



NATIONAL INTEGRATED ACCREDITATION FOR HEALTHCARE ORGANIZATIONS (NIAHO®)

Interpretive Guidelines and Surveyor Guidance - Version 11

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Use of NIAHO® Interpretive Guidelines and Surveyor Guidance

Effective Date

NIAHO® Accreditation Requirements, Interpretive Guidelines and Surveyor Guidance, Revision 11:

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National Professional Organizations- Standards of Practice

Standards of practice of the national professional organizations referenced in these NIAHO® Accreditation Requirements are consultative and considered in the accreditation decision.

Federal Laws, Rules and Regulations

The most current version of Federal law and the CFR referenced in these NIAHO® Accreditation Requirements are incorporated herein by reference and constitute NIAHO® accreditation requirements.

This NIAHO® Accreditation Requirements, Interpretive Guidelines and Surveyor Guidance document is based upon the Centers for Medicare and Medicaid Services Conditions of Participation 42 CFR § 482 and State Operations Manual Regulations and Interpretive Guidelines for Hospitals. These Interpretive Guidelines also are periodically updated based on notices distributed from CMS. Hospitals participating in the Medicare and Medicaid program are expected to comply with current Conditions of Participation. When new or revised requirements are published hospitals are expected to demonstrate compliance in a time frame consistent with the effective date published by Centers for Medicare and Medicaid Services in the Federal Register.

Life Safety Code®

The Life Safety Code® of the National Fire Protection Association referenced in these NIAHO® Accreditation Requirements is incorporated herein by reference and constitute NIAHO® accreditation requirements.

GLOSSARY

AANA	American Association of Nurse Anesthetists
AOA	American Osteopathic Association
AMA	American Medical Association
AORN	Association of periOperative Registered Nurses
APIC	Association of Professionals in Infection Control and Epidemiology
ASA	American Society of Anesthesiologists
CDC	Centers for Disease Control and Prevention
CEO	Chief Executive Officer
CFR	Code of Federal Regulations
CMS	Centers for Medicare and Medicaid Services
CoP	CMS Conditions of Participation for Hospitals 42 C.F.R § 482
CRNA	Certified Registered Nurse Anesthetist
DEA	Drug Enforcement Administration Federal Narcotics Registration Certificate
FDA	Food and Drug Administration
HAI	Hospital Acquired Infection
HHA	Home Health Agency
HVAC	Heating Ventilating and Air Conditioning
ISMP	Institute for Safe Medication Practices
ISO	International Organization of Standardization
LSC	Life Safety Code® of the National Fire Protection Association
MHAUS	Malignant Hyperthermia Association of the United States
NFPA	National Fire Protection Association

NIAHO	National Integrated Accreditation for Healthcare Organizations
NPDB	National Practitioner Data Bank
OIG	Office of Inspector General, Department of Health and Human Services
PRN (prn)	Pro re nata, as the occasion arises, when necessary
QIO	Quality Improvement Organization
QMS	Quality Management System
QLP	Qualified Licensed Practitioner
RN	Registered Nurse
Secretary	Secretary of the Department of Health and Human Services
SMDA	Safe Medical Devices Act of 1990
SNF	Skilled Nursing Facility
SR	Standard Requirement (accreditation requirement)

QUALITY MANAGEMENT SYSTEM (QM)

QM.1 QUALITY MANAGEMENT SYSTEM

The 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 that the organization implements and maintains an effective quality management system. This quality management system shall ensure that corrective and preventive actions taken by the organization are implemented, measured and monitored.

In addition to any other Quality Management System standard, the organization is required to comply with QM.1 at all times as a part of its Quality Management System. Until the organization achieves ISO 9001 Compliance/ Certification, the organization shall follow at a minimum the ISO 9001 methodology specified in QM.2, SR.3.

SR.1 The organization must develop, implement, and maintain an ongoing system for managing quality and patient safety.

SR.1a As a part of the Quality Management System for addressing performance improvement and patient safety, the organization must select projects or similar activities that focus attention on various processes, functions and areas of the organization.

SR.1a (1) The number and scope of these projects or similar activities will be conducted annually and be proportional to the scope and complexity of the organization's operations and services offered.

SR.1a (2) These projects or similar activities will be documented to include the rationale for selection and measurable progress achieved.

SR.1a (3) If the organization participates in a Quality Improvement Organization (QIO) cooperative project, the organization must demonstrate that information and supporting documentation is provided to the QIO. If the hospital does not participate in a QIO, the projects and activities are required to be of comparable effort.

SR.2 The organization must implement hospital-wide quality assessment and performance improvement efforts to address priorities for improved quality of care and patient safety and that corrective and preventive actions are implemented and evaluated for effectiveness.

SR.3 The organization will assure that adequate resources are allocated for measuring, assessing, improving, and sustaining the hospital's performance and reducing risk to patients.

QM.2 ISO 9001 QUALITY MANAGEMENT SYSTEM

- SR.1 Compliance with the ISO 9001 standard must occur within three (3) years after the initial deemed NIAHO® accreditation. The Organization shall either demonstrate compliance with the ISO 9001 Quality Management System principles through a NIAHOSM accreditation survey or maintain Certification through an Accredited Registrar. Only certificates covered by an accreditation **under** an IAF MLA (International Accreditation Forum Multilateral Recognition Agreement) signatory shall be eligible. The organization shall maintain ISO 9001 compliance **or** formal Certification in order remain eligible for NIAHO® Accreditation.
- SR.2 An Accredited Registrar recognized by an IAF MLA (International Accreditation Forum Multilateral Recognition Agreement) shall meet the following minimum criteria:
- SR.2a Shall be accredited for IAF Scope 38; and,
- SR.2b Must have certified or conducted a pre-assessment at a minimum of 12 hospitals.
- SR.3 The organization will initiate and continue implementation of the ISO 9001 methodology to achieve compliance or certification as stated in QM.1 SR.1. At a minimum, the organization must be able to demonstrate at the time of the NIAHO® Accreditation survey, evidence of the following:
- SR.3a Control of Documents: the organization's documents (i.e. policies, procedures, forms) are structured in a manner to ensure that only the proper revisions are available for use;
- SR.3b Control of Records: the organization ensures that suitable records are maintained for the CoP and NIAHO® requirements;
- SR.3c Internal Surveys (Internal Audits): the organization conducts internal reviews of its processes and resultant corrective/preventive action measures have been implemented and verified to be effective;
- SR.3d Corrective and Preventive Action: the organization will have a mechanism in place to document and monitor corrective and preventive action implemented in some manner to address improvement and changes, where appropriate;
- SR.3e The organization has established measurable quality objectives, the results are analyzed, addressed, and;
- SR.3f Appropriate information has been submitted to the oversight group for quality management as required in QM.6 SR.1 as well as **senior** management for review and analysis during a management review process.

Interpretive Guidelines:

The ISO 9001 requirements are assessed during each survey of the organization. The organization has 3 years from the initial deemed NIAHO® accreditation to achieve compliance or certification to ISO 9001. If the organization is currently certified to ISO 9001, the Registrar

that currently certifies the organization must be verified using current criteria established under SR.2a and SR.2b. This should be verified prior to the organization's accreditation survey.

The organization shall demonstrate that aspects consistent with ISO 9001 methodologies identified in QM.2, SR.3a-SR.3f are present. These aspects may not be at a level of compliance with ISO 9001, but will be in place in some manner. If the survey team is conducting the annual ISO periodic survey during the NIAHO® survey, the survey team will assess the applicable ISO 9001 requirements and review the status of findings and corrective action(s) taken to validate that they have been implemented. A separate ISO 9001 report will be created to indicate any findings as a result of the ISO survey, when applicable.

If the organization has failed to meet the requirements within the timeframe as described above regarding ISO 9001 compliance or certification, the Jeopardy Status process may be initiated.

Surveyor Guidance:

The lead surveyor will be provided information regarding the organization with regard to their current compliance or certification status to ISO 9001 prior to the accreditation survey.

The lead surveyor will describe the process to the senior leadership for being in compliance with or attaining certification to ISO 9001, if the organization is not already ISO certified.

If the organization is already certified to ISO 9001 and the survey team is not conducting the periodic annual survey required by ISO at the time of the NIAHO® survey, the lead surveyor will verify that the Registrar is an Accredited Registrar in accordance with QM.2, SR.2.

The survey team will verify that the organization has implemented mechanisms to demonstrate that similar practices in place, consistent with ISO methodologies as listed in QM.2, SR.3a – SR.3f, are present in some manner and continued through the period the hospital is required to maintain compliance or certification to ISO 9001 at which time the full scope of the ISO 9001 requirements must be met as stated within the timeframe under QM.2, SR.1.

QM.3 QUALITY OUTLINE/PLAN

The organization shall clearly outline its methodology, practice and related policies for addressing how quality and performance are measured, monitored, analyzed, and **continually improving health outcomes and reducing risks for patients**.

Interpretive Guidelines:

The organization will present documentation to the survey team that clearly defines how quality and performance are measured, monitored, analyzed, and continually improved.

Surveyor Guidance:

The organization can document conformance in a variety of ways. An example would include a

Quality Manual or Performance Improvement / Quality Management Plan. Verify that the organization has clearly defined how they measure quality and performance. The monitoring methods, data analysis, and effectiveness of action(s) taken will be verified.

QM.4 MANAGEMENT REPRESENTATIVE

A management representative shall be designated and shall have the responsibility and authority for ensuring that the requirements of the Quality Management System are implemented and maintained.

Interpretive Guidelines:

The senior leadership is required to designate an individual as a Management Representative. A requirement of ISO 9001 is to define the Management Representative's responsibilities. The Management Representative is responsible for the process for internal reviews (internal audit) and management reviews to ensure that corrective and preventive action(s) are carried out and are measured for effectiveness.

Surveyor Guidance:

*Verify documentation to demonstrate that the Management Representative has been identified and **that** there is a defined scope of responsibilities for this individual.*

QM.5 DOCUMENTATION AND MANAGEMENT REVIEWS

Any **variations, deficiencies or non-conformities** identified by the organization shall be addressed. Appropriate corrective or preventive action will be determined, applied, and documented. Documentation of activities may take the form of a Failure, Mode and Effect Analysis, Root Cause Analysis, Performance Report, Non-Conformity Report, specific Improvement Project analysis, etc. This documentation shall become a part of the Management Review performed at regular intervals, at a minimum of once annually.

Interpretive Guidelines:

The organization is to have identified, applied and documented nonconformity (non-compliance) throughout the organization and the subsequent corrective/preventive action(s) taken. The organization can demonstrate this in various ways, but there should be information present that validates that the organization has corrected the nonconformity and that the action(s) implemented have been effective and sustained. The organization should be able to demonstrate that planned actions were effective by quantifiable measurement subject to internal reviews (internal audits) or other means,

The results of these activities are communicated to senior leadership, usually conducted as a part of management review.

*A management review is defined as a formal evaluation by **senior leadership** of the status, adequacy and effectiveness of the quality management system (QMS).*

Surveyor Guidance:

Review examples of the following: Nonconformity Report, Root Cause Analysis, Failure Mode and Effects Analysis, or other documents that the organization can demonstrate a means of recording non-conformity and the subsequent follow-up to determine that the action(s) taken have been effective. If there are different means for reporting non-conformity, the surveyor will determine the consistency of the process to ensure its effectiveness.

QM.6 SYSTEM REQUIREMENTS

In establishing the Quality Management System, the organization shall be required to have the following as a part of this system:

- SR.1 Interdisciplinary group to oversee the Quality Management System with representation from/for Administration, Nursing, Pharmacy Services, Ancillary Services, Information Management, Risk / Safety Management, Quality Facilitator/Management Representative, and Medical staff members who must be doctors of medicine or osteopathy. This interdisciplinary group shall conduct Management Reviews regarding the effectiveness of the Quality Management System;
- SR.2 **The organization shall define and document the Quality Management System in place**, to include clinical and non-clinical services;
- SR.3 Statement of the Quality Policy;
- SR.4 Measurable Quality Objectives; and,
- SR.5 Goal Measurement / Prioritization of activities **to include:**
 - SR.5a Focus on high-risk, problem-prone areas, processes or functions;
 - SR.5b Consideration of the incidence, prevalence and severity of problems in these areas, processes or functions;
 - SR.5c Health outcomes, patient safety, and quality of care.

