type: none"> • <i>a registered nurse who has a master’s degree in psychiatric and mental health nursing, or</i> • <i>its equivalent, from a school of nursing accredited by the National League for Nursing, or be qualified by education and experience in the care for the mentally ill.</i> <p><i>The director must demonstrate competence:</i></p> <ul style="list-style-type: none"> • <i>to participate in interdisciplinary formulation of individual treatment plans;</i> • <i>to give skilled nursing care and therapy; and</i> • <i>to direct, monitor, and evaluate the nursing care furnished.</i>
§412.27(d)(3)(ii)	(3) (ii) <i>The staffing pattern must ensure the availability of a registered nurse 24 hours each day. There must be adequate numbers of registered nurses, licensed practical nurses, and mental health workers to provide the nursing care necessary under each inpatient’s active treatment program.</i>	34.01.32	<p>PPS Excluded Psychiatric Units: Staffing <i>The staffing pattern shall ensure the availability of a registered nurse 24 hours each day.</i></p> <p><i>There must be adequate numbers of registered nurses, licensed practical nurses, and mental health workers to provide the nursing care necessary under each inpatient’s active treatment program.</i></p>

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§412.27(d)(4)	(4) <i>Psychological services. The unit must provide or have available psychological services to meet the needs of the inpatients. The services must be furnished in accordance with acceptable standards of practice, service objectives, and established policies and procedures.</i>	34.01.33	<p><u>PPS Excluded Psychiatric Units: Psychological Services</u> <i>The unit must provide or have available psychological services to meet the needs of the inpatients.</i></p> <p><i>The services must be furnished in accordance with acceptable standards of practice, service objectives, and established policies and procedures.</i></p>
§412.27(d)(5)	(5) <i>Social services. There must be a director of social services who monitors and evaluates the quality and appropriateness of social services furnished. The services must be furnished in accordance with accepted standards of practice and established policies and procedures. Social service staff responsibilities must include, but are not limited to, participating in discharge planning, arranging for follow-up care, and developing mechanisms for exchange of appropriate information with sources outside the hospital.</i>	34.01.34	<p><u>PPS Excluded Psychiatric Units: Social Services</u> <i>There must be a director of social services who monitors and evaluates the quality and appropriateness of social services furnished.</i></p> <p><i>The services must be furnished in accordance with accepted standards of practice and established policies and procedures.</i></p> <p><i>Social service staff responsibilities must include, but are not limited to,</i></p> <ul style="list-style-type: none"> • <i>participating in discharge planning,</i> • <i>arranging for follow-up care, and</i> • <i>developing mechanisms for exchange of appropriate information with sources outside the hospital.</i>
§412.27(d)(6)	(6) <i>Therapeutic activities. The unit must provide a therapeutic activities program.</i>	34.01.35	<p><u>PPS Excluded Psychiatric Units: Therapeutic Activities</u> <i>The unit must provide a therapeutic activities program.</i></p>
§412.27(d)(6)(i)	(6) (6)(i) <i>The program must be appropriate to the needs and interests of inpatients and be directed toward restoring and maintaining optimal levels of physical and psychosocial functioning.</i>	34.01.36	<p><u>PPS Excluded Psychiatric Units: Program Scope</u> <i>The program must be appropriate to the needs and interests of inpatients and be directed toward restoring and maintaining optimal levels of physical and psychosocial functioning.</i></p>
§412.27(d)(6)(ii)	(6) (6)(ii) <i>The number of qualified therapists, support personnel, and consultants must be adequate to provide comprehensive therapeutic activities consistent with each inpatient’s active treatment program.</i>	34.01.37	<p><u>PPS Excluded Psychiatric Units: Program Staffing</u> <i>The number of qualified therapists, support personnel, and consultants must be adequate to provide comprehensive therapeutic activities consistent with each inpatient’s active treatment program.</i></p>

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412.29	<p>Classification criteria for payment under the inpatient rehabilitation facility prospective payment system.</p> <p>To be excluded from the prospective payment systems described in § 412.1(a)(1) and to be paid under the prospective payment system specified in § 412.1(a)(3), an inpatient rehabilitation hospital or an inpatient rehabilitation unit of a hospital (otherwise referred to as an IRF) must meet the following requirements:</p>	33.01.00	<p><u>Inpatient Rehabilitation Facility (IRF) Prospective Payment System: Classification Criteria for Payment.</u></p> <p>To be excluded from the prospective payment systems described in §412(a)(1) and to be paid under the prospective payment system specified in §412.1(a)(3), an inpatient rehabilitation unit of a hospital (otherwise referred to as an IRF) must meet the following requirements:</p>
412.29(a)	<p>(a) Have (or be part of a hospital that has) a provider agreement under part 489 of this chapter to participate as a hospital.</p>	33.01.01	<p><u>Inpatient Rehabilitation Facility (IRF): Provider Agreement.</u></p> <ul style="list-style-type: none"> • Have (or be part of a hospital that has) a provider agreement under part 489 of 42 CFR 489 to participate as a hospital.
§412.29(b); §412.29(b)(1); §412.29(b)(1)(i); §412.29(b)(1)(ii); §412.29(b)(2); §412.29(b)(2)(i); §412.29(b)(2)(ii); §412.29(b)(2)(iii); §412.29(b)(2)(iv); §412.29(b)(2)(v); §412.29(b)(2)(vi); §412.29(b)(2)(vii); §412.29(b)(2)(viii); §412.29(b)(2)(ix); §412.29(b)(2)(x); §412.29(b)(2)(xi); §412.29(b)(2)(xii); §412.29(b)(2)(xiii); §412.29(b)(2)(xiii)(A); §412.29(b)(2)(xiii)(B); §412.29(b)(2)(xiii)(C)	<p>(b) Except in the case of a “new” IRF or “new” IRF beds, as defined in paragraph (c) of this section, an IRF must show that, during its most recent, consecutive, and appropriate 12-month time period (as defined by CMS or the Medicare contractor), it served an inpatient population that meets the following criteria:</p> <p>(1) For cost reporting periods beginning on or after July 1, 2004, and before July 1, 2005, the IRF served an inpatient population of whom at least 50 percent, and for cost reporting periods beginning on or after July 1, 2005, the IRF served an inpatient population of whom at least 60 percent required intensive rehabilitation services for treatment of one or more of the conditions specified at paragraph (b)(2) of this section. A patient with a comorbidity, as defined at §412.602 of this part, may be included in the inpatient population that counts toward the required applicable percentage if—</p> <p>(i) The patient is admitted for inpatient rehabilitation for a condition that is not one of the conditions specified in paragraph (b)(2) of this section;</p>	33.01.02	<p><u>Inpatient Rehabilitation Facility (IRF): Requirement to Serve Inpatient Population.</u></p> <p>Except in the case of a “new” IRF or “new” IRF beds, as defined in paragraph (c) of 42 CFR 412.29, an IRF must show that, during its most recent, consecutive, and appropriate 12-month time period (as defined by CMS or the Medicare contractor), it served an inpatient population that meets the following criteria:</p> <p>(1) For cost reporting periods beginning on or after July 1, 2004, and before July 1, 2005, the IRF served an inpatient population of whom at least 50 percent, and for cost reporting periods beginning on or after July 1, 2005, the IRF served an inpatient population of whom at least 60 percent required intensive rehabilitation services for treatment of one or more of the conditions specified at paragraph (b)(2) of 42 CFR 412.29.</p> <p>A patient with a comorbidity, as defined at §412.602 of 42 CFR 412.602, may be included in the inpatient population that counts toward the required applicable percentage if—</p> <p>(i) The patient is admitted for inpatient rehabilitation for a condition that is not one of the conditions specified in paragraph (b)(2) of 42 CFR 412.29;</p>