Interpretive Guidelines:

The Management Representative supports and facilitates the Quality Management System; however, it is the responsibility of senior leadership to review these activities and see that appropriate actions are taken for continual improvement. The Quality Manual or other similar document outlines the process that the organization has in place. The Quality Manual will include or reference the policies and procedures for the Quality Management System, Quality Policy, and Quality Objectives. The organization must carry out Management Reviews which encompass review of corrective/preventive actions taken, results from internal reviews (internal audits), customer (patient) satisfaction, data analysis and other performance improvement activities.

The Management Review Process is to be carried out by senior leadership throughout the organization.

Surveyor Guidance:

Verify that management reviews have taken place and there are appropriate minutes recorded.

The Quality Management System will be documented in a Quality Manual, Performance Improvement Plan or similar document as identified by the organization. A part of the Quality Management System will include or reference the Quality Policy, Quality Objectives, and how processes and services are monitored and measured.

QM.7 MEASUREMENT, MONITORING, ANALYSIS

The organization shall evaluate organized services and processes, both direct and supportive, including services provided by contracted services. The monitoring shall include the use of internal reviews (audits) of [key processes as defined by the organization](#) at scheduled intervals, not to exceed one year, and data related to these processes. [Individuals assigned to perform internal reviews \(audits\) of key processes shall not review \(audit\) any processes they are assigned to or manage.](#) Measurement, monitoring and analysis of processes throughout the organization requires established measures that have the ability to detect variation, identify problem processes, identify both positive and negative outcomes, and effectiveness of actions taken to improve performance and/or reduce risks. The governing body of the organization must define the frequency and detail of the measurement. Those functions to be measured, at a minimum, must include the following:

- SR.1 Threats to patient safety (i.e. falls, pt. identification, injuries);
- SR.2 Medication therapy/medication use; to include medication reconciliation, [high risk drugs](#), look alike- sound alike medications, and the use of dangerous abbreviations;
- SR.3 Operative and invasive procedures; to include wrong site/wrong patient/wrong procedure surgery;
- SR.4 Anesthesia/moderate sedation [adverse events](#);
- SR.5 Blood and blood components-[adverse events/usage](#);
- SR.6 Restraint use/seclusion;
- SR.7 Effectiveness of pain management system;
- SR.8 Infection [prevention and](#) control system, including hospital acquired infections (HAI);
- SR.9 Utilization Management System;
- SR.10 Patient flow issues, to include reporting of patients held in the Emergency Department or

the PACU for extended periods of time (as defined by the organization);

SR.11 Customer satisfaction, both clinical and support areas;

SR.12 Discrepant pathology reports;

SR.13 Unanticipated deaths

SR.14 Adverse events/ Near misses;

SR.15 Readmissions and unplanned returns to surgery (as defined);

SR.16 Critical and/or pertinent processes, both clinical and supportive;

SR.17 Medical record delinquency; and,

SR.18 Physical Environment Management Systems

Interpretive Guidelines:

In order for the organization to continually improve its Quality Management System, the services and processes must be measured to determine their effectiveness. Through an internal review (internal audit) mechanism, the organization will determine where corrective/preventive action(s) are to be taken and have a process in place to determine the effectiveness of action(s) taken.

As a part of this measurement component, the functions listed above must be measured for the organization to determine the effectiveness of these processes for continual improvement and preserving the safety of the patients and staff.

The organization should have collected and analyzed data in the respective functions listed above to demonstrate that these processes are closely monitored.

All departments and services provided are to be included as a part of the quality management oversight for the organization. This will include, but is not limited to: Inpatient services, anesthesia services, surgical services, contract services, outpatient services, rehabilitation services, and other support services.

An Adverse Event shall be defined as an unexpected occurrence or variation that led to death or serious physical or psychological harm. This definition includes the National Quality Forum (NQF) “never or adverse events” that are errors in medical care that are clearly identifiable, preventable and serious in their consequences for patients.

Surveyor Guidance:

The organization can demonstrate the effectiveness of its Quality Management System through the analysis of data and follow up where variation exists in order to implement corrective/preventive action. Evaluate the internal survey process and subsequent effectiveness of action(s) taken to improve performance. The organization will be assessed according to its ability to effectively monitor and measure those areas listed above.

Look for data analysis and measures in place to determine the effectiveness of these processes.

QM.8 PATIENT SAFETY SYSTEM

- SR.1 The organization shall have a means for establishing clear expectations for identifying and detecting the prevalence and severity of incidents that impact or threaten patient safety. This shall include medical errors and adverse patient events.
- SR.2 The organization's Patient Safety System shall be documented and shall address the following:
 - SR.2a Detection;
 - SR.2b Preventative and corrective action;
 - SR.2c Defined processes to reduce risk;
 - SR.2d Implementation of action plans;
 - SR.2e On-going measurement to ensure action effectiveness;
 - SR.2f Management review of response and resource allocation utilizing the results of patient adverse events and other data analysis; and,
 - SR.2g Policy and procedure of informing patients and/or their families about unexpected adverse events.

Interpretive Guidelines:

In certain circumstances, there are incidents that impact or threaten patient safety. It is the responsibility of the organization to develop means of controlling processes to ensure the processes are safe for patients and staff as they are carried out.

The organization has to identify, implement and regularly assess the means by which these incidents are prevented or when they occur. The incidents are studied to detect nonconformance and where risk points or failures are an inherent part of the process and work to remove these risk points or failures from the system.

Surveyor Guidance:

The organization's creation of an environment that is safe for patients and staff is imperative. Assess the ability of the organization to detect and prevent adverse patient events, act accordingly to improve these processes through corrective/preventive action and monitoring the effectiveness of their efforts. This could be done by reviewing root cause analyses and/or failure modes and effects analysis where such processes or events have been studied and the associated documentation to support findings, corrective/preventive action(s) taken and the follow-up to determine their effectiveness.

When such incidents occur, a process must be in place to address customer (patient) communication, how the patients are informed and their right to know the circumstances of events. Such communication does not imply wrong doing on the part of the organization or its staff members. The process identifies the most effective way of responding to such events. The process also requires a level of communication for the customer (patient) to know that the organization is acting responsibly and will promote the safest environment possible.

GOVERNING BODY (GB)

GB.1 LEGAL RESPONSIBILITY

There must be an effective governing body that is legally responsible for the conduct of the organization. The governing body is responsible for all services provided in the organization including all contracted services. If an organization does not have an organized governing body, the persons legally responsible for the conduct of the organization must carry out the functions specified that pertain to the governing body.

- SR.1 The governing body (or organized group or individual who assumes full legal authority and responsibility for operations of the hospital), medical staff, and administrative officials (to include the chief executive officer, chief financial officer, and nurse executive) are responsible and accountable for ensuring that the following:
- SR.1a The organization is in compliance with all applicable Federal and State laws and in accordance with organization policies and procedures regarding the health and safety of its patients;
 - SR.1b The organization is licensed by the appropriate State or local authority responsible for licensing hospitals;
 - SR.1c Criteria that includes aspects of individual character, competence, training, experience and judgment is established for the selection of individuals working for the organization, directly or under contract, and/or appointed through the formal medical staff appointment process; and,
 - SR.1d The personnel working in the organization are properly licensed or otherwise meet all applicable Federal, State and local laws.

Interpretive Guidelines:

There should only be one governing body responsible for the day-to-day operation of the organization. If more than one governing body is identified (ex. a healthcare system with local and system governing bodies), the reporting structure and responsibility of the respective bodies should be identified and differentiated. In the absence of an organized governing body, the organization must provide written documentation that identifies the individual or individuals that are responsible for the conduct of hospital operations.

Surveyor Guidance:

Verify that the hospital has an organized governing body and/or has written documentation that identifies the individual or individuals that are responsible for the conduct of the hospital operations.

Interview the hospital leadership to determine the reporting structure regarding how information flows to and from the governing body.

The reporting structure may include written reports, presentations by staff at board meetings, or other means.

GB.2 INSTITUTIONAL PLAN AND BUDGET

- SR.1 The organization shall have an overall plan that includes an annual operating budget that contains all anticipated income and expenses and is prepared according to generally accepted accounting principles.
- SR.2 The plan must provide for capital expenditures for at least a 3-year period including the year identified in GB.2, SR.1. 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 lesser amount established by the State in which the organization is located in accordance with Section 1122(g)(1) of the Social Security Act and is related to:
- SR.2a. acquisition of land;
 - SR.2b. improvement of land, buildings and equipment, or
 - SR.2c. replacement, modernization or expansion of buildings or equipment.
- SR.3 The plan must be reviewed and updated annually.
- SR.4 The plan must be prepared under the direction of the governing body and by a committee consisting of representatives of the governing body, the administrative staff, and the medical staff of the institution.
- SR.5 If required, the plan must be submitted for review in accordance with Section 1122 of the Social Security Act or, as applicable, to the appropriate health planning agency in the State.

Surveyor Guidance:

Verify that an institutional plan and budget exists, includes descriptions of items and complies with all standard requirements. It is not within the scope of activities or responsibility of the surveyor to review and assess the amounts or structure of the institutional plan and budget.

Assess the process for developing the budget and the parties involved. Verify that the institutional plan and budget are updated at least annually and that the process is done under the direction of the governing body and members of the administrative staff and medical staff.

GB.3 CONTRACTED SERVICES

- SR.1 The governing body shall require annual management reviews of selected indicators to **ensure that** contracted services (including joint ventures or shared services) provide services that are safe and effective and that comply with all applicable NIAHO® standards.

- SR.2 The governing body is responsible for services furnished in the hospital whether or not they are furnished under contract. The organization must evaluate and select contracted services (including all joint ventures or shared services) (and non-contracted services) entities/individuals based on their ability to supply products and/or services in accordance with the organization's requirements. Criteria for selection, evaluation, and re-evaluation shall be established. The criteria for selection will include the requirement that the contracted entity or individual to provide the products/services in a safe and effective manner and comply with all applicable NIAHO® standards, and standards required for all contracted services.
- SR.3 A documented list of contracted companies and individuals, including their scope/nature of services shall be maintained.
- SR.4 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 GB.2, SR.2, furnishes the contracted services in a manner that permits the hospital to comply with all applicable requirements for the contracted services, including, but not limited to, the requirements in Medical Staff (MS.2, MS.3, MS.7, MS.11) and Governing Body (GB.1) with regard to the distant-site telemedicine entity's physicians and practitioners providing telemedicine services. The governing body of the hospital whose patients are receiving the telemedicine services may, in accordance with MS.20, SR.1, 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.
- SR.5 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 Medical Staff (MS.2, MS.3, MS.7, MS.11) and Governing Body (GB.1) 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 MS.20, SR.2, grant privileges based on its medical staff recommendations that rely on information provided by the distant-site hospital.
- SR.5a The distant-site hospital providing the telemedicine services is a Medicare participating hospital.
- SR.5b 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.
- SR.5c 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.

Interpretive Guidelines:

The governing body is responsible for assuring that hospital services are provided in compliance with NIAHO® standards and according to acceptable standards of practice regardless of whether the services are provided directly by hospital employees or by a contracted entity.

When services are provided by a contracted entity, the governing body must identify the criteria for selection and procurement of services, and the means of evaluating the contracted entity.

The organization will prioritize the review of contracted services to ensure that patient care services or those services that would also be carried out by staff employed by the organization to ensure these are comparable. Other contracts will be assessed in accordance with the organization's policy as defined. It is not the expectation that such contracts as that for cable television or plumbing, for example, would be assessed in the same manner as those related to patient care services. However, if services provided under contract will have an impact in some manner for patient care services, the organization will review these services and monitor the appropriate measures to ensure the expectations of the organization and needs of the patient are being met.

There may be arrangements where services are provided through one or more of the following: joint ventures; informal agreements; shared services; or, lease arrangements. These services are also subject to the criteria for selection and evaluation process.

Surveyor Guidance:

Determine the services that are carried out by a contracted entity and the scope of their responsibilities. In a sampling of these contracts, review a contract to see that it addresses the criteria for selection and the evaluation processes identified in the organization's policies and procedures. Verify that the organization has a mechanism in place to review the contract and performance of each entity no less than once annually.

CHIEF EXECUTIVE OFFICER (CE)

CE.1 QUALIFICATIONS

The governing body must appoint a chief executive officer who is qualified through education and experience to be responsible for managing the organization.

CE.2 RESPONSIBILITIES

The chief executive officer is responsible for operating the organization, according to the authority conferred by the governing body. The chief executive officer shall provide for the organization's compliance with applicable law and regulation, including State licensure laws.

Surveyor Guidance:

Review the established requirements including education and experience required of the chief executive officer. This may be in the form of a job description or other document that adequately describes the scope of responsibilities.

Verify that the governing body for the organization has appointed a chief executive officer and that he or she has met the requirement for this role within the organization and that he or she is responsible for managing the entire hospital.

MEDICAL STAFF (MS)

MS.1 ORGANIZED MEDICAL STAFF

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.

MS.2 ELIGIBILITY

- SR.1 The governing body shall determine, in accordance with State law, which categories of practitioners are eligible candidates for appointment to the medical staff. The medical staff must include doctors of medicine or osteopathy. In accordance with State law, including scope-of-practice laws, the medical staff may also include other categories of non-physician practitioners determined as eligible for appointment by the Governing body.
- SR.2 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.
- SR.3 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 MS.2.

Interpretive Guidelines:

The hospital may have only one medical staff for the entire hospital (including all campuses, provider-based locations, satellites, remote locations, etc.). 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. The single medical staff is responsible for the quality of medical care provided to patients by the hospital.

The hospital shall have an organized medical staff that is composed of fully licensed doctors of medicine or osteopathy. In accordance with State law, the medical staff may also include other non-physician practitioners. These other non-physician practitioners may include physician assistants, certified registered nurse anesthetists (CRNA), advance practice registered nurses, midwives, psychologists, or other designated professionals who are approved by the medical staff and governing body and eligible for appointment.

Surveyor Guidance:

Review documentation and verify that the governing body has determined and stated the categories of practitioners who are eligible candidates for appointment to the medical staff. Confirm that the governing body appoints all members to the medical staff in accordance with

established policies that have been based on the individual practitioner's scope of clinical expertise and in accordance with Federal and State law.

MS.3 ACCOUNTABILITY

The medical staff shall be organized in a manner approved by and accountable to the governing body and shall be responsible for the quality of the medical care provided to patients.

Interpretive Guidelines:

The medical staff shall be organized in a manner approved by and accountable to the governing body and shall be responsible for the quality of the medical care provided to patients.

All patients must be under the care of a member of the medical staff or under the care of a practitioner who is directly under the supervision of a member of the medical staff. All patient care is provided by or in accordance with the orders of a 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.

Surveyor Guidance:

Verify that the governing body is accountable for the medical staff and the quality of patient care services.

Validate the process by which the governing body monitors these activities of medical staff members.

MS.4 RESPONSIBILITY

The responsibility for organization and conduct of the medical staff must be assigned to an individual doctor of medicine or osteopathy or, when permitted by State law, a doctor of dental surgery or dental medicine or doctor of podiatric medicine, when permitted by State law of the State in which the hospital is located.

Interpretive Guidelines:

The medical staff must be accountable to the hospital's governing body for the quality of medical care provided to patients. The responsibility for organization and conduct of the medical staff must be assigned to an individual doctor of medicine or osteopathy or, when permitted by State law, a doctor of dental surgery or dental medicine or doctor of podiatric medicine, when permitted by State law of the State in which the hospital is located.

Surveyor Guidance:

Validate the process by which the governing body monitors the quality of medical care provided

to patients.

Verify that an individual doctor of medicine or osteopathy, a doctor of dental surgery or dental medicine or doctor of podiatric medicine, when permitted by State law of the State in which the hospital is located, is responsible for the conduct and organization of the medical staff.

MS.5 EXECUTIVE COMMITTEE

- SR.1 The medical staff shall meet at regular intervals and minutes shall be maintained. If the medical staff has an executive committee, a majority of the members of the committee shall be doctors of medicine or osteopathy.
- SR.2 The chief executive officer and the nurse executive of the organization or designee shall attend each executive committee meeting on an ex-officio basis, with or without vote.

Surveyor Guidance:

Verify that the hospital has an executive committee and that the majority of members are doctors of medicine or osteopathy. If an executive committee is in place, the chief executive officer and nurse executive (or designee) are a part of the committee on an ex-officio basis.

Review meeting minutes of the executive committee to verify the participation of the medical staff, CEO and CNO (or designee) attend these meetings.

MS.6 MEDICAL STAFF PARTICIPATION

The medical staff shall participate in at least the following organization activities:

- SR.1 Medication management oversight;
- SR.2 Infection prevention and control oversight;
- SR.3 Tissue review;
- SR.4 Utilization review;
- SR.5 Medical record review; and,
- SR.6 Quality Management System.
- SR.7 Reports and recommendations from these activities shall be prepared and shared with the medical executive committee and the governing body.

Surveyor Guidance:

Verify through the review of minutes, data or other documentation that the medical staff

participates in at least the following activities of the organization:

- *Medication management oversight;*
- *Infection control oversight;*
- *Tissue review;*
- *Utilization review;*
- *Medical record review; and,*
- *Quality Management System.*

Sample reports and recommendations from these activities to verify that information, data and other documentation are shared with the medical executive committee and the governing body and actions taken by medical staff and governing body are evaluated to ensure implementation and effectiveness

MS.7 MEDICAL STAFF BYLAWS

- SR.1 The medical staff shall be appointed by the governing body and operate under bylaws, rules and regulations adopted and enforced by the medical staff and approved by the governing body.
- SR.2 Changes to the medical staff bylaws, rules and regulations shall require approval of the medical staff and the governing body.
- SR.3 The medical staff bylaws shall describe the organization of the medical staff and include a statement of the duties and privileges of each category of medical staff to ensure that acceptable standards are met for providing patient care for all diagnostic, medical, surgical, and rehabilitative services.
- SR.4 Medical staff bylaws shall include provisions for mechanisms for corrective action, including indications and procedures for automatic and summary suspension of medical staff membership or clinical privileges.

Interpretive Guidelines:

The governing body and medical staff must approve, adopt, and enforce medical staff bylaws rules and regulations in accordance with State and Federal law to ensure that acceptable standards are met for providing patient care for all diagnostic, medical, surgical, and rehabilitative services.

The bylaws, rules and regulations shall define the duties and privileges of each category for the medical staff. The bylaws shall also include a mechanism for corrective action to include indications and procedures that define the process for automatic and summary suspension of the medical staff as it relates to membership and clinical privileges.

Any changes made to the bylaws, rules and regulations will be approved by the medical staff and governing body. Neither the medical staff nor governing body may unilaterally amend the bylaws, rules and regulations.

Surveyor Guidance:

Verify and review the medical staff bylaws, rules and regulations to ensure that are in accordance with Federal and State laws and regulations. The bylaws should state or reference approval by the medical staff and governing body.

Review the process the hospital has defined for addressing how bylaws, rules and regulation revisions are made and approved by the medical staff and governing body.

Verify that there are written criteria stated within the bylaws, rules and regulations that define the duties and privileges of each category for the medical staff in accordance with acceptable standards of care.

MS.8 APPOINTMENT

The medical staff bylaws shall describe the qualifications to be met by a candidate in order for the medical staff to recommend that the governing body appoint the candidate. Those qualifications shall include the following:

SR.1 Initial appointment to the medical staff:

SR.1a Primary source verification of licensure, education, specific training, experience, (AMA Master Profile is acceptable) and current competence

SR.1a (1) Verification of ECFMG (as applicable);

SR.1b Current Federal Narcotics Registration Certificate (DEA) number (if required);

SR.1c Two peer recommendations;

SR.1d Review of involvement in any professional liability action; and,

SR.1e Receipt of database profiles from NPDB, OIG Medicare/Medicaid Exclusions.

SR.2 Reappointment to the medical staff:

SR.2a Primary source verification of current licensure and any required certifications;

SR.2b Federal Narcotics Registration Certificate (DEA) number (if required);

SR.2c Review of involvement in any professional liability action; and,

SR.2d Review of individual performance data for variation from benchmark. Variation shall go to Peer Review for determination of validity, written explanation of findings and, if appropriate, an action plan to include improvement strategies (See MS.9).

SR.2e Receipt of database profiles from NPDB, OIG Medicare/Medicaid Exclusions.

Surveyor Guidance:

Sample records of medical staff appointments to determine that the governing body is involved in appointments of medical staff members and the elements defined within this standard have been reviewed.

Verify that there are written criteria for appointments to the medical staff.

Review and verify the mechanism to examine credentials of individual prospective members (new appointments or reappointments) by the medical staff.

MS.9 PERFORMANCE DATA

Practitioner specific performance data is required to be evaluated, analyzed and appropriate action taken as necessary when variation is present and/or standard of care has not been met as determined by the medical staff. Performance data will be collected periodically within the reappointment period or as required as a part of the peer review process. This may include comparative and/or national data if available.

Areas required to be measured (as applicable) **may** include:

- SR.1 Blood use (may include AABB transfusion criteria);
- SR.2 Prescribing of medications: Prescribing patterns, trends, errors and appropriateness of prescribing for Drug Use Evaluations;
- SR.3 Surgical Case Review: appropriateness and outcomes for selected high-risk procedures as defined by the medical staff;
- SR.4 Specific department indicators that have been defined by the medical staff;
- SR.5 **Anesthesia/ Moderate Sedation Adverse Events;**
- SR.6 **Readmissions/ unplanned returns to surgery (as defined)**
- SR.7 Appropriateness of care for non-invasive procedures/interventions;
- SR.8 Utilization data;
- SR.9 Significant deviations from established standards of practice; and,
- SR.10 Timely and legible completion of patients' medical records.

SR.11 Any variant **that** should be analyzed for statistical significance.

Interpretive Guidelines:

The governing body must ensure that the medical staff is accountable to the governing body for the quality of care provided to patients. The governing body must be provided with information (data) in order to evaluate the quality of care provided to patients.

The hospital must define and measure the respective elements within this standard to generate a quality profile for each medical staff member to be used for evaluation as a part of the appointment and reappointment process.

Surveyor Guidance:

Verify that the governing body is periodically apprised of the medical staff evaluation of patient care services provided hospital wide using indicators and other measures as stated within this standard.

Sample medical staff quality (reappointment) profiles or other documentation to validate that this data is being measured and a part of the appointment and reappointment process.

MS.10 CONTINUING EDUCATION

All individuals with delineated clinical privileges shall participate in continuing education that is at least in part related to their clinical privileges.

SR.1 This documentation shall be considered in decisions about reappointment or renewal or revision of clinical privileges.

SR.2 Action on an individual's application for appointment/ reappointment or initial or subsequent clinical privileges is withheld until the information is available and verified.

MS.11 GOVERNING BODY ROLE

SR.1 The governing body shall appoint members of the medical staff and approve clinical privileges after considering the recommendations of the existing members of the medical staff and ensure that the medical staff is accountable to the governing body for the quality of care provided to patients.

SR.2 The governing body may elect to delegate the authority to render initial appointment, reappointment, and renewal or modification of clinical privileges decisions to a committee of the governing body.

SR.3 The governing body shall ensure that under no circumstances is medical staff membership or professional privileges in the organization dependent solely upon certification, fellowship, or membership in a specialty body or society.

SR.4 A complete application shall be acted on within a reasonable period of time, as specified in the medical staff bylaws.

Interpretive Guidelines:

The governing body, with the advice of the medical staff, is responsible for the appointment and reappointment of the individual practitioners of the medical staff and their respective delineation of privileges.

This process may be carried out by a committee that has been delegated by the governing body to oversee the appointment and reappointment of medical staff members and their respective delineation of privileges. The process for appointment and reappointment will be carried out within a reasonable timeframe as defined within the medical staff bylaws.

The hospital cannot grant appointment, reappointment and allow privileges that are solely based upon certification, fellowship, or membership in a specialty body or society.

Surveyor Guidance:

Verify the process for the appointment and reappointment of medical staff members. This process may be delegated to a committee (e.g. Credentials Committee).

Verify the timeframe for the credentialing and privileging process to see that actions are taken as required in the medical staff bylaws.

Review a sampling of records of medical staff appointments to determine that the governing body is involved in appointments of medical staff members and that privileges are not based solely based upon certification, fellowship, or membership in a specialty body or society.

MS.12 CLINICAL PRIVILEGES

SR.1 The medical staff bylaws shall include criteria for determining the privileges to be granted to individual practitioners and a procedure for applying the criteria to those individuals that request privileges.