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<p>(ii) <i>The patient has a comorbidity that falls in one of the conditions specified in paragraph (b)(2) of this section; and</i></p> <p>(iii) <i>The comorbidity has caused significant decline in functional ability in the individual that, even in the absence of the admitting condition, the individual would require the intensive rehabilitation treatment that is unique to inpatient rehabilitation facilities paid under subpart P of this part and that cannot be appropriately performed in another care setting covered under this title.</i></p> <p>(2) <u>List of conditions.</u></p> <p>(i) <i>Stroke.</i></p> <p>(ii) <i>Spinal cord injury.</i></p> <p>(iii) <i>Congenital deformity.</i></p> <p>(iv) <i>Amputation.</i></p> <p>(v) <i>Major multiple trauma.</i></p> <p>(vi) <i>Fracture of femur (hip fracture).</i></p> <p>(vii) <i>Brain injury.</i></p> <p>(viii) <i>Neurological disorders, including multiple sclerosis, motor neuron diseases, polyneuropathy, muscular dystrophy, and Parkinson's disease.</i></p> <p>(ix) <i>Burns.</i></p> <p>(x) <i>Active, polyarticular rheumatoid arthritis, psoriatic arthritis, and seronegative arthropathies resulting in significant functional impairment of ambulation and</i></p>	<p>(ii) <i>The patient has a comorbidity that falls in one of the conditions specified in paragraph (b)(2) of 42 CFR 412.29; and</i></p> <p>(iii) <i>The comorbidity has caused significant decline in functional ability in the individual that, even in the absence of the admitting condition, the individual would require the intensive rehabilitation treatment that is unique to inpatient rehabilitation facilities paid under subpart P of 42 CFR 412 and that cannot be appropriately performed in another care setting covered under this title.</i></p> <p>(2) <u>List of conditions.</u></p> <p>(i) <i>Stroke</i></p> <p>(ii) <i>Spinal cord injury</i></p> <p>(iii) <i>Congenital deformity</i></p> <p>(iv) <i>Amputation</i></p> <p>(v) <i>Major multiple trauma</i></p> <p>(vi) <i>Fracture of femur (hip fracture)</i></p> <p>(vii) <i>Brain injury</i></p> <p>(viii) <i>Neurological disorders, including multiple sclerosis, motor neuron diseases, polyneuropathy, muscular dystrophy, and Parkinson's disease</i></p> <p>(ix) <i>Burns</i></p> <p>(x) <i>Active polyarticular rheumatoid arthritis, psoriatic arthritis, and seronegative arthropathies resulting in significant functional impairment of ambulation and other</i></p>
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	<p><i>other activities of daily living that have not improved after an appropriate, aggressive, and sustained course of outpatient therapy services or services in other less intensive rehabilitation settings immediately preceding the inpatient rehabilitation admission or that result from a systemic disease activation immediately before admission, but have the potential to improve with more intensive rehabilitation.</i></p> <p>(xi) <i>Systemic vasculidities with joint inflammation, resulting in significant functional impairment of ambulation and other activities of daily living that have not improved after an appropriate, aggressive, and sustained course of outpatient therapy services or services in other less intensive rehabilitation settings immediately preceding the inpatient rehabilitation admission or that result from a systemic disease activation immediately before admission, but have the potential to improve with more intensive rehabilitation.</i></p> <p>(xii) <i>Severe or advanced osteoarthritis (osteoarthrosis or degenerative joint disease) involving two or more major weight bearing joints (elbow, shoulders, hips, or knees, but not counting a joint with a prosthesis) with joint deformity and substantial loss of range of motion, atrophy of muscles surrounding the joint, significant functional impairment of ambulation and other activities of daily living that have not improved after the patient has participated in an appropriate, aggressive, and sustained course of outpatient therapy services or services in other less intensive rehabilitation settings immediately preceding the inpatient rehabilitation admission but have the potential to improve with more intensive rehabilitation. (A joint replaced by a prosthesis no longer is considered to have osteoarthritis, or other arthritis, even though this condition was the reason for the joint replacement.)</i></p>	<p><i>activities of daily living that have not improved after an appropriate, aggressive, and sustained course of outpatient therapy services or services in other less intensive rehabilitation settings immediately preceding the inpatient rehabilitation admission or that result from a systemic disease activation immediately before admission, but have the potential to improve with more intensive rehabilitation.</i></p> <p>(xi) <i>Systemic vasculidities with joint inflammation, resulting in significant functional impairment of ambulation and other activities of daily living that have not improved after an appropriate, aggressive, and sustained course of outpatient therapy services or services in other less intensive rehabilitation settings immediately preceding the inpatient rehabilitation admission or that result from a systemic disease activation immediately before admission, but have the potential to improve with more intensive rehabilitation.</i></p> <p>(xii) <i>Severe or advanced osteoarthritis (osteoarthrosis or degenerative joint disease) involving two or more major weight bearing joints (elbow, shoulders, hips, or knees, but not counting a joint with a prosthesis) with joint deformity and substantial loss of range of motion, atrophy of muscles surrounding the joint, significant functional impairment of ambulation and other activities of daily living that have not improved after the patient has participated in an appropriate, aggressive, and sustained course of outpatient therapy services or services in other less intensive rehabilitation settings immediately preceding the inpatient rehabilitation admission but have the potential to improve with more intensive rehabilitation. (A joint replaced by a prosthesis no longer is considered to have osteoarthritis, or other arthritis, even though this condition was the reason for the joint replacement.)</i></p>
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	<p>(xiii) <i>Knee or hip joint replacement, or both, during an acute hospitalization immediately preceding the inpatient rehabilitation stay and also meet one or more of the following specific criteria:</i></p> <p>(A) <i>The patient underwent bilateral knee or bilateral hip joint replacement surgery during the acute hospital admission immediately preceding the IRF admission.</i></p> <p>(B) <i>The patient is extremely obese with a Body Mass Index of at least 50 at the time of admission to the IRF.</i></p> <p>(C) <i>The patient is age 85 or older at the time of admission to the IRF.</i></p>		<p>(xiii) <i>Knee or hip joint replacement, or both, during an acute hospitalization immediately preceding the inpatient rehabilitation stay and also meet one or more of the following specific criteria:</i></p> <p>(A) <i>The patient underwent bilateral knee or bilateral hip joint replacement surgery during the acute hospital admission immediately preceding the IRF admission.</i></p> <p>(B) <i>The patient is extremely obese with a Body Mass Index of at least 50 at the time of admission to the IRF.</i></p> <p>(C) <i>The patient is age 85 or older at the time of admission to the IRF.</i></p>
<p>§412.29(c); §412.29(c)(1); §412.29(c)(2); §412.29(c)(3); §412.29(c)(4)</p>	<p>(c) <i>In the case of new IRFs (as defined in paragraph (c)(1) of this section) or new IRF beds (as defined in paragraph (c)(2) of this section), the IRF must provide a written certification that the inpatient population it intends to serve meets the requirements of paragraph (b) of this section. This written certification will apply until the end of the IRF's first full 12-month cost reporting period or, in the case of new IRF beds, until the end of the cost reporting period during which the new beds are added to the IRF.</i></p> <p>(1) New IRFs. <i>An IRF hospital or IRF unit is considered new if it has not been paid under the IRF PPS in subpart P of this part for at least 5 calendar years. A new IRF will be considered new from the point that it first participates in Medicare as an IRF until the end of its first full 12-month cost reporting period.</i></p>	<p style="text-align: center;">33.01.03</p>	<p><u>Inpatient Rehabilitation Facility (IRF): Written Certification For New IRFs.</u></p> <p><i>In the case of new IRFs (as defined in paragraph (c)(1) of 42 CFR 412.29) or new IRF beds (as defined in paragraph (c)(2) of 42 CFR 412.29), the IRF must provide a written certification that the inpatient population it intends to serve meets the requirements of paragraph (b) of 42 CFR 412.29.</i></p> <p><i>This written certification will apply until the end of the IRF's first full 12-month cost reporting period or, in the case of new IRF beds, until the end of the cost reporting period during which the new beds are added to the IRF.</i></p> <p><u>New IRFs.</u></p> <p><i>An IRF hospital or IRF unit is considered new if it has not been paid under the IRF PPS in subpart P of this part for at least 5 calendar years. A new IRF will be considered new from the point that it first</i></p>