SR.2 Appointment or reappointments to the medical staff and the granting, renewal, or revision of clinical privileges shall be made for a period defined by State law or if permitted by State law, not to exceed three years.

SR.3 All individuals who are permitted by the organization and by law to provide patient care services independently in the organization shall have delineated clinical privileges.

SR.4 There shall be a provision in the medical staff bylaws for a mechanism to ensure that all individuals with clinical privileges provide services only within the scope of privileges granted.

SR.4a There shall be a provision to authorize [Qualified Licensed Practitioners](#) to order outpatient services that are within their scope of service to order.

- SR.5 If available and/or required by the medical staff to hold or maintain clinical privileges, include a review of individual performance data variation from criteria determined by the medical staff to identify need for training or proctoring that may be required.
- SR.6 The medical staff bylaws shall provide a mechanism for consideration of automatic suspension of clinical privileges in any of the following instances:
- SR.6a Revocation/restriction of professional license;
 - SR.6b Revocation/suspension/probation of Federal Narcotics Registration Certificate (DEA);
 - SR.6c Failure to maintain the specified amount of professional liability insurance; or,
 - SR.6d Non-compliance with written medical record delinquency or deficiency requirements.
- SR.7 The medical staff bylaws shall provide a mechanism for immediate and automatic suspension of clinical privileges due to the termination or revocation of the practitioner's Medicare or Medicaid status.
- SR.8 The medical staff bylaws shall contain fair hearing and appeal provisions for any adverse actions regarding the appointment, reappointment, suspension, reduction, or revocation of privileges of any individual who has applied for or has been granted clinical privileges.

Interpretive Guidelines:

The medical staff must develop criteria for determining the privileges to be granted to individual practitioners. These criteria must be included in the bylaws. There must also be a procedure in place to ensure that these criteria have been met prior to privileges being granted. The medical staff bylaws will govern the process to ensure that services are provided by practitioners only within their scope of granted privileges.

The medical staff will define the criteria and have a mechanism for consideration of automatic suspension of clinical privileges of a practitioner at a minimum when:

- *The practitioner's professional license has been revoked or suspended for any reason;*
- *The practitioner's DEA certificate has been revoked, suspended or on probation for any reason;*
- *The practitioner has failed to maintain the minimum specified amount of professional liability insurance as required in the medical staff bylaws; and,*
- *Written medical record delinquency or deficiency requirements have not been met.*

The medical staff will also have a written mechanism for immediate and automatic suspension of clinical privileges due to the termination or revocation of the practitioner's Medicare or Medicaid status.

For any adverse actions regarding the appointment, reappointment, suspension, reduction or revocation of privileges of any individual who has applied for or has been granted clinical privileges, there will be a mechanism that provides the practitioner a fair hearing and appeal process. Once this process is complete, the medical staff will document the findings and resolutions in writing.

Surveyor Guidance:

Review and verify that the medical staff bylaws contain criteria for granting clinical privileges to individual practitioners and that a procedure exists for applying these criteria.

Review and verify the defined circumstances for withdrawing, suspending, or terminating privileges of an individual practitioner.

Verify the process in place to ensure practitioners only provide care to patients within the scope of the privileges granted by the governing body.

Review and verify the process for fair hearing and appeals and follow the documentation for an example of how this process was carried out by the medical staff.

MS.13 TEMPORARY CLINICAL PRIVILEGES

When dictated by urgent patient care need or when an application is complete without any negative or adverse information before action by the medical staff or governing body, the chief executive officer, or designee, may grant temporary clinical privileges:

- SR.1 On the recommendation of a member of the medical executive committee, president of the medical staff, or medical director (as defined by the medical staff);
- SR.2 For a period of time not to exceed 120 days.
- SR.3 Criteria for granting temporary privileges:
 - SR.3a Primary verification of education (AMA/AOA Profile is acceptable);
 - SR.3b Demonstration of current competence;
 - SR.3c Primary verification of State professional licenses;
 - SR.3d Receipt of professional references (including current competence); and,

SR.3e Receipt of database profiles from AMA, AOA, NPDB, and OIG Medicare/Medicaid Exclusions.

SR.4 The medical staff bylaws shall include a process for approving practitioners for care of patients in the event of an emergency or disaster.

SR.5 If the organization provides medical staff services through use of locum tenens or similar temporary medical service that may be used for a period not to exceed six months; the medical staff will define within the medical staff bylaws the process regarding the approval of physicians and other practitioners providing such services. The medical staff will complete the required credentialing and privileging requirements defined by the medical staff.

Interpretive Guidelines:

Under certain circumstances, such as urgent patient care need or when an application is complete without any negative or adverse information, the medical staff and governing body may not be able to take immediate action on approving the privileges of a practitioner. Under these circumstances, the chief executive officer, or designee, may grant temporary clinical privileges on the recommendation of a member of the medical executive committee, president of the medical staff, or medical director (as defined by the medical staff), for a period of time not to exceed 120 days.

The minimum criteria as defined under MS.13, SR.3 will apply for granting temporary privileges.

Surveyor Guidance:

Review and verify that the hospital has a process in place to grant temporary privileges and the circumstances when this process may be completed.

Sample records and supporting documentation where a practitioner has been granted temporary privileges to validate the process that was followed.

MS.14 CORRECTIVE OR REHABILITATION ACTION

The medical staff bylaws shall provide a mechanism for management of medical staff corrective or rehabilitative action. This documented action may result from unprofessional demeanor and conduct and/or this behavior is likely to be detrimental to patient safety or the delivery of quality care or is disruptive to organization operations. Any officer of the medical staff, the CEO, or any officer of the board may initiate this corrective or rehabilitative action.

Interpretive Guidelines:

There may be circumstances when a practitioner has been determined to have acted in an unprofessional manner or has presented signs of impairment that would prevent him/her from carrying out patient care safely or disrupting the operations of the organization. The medical staff must provide a mechanism for managing the process for taking corrective or rehabilitative action when a practitioner's conduct is in question. An officer of the medical staff, CEO, or any officer of the board may initiate the process for corrective or rehabilitative action.

The medical staff shall define examples of circumstances or criteria for applying the process for implementing corrective or rehabilitative action.

All hospital staff should be instructed in the process to follow when a practitioner is conducting him/herself in an unprofessional manner or present signs of impairment that would jeopardize the safety and quality of patient care.

Surveyor Guidance:

Review and verify that the medical staff bylaws address the mechanism for managing practitioners when corrective or rehabilitative action may be required.

Verify that the hospital has defined the circumstances when corrective or rehabilitative action may be taken.

Sample records and supporting documentation of a practitioner who has been subject to corrective and rehabilitative action and the process followed in order to promote patient safety and the quality of care provided.

MS.15 ADMISSION REQUIREMENTS

Patients are admitted to the organization only on the recommendation of a licensed practitioner permitted by the State to admit patients to the organization.

SR.1 The governing body shall ensure that every patient is under the care of a:

SR.1a Doctor of medicine or osteopathy who may delegate such care to other qualified health care professionals to the extent allowed by State law;

SR.1b 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/her license;

SR.1c Doctor of podiatric medicine, only with respect to functions authorized by the State;

SR.1d Doctor of optometry who is legally authorized to practice optometry by the State;

SR.1e Chiropractor who is licensed by the State and 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;
or,

SR.1f Clinical psychologist (doctoral degree in psychology), but only with respect to clinical psychologist services as defined in 42 CFR §410.71 and only to the extent permitted by State law.

SR.2. The governing body shall ensure that:

SR.2a A doctor of medicine or osteopathy is on duty or on call at all times; and,

SR.2b A doctor of medicine or osteopathy is responsible for the care of each patient with respect to any medical or psychiatric problem that is present on admission or develops during hospitalization and is not within the scope of practice of the licensed practitioners specified in MS.15, SR 1b-1f as that scope of practice is defined by the medical staff and State law.

Interpretive Guidelines:

The hospital may admit patients only on the recommendation of a licensed practitioner permitted by the State. The governing body is responsible for ensuring that every patient admitted is under the care of licensed practitioner (as defined by MS.15, SR.1).

The governing body must ensure that a doctor of medicine or osteopathy is on duty or on call at all times. The governing body must also ensure a doctor of medicine or osteopathy is responsible for the care of each patient with respect to any medical or psychiatric problem that is present on admission or develops during hospitalization and is not within the scope of practice of the licensed practitioners specified in MS. 15, SR 1b-1f as that scope of practice is defined by the medical staff and State law.

Surveyor Guidance:

Review the Medical Staff Bylaws, Rules and Regulations to verify that admitting privileges are limited to practitioners who have been approved by the medical staff and governing body and as permitted by State law.

Although the practitioners that are licensed and permitted by State law to admit patients, in some organizations, the admission of patients must be done under the service of specific practitioners as defined in the medical staff bylaws, rules and regulations. Verify the organization's process for addressing these admission requirements to ensure that patients are admitted under the appropriate service.

The medical staff bylaws, rules and regulations will define which practitioners by category (i.e. Active, Associate, Courtesy, Consulting, etc.) staff may admit patients. Verify that admitting privileges are limited to those practitioners holding the appropriate status with the Medical Staff.

Verify *that* the governing body has established and monitors the enforcement of policies to ensure an MD or DO is on duty or on call at all times. The medical staff will normally distribute an “on-call” schedule of practitioners by service. Verify how such a list is communicated to appropriate departments/ units throughout the hospital.

If non-MD/ DOs admit patients, verify that every patient is being monitored by an MD/ DO who is responsible for any medical or psychiatric problem outside the scope of practice of the admitting practitioner.

MS.16 MEDICAL RECORD MAINTENANCE

SR.1 The medical staff bylaws shall include the requirement for the preparation and maintenance of a complete and accurate medical record for each patient and policies and procedures for dealing with medical record delinquencies.

SR.2 The medical staff bylaws shall require that the medical staff have periodic meetings at regular intervals to review and analyze medical records of the patients for adequacy and quality of care.

Interpretive Guidelines:

The medical staff shall require that the preparation and maintenance of complete and accurate medical records be in place for each patient. There should be defined policies and procedures for dealing with medical record delinquencies.

The process for medical records completion and the actions taken must be enforced by hospital policy.

In order to ensure that there is an effective process in place, the medical staff must regularly review and analyze medical records to ensure the adequacy and quality of patient care.

Surveyor Guidance:

Review and verify that the process and respective policies and procedures are in place for addressing medical record delinquency.

Review and validate that the hospital has a means of determining its medical record delinquency rate and how this is defined.

Validate the enforcement of the medical staff bylaws, policies and procedures for practitioners delinquent in medical records completion.

Review and verify that the medical staff meets regularly to review and analyze medical records for the adequacy and quality of care provided. The medical staff shall maintain minutes or other records to verify the scope of the reviews conducted and the subsequent actions taken to address any findings.

MS.17 HISTORY AND PHYSICAL

- SR.1 The medical staff bylaws shall include a requirement that a medical history and physical examination (H&P) for each patient shall be done no more than 30 days before or 24 hours after an admission or registration, but prior to surgery or other procedure requiring anesthesia services and placed in the patient's medical record within 24 hours after admission. The H&P must be in the medical record prior to any high-risk procedure, [surgery or other procedure requiring anesthesia services](#).
- SR.1a An [H&P](#) completed within 30 days prior to admission or registration shall include an entry in the medical record documenting an examination for any change in the patient's current medical condition completed by a doctor of medicine or osteopathy, oromaxillofacial surgeon or other qualified individual who has been granted these privileges by the medical staff in accordance with State law.
- SR.1b This examination and update of the patient's current medical condition shall be completed and placed in the medical record within 24 hours after admission or registration, but prior to surgery or other procedure requiring anesthesia services.
- SR.2 A doctor of medicine or osteopathy, oromaxillofacial surgeon shall [perform](#) the H&P described above. Alternatively, a physician's assistant or advance practice nurse may perform [an H&P](#) if permitted by State law and scope of practice.
- SR.3 The content of the HP examination and applicability shall be determined by the medical staff and may be done by the individuals described in [MS.17](#), SR. 2. The content of the H&P examination will be determined by an assessment of the patient's condition and any co-morbidities in relation to the reason for admission or surgery. This [H&P](#) examination must be in the medical record prior to any high-risk procedure, surgery, or other procedure requiring anesthesia services and within 24 hours of admission or registration as stated in MS.17, SR.1.