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	<p>(2) New IRF beds. Any IRF beds that are added to an existing IRF must meet all applicable State Certificate of Need and State licensure laws. New IRF beds may be added one time at any point during a cost reporting period and will be considered new for the rest of that cost reporting period. A full 12-month cost reporting period must elapse between the delicensing or decertification of IRF beds in an IRF hospital or IRF unit and the addition of new IRF beds to that IRF hospital or IRF unit. Before an IRF can add new beds, it must receive written approval from the appropriate CMS RO, so that the CMS RO can verify that a full 12-month cost reporting period has elapsed since the IRF has had beds delicensed or decertified. New IRF beds are included in the compliance review calculations under paragraph (b) of this section from the time that they are added to the IRF.</p> <p>(3) Change of ownership or leasing. An IRF hospital or IRF unit that undergoes a change of ownership or leasing, as defined in §489.18 of this chapter, retains its excluded status and will continue to be paid under the prospective payment system specified in §412.1(a)(3) before and after the change of ownership or leasing if the new owner(s) of the IRF accept assignment of the previous owners' Medicare provider agreement and the IRF continues to meet all of the requirements for payment under the IRF prospective payment system. If the new owner(s) do not accept assignment of the previous owners' Medicare provider agreement, the IRF is considered to be voluntarily terminated and the new owner(s) may re-apply to participate in the Medicare program. If the IRF does not continue to meet all of the requirements for payment under the IRF</p>	<p>participates in Medicare as an IRF until the end of its first full 12-month cost reporting period.</p> <p><u>New IRF beds.</u></p> <p>Any IRF beds that are added to an existing IRF must meet all applicable State Certificate of Need and State licensure laws. New IRF beds may be added one time at any point during a cost reporting period and will be considered new for the rest of that cost reporting period. A full 12-month cost reporting period must elapse between the delicensing or decertification of IRF beds in an IRF hospital or IRF unit and the addition of new IRF beds to that IRF hospital or IRF unit. Before an IRF can add new beds, it must receive written approval from the appropriate CMS RO, so that the CMS RO can verify that a full 12-month cost reporting period has elapsed since the IRF has had beds delicensed or decertified. New IRF beds are included in the compliance review calculations under paragraph (b) of 42 CFR 412.29 from the time that they are added to the IRF.</p> <p><u>Change of ownership or leasing.</u></p> <p>An IRF hospital or IRF unit that undergoes a change of ownership or leasing, as defined in §489.18 of 42 CFR 489.18, retains its excluded status and will continue to be paid under the prospective payment system specified in §412.1(a)(3) before and after the change of ownership or leasing if the new owner(s) of the IRF accept assignment of the previous owners' Medicare provider agreement and the IRF continues to meet all of the requirements for payment under the IRF prospective payment system. If the new owner(s) do not accept assignment of the previous owners' Medicare provider agreement, the IRF is considered to be voluntarily terminated and the new owner(s) may re-apply to participate in the Medicare program. If the IRF does not continue to meet all of the requirements for payment under the IRF prospective payment system, then the IRF loses its excluded status and is paid according to the prospective payment systems described in §412.1(a)(1).</p>
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	<p><i>prospective payment system, then the IRF loses its excluded status and is paid according to the prospective payment systems described in §412.1(a)(1).</i></p> <p>(4) Mergers. <i>If an IRF hospital (or a hospital with an IRF unit) merges with another hospital and the owner(s) of the merged hospital accept assignment of the IRF hospital's provider agreement (or the provider agreement of the hospital with the IRF unit), then the IRF hospital or IRF unit retains its excluded status and will continue to be paid under the prospective payment system specified in §412.1(a)(3) before and after the merger, as long as the IRF hospital or IRF unit continues to meet all of the requirements for payment under the IRF prospective payment system. If the owner(s) of the merged hospital do not accept assignment of the IRF hospital's provider agreement (or the provider agreement of the hospital with the IRF unit), then the IRF hospital or IRF unit is considered voluntarily terminated and the owner(s) of the merged hospital may reapply to the Medicare program to operate a new IRF.</i></p>		<p><u>Mergers.</u></p> <p><i>If an IRF hospital (or a hospital with an IRF unit) merges with another hospital and the owner(s) of the merged hospital accept assignment of the IRF hospital's provider agreement (or the provider agreement of the hospital with the IRF unit), then the IRF hospital or IRF unit retains its excluded status and will continue to be paid under the prospective payment system specified in §412.1(a)(3) before and after the merger, as long as the IRF hospital or IRF unit continues to meet all of the requirements for payment under the IRF prospective payment system. If the owner(s) of the merged hospital do not accept assignment of the IRF hospital's provider agreement (or the provider agreement of the hospital with the IRF unit), then the IRF hospital or IRF unit is considered voluntarily terminated and the owner(s) of the merged hospital may reapply to the Medicare program to operate a new IRF.</i></p>
<p>§412.29(d)</p>	<p><i>An inpatient rehabilitation unit must:</i></p> <p>(d) <i>Have in effect a preadmission screening procedure under which each prospective patient's condition and medical history are reviewed to determine whether the patient is likely to benefit significantly from an intensive inpatient hospital program. This procedure must ensure that the preadmission screening for each Medicare Part A Fee-for-Service patient is reviewed and approved by a rehabilitation physician prior to the patient's admission to the IRF.</i></p>	<p>33.01.04</p>	<p><u>Inpatient Rehabilitation Facility (IRF): Preadmission Screening.</u></p> <p><i>An inpatient rehabilitation unit must:</i></p> <ul style="list-style-type: none"> • <i>Have in effect a preadmission screening procedure under which each prospective patient's condition and medical history are reviewed to determine whether the patient is likely to benefit significantly from an intensive inpatient program.</i> <p><i>This procedure must ensure that the preadmission screening for each Medicare Part A Fee-for-Service patient is reviewed and approved by a rehabilitation physician prior to the patient's admission to the IRF.</i></p>

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§412.29(e)	<p>An inpatient rehabilitation unit must:</p> <p>(e) Have in effect a procedure to ensure that patients receive close medical supervision, as evidenced by at least 3 face-to-face visits per week by a licensed physician with specialized training and experience in inpatient rehabilitation to assess the patient both medically and functionally, as well as to modify the course of treatment as needed to maximize the patient's capacity to benefit from the rehabilitation process.</p>	33.01.05	<p>Medical Supervision.</p> <p>An inpatient rehabilitation unit must:</p> <ul style="list-style-type: none"> • Have in effect a procedure to ensure that patients receive close medical supervision, as evidenced by at least 3 face-to-face visits per week by a licensed physician with specialized training and experience in inpatient rehabilitation to assess the patient both medically and functionally, as well as to modify the course of treatment as needed to maximize the patient's capacity to benefit from the rehabilitation process.
§412.29(f)	<p>An inpatient rehabilitation unit must:</p> <p>(f) Furnish, through the use of qualified personnel, rehabilitation nursing, physical therapy, and occupational therapy, plus, as needed, speech-language pathology, social services, psychological services (including neuropsychological services), and orthotic and prosthetic services.</p>	33.01.06	<p>Personnel Qualifications.</p> <p>An inpatient rehabilitation unit must:</p> <ul style="list-style-type: none"> • Furnish, through the use of qualified personnel, rehabilitation nursing, physical therapy, and occupational therapy, plus, as needed, speech-language pathology, social services, psychological services (including neuropsychological services), and orthotic and prosthetic services.
§412.29(g)	<p>An inpatient rehabilitation unit must:</p> <p>(g) Have a director of rehabilitation who—</p> <ol style="list-style-type: none"> (1) Provides services to the IRF hospital and its inpatients on a full-time basis or, in the case of a rehabilitation unit, at least 20 hours per week; (2) Is a doctor of medicine or osteopathy; (3) Is licensed under State law to practice medicine or surgery; and (4) Has had after completing a one-year hospital internship, at least 2 years of training or experience in the medical-management of inpatients requiring rehabilitation services. 	33.01.07	<p>Medical Director of Rehabilitation – Qualifications.</p> <p>An inpatient rehabilitation unit must have a director of rehabilitation who:</p> <ol style="list-style-type: none"> 1. Provides services to the IRF hospital and its inpatients on a full-time basis or, in the case of a rehabilitation unit, at least 20 hours per week; 2. Is a doctor of medicine or osteopathic medicine; 3. Is licensed under State law to practice medicine or surgery; and 4. Has had, after completing a one-year hospital internship, at least two years of training or experience in the medical management of inpatients requiring rehabilitation services.

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§412.29(h)	(1) <i>Have a plan of treatment for each inpatient that is established, reviewed, and revised as needed by a physician in consultation with other professional personnel who provide services to the patient.</i>	33.01.08	<p><u>Plan of Treatment.</u> <i>The inpatient rehabilitation unit must:</i></p> <ul style="list-style-type: none"> • <i>Have a plan of treatment for each inpatient that is established, reviewed, and revised as needed by a physician in consultation with other professional personnel who provide services to the patient.</i>
§412.29(i)	(i) <i>Use a coordinated interdisciplinary team approach in the rehabilitation of each inpatient, as documented by the periodic clinical entries made in the patient's medical record to note the patient's status in relationship to goal attainment and discharge plans, and that team conferences are held at least once per week to determine the appropriateness of treatment.</i>	33.01.09	<p><u>Coordinated Interdisciplinary Team Approach.</u> <i>The inpatient rehabilitation unit must:</i></p> <ul style="list-style-type: none"> • <i>Use a coordinated interdisciplinary team approach in the rehabilitation of each inpatient, as documented by the periodic clinical entries made in the patient's medical record to note the patient's status in relationship to goal attainment and discharge plans, and that team conferences are held at least once per week to determine the appropriateness of treatment.</i>
§412.29(j)	(j) <i>Retroactive adjustments. If a new IRF (or new beds that are added to an existing IRF) are excluded from the prospective payment systems specified in §412.1(a)(1) and paid under the prospective payment system specified in §412.1(a)(3) for a cost reporting period under paragraph (c) of this section, but the inpatient population actually treated during that period does not meet the requirements of paragraph (b) of this section, we adjust payments to the IRF retroactively in accordance with the provisions in §412.130.</i>	33.01.10	<p><u>Retroactive Adjustments.</u> <i>If a new IRF (or new beds that are added to an existing IRF) are excluded from the prospective payment systems specified in §412.1(a)(1) and paid under the prospective payment system specified in §412.1(a)(3) for a cost reporting period under paragraph (c) of 42 CFR 412.29, but the inpatient population actually treated during that period does not meet the requirements of paragraph (b) of 42 CFR 412.29, we adjust payments to the IRF retroactively in accordance with the provisions in §412.130.</i></p>
§483.10	<p><u>Resident rights.</u> <i>The resident has a right to a dignified existence, self-determination, and communication with and access to persons and services inside and outside the facility. A facility must protect and promote the rights of each resident, including each of the following rights:</i></p>	32.01.01	<p><u>Residents' Rights.</u> <i>The resident has the right to a dignified existence, self-determination and communication with and access to persons and services inside and outside the facility. A facility must protect and promote the rights of each resident, including each of the following rights</i></p>

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<p>§483.10(b)(3)</p>	<p><i>Notice of rights and services.</i> (1) <i>The resident has the right to be fully informed in language that he or she can understand of his or her total health status, including but not limited to, his or her medical condition;</i></p>	<p>32.01.02</p>	<p><u>Notice of Rights and Services</u> <i>The resident has the right to be fully informed in language that he or she can understand of his or her total health status, including but not limited to, his or her medical condition;</i></p>
<p>§483.10(b)(4)</p>	<p>(2) <i>The resident has the right to refuse treatment, to refuse to participate in experimental research, and to formulate an advance directive as specified in paragraph (8) of this section; and</i></p>	<p>32.01.03</p>	<p><u>Right to Refuse Treatment</u> <i>The resident has the right to refuse treatment, to refuse to participate in experimental research, and to formulate an advance directive as specified in paragraph 8 of 42 CFR 483.10; and</i></p>
<p>§483.10(b)(5) §483.10(b)(5)(i) §483.10(b)(5)(i)(A) §483.10(b)(5)(i)(B) §483.10(b)(5)(ii) §483.10(b)(6)</p>	<p>(1) <i>The facility must—</i> (i) <i>Inform each resident who is entitled to Medicaid benefits, in writing, at the time of admission to the nursing facility or, when the resident becomes eligible for Medicaid of—</i> (A) <i>The items and services that are included in nursing facility services under the State plan and for which the resident may not be charged;</i> (B) <i>Those other items and services that the facility offers and for which the resident may be charged, and the amount of charges for those services; and</i> (ii) <i>Inform each resident when changes are made to the items and services specified in paragraphs (5)(i) (A) and (B) of this section.</i> (6) <i>The facility must inform each resident before, or at the time of admission, and periodically during the resident’s stay, of services available in the facility and of charges for those services, including any charges for services not covered under Medicare or by the facility’s per diem rate.</i></p>	<p>32.01.04</p>	<p><u>Medicaid and Medicare Notification.</u> <i>The facility must--</i> (i) <i>Inform each resident who is entitled to Medicaid benefits, in writing, at the time of admission to the nursing facility or, when the resident becomes eligible for Medicaid of--</i> (A) <i>The items and services that are included in nursing facility services under the State plan and for which the resident may not be charged;</i> (B) <i>Those other items and services that the facility offers and for which the resident may be charged, and the amount of charges for those services; and</i> (ii) <i>Inform each resident when changes are made to the items and services specified in paragraphs (5)(i)(A) and (B) of 42 CFR 483.10.</i> <i>The facility must inform each resident before, or at the time of admission, and periodically during the resident’s stay, of services available in the facility and of charges for those services, including any charges for services not covered under Medicare or by the facility’s per diem rate.</i></p>
<p>§483.10(b)(8)</p>	<p>(8) <i>The facility must comply with the requirements specified in subpart I of part 489 of this chapter relating to maintaining written policies and procedures regarding</i></p>	<p>32.01.05</p>	<p><u>Advance Directives</u> <i>The facility must comply with the requirements specified in subpart I of part 489 of 42 CFR 489 relating to maintaining written policies and</i></p>