Interpretive Guidelines:

The medical record must be completed by an authorized practitioner and contain a H&P (as required for all inpatient and certain outpatient settings, as applicable). The H&P must be performed no more than 30 days prior to admission (or procedure or service that requires a H & P) or within one day after admission.

The H&P must be placed in the patient's medical record within 24 hours of admission (or procedure or service that requires an H&P). In the event that the H & P is completed within 30 days prior to admission, the hospital must ensure that this H&P is updated to document any changes in the patient's condition.

- *If there are no changes to the H&P as [documented](#), the physician or [qualified licensed practitioner](#) can simply document an update note stating [that](#):*
 - *The H&P has been reviewed,*
 - *The patient has been examined, and,*

- *The physician or **qualified licensed practitioner** concurs with the findings of the H&P completed on the specified date or that “no change” has occurred in the patient’s condition since the H&P was completed.*
- *The practitioner completing the update is responsible for ensuring that the H&P that is documented in the medical record is complete and accurate.*
- *The completed H&P would be authenticated by the practitioner who conducted the H&P.*
- *Authentication includes dating and timing of this medical record entry. Therefore, it is not necessary to document the time the H&P was physically placed in the medical record.*
- *For the purposes of this requirement, the term “admission” applies to any admission regardless of whether care is being provided on an inpatient or outpatient basis.*

*A doctor of medicine or osteopathy or alternatively, a **qualified licensed practitioner**, may perform a history and physical, if so privileged by the medical staff and permitted by State law and scope of practice. If the patient is admitted only for oral or maxillofacial surgery, the H&P may be performed by an oral and maxillofacial surgeon who has been granted such privileges by the medical staff, in accordance with State law.*

If a short form H&P is used, the minimal content and applicability must be determined by the medical staff. This short form H&P may be used for non-inpatients and be completed by the individuals described above. Without exception, the H&P must be in the medical record prior to any high-risk procedure.

Surveyor Guidance:

Determine that the medical records contain an H&P completed for each patient by an authorized practitioner.

Request and review a sampling of open and closed medical records for verification of completion of the H&P should include, but not limited to:

- *Surgical patients*
- *At least one per in-patient unit or clinical tracer*
- *Moderate/conscious sedation*

In a sampling of patient medical records, verify that the completion of the H&P was within the specified time frame and appropriate documentation noted.

- *Verify the content and completeness of the H&P per organization policy.*
- *In some cases the organization may accept an H&P that has been completed in a practitioner’s office. When this is allowed, verify the process for ensuring that the appropriate documentation is present and completed per the requirements of the organization and that the H&P was completed within the required timeframe.*

- *Verify that the H&P was completed no more than 30 days before or 24 hours after admission or registration and, in all cases involving surgery or procedures requiring anesthesia services or moderate/conscious sedation, prior to the surgery or procedure.*
- *Verify that this documentation of the H&P was placed in the medical record within 24 hours after admission or registration, and in all cases involving surgery or procedures requiring anesthesia services or moderate/conscious sedation prior to the surgery or procedure.*
- *Where the H&P is completed within 30 days before admission or registration and in all cases involving surgery or procedures requiring anesthesia services or moderate/conscious sedation, the hospital must ensure that this H&P is updated to document any changes in the patient's condition.*
 - *If there are no changes to the H&P as written, the physician or **qualified licensed practitioner** can simply document an update note stating **that**:*
 - *The H&P has been reviewed,*
 - *The patient has been examined, and*
 - *The physician or **qualified licensed practitioner** concurs with the findings of the H&P completed on the specified date or that "no change" has occurred in the patient's condition since the H&P was completed.*

MS.18 CONSULTATION

The medical staff shall define in its bylaws the circumstances and criteria under which consultation or management by a physician or other qualified licensed independent practitioner is required.

Surveyor Guidance:

Review and verify the circumstances and criteria which require consultation or management by a physician or other qualified licensed independent practitioner.

MS.19 AUTOPSY

- SR 1 The medical staff shall attempt to secure autopsies in all cases of unusual deaths and those of medical-legal and educational interest.
- SR 2 Mechanisms for documenting permission to perform an autopsy shall be defined.
- SR 3 There shall be a system for notifying the medical staff and specifically the attending practitioner when an autopsy is being performed.

Surveyor Guidance:

Verify that the medical staff has policies requiring practitioners to attempt to secure permission to perform autopsies in cases involving unusual deaths and those of medical-legal or educational interest.

Verify that there is a mechanism for documenting how permission is given to perform an autopsy.

For autopsies performed, validate the process for notifying the attending practitioner when it was performed.

Verify that the medical staff has a process to review autopsies taking place within the hospital.

MS.20 TELEMEDICINE

SR.1 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 MS.8, 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 requirements stated above, 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:

SR.1a The distant-site telemedicine entity's medical staff credentialing and privileging process and standards at least meet the standards stated in 42 CFR 482.12(a) and 482.22(a).

SR.1b 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.

SR.1c 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.

SR.1d 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 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.

- SR.2 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 of MS.8, 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:
- SR.2a The distant-site hospital providing the telemedicine services is a Medicare-participating hospital.
 - SR.2b 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.
 - SR.2c 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.
 - SR.2d 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.
- SR.3 The Medical Staff will define and apply criteria for determining the privileges to be granted to individual practitioners and a procedure for applying the criteria to individuals requesting privileges. 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 these requirements.

Interpretive Guidelines:

While hospitals may use third-party credentialing verification organizations to compile and verify the credentials of practitioners applying for privileges, the hospital's governing body is still legally responsible for all privileging decisions.

Telemedicine is the provision of clinical services to patients by practitioners from a distance via electronic communications.

A distant-site telemedicine entity is one that:

- *Provides telemedicine services;*

- *Is not a Medicare-participating hospital (therefore, a non-Medicare-participating hospital that provides telemedicine services would be considered a distant-site telemedicine entity also); and,*
- *Provides contracted services in a manner that enables a hospital using its services to meet all applicable CoPs and NIAHO® accreditation requirements, particularly those requirements related to the credentialing and privileging of practitioners providing telemedicine services to the patients of a hospital.*

Note: Cross reference to GB.3 SR 4-5

Surveyor Guidance:

Review agreements with any distance-site telemedicine providers.

Verify the process in place for review and approval of credentialing documentation and other information provided.

Review the process for granting and approval of privileges for the telemedicine physicians and practitioners.

NURSING SERVICES (NS)

NS.1 NURSING SERVICE

- SR.1 The organization must have a well-organized nursing service with a plan of administrative authority and delineation of responsibilities for delivery of patient care.
- SR.2 There shall be 24-hour nursing services and a registered nurse must supervise and evaluate the nursing care for each patient. A registered nurse or licensed practical nurse shall be on duty at all times except in facilities that have been granted a waiver in accordance with 42 CFR §488.54(c), Federal law, rules or regulations.
- SR.3 The nursing service must develop and maintain a procedure to ensure that nursing personnel for whom licensure is required have a valid and current licensure. Nursing services must be provided or supervised by a registered nurse.
- SR.4 There shall be adequate numbers of licensed registered nurses, licensed practical nurses, supervisory, and other staff to provide nursing care to all patients as needed. A registered nurse must be immediately available for the bedside care of every patient, as required by State law.
- SR.5 A registered nurse shall make any decisions regarding delegation of nursing care to other nursing staff, based on individual patient need and staff qualifications.
- SR.6 Non-employee licensed nurses who are working in the organization must adhere to the policies and procedures of the organization. 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 service.

Interpretive Guidelines:

The hospital must have an organized nursing service and must provide on-site nursing services 24 hours a day, seven days a week with at least one registered nurse providing or supervising the service 24 hours a day, 7 days a week.

Exception: Small rural hospitals operating under a waiver as discussed in the CMS Conditions of Participation Section §482.23(b) (1).

Nursing services are required to be furnished to inpatients by the hospital. The hospital is required to have a registered nurse on duty at all times (unless the exception applies as a small rural hospital under waiver).

A registered nurse must make all patient care assignments. The nurse executive and the hospital are responsible for ensuring that nursing personnel with the appropriate competence, qualifications and skills have been assigned to provide nursing care for each patient to meet their care needs.

If services are provided by contracted (non-employee) staff, the director of nursing service must supervise and evaluate the clinical activities being performed by these individuals. Non-employee staff are required to adhere to the policies and procedures of the organization and will receive an orientation regarding the organization's policies and procedures prior to working on-site for the organization.

Staffing:

The hospital must provide nursing services 24 hours a day, 7 days a week. An LPN can provide nursing services if an RN supervises that care. The RN must be immediately available for the bedside care of those patients,

Exception for small and rural hospitals: CMS Conditions of Participation §488.54 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. The hospital must have met the criteria for this exception to apply.

Definitions:

"Rural" is defined, as all areas not delineated as "urbanized" areas by the Census Bureau, in the most recent census.

"Temporary" is defined as a one year period or less and the waiver cannot be renewed.

Surveyor Guidance:

Interview the nurse executive. The following may be requested prior to meeting the nurse executive:

- *Organizational chart(s) for nursing services for all locations where the hospital provides nursing services;*
- *Job descriptions or description of responsibilities for all nursing personnel including the nurse executive.*

The organization will have multiple patient care units. Sample at least one job description from each of these units. During the review of the organization, observe the nursing care in progress to determine how adequate staffing is determined as it applies to the delivery of care.

Review samples of the following documentation:

- *Staffing schedules;*
- *Unit assignment sheets;*
- *Nursing policies and procedures; and,*
- *Internal survey and staffing variance reports.*

Interview patients to verify how nursing care has been provided. Secure hospital and patient permission before the interviews.

Review the nurse-staffing schedule (or similar documentation to apply staff) for a minimum of a one-week period. If minimal or less than desired staffing for the period is noted, review additional nurse-staffing schedules for a second week period to identify any patterns or trends for insufficient staffing.

Verify that nursing assignments include consideration of the complexity of the patient's care needs and that the nursing staff that care for the patients are competent and have the required qualifications.

Review the process for determining how nursing assignments and staffing are applied in the patient care setting. This process should encompass the following:

- *Patient needs;*
- *Acuity of patients;*
- *Special needs of individual patients; and,*
- *Competence and qualifications of nursing personnel.*

Verify the daily RN coverage for every unit of the hospital to determine that at least one RN for each unit and shift is on duty 24/7.

(Exception for small and rural hospitals: CMS Conditions of Participation 42 CFR §488.54 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 CMS regional office.)

The following must have been met in order for the waiver to have been granted:

- *50 or fewer inpatient beds;*
- *The character and seriousness of the deficiencies do not adversely affect the health and safety of patients; and,*
- *The hospital meets all the other statutory requirements in section 1861(e)(1-8) of the Social Security Act.*

In order for the waiver to be granted, the hospital has made and continues to make a good faith effort to comply with the 24 hour nursing requirement.

When contracted (non-employee) personnel are used by the organization, these individuals must adhere to the practices, policies and procedures of the organization. Verify the process for orienting these contracted individuals to the hospital, unit(s) they are assigned to, policies and procedures, documentation requirements (particularly if a computerized medical record is utilized), and mandatory requirements for safety and emergency procedures to be followed.

Competency requirements will vary unit to unit within the organization. Determine the means by which competence is verified for the contracted individual(s) prior to their working in the organization. The competency requirements for contracted staff should be comparable to employed staff performing these similar duties. Verify there is appropriate supervision from qualified hospital employed staff for these contracted individuals.

Verify the process for evaluation of contract staff for monitoring of performance and how this information is shared with the individual and contracted agency.

Review the recruitment efforts and methods used by the hospitals' administration by requesting copies of materials and demonstration of other methods to meet the nursing staff needs for the hospital.

Compare the hospital salaries with those offered from other facilities in the area.

If a nursing shortage exists, determine if it is a temporary shortage of qualified nursing personnel in the area or attributable to other reasons and how the hospital is addressing the issue.

NS.2 NURSE EXECUTIVE

- SR.1 The nurse executive must be a licensed registered nurse with either a master degree, actively pursuing a master's degree or equivalent experience in comparable positions.
- SR.2 The nurse executive is responsible for the operation of the service, including determining the types and numbers of staff necessary to provide nursing care for all patient care areas of the organization and standards of nursing practice.
- SR.3 The nurse executive is responsible for the development, approval and implementation of all nursing service policies and procedures.