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<p><i>advance directives. These requirements include provisions to inform and provide written information to all adult residents concerning the right to accept or refuse medical or surgical treatment and, at the individual's option, formulate an advance directive. This includes a written description of the facility's policies to implement advance directives and applicable State law. Facilities are permitted to contract with other entities to furnish this information but are still legally responsible for ensuring that the requirements of this section are met.</i></p> <p><i>If an adult individual is incapacitated at the time of admission and is unable to receive information (due to the incapacitating condition or a mental disorder) or articulate whether or not he or she has executed an advance directive, the facility may give advance directive information to the individual's family or surrogate in the same manner that it issues other materials about policies and procedures to the family of the incapacitated individual or to a surrogate or other concerned persons in accordance with State law.</i></p> <p><i>The facility is not relieved of its obligation to provide this information to the individual once he or she is no longer incapacitated or unable to receive such information.</i></p> <p><i>Follow-up procedures must be in place to provide the information to the individual directly at the appropriate time.</i></p> <p><i>"Advance directive" means a written instruction, such as a living will or durable power of attorney for health care recognized under State law, relating to the provision of health care when the individual is incapacitated.</i></p>	<p><i>procedures regarding advance directives. These requirements include provisions to inform and provide written information to all adult residents concerning the right to accept or refuse medical or surgical treatment and, at the individual's option, formulate an advance directive. This includes a written description of the facility's policies to implement advance directives and applicable State law. Facilities are permitted to contract with other entities to furnish this information but are still legally responsible for ensuring that the requirements of 42 CFR 483.10 are met.</i></p> <p><i>If an adult individual is incapacitated at the time of admission and is unable to receive information (due to the incapacitating condition or a mental disorder) or articulate whether or not he or she has executed an advance directive, facility may give advance directive information to the individual's family or surrogate in the same manner that it issues other materials about policies and procedures to the family of the incapacitated individual or to a surrogate or other concerned persons in accordance with State law.</i></p> <p><i>The facility is not relieved of its obligation to provide this information to the individual once he or she is no longer incapacitated or unable to receive such information. Follow-up procedures must be in place to provide the information to the individual directly at the appropriate time.</i></p> <p><i>"Advance directive" means a written instruction, such as a living will or durable power of attorney for health care recognized under State law, relating to the provision of health care when the individual is incapacitated.</i></p>	
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<p>§483.10(d) §483.10(d)(1)</p>	<p>(d) <i>Free choice. The resident has the right to—</i> (1) <i>Choose a personal attending physician;</i></p>	<p>32.01.06</p>	<p><u>Personal Physician</u> <i>The resident shall have the right to choose a personal attending physician.</i></p>
<p>§483.10(d)(2)</p>	<p>(2) <i>Be fully informed in advance about care and treatment and of any changes in that care or treatment that may affect the resident’s well-being; and</i></p>	<p>32.01.07</p>	<p><u>Informed of Care & Treatment</u> <i>The resident has the right to: Be fully informed in advance about care and treatment and of any changes in that care or treatment that may affect the resident’s well being.</i></p>
<p>§483.10(d)(3)</p>	<p>(3) <i>Unless adjudged incompetent or otherwise found to be incapacitated under the laws of the State, participate in planning care and treatment or changes in care and treatment.</i></p>	<p>32.01.08</p>	<p><u>Participation in Care</u> <i>Unless adjudged incompetent or otherwise found to be incapacitated under the laws of the State, participate in planning care and treatment or changes in care and treatment.</i></p>
<p>§483.10(e) §483.10(e)(1) §483.10(e)(2) §483.10(e)(3) §483.10(e)(3)(i) §483.10(e)(3)(ii)</p>	<p><i>Privacy and confidentiality. The resident has the right to personal privacy and confidentiality of his or her personal and clinical records.</i> (1) <i>Personal privacy includes accommodations, medical treatment, written and telephone communications, personal care, visits, and meetings of family and resident groups, but this does not require the facility to provide a private room for each resident;</i> (2) <i>Except as provided in paragraph (e)(3) of this section, the resident may approve or refuse the release of personal and clinical records to any individual outside the facility;</i> (3) <i>The resident’s right to refuse release of personal and clinical records does not apply when—</i> (i) <i>The resident is transferred to another health care institution; or</i> (ii) <i>Record release is required by law.</i></p>	<p>32.01.09</p>	<p><u>Personal Privacy & Confidentiality.</u> <i>The resident has the right to personal privacy and confidentiality of his/her personal and clinical records.</i> (1) <i>Personal privacy includes accommodations, medical treatment, written and telephone communications, personal care, visits, and meetings of family and resident groups but this does not require the facility to provide a private room for each resident.</i> (2) <i>Except as provided in paragraph (e)(3) of 42 CFR 483.10, the resident may approve or refuse the release of personal and clinical records to any individual outside the facility.</i> (3) <i>The resident's right to refuse release of personal and clinical records does not apply when—</i> (1) <i>The resident is transferred to another healthcare institution.</i> (2) <i>Record release is required by law.</i></p>
<p>§483.10(h)</p>	<p><i>Work. The resident has the right to—</i> (1) <i>Refuse to perform services for the facility;</i> (2) <i>Perform services for the facility, if he or she chooses, when—</i></p>	<p>32.01.10</p>	<p><u>Work</u> <i>The resident shall have the right to:</i> (1) <i>Refuse to perform services for the facility.</i> (2) <i>Perform services for the facility, if he or she chooses, when;</i></p>

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	<ul style="list-style-type: none"> (i) <i>The facility has documented the need or desire for work in the plan of care;</i> (ii) <i>The plan specifies the nature of the services performed and whether the services are voluntary or paid;</i> (iii) <i>Compensation for paid services is at or above prevailing rates; and</i> (iv) <i>The resident agrees to the work arrangement described in the plan of care.</i> 		<ul style="list-style-type: none"> (i) <i>The facility has documented the need or desire for work in the plan of care.</i> (ii) <i>The plan specifies the nature of the services performed, and whether the services are voluntary or paid.</i> (iii) <i>Compensation for paid services is at or above prevailing rates.</i> (iv) <i>The resident agrees to the work arrangement described in the plan of care.</i>
§483.10(i)	<p><i>Mail.</i> <i>The resident has the right to privacy in written communications, including the right to—</i></p> <ul style="list-style-type: none"> (1) <i>Send and promptly receive mail that is unopened; and</i> (2) <i>Have access to stationery, postage, and writing implements at the resident’s own expense.</i> 	32.01.11	<p>Mail <i>The resident has the right to privacy in written communications, including the right to:</i></p> <ul style="list-style-type: none"> (1) <i>Send and promptly receive mail that is unopened.</i> (2) <i>Have access to stationery, postage, and writing implements at the resident’s own expense.</i>
§483.10(j) §483.10(j)(1)(vii) §483.10(j)(1)(viii)	<p><i>Access and visitation rights.</i></p> <ul style="list-style-type: none"> (1) <i>The resident has the right and the facility must provide immediate access to any resident by the following:</i> <ul style="list-style-type: none"> (vii) <i>Subject to the resident’s right to deny or withdraw consent at any time, immediate family or other relatives of the resident; and</i> (viii) <i>Subject to reasonable restrictions and the resident’s right to deny or withdraw consent at any time, others who are visiting with the consent of the resident</i> 	32.01.12	<p>Access & Visitation Rights <i>The resident has the right and the facility must provide immediate access to any resident by the following:</i></p> <ul style="list-style-type: none"> (vii) <i>Subject to the resident’s right to deny or withdraw consent at any time, immediate family or other relatives of the resident.</i> (viii) <i>Subject to reasonable restrictions and the resident’s right to deny or withdraw consent at any time, others who are visiting with the consent of the resident.</i>
§483.10(l)	<p><i>Personal property.</i> <i>The resident has the right to retain and use personal possessions, including some furnishings, and appropriate clothing, as space permits, unless to do so would infringe upon the rights or health and safety of other residents.</i></p>	32.01.13	<p>Personal Possessions <i>The resident has the right to retain and use personal possessions, including some furnishings, and appropriate clothing, as space permits, unless to do so would infringe upon the rights or health and safety of other residents.</i></p>

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<p>§483.10(m)</p>	<p><i>Married couples. The resident has the right to share a room with his or her spouse when married residents live in the same facility and both spouses consent to the arrangement.</i></p>	<p>32.01.14</p>	<p><u>Married Couples</u> <i>The resident has the right to share a room with his or her spouse when married residents live in the same facility and both spouses consent to the arrangement.</i></p>
<p>§483.12(a)(1)</p>	<p><i>Admission, transfer and discharge rights. (a) Transfer and discharge— (1) Definition: Transfer and discharge includes movement of a resident to a bed outside of the certified facility whether that bed is in the same physical plant or not. Transfer and discharge does not refer to movement of a resident to a bed within the same certified facility.</i></p>	<p>32.01.15</p>	<p><u>Transfer & Discharge: Definition</u> Transfer and discharge includes movement of a resident to a bed outside of the certified facility whether that bed is in the same physical plant or not. Transfer and discharge does not refer to movement of a resident to a bed within the same certified facility.</p>
<p>§483.12(a)(2) §483.12(a)(2)(i) §483.12(a)(2)(ii) §483.12(a)(2)(iii) §483.12(a)(2)(iv) §483.12(a)(2)(v) §483.12(a)(2)(vi)</p>	<p><i>(a) Transfer and discharge requirements. The facility must permit each resident to remain in the facility, and not transfer or discharge the resident from the facility unless—</i></p> <ul style="list-style-type: none"> <i>(i) The transfer or discharge is necessary for the resident's welfare and the resident's needs cannot be met in the facility;</i> <i>(ii) The transfer or discharge is appropriate because the resident's health has improved sufficiently so the resident no longer needs the services provided by the facility;</i> <i>(iii) The safety of individuals in the facility is endangered;</i> <i>(iv) The health of individuals in the facility would otherwise be endangered;</i> <i>(v) The resident has failed, after reasonable and appropriate notice, to pay for (or to have paid under Medicare or Medicaid) a stay at the facility. For a resident who becomes eligible for Medicaid after admission to a facility, the facility may charge a resident only allowable charges under Medicaid; or</i> <i>(vi) The facility ceases to operate.</i> 	<p>32.01.16</p>	<p><u>Transfer and Discharge Requirements.</u> The facility must permit each resident to remain in the facility, and not transfer or discharge the resident from the facility unless—</p> <ul style="list-style-type: none"> <i>(i) The transfer or discharge is necessary for the resident's welfare and the resident's needs cannot be met in the facility.</i> <i>(ii) The transfer or discharge is appropriate because the resident's health has improved sufficiently so the resident no longer needs the services provided by the facility.</i> <i>(iii) The safety of individuals in the facility is endangered.</i> <i>(iv) The health of the individuals in the facility would otherwise be endangered.</i> <i>(v) The resident has failed, after reasonable and appropriate notice, to pay for (or to have paid under Medicare or Medicaid) a stay at the facility. For a resident who becomes eligible for Medicaid after admission to a facility, the facility may charge resident allowable charges only under Medicaid.</i> <i>(vi) The facility ceases to operate.</i>

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<p>§483.12(a)(3) §483.12(a)(3)(i) §483.12(a)(3)(ii)</p>	<p>(3) <i>Documentation.</i> When the facility transfers or discharges a resident under any of the circumstances specified in paragraphs (a)(2)(i) through (v) of this section, the resident’s clinical record must be documented. The documentation must be made by—</p> <ul style="list-style-type: none"> (i) The resident’s physician when transfer or discharge is necessary under paragraph (a)(2)(i) or paragraph (a)(2)(ii) of this section; and (ii) A physician when transfer or discharge is necessary under paragraph (a)(2)(iv) of this section. 	<p style="text-align: center;">32.01.17</p>	<p>Documentation When the facility transfers or discharges a resident under any of the circumstances specified in paragraphs (a)(2)(i) through (v) of 42 CFR 483.12, the resident’s clinical record must be documented. The documentation must be made by--</p> <ul style="list-style-type: none"> (i) The resident’s physician when transfer or discharge is necessary under paragraph (a)(2)(i) or paragraph (a)(2)(ii) of 42 CFR 483.12; and (ii) A physician when transfer or discharge is necessary under paragraph (a)(2)(iv) of 42 CFR 483.12.
<p>§483.12(a)(4) §483.12(a)(4)(i) §483.12(a)(4)(ii) §483.12(a)(4)(iii)</p>	<p>(4) <i>Notice before transfer.</i> Before a facility transfers or discharges a resident, the facility must—</p> <ul style="list-style-type: none"> (i) Notify the resident and, if known, a family member or legal representative of the resident of the transfer or discharge and the reasons for the move in writing and in a language and manner they understand. (ii) Record the reasons in the resident’s clinical record; and (iii) Include in the notice the items described in paragraph (a)(6) of this section. 	<p style="text-align: center;">32.01.18</p>	<p>Notice Before Transfer Before a facility transfers or discharges a resident, the facility must—</p> <ul style="list-style-type: none"> (ii) Notify the resident and, if known, a family member or legal representative of the resident of the transfer or discharge and the reasons for the move in writing and in a language and manner they understand. (iii) Record the reasons in the resident’s clinical record; and (iv) Include in the notice the items described in paragraph (a)(6) of 42 CFR 483.12.
<p>§483.12(a)(5) §483.12(a)(5)(i) §483.12(a)(5)(ii) §483.12(a)(5)(ii)(A) §483.12(a)(5)(ii)(B) §483.12(a)(5)(ii)(C) §483.12(a)(5)(ii)(D) §483.12(a)(5)(ii)(E)</p>	<p>(5) <i>Timing of the notice.</i></p> <ul style="list-style-type: none"> (i) Except as specified in paragraphs (a)(5)(ii) and (a)(8) of this section, the notice of transfer or discharge required under paragraph (a)(4) of this section must be made by the facility at least 30 days before the resident is transferred or discharged. (ii) Notice may be made as soon as practicable before transfer or discharge when— <ul style="list-style-type: none"> (A) the safety of individuals in the facility would be endangered under paragraph (a)(2)(iii) of this section; (B) The health of individuals in the facility would be endangered, under paragraph (a)(2)(iv) of this 	<p style="text-align: center;">32.01.19</p>	<p>Timing of the Notice</p> <ul style="list-style-type: none"> (i) Except when specified in paragraph (a)(5)(ii) of 42 CFR 483.12, the notice of transfer or discharge required under paragraph (a)(4) of 42 CFR 483.12 must be made by the facility at least 30 days before the resident is transferred or discharged. (ii) Notice may be made as soon as practicable before transfer or discharge when-- <ul style="list-style-type: none"> (A) The safety of individuals in the facility would be endangered under paragraph (a)(2)(iii) of 42 CFR 483.12; (B) The health of individuals in the facility would be endangered, under paragraph (a)(2)(iv) of 42 CFR 483.12; (C) The resident’s health improves sufficiently to allow a more immediate transfer or discharge, under paragraph (a)(2)(ii)

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	<p>section;</p> <p>(C) <i>The resident's health improves sufficiently to allow a more immediate transfer or discharge, under paragraph (a)(2)(ii) of this section;</i></p> <p>(D) <i>An immediate transfer or discharge is required by the resident's urgent medical needs, under paragraph (a)(2)(i) of this section; or</i></p> <p>(E) <i>A resident has not resided in the facility for 30 days.</i></p>		<p><i>of 42 CFR 483.12;</i></p> <p>(D) <i>An immediate transfer or discharge is required by the resident's urgent medical needs, under paragraph (a)(2)(i) of 42 CFR 483.12; or</i></p> <p>(E) <i>(E) A resident has not resided in the facility for 30 days.</i></p>
<p>§483.12(a)(6) §483.12(a)(6)(i) §483.12(a)(6)(ii) §483.12(a)(6)(iii) §483.12(a)(6)(iv) §483.12(a)(6)(v) §483.12(a)(6)(vi) §483.12(a)(6)(vii)</p>	<p>(6) <i>Contents of the notice.</i> <i>The written notice specified in paragraph (a)(4) of this section must include the following:</i></p> <p>(i) <i>The reason for transfer or discharge;</i></p> <p>(ii) <i>The effective date of transfer or discharge;</i></p> <p>(iii) <i>The location to which the resident is transferred or discharged;</i></p> <p>(iv) <i>A statement that the resident has the right to appeal the action to the State;</i></p> <p>(v) <i>The name, address and telephone number of the State long term care ombudsman;</i></p> <p>(vi) <i>For nursing facility residents with developmental disabilities, the mailing address and telephone number of the agency responsible for the protection and advocacy of developmentally disabled individuals established under Part C of the Developmental Disabilities Assistance and Bill of Rights Act; and</i></p> <p>(vii) <i>For nursing facility residents who are mentally ill, the mailing address and telephone number of the agency responsible for the protection and advocacy of mentally ill individuals established under the Protection and Advocacy for Mentally Ill Individuals Act.</i></p>	32.01.20	<p>Contents of the Notice <i>The written notice specified in paragraph (a)(4) of 42 CFR 483.12 must include the following:</i></p> <p>(i) <i>The reason for transfer or discharge.</i></p> <p>(ii) <i>The effective date of transfer or discharge.</i></p> <p>(iii) <i>The location to which the resident is transferred or discharged.</i></p> <p>(iv) <i>A statement that the resident has the right to appeal the action to the state.</i></p> <p>(v) <i>The name, address and telephone number of the state long term care ombudsman.</i></p> <p>(vi) <i>For nursing facility residents with developmental disabilities, the mailing address and telephone number of the agency responsible for the protection and advocacy of developmentally disabled individuals.</i></p> <p>(vii) <i>For nursing facility residents who are mentally ill, the mailing address and telephone number of the agency responsible for the protection and advocacy of mentally ill individuals</i></p>
§483.12(a)(7)	<p>(7) <i>Orientation for transfer or discharge. A facility must provide sufficient preparation and orientation to residents to ensure safe and orderly transfer or discharge</i></p>	32.01.21	<p>Orientation for Transfer or Discharge. <i>A facility must provide sufficient preparation and orientation for residents to ensure safe and orderly transfer or discharge from the</i></p>