Interpretive Guidelines:

The nurse executive is a member of senior leadership and must be appropriately qualified. The nurse executive must have a nursing master's degree, or is actively pursuing a nursing master's degree, or can demonstrate the equivalent experience in comparable positions. The hospital may have only one nursing service hospital-wide and one single nurse executive.

Operation of service:

The nursing service must ensure that patient needs are met. This includes ongoing assessments of patients' needs and nursing staff is provided to meet those needs.

The nurse executive must be a currently licensed RN and he/she is responsible for the operation of the nursing service, including the quality of patient care provided by the nursing service.

The nurse executive must determine the sufficient numbers, types, and qualifications of supervisory and staff nursing personnel to meet the appropriate nursing needs and care of the patient population of each department or nursing unit.

Appropriate staffing and personnel for patient care units is described in NS.1 (See staffing under Interpretive Guidelines)

Although specific titles may vary, the hierarchy of the nursing service will include some variation of:

- *Assistant/Associate Directors(s)*
- *Supervisors/Coordinators*
- *Head Nurses/Nurse Managers*
- *Staff Nurses*
- *Unit Secretaries/Clerks*
- *Nursing Assistants/Aides*

Surveyor Guidance:

Review the nurse executive's job description. Verify that he or she has the appropriate education, licensure and experience for this position in the organization for operation of the nursing service.

Verify that the nurse executive determines appropriate staffing and personnel for patient care units as described in NS.1 (See staffing under Interpretive Guidelines and Surveyor Guidance).

Review the organizational chart or plan for nursing services. Determine that the chart or plan describes or displays lines of authority that delegates responsibility within the department or nursing unit.

Verify that the nurse executive is involved in the development of and approves the nursing service patient care policies and procedures.

Evaluate the nursing service to ensure that it is appropriate according to the following:

- *Physical layout and size of the hospital;*
- *Number of patients;*
- *Intensity of illness and nursing needs;*
- *Availability of nurses' aides and assistants and other support processes are provided (e.g., housekeeping services, unit secretaries); and,*
- *Training and experience of personnel.*

NS.3 ASSESSMENT AND PLAN OF CARE

SR.1 The hospital must ensure that the nursing staff develops, and keeps current, a nursing care plan for each patient. Nursing staff shall develop and maintain a plan of care for each patient within 24 hours of admission that reflects the findings of a completed nursing assessment and input of other disciplines, as appropriate. The nursing care plan may be part of an interdisciplinary care plan.

SR.2 Nursing staff shall complete an assessment of a patient's condition within twenty four hours of admission to an inpatient setting.

SR.2a The nursing assessment will include but not be limited to:

- Allergies
- Admitting problem
- History of pain and current status
- Preexisting or other conditions (i.e. Pregnancy, COPD, Diabetes)
- Current medications (what time last dose, including any illicit drugs)
- ADL needs
- Dietary Requirements
- All other requirements per hospital nursing policies

SR.2b Nursing staff will complete an assessment according to the hospital nursing policies in all other areas of the organization (Outpatient, clinics, surgical centers etc.).

SR.3 Nursing staff will reassess the patient at regular time defined intervals and if the patient's condition changes.

SR.3a The patient's plan of care is reviewed and revised, at regular intervals and as necessary, when the patient's condition has changed.

Interpretive Guidelines:

A nursing assessment will be completed within 24 hours of admission to an inpatient setting and according to hospital policies in other areas of the organization such as clinics, outpatient surgery etc. While the list of requirements to be included in the initial nursing assessment is specific, the complete nursing assessment should reflect the philosophy of the nursing department on patient care. The use of nursing diagnosis, pathways, or clinical guidelines are allowed and encouraged if they meet the minimum requirements. All nursing assessments should collect enough data for the nurse to be able to develop a plan of care to keep the patient safe and address the presenting and relevant concomitant conditions.

A plan of care begins within 24 hours of admission of the patient. The plan of care includes planning the patient's care from admission through discharge and the respective care processes involved. If interdisciplinary findings are indicated, these shall also be a part of the plan of care and documented in the medical record.

The plan of care is based on assessing the patient's nursing care needs (not solely those needs related to the admitting diagnosis) and developing appropriate goals, nursing interventions in response to those needs, and evaluate the patient's progress toward those goals.

The plan of care is maintained and updated based upon ongoing assessments of the patient's needs and the patient's response to interventions, in response to assessments.

The plan of care is included as a part of the patient's medical record.

Surveyor Guidance:

Select a sample of medical records to review the following:

- *Nursing assessments;*
- *Nursing re-assessments;*
- *Nursing care plans and updates, as indicated;*
- *Nursing notes, and,*
- *Medication administrations records (MARs).*

This should be a part of the review for each inpatient area visited. In evaluation of the plan of care, the following will be reviewed:

- *The plan has been developed within 24 hours of inpatient admission for each patient;*
- *The plan reflects findings of the assessments and outlines the patient goals and as appropriate includes both, physiological and psychosocial factors;*
- *The discharge planning process has been initiated;*
- *The plan is consistent with the attending MD/DO's plan for medical care;*
- *The plan includes [reference](#)/inclusion to interdisciplinary assessments (as applicable); and,*
- *The plan is revised as the needs of the patient changes.*

STAFFING MANAGEMENT (SM)

SM.1 LICENSURE OR CERTIFICATION

The organization shall have a policy and practice for outlining and verifying that each staff member possesses a valid and current license or certification as required by the organization and Federal and State law. This written policy shall be strictly enforced and compliance data reported to Quality Management Oversight.

Surveyor Guidance:

Review and validate the hospital's policy and practice for performing primary verification of the current licensure and/or certification of all staff members as required by the organization, and Federal and State law.

Review the process in place to enforce compliance and that data regarding verification and expirations is shared with Quality Management Oversight and/or Human Resources (Personnel) as needed, if this process is completed at the individual department level).

SM.2 PROFESSIONAL SCOPE

All staff, including contract staff, students, and volunteers, shall function within the limits of their scope of service as defined by their professional practice act, State law, and/or organization policy at all times. This written policy shall be strictly enforced and variations reported to Quality Management Oversight.

Surveyor Guidance:

Review the policy and verify that the hospital has a means of ensuring that all staff, including contract staff, students, and volunteers are functioning within the limits of their scope of service as it has been defined by the hospital, respective professional practice acts and State law.

Verify the process for communicating any variations from provided services to Quality Management Oversight.

SM.3 DEPARTMENT SCOPE OF SERVICE

Each department, whether clinical or supportive, and each patient unit, shall have a written scope of service that includes at least:

SR.1 The hours of operation;

SR.2 Patient populations served;

SR.3 Skill mix;

- SR.4 Core staffing and methods for determining and modifying staffing to meet patient or process needs; and,
- SR.5 Description of assessment and reassessment practices, including timeframes.
- SR.6 Organization policies will identify how often, and under what circumstances, each department's scope of service must be reviewed and updated (i.e. if new service is added or discontinued, change of population served, etc.).

Interpretive Guidelines:

The hospital will have a description of the scope of services provided, whether clinical or supportive, and each patient unit. This scope of service will address the following:

- *The hours of operation;*
- *Patient populations served;*
- *Skill mix;*
- *Core staffing and methods for determining and modifying staffing to meet patient or process needs; and,*
- *Description of assessment and reassessment practices, including timeframes.*

The hospital will describe and illustrate the sequence and interaction of these processes (services).

Surveyor Guidance:

Verify that the hospital has a description of the scope of services provided for all services including clinical or supportive, and encompasses each patient unit.

Verify that the scopes of service include the items listed above within the Interpretive Guidelines.

Review the documents and/or illustration that describe the sequence and interaction of these processes (services).

SM.4 DETERMINING AND MODIFYING STAFFING

- SR.1 The method for determining and modifying staffing shall be validated through periodic reporting of variance from core staffing, outlining justification and linking that justification with patient and process outcomes, including any untoward patient events or process failures.
- SR.2 This validation shall be done and reported to Quality Management Oversight, when indicated.

Interpretive Guidelines:

The hospital will develop a method for determining and modifying staffing. Staffing will be validated through periodic reporting of variance from core staffing, and outline the justification and link for that justification with patient and process outcomes, including any untoward patient events or process failures. Validation of the measures regarding the impact of staffing on processes will be reported to Quality Management Oversight, when indicated.

Surveyor Guidance:

Review and verify the method(s) used by the hospital for determining and modifying staffing when indicated.

Validate that there is a means in place for reporting variances and other associated information to Quality Management Oversight.

SM.5 JOB DESCRIPTION

All staff, whether clinical or supportive, including contract staff, students and volunteers shall have a current job description (or job responsibilities) available that contains the experience, educational and physical requirements, supervision (as indicated) and performance expectations for that position.

Surveyor Guidance:

Review and verify a sampling of job descriptions to verify that the hospital has identified the appropriate experience, educational and physical requirements and performance expectations for the positions reviewed. This includes contracted staff for nursing and/or other areas of the organization.

SM.6 ORIENTATION

All staff, whether clinical or supportive, including contract staff, students and volunteers, shall receive an orientation to specific job duties and responsibilities, and their work environment, as required by Federal and State law and regulation and the organization. The orientation shall take place prior to the individual functioning independently in their job.

SR.1 Members of the medical staff will receive an orientation developed and approved by the organization that includes general safety practices, emergency procedures, infection control, confidentiality and other issues as required by the organization.

Interpretive Guidelines:

The hospital will require that all staff, including contract staff, students and volunteers receive an orientation prior to working independently in their respective roles for the hospital.

This orientation will address, at a minimum, the following topics:

- *Organizational structure;*

- *Patient confidentiality and ethics;*
- *Document control, retrieval and verification (specific to policies, procedures, and work instructions/protocols);*
- *Internal reporting requirements for adverse patient events;*
- *Patient safety;*
- *General safety (work environment);*
- *Emergency procedures;*
- *Infection control and universal precautions; and,*
- *Other issues as required by the hospital and Federal and State law and regulation.*

Orientation to specific job duties may be addressed within the department or service where the employee is assigned, but completed prior to the employee working independently.

Verify the process in place for members of the medical staff completing a general orientation as noted within SM6, SR.1.

SM.7 STAFF EVALUATIONS

- SR.1 The performance/competency evaluation shall contain indicators that will objectively measure the ability of staff to perform all job duties as outlined in the job description. Relevant indicators may be selected from the list of indicators for measurement as outlined below.
- SR.2 The staff shall be evaluated initially and on an on-going basis against indicators that measure issues and opportunities for improvement. The measures selected may be considered from the following:
- SR.2a Variations and problem processes identified through the analysis of outcomes measurement as required by the Quality Management System;
 - SR.2b High-risk, low volume procedures;
 - SR.2c New technology/equipment/processes;
 - SR.2d Customer satisfaction feedback;
 - SR.2e Scheduled training session outcomes;
 - SR.2f Staff learning needs assessments that include variations identified through prior staff performance measurement;
 - SR.2g Staff feedback;

- SR.2h Medical staff feedback;
- SR.2i Requirements of Federal or State law; and,
- SR.2j Other indicators as determined by the organization.
- SR.3 Indicator measurement for contract staff may be modified based on organization outcomes and frequency of service of individuals. Modification of this measurement(s) will be made when needed and shall be justified by data analysis.
- SR.4 The organization shall aggregate objective performance data from sources that may include; individual evaluations, incident reports, risk management, staff and patient feedback, and/or data analysis to identify variations for further training, coaching, and mentoring.
- SR.4a Reassessment of objective data shall follow any intervention.
- SR.4b The outcomes of this aggregated data will be reported to Quality Management Oversight as needed to monitor staff performance improvement.
- SR.5 The organization shall have a policy and procedure for sharing results of individual performance evaluations/competence assessment with staff members that allows for staff feedback within a timeframe defined by the organization, not to exceed one calendar year.
- SR.6 The organization shall require each staff member, including contract staff, to participate in continuing education as required by individual licensure/certification, professional association, law or regulation, or organization policy. Compliance with this standard shall be reported to Quality Management Oversight.

Interpretive Guidelines:

The hospital must continually evaluate the performance/competency of staff. This process of evaluation must include the use of indicators that will objectively measure the ability of staff to perform all job duties as outlined in the job description. These indicators may address one or more of the following:

- *Variations and problem processes identified through the analysis of outcomes measurement as required by the Quality Management System;*
- *High-risk, low volume procedures;*
- *New technology/equipment/processes;*
- *Customer satisfaction feedback;*
- *Scheduled training session outcomes;*
- *Staff learning needs assessments that include variations identified through prior staff performance measurement;*

- *Staff feedback;*
- *Medical staff feedback; and,*
- *Requirements of Federal or State law.*

The hospital will have a policy and procedure for sharing results of individual performance evaluations/competence assessment with staff members that allows for staff feedback within a timeframe defined by the organization, not to exceed one calendar year.