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	<i>from the facility.</i>		<i>facility.</i>
<p>§483.13 §483.13(a)</p>	<p><i>Resident behavior and facility practices.</i> <i>(a) Restraints. The resident has the right to be free from any physical or chemical restraints imposed for purposes of discipline or convenience, and not required to treat the resident’s medical symptoms.</i></p>	32.02.01	<p><u>Restraints</u> The facility has a policy that states: <i>The resident has the right to be free from any physical or chemical restraints imposed for purposes of discipline or convenience, and not required to treat the resident’s medical symptoms.</i></p>
<p>§483.13(b)</p>	<p><i>(b) Abuse. The resident has the right to be free from verbal, sexual, physical, and mental abuse, corporal punishment, and involuntary seclusion.</i></p>	32.02.02	<p><u>Abuse</u> The facility shall have a policy that states: <i>The resident has a right to be free from verbal, sexual, physical, and mental abuse, corporal punishment, and involuntary seclusion.</i></p>
<p>§483.13(c) §483.13(c)(1)(i)</p>	<p><i>(c) Staff treatment of residents.</i> <i>The facility must develop and implement written policies and procedures that prohibit mistreatment, neglect, and abuse of residents and misappropriation of resident property.</i></p> <p><i>(1) The facility must—</i> <i>(i) Not use verbal, mental, sexual, or physical abuse, corporal punishment, or involuntary seclusion;</i></p>	32.02.03	<p><u>Staff Treatment of Residents</u> <i>The facility must develop and implement written policies and procedures that prohibit mistreatment, neglect, and abuse of residents and misappropriation of resident property.</i> <i>The facility must:</i> <i>Not use verbal, mental, sexual, or physical abuse, corporal punishment or involuntary seclusion.</i></p>
<p>§483.13(c)(1)(ii) §483.13(c)(1)(ii)(A) §483.13(c)(1)(ii)(B) §483.13(c)(1)(ii)(B)(i) ii)</p>	<p><i>(1) The facility must—</i> <i>(ii) Not employ individuals who have been—</i> <i>(A) Found guilty of abusing, neglecting, or mistreating residents by a court of law; or</i> <i>(B) Have had a finding entered into the State nurse aide registry concerning abuse, neglect, mistreatment of residents or misappropriation of their property; and</i> <i>(iii) Report any knowledge it has of actions by a court of law against an employee, which would indicate unfitness for service as a nurse aide or other facility staff to the State nurse aide registry or licensing authorities.</i></p>	32.02.04	<p><u>Screening of Staff</u> <i>The facility must not employ individuals who have been:</i> <i>(A) Found guilty of abusing, neglecting, or mistreating residents by a court of law OR</i> <i>(B) Have had a finding entered into the state nurse aide registry concerning abuse, neglect, mistreatment of residents or misappropriation of their property AND</i> <i>(iii) Report any knowledge it has of actions by a court of law against an employee, which would indicate unfitness for serve as a nurse aide or other facility staff to the state nurse aide registry or licensing authorities.</i></p>
<p>§483.13(c)(2)</p>	<p><i>(2) The facility must ensure that all alleged violations involving mistreatment, neglect, or abuse, including</i></p>	32.02.05	<p><u>Reporting of Patient Mistreatment, Neglect, or Abuse</u> <i>The facility must ensure that all alleged violations involving</i></p>

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	<i>injuries of unknown source, and misappropriation of resident property are reported immediately to the administrator of the facility and to other officials in accordance with State law through established procedures (including to the State survey and certification agency).</i>		<i>mistreatment, neglect, or abuse, including injuries of unknown source and misappropriation of resident property are reported immediately to the administrator of the facility and to other officials in accordance with state law through established procedures (including to the State survey and certification agency).</i>
§483.13(c)(3)	(3) <i>The facility must have evidence that all alleged violations are thoroughly investigated, and must prevent further potential abuse while the investigation is in progress.</i>	32.02.06	Investigation of Alleged Abuse <i>The facility must have evidence that all alleged violations are thoroughly investigated and must prevent further potential abuse while the investigation is in progress.</i>
§483.13(c)(4)	(4) <i>The results of all investigations must be reported to the administrator or his designated representative and to other officials in accordance with State law (including to the State survey and certification agency) within 5 working days of the incident, and if the alleged violation is verified appropriate corrective action must be taken.</i>	32.02.07	Reporting of Investigations <i>The facility must ensure:</i> <i>The results of all investigations must be reported to the administrator or his designated representative and to other officials in accordance with state law (including to the state survey and certification agency) within 5 working days of the incident, and if the alleged violation is verified appropriate corrective action must be taken.</i>
§483.15(f) §483.15(f)(1) §483.15(f)(2) §483.15(f)(2)(i) §483.15(f)(2)(i)(A) §483.15(f)(2)(i)(B) §483.15(f)(2)(ii) §483.15(f)(2)(iii) §483.15(f)(2)(iv)	<i>Activities.</i> (1) <i>The facility must provide for an ongoing program of activities designed to meet, in accordance with the comprehensive assessment, the interests and the physical, mental, and psychosocial well-being of each resident.</i> (2) <i>The activities program must be directed by a qualified professional who—</i> (i) <i>Is a qualified therapeutic recreation specialist or an activities professional who—</i> (A) <i>Is licensed or registered, if applicable, by the State in which practicing; and</i> (B) <i>Is eligible for certification as a therapeutic recreation specialist or as an activities professional by a recognized accrediting body on or after October 1, 1990; or</i> (ii) <i>Has 2 years of experience in a social or recreational</i>	32.03.02	Activities <i>The facility must provide for an ongoing program of activities designed to meet, in accordance with the comprehensive assessment, the interests and the physical, mental, and psychosocial well-being of each resident.</i> <i>The activities program must be directed by a qualified professional who is a qualified therapeutic recreation specialist or an activities professional who:</i> (A) <i>Is licensed or registered, if applicable by the state in which practicing; and</i> (B) <i>Is eligible for certification as a therapeutic recreation specialist or as an activities professional by a recognized accrediting body on or after October 1, 1990; or</i> (i) <i>has 2 years of experience in a social or recreational program</i>