The hospital may modify indicator measurement for contract staff based on organization outcomes and frequency of service of individuals. This measurement modification will be made when needed and shall be justified by data analysis.

The organization shall aggregate the objective performance data from sources that may include; individual evaluations, incident reports, risk management, staff and patient feedback, and/or data analysis to identify variations for further training, coaching, and mentoring.

In order to continually improve the fulfillment of their job responsibilities, the hospital shall require each staff member, including contract staff, to participate in continuing education as required by individual licensure/certification, professional association, law or regulation, or hospital policy.

Surveyor Guidance:

In a sampling of personnel records, verify that the hospital has a performance/competency evaluation process that includes appropriate measures as stated within the Interpretive Guidelines for [SM. 7](#).

Verify the policy and practice the hospital uses to validate the competency of staff occurs within a specified timeframe no less than once per calendar year.

Verify the policy and practice that the hospital uses to measure contract staff performance is based upon outcomes and frequency of service.

Verify that the hospital requires and makes provisions for each staff member, including contract staff, to participate in continuing education as required by individual licensure/certification, professional association, law or regulation, or hospital policy.

MEDICATION MANAGEMENT (MM)

MM.1 MANAGEMENT PRACTICES

- SR.1 The organization shall have a pharmacy service that meets the needs of the patients. Medications will be prepared and administered in accordance with accepted professional principles. The pharmacy service will be directed by a full time, part time, or consulting registered pharmacist responsible for developing, supervising, and coordinating all the activities of the pharmacy services. The pharmacy service must have an adequate number of qualified personnel to ensure effective medication management services, including emergency services.
- SR.2 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 Sec. 482.12(c), and accepted standards of practice.
- SR.2a Drugs and biologicals may be prepared and administered on the orders of other practitioners not specified under Sec. 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.
- SR.2b 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 Sec. 482.24(c)(3).
- SR.2c 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.
- SR.3 All compounding, packaging, and dispensing of medication shall be under the supervision of a pharmacist.
- SR.4 All drugs and biologicals must be controlled, secured and distributed in accordance with applicable standards of practice and consistent with Federal and State law at all times.
- SR.4a Drugs listed as Schedule II, III, IV, and V of the Comprehensive Drug Abuse Prevention and Control Act of 1970 must be kept locked within a secure area.
- SR.4b Only personnel authorized by the pharmacy service shall have access to locked areas.
- SR.5 Outdated, mislabeled, or otherwise unusable medications shall not be available for patient use.
- SR.6 Medications prescribed without specific duration or number of doses shall automatically be stopped after a reasonable time that has been predetermined by the medical staff.

- SR.7 Blood transfusions and intravenous medications must be administered in accordance with State law and approved medical staff policies and procedures.
- SR.8 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. If the hospital allows a patient to self-administer specific hospital-issued medications, then the hospital must have policies and procedures in place to:
- SR.8a Ensure that a practitioner responsible for the care of the patient has issued an order, consistent with hospital policy, permitting self-administration.
 - SR.8b Assess the capacity of the patient (or the patient's caregiver/support person where appropriate) to self-administer the specified medication(s).
 - SR.8c Instruct the patient (or the patient's caregiver/support person where appropriate) in the safe and accurate administration of the specified medication(s).
 - SR.8d Address the security of the medication(s) for each patient.
 - SR.8e 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.
 - SR.8f 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:
 - SR.8f (1) 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.
 - SR.8f (2) 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).
 - SR.8f (3) Identify the specified medication(s) and visually evaluate the medication(s) for integrity.
 - SR.8f (4) Address the security of the medication(s) for each patient.
 - SR.8f (5) 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.

- SR.9 Hospitals may use pre-printed and electronic standing orders, order sets, and protocols for patient orders only if the hospital:
- SR9.a Establishes that such orders and protocols have been reviewed and approved by the medical staff and the hospital's nursing and pharmacy leadership;
 - SR.9b Demonstrates that such orders and protocols are consistent with nationally recognized and evidence-based guidelines;
 - SR.9c 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
 - SR.9d 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.

Interpretive Guidelines:

All medication management practices, including preparation and administration, shall be administered by or under the supervision of nursing or other qualified personnel in accordance with applicable Federal and State laws. Drugs and biologicals must be prepared and administered in accordance with:

- *Federal and State laws;*
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, including which medications they may prescribe and administer, including controlled substances.
- *Orders of the practitioner or practitioners responsible for the patient's care;*
In accordance with standard practice, all practitioner orders for the administration of drugs and biological must include at least the following:
 - *Name of the patient;*
 - *Age and weight of the patients, or other dose calculation requirements, where applicable;*
 - *Date and time of the order;*
 - *Drug name;*
 - *Dose, frequency, and route;*
 - *Exact strength or concentration, when applicable;*
 - *Quantity and/or duration, when applicable;*

- *Specific instructions for use, when applicable; and*
- *Name of the prescriber.*

- *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 (Example such as ISMP, CDC, etc.).

The organization shall have a pharmacy service administered in accordance with accepted professional principles and directed by a full time, part time, or consulting registered pharmacist responsible for developing, supervising, and coordinating all the activities of the pharmacy services.

Direction of pharmaceutical services may not require continuous on-premise supervision at the hospital's single pharmacy or at any pharmacy location but may be accomplished through regularly scheduled visits, and/or telemedicine in accordance with Federal and State law and regulations and accepted professional principles.

The pharmaceutical services staff must be sufficient in types, numbers, and training to provide quality services, including twenty four (24) hour, seven (7) day emergency coverage. In the alternative, there must be an arrangement for emergency services, as determined by the needs of the patients and as specified by the medical staff and within the scope and complexities of services provided.

All compounding, packaging, and dispensing of medication shall be under the supervision of a licensed pharmacist.

All medications (listed as Schedule II, III, IV, and V of the Comprehensive Drug Abuse Prevention and Control Act of 1970) must be kept and locked in a secured container and/or room. In the event these drugs are stored in a container that is readily portable, it must be stored in a locked room, monitored location, or secured location that will ensure their security when not in use. Only personnel authorized by the pharmacy service shall have access to locked areas.

The hospital must have a pharmacy labeling, inspection, and inventory management system that ensures that outdated, mislabeled, or otherwise unusable medications are not available for patient use.

The hospital will ensure that medications prescribed without specific duration or number of doses shall automatically be stopped after a reasonable time that has been predetermined by the medical staff.

Medication security:

- *Drugs and biologicals are stored in accordance with manufacturer's directions and State and Federal requirements.*

- *Hospital policies and procedures need to define which personnel are authorized to have access to locked areas based on their own needs as well as State and Local law.*
- *Non-controlled drugs and biologicals are to be stored in a secure area in a manner that prevents tampering and diversion.*
- *A medication is considered secure if unauthorized individuals are prevented from obtaining access.*
- *A secure area is one in which staff are actively providing patient care or preparing to receive patients with procedures to ensure limited entry and exit to appropriate staff, patients, and visitors.*
 - *This includes critical care areas or labor and delivery suites which actively provide patient care around the clock and the operating room when staffed and providing care.*
 - *All non-controlled substances are to be locked when a patient care area is not staffed.*
 - *When not in use, an operating room would not be considered secure and all drugs and biologicals are expected to be locked.*

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:

- *Personnel Authorized to Administer Medication.*
- *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 of administered medications;*
 - *Equipment, devices, special procedures, and/or techniques required for medication administration;*

As appropriate, patients may need to self-administer non-controlled drugs and biologicals; the hospital will authorize the patient to have access to these medications. (Such non-controlled medications may include i.e. nitroglycerine tablets and inhalers). The provision for patient self-administration would also include other nonprescription medications at the bedside (i.e. lotions,

creams, and/or rewetting eye drops. The hospital will have policies and procedures in place regarding patient self-administration of non-controlled drugs and biologicals consistent with safe medication practices. There will be measures in place to properly secure such non-controlled drugs and biologicals. The policies and procedures will define the means for determining the competence to self-administer such drugs and biologicals and provide education to the patient as necessary to ensure safe self-administration of these drugs and biologicals.

Policies and procedures address:

- *Personnel authorized to administer medications*
- *Security and monitoring of carts or emergency boxes, locked or unlocked, containing drugs and biologicals in all patient care areas to ensure their safe storage, availability in emergency situations, and patient safety.*
- *Medications brought to the hospital by patients and their families*
- *Sample Medications*
- *Investigational medications*
- *Practices to minimize and prevent medication errors based on professional standards of practice including;*
 - *Proactive review and analysis of external alerts, internal practice variances and adverse drug events*
 - *Labeling of medications*
 - *High-alert medications - dosing limits, administration guidelines, packaging, labeling and storage*
 - *Guidelines/criteria for selection from a menu of medication options addressing similar indications for use e.g. pain meds*
 - *Limiting the variety of medication-related devices and equipment. For Example limit the types of general-purpose infusion pumps to one or two*
 - *Availability of up-to-date medication information*
 - *Availability of pharmacy expertise. Pharmacist available on-call when pharmacy does not operate 24 hours a day*
 - *Avoidance of dangerous abbreviations*
 - *Alert systems for look-like and sound-alike drug names*
 - *Use of facility approved pre-printed order sheets whenever possible*
 - *That orders to "resume previous orders" are prohibited*
 - *A voluntary, non-punitive, reporting system to monitor and report adverse drug events (including medication errors and adverse drug reactions)*
 - *The preparation, distribution, administration and proper disposal of hazardous medications*
 - *Drug recalls*
 - *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*
 - *Identification of when weight-based dosing is required; (i.e. pediatric dosing, chemo, contrast, etc.)*
 - *Other relevant performance improvement activities*

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:

- *Patient identity. Acceptable patient identifiers include but are not limited to: the patient's full name; an identification number assigned by the hospital; or date of birth. Identifiers must be confirmed by patient wrist band, patient identification card, patient statement (when possible) or other means outlined in the hospital's policy. The patient's identification must be confirmed to be in agreement with the medication administration record and medication labeling prior to medication administration to ensure that the medication is being given to the correct patient.*
- *Correct medication, to ensure that the medication being given to the patient matches that prescribed for the patient;*
- *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);*
- *Correct route, to ensure that the method of administration – orally, intramuscular, intravenous, etc., is the appropriate one for that particular medication and patient; and*
- *Appropriate time, to ensure adherence to the prescribed frequency and time of administration.*

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. 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:*

- *Medications **not eligible** for scheduled dosing times;*
- *Medications **eligible for** scheduled dosing times;*
- *Administration of eligible medications outside of their scheduled dosing times and windows;*
and
- *Evaluation of medication administration timing policies, including adherence to them.*

Medications not eligible for scheduled dosing times:

The policies and procedures must identify medications 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*
- *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.

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. 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.

Time-critical scheduled medications:

Time-critical scheduled medications are those medications 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;*
- *Insulin;*
- *Anticonvulsants;*
- *Immunosuppressive agents;*
- *Pain medication;*
- *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;*
- *Medications prescribed more frequently than every 4 hours.*

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.*

- 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.

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 medication errors that are the result of missed or late dose administration must be reported to the attending physician **immediately** in accordance with requirement MM.6, SR.3.*

Evaluation of medication administration timing policies

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. 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.

Standing orders

Hospitals may adopt policies and procedures that permit the use of standing orders to address well- defined clinical scenarios involving medication administration. The policies and procedures must address the process by which a standing order is developed; approved; monitored; initiated by authorized staff; and subsequently authenticated by physicians or practitioners responsible for the care of the patient.

The specific criteria for a nurse or other authorized personnel to initiate the execution of a particular standing order must be clearly identified in the protocol for the order, i.e., the specific clinical situations, patient conditions, or diagnoses in which initiating the order would be appropriate. Policies and procedures must address the education of the medical, nursing, and other applicable professional staff on the conditions and criteria for using standing orders and the individual staff responsibilities associated with their initiation and execution.

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. 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 42 CFR §482.23(c)(3).