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	<p><i>program within the last 5 years, 1 of which was full-time in a patient activities program in a health care setting; or</i></p> <p>(iii) <i>Is a qualified occupational therapist or occupational therapy assistant; or</i></p> <p>(iv) <i>Has completed a training course approved by the State</i></p>		<p><i>within the last 5 years, 1 of which was full-time in a patient activities program in a health care setting; or</i></p> <p>(ii) <i>is a qualified occupational therapist or occupational therapy assistant; or</i></p> <p>(iii) (iv) <i>has completed a training course approved by the State.</i></p>
<p>§483.15(g) §483.15(g)(1)</p>	<p>Social Services.</p> <p>(1) <i>The facility must provide medically-related social services to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident.</i></p>	32.03.04	<p>Social Services</p> <p><i>The facility must provide medically-related social services to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident.</i></p>
<p>§483.15(g)(2) §483.15(g)(3) §483.15(g)(3)(i) §483.15(g)(3)(ii)</p>	<p>(2) <i>A facility with more than 120 beds must employ a qualified social worker on a full-time basis.</i></p> <p>(3) <i>Qualifications of social worker. A qualified social worker is an individual with—</i></p> <p style="padding-left: 20px;">(i) <i>A bachelor’s degree in social work or a bachelor’s degree in a human services field including but not limited to sociology, special education, rehabilitation counseling, and psychology; and</i></p> <p style="padding-left: 20px;">(ii) <i>One year of supervised social work experience in a health care setting working directly with individuals.</i></p>	32.03.05	<p>Qualification of Social Worker</p> <p><i>A facility with more than 120 beds must employ a qualified social worker on a full-time basis.</i></p> <p><i>A qualified social worker is an individual with:</i></p> <p style="padding-left: 20px;">(i) <i>A bachelor’s degree in human services including but not limited to sociology, special education, rehabilitation counseling, and psychology; and</i></p> <p style="padding-left: 20px;">(ii) <i>one year of supervised social work experience in a health care setting working directly with individuals.</i></p>
<p>§483.20(l) §483.20(l)(1) §483.20(l)(2) §483.20(l)(3)</p>	<p>Discharge summary.</p> <p><i>When the facility anticipates discharge a resident must have a discharge summary that includes—</i></p> <p>(1) <i>A recapitulation of the resident’s stay;</i></p> <p>(2) <i>A final summary of the resident’s status to include items in paragraph (b)(2) of this section, at the time of the discharge that is available for release to authorized persons and agencies, with the consent of the resident or legal representative; and</i></p> <p>(3) <i>A post-discharge plan of care that is developed with the</i></p>	32.03.06	<p>Discharge Summary</p> <p><i>When the facility anticipates discharge a resident must have a discharge summary that includes</i></p> <p style="padding-left: 20px;">(1) <i>a recapitulation of the resident’s stay,</i></p> <p style="padding-left: 20px;">(2) <i>a final summary of the resident’s status to include items in paragraph (b)(2) of 42 CFR 483.20, at the time of the discharge that is available for a release to authorized persons and agencies, with the consent of the resident or legal representative, and</i></p> <p style="padding-left: 20px;">(3) <i>a post discharge plan of care that is developed with the</i></p>

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	<i>participation of the resident and his or her family, which will assist the resident to adjust to his or her new living environment.</i>		<i>participation of the resident and his or her family, which will assist the resident to adjust to his or her new living environment.</i>
<p>§483.45 §483.45(a) §483.45(a)(1) §483.45(a)(2)</p>	<p><i>Specialized rehabilitative services. Provision of services. If specialized rehabilitative services such as but not limited to physical therapy, speech language pathology, occupational therapy, and mental health rehabilitative services for mental illness and mental retardation, are required in the resident’s comprehensive plan of care, the facility must—</i></p> <p>(1) <i>Provide the required services; or</i> (2) <i>Obtain the required services from an outside resource (in accordance with § 483.75(h) of this part) from a provider of specialized rehabilitative services.</i></p>	32.04.01	<p><u>Specialized Rehabilitative Services: Provision of Services</u> <i>If specialized rehabilitative services such as, but not limited to, physical therapy, speech-language pathology, occupational therapy, and health rehabilitative services for mental illness and mental retardation are required in the resident’s comprehensive plan of care, the facility must</i></p> <p>(1) <i>provide the required services or</i> (2) <i>obtain the required services from an outside resource (in accordance with §483.75(h) of 42 CFR 483.75) from a provider of specialized rehabilitative services</i></p>
§483.45(b)	<p><i>Qualifications. Specialized rehabilitative services must be provided under the written order of a physician by qualified personnel.</i></p>	32.04.02	<p><u>Rehabilitative Service Orders: Qualifications</u> <i>Specialized rehabilitative services must be provided under the written order of a physician by qualified personnel.</i></p>
§483.55	<p><i>Dental services. The facility must assist residents in obtaining routine and 24-hour emergency dental care.</i></p>	32.05.01	<p><u>Dental Services</u> <i>The facility must assist residents in obtaining routine and 24-hour emergency dental care.</i></p>
<p>§483.55(a)(1) §483.55(a)(2)</p>	<p>(a) <i>Skilled nursing facilities. A facility</i></p> <p>(1) <i>Must provide or obtain from an outside resource, in accordance with § 483.75(h) of this part, routine and emergency dental services to meet the needs of each resident;</i></p> <p>(2) <i>May charge a Medicare resident an additional amount for routine and emergency dental services;</i></p>	32.05.02	<p><u>SKILLED NURSING FACILITIES: Patient Liability for Dental Care</u> <i>A facility –</i></p> <p>(1) <i>Must provide or obtain from an outside resource, in accordance with §483.75(h) of 42 CFR 483.75, routine and emergency dental services to meet the needs of each resident.</i></p> <p>(2) <i>May charge a Medicare resident an additional amount for routine and emergency dental services.</i></p>
<p>§483.55(a) §483.55(a)(3) §483.55(a)(3)(i) §483.55(a)(3)(ii)</p>	<p>(b) <i>Skilled nursing facilities. A facility</i></p> <p>(3) <i>Must if necessary, assist the resident—</i></p> <p>(i) <i>In making appointments; and</i> (ii) <i>By arranging for transportation to and from the</i></p>	32.05.03	<p><u>SKILLED NURSING FACILITIES: Resident Dental Appointments</u> <i>The facility must, if necessary, assist the resident:</i></p> <p>(i) <i>in making appointments; and</i></p>

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<p>§483.55(a)(4)</p>	<p>dentist’s office; and (4) Promptly refer residents with lost or damaged dentures to a dentist.</p>		<p>(ii) <i>by arranging for transportation to and from the dentist’s office; and</i> <i>Promptly refer residents with lost or damaged dentures to a dentist.</i></p>
<p>§483.55(b) §483.55(b)(1) §483.55(b)(1)(i) §483.55(b)(1)(ii)</p>	<p>(b) Nursing facilities. The facility (1) Must provide or obtain from an outside resource, in accordance with § 483.75(h) of this part, the following dental services to meet the needs of each resident: (i) Routine dental services (to the extent covered under the State plan); and (ii) Emergency dental services;</p>	<p>32.05.04</p>	<p><u>NURSING FACILITIES: Provision of Dental Services.</u> <i>Nursing facilities. The facility</i> (1) <i>Must provide or obtain from an outside resource, in accordance with 483.75(h) of this part, the following dental services to meet the needs of each resident:</i> (i) <i>Routine dental services (to the extent covered under the state plan)</i> (ii) <i>Emergency dental services</i></p>
<p>§483.55(b) §483.55(b)(2) §483.55(b)(2)(i) §483.55(b)(2)(ii) §483.55(b)(3)</p>	<p>(b) Nursing facilities. The facility (2) Must, if necessary, assist the resident— (i) In making appointments; and (ii) By arranging for transportation to and from the dentist’s office; and (3) Must promptly refer residents with lost or damaged dentures to a dentist.</p>	<p>32.05.05</p>	<p><u>NURSING FACILITIES: Appointments and Referrals. Nursing facilities.</u> <i>The facility must, if necessary, assist the resident—</i> (i) <i>In making appointments.</i> (ii) <i>By arranging for transportation to and from the dentist’s office.</i> <i>Must promptly refer residents with lost or damaged dentures to a dentist.</i></p>

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