The policies and procedures must also establish a process for monitoring and evaluating the use of standing orders, including proper adherence to the order's protocol. There must also be a process for the identification and timely completion of any requisite updates, corrections, modifications, or revisions.

Surveyor Guidance:

Verify that the pharmacist is properly licensed and is a full-time or part-time employee or employed on a consultative basis.

Review and verify the job description or 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.

Verify that the pharmacy director is actively involved in those committees responsible for establishing medication-related policies and procedures.

Verify that the pharmaceutical services are provided by staff 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.

In review of the pharmacy, review the process for the preparation and administration of medications. Verify that medications are prepared and administered in accordance with Federal and State laws, accepted national standards of practice, manufacturer's directions, and hospital policy.

Verify that there is an effective method for the administration of drugs. Use the following indicators for assessing drug administration:

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.

Verify that nursing staff authorized to administer drugs and biologicals are practicing within their State-permitted scope of practice.

Are personnel other than nursing personnel administering drugs or biologicals? If yes, determine if those personnel are administering drugs or biologicals in accordance with Federal and State laws and regulations.

Verify that there are policies and procedures approved by medical staff addressing the timing of medication administration.

Verify that the hospital has, consistent with its policies, identified medications which are:

- *Not eligible for scheduled dosing times;*
- *Eligible for scheduled dosing times and are time-critical; and*
- *Eligible for scheduled dosing times and are not time-critical.*

Verify the hospital has established total windows of time that do not exceed the following:

- *1 hour for time-critical scheduled medications*
- *2 hours for medications prescribed more frequently than daily, but no more frequently than every 4 hours; and*
- *4 hours for medications prescribed for daily or longer administration intervals.*

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?

Review a sample of medical records to determine whether medication administration conformed to a practitioner's order (i.e., 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.

Observe the preparation of drugs and their administration to patients [medication pass] in order to verify that procedures are being followed:

- *Verify that a patient's identity is confirmed prior to medication administration.*
- *Verify that procedures to assure the correct medication, dose, and route are followed.*
- *Verify that drugs are administered in accordance with the hospital's established policies and procedures for timely medication administration.*
- *Observe if the nurse remains with the patient until medication is taken.*
- *Review the process followed when medications are not given on time and what action(s) are taken*

Interview personnel who administer medication to verify their understanding of the policies regarding timeliness of medication administration:

- *Verify that the staff are able to identify time-critical and non-time-critical scheduled medications as well as medications not eligible for scheduled dosing times.*
- *Verify that the staff are able to describe requirements for the timing of administration of time critical and non-time critical medications in accordance with the hospital's policies.*

If the hospital uses standing orders, verify that there are policies and procedures that address the process by which a standing order is developed; approved; monitored; initiated by

authorized staff; and subsequently authenticated by physicians or practitioners responsible for the care of the patient.

Review one or more standing orders involving medication administration, including the documentation on the development of the order, evidence of training of personnel on the order's protocol, and periodic evaluation of the use of the standing order, including adherence to policies.

Interview nursing staff to determine whether they initiate medications in accordance with standing orders. Are they following the policies and procedures?

In a sampling of patient records, review and verify medication orders (and the ordering process), medication administration records, and appropriate medication related documentation in the medical record.

Review a sample of medication administration records (MARs) to verify that they conform to practitioner's orders, that the order is current and that the drug and dosage are correct and administered as ordered.

Review the unit dose system utilized in the pharmacy to verify that each single unit dose package includes:

- *Name and strength of the drug;*
- *Lot and control number equivalent; and,*
- *Expiration date.*

Determine by inspection whether all medications are stored in a manner that prevents unauthorized access. Review patient care areas:

- *Verify that the labels of individual medications conform to State laws.*
- *Verify that medications prescribed for a patient include:*
 - *Patient's full name;*
 - *Prescriber's name;*
 - *Strength and quantity of the drug dispensed; and,*
 - *Appropriate directions and cautionary statements are included as well as the expiration date.*
- *Review and verify that medications provided in floor stock containers include:*
 - *Name and strength of the drug;*
 - *Lot and control number equivalent; and*
 - *Expiration date.*

Inspect patient-specific and floor stock medications to identify expired, mislabeled or unusable medications.

Review the hospital policies and procedures governing patient self-administration of drugs and biologicals.

Verify that those administering intravenous medications are working within their scope of practice in accordance with State law and hospital policy.

Review infusion records to verify the process followed is consistent with the training provided and policies and procedures are followed.

Discuss the process for addressing adverse drug reactions and the procedure to be followed when this occurs.

MM.2 FORMULARY

The medical staff or pharmaceutical oversight group shall select a list of medications to be available within the organization. The list shall be available to all appropriate staff at all times.

Interpretive Guidelines:

The medical staff or pharmaceutical oversight group shall select a list of medications (formulary) to be available within the organization. The list shall be available to all appropriate staff at all times.

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 dispensing or administration. At a minimum, the criteria include the indication for use, effectiveness, risks (including propensity for medication errors, abuse potential, and [adverse](#) events), and costs.

The formulary may be maintained either electronically on the hospital's information management system or in a hardcopy form. The hospital will ensure a means of notifying the hospital staff and medical staff when changes are made to the formulary.

The hospital will have a process in place that addresses medication-related issues to include:

- *Communicating with appropriate prescribers and staff;*
- *Developing approved substitution protocols;*
- *Educating appropriate [QLPs](#), appropriate health care professionals, and staff about these protocols; and*
- *Obtaining medications in the event of a disaster.*

The hospital will have a policy and procedure in place to address the process for requests for medications to be added to the formulary before the medications are available for dispensing and administration and that the medical staff oversees this process.

The hospital should have processes to approve and procure medications that are not on the hospital's formulary.

Surveyor Guidance:

Verify that the pharmacy has an established formulary that of medications that are available in the hospital.

Verify that there is a process for creation and periodic review of a formulary system.

Validate the policy and procedure in place to address the process for requests for medications to be added to the formulary before the medications are available for dispensing and administration

Verify that the hospital has a process to approve and procure medications that are not on the hospital's formulary.

MM.3 SCHEDULED DRUGS

SR.1 Current and accurate records must be kept of the receipt and disposition of all scheduled drugs, and in compliance with all Federal and State documentation requirements.

SR.2 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.

Interpretive Guidelines:

The hospital must maintain a record system to maintain current and accurate records of the receipt and disposition of all scheduled drugs that is in compliance with all Federal and State documentation requirements.

This record system will address the following for all scheduled drugs:

- *Accountability procedures to ensure control of the distribution, use, and disposition;*
- *Current and accurate receipt and disposition;*
- *Ability to trace the process for moving scheduled drugs throughout the service 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;*
- *Identity of the pharmacist responsible for determining that all drug records are in order and that an account of all scheduled drugs is maintained and reconciled;*

- *Accounting of all scheduled drugs and any discrepancies in count are reconciled promptly; and,*
- *Capability to readily identify 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.*

The hospital must develop and implement policies and procedures to minimize abuses and losses of controlled substances. These procedures must outline, in accordance with applicable Federal and State laws, the reporting process to the individual responsible for the pharmaceutical service, and to the chief executive officer, as appropriate.

Surveyor Guidance:

Verify that the record system provides information on scheduled drugs in a readily retrievable manner.

Validate that the records can trace the movement of scheduled drugs throughout the service 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.

Verify that this system provides documentation on scheduled drugs in a readily retrievable manner to facilitate reconciliation of the receipt and disposition of all scheduled drugs.

Verify that 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. Narcotic count sheets and reconciliation sheets could be sampled when discrepancies are present and the action(s) taken by the hospital to address these discrepancies.

Validate the hospital system to readily identify 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.

Determine if controlled drug losses are reported to appropriate authorities in accordance with State and Federal laws.

MM.4 MEDICATION ORDERS

All medication orders shall:

- SR.1 Include the name of the drug, the dosage and frequency of administration and the route of administration.
- SR.2 Be in writing and signed, including date and time, by the practitioner or practitioners responsible for the care of the patient as specified under 42 CFR§482.12(c) and authorized to write such orders by hospital policy and in accordance with State law.

- SR.2a 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.
- SR.3 Telephone or verbal orders are to be used infrequently and when used must be accepted only by personnel authorized by the medical staff and in accordance with Federal and State law.
- SR.4 Verbal orders must be signed or initialed by the prescribing practitioner must be authenticated in accordance with Federal and State law. If there is not State law that designates a specific timeframe for the authentication of verbal orders, the orders must be authenticated within a time specified by hospital policy.
- SR.5 Orders for drugs and biologicals may be documented and signed by other practitioners not specified under 42 CFR§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

Interpretive Guidelines:

Elements to be included in any medication order (including all written, and verbal/telephone orders) include:

- *Name of patient;*
- *Age and weight of patient, or other dose calculation requirements, when appropriate;*
- *Date and time of the order;*
- *Drug name;*
- *Dosage form (e.g., tablets, capsules, inhalants);*
- *Exact strength or concentration;*
- *Dose, frequency, and route;*
- *Quantity and/or duration; when applicable*
- *Indication for use when appropriate (including orders for **PRN** administration and/or multiple uses of medication);*
- *Specific instructions for use (i.e. more than one medication for same use such as a pain, nausea);*
- *Name of prescriber.*

Hospitals should establish policies and procedures that:

- *Describe limitations or prohibitions on use of verbal/telephone orders;*

- *Provide a mechanism to ensure validity/authenticity of the prescriber;*
- *List the elements required for inclusion in a complete verbal/telephone order ;*
- *Describe situations in when verbal/telephone orders may be used;*
- *List and define the individuals who may send and receive verbal/telephone orders; and,*
- *Provide guidelines for clear and effective communication of verbal/telephone orders.*

If a hospital uses other written protocols or standing orders for drugs or biologicals that have been reviewed and approved by the medical staff, initiation of such protocols or standing orders requires an order from a practitioner responsible for the patient's care.

The entire verbal/telephone order should be written down and then repeated back to the prescriber and be signed by the individual receiving the order. Verbal orders must be documented in the patient's medical record, and be reviewed, countersigned, and timed by the prescriber as soon as possible.

Verbal/Telephone orders, when used, should be used infrequently. The hospital will work to continually reduce verbal/telephone orders.

Surveyor Guidance:

In a sampling of patient records, validate that all drug orders, including verbal orders, contain the elements as described in the Interpretive Guidelines for [MM.4](#) and are written in the patient charts and signed by the practitioner caring for the patient.

In a sampling of patient records, verify that the prescriber has reviewed and authenticated the orders in accordance with medical staff policy and/or applicable State laws.

Verify the process for authentication of verbal orders to ensure these are within the timeframes as stated according to Federal or State law. If there is not a State law in place, verify that these orders are authenticated within the timeframe in accordance with hospital policy.

Verify the process for handling of verbal orders and that measures are in place to effectively reduce [verbal orders](#) when possible.

MM.5 REVIEW OF MEDICATION ORDERS

A licensed pharmacist must review all medication orders prior to administration of the first dose to a patient. If [a licensed pharmacist is not available at the time of a first dose administration](#), the following shall occur:

- SR.1 The practitioner caring for the patient must determine the urgency of administration.
- SR.2 When a pharmacist is not available medications shall be retrieved from the pharmacy or [medication](#) storage area (including automated dispensing) only by licensed staff designated by the pharmacy service and approved by the medical staff, in accordance with principles of patient safety and Federal and State law.

- SR.3 The licensed individual that obtains the medication shall have an orientation to the storage area for the medication.
- SR.4 All high-risk medications in [the pharmacy or medication storage area](#) shall be segregated and unavailable.
- SR.5 There shall be a documented protocol requiring that this licensed individual have access to appropriate information to process the order in a formal manner. Information shall include:
- SR.5a potential drug-drug interactions;
 - SR.5b potential allergies or cross sensitivities;
 - SR.5c proper dose ranges;
 - SR.5d proper indications for administration; and,
 - SR.5e Other contraindications (pregnancy, breast feeding etc.).
- SR.6 [The licensed individual shall follow the pharmacy protocol for identification of the drug removed for verification of the drug by the pharmacist upon next arrival at the facility.](#)
- SR.7 The removal of the medication must be documented, tracked, and trended and the results analyzed to determine need for additional pharmacy staff or medication storage resources and appropriateness of any pharmacy after-hour practices, as appropriate.

Interpretive Guidelines:

All medication orders (except in emergency situations) should be reviewed for appropriateness by a pharmacist or doctor of medicine or osteopathy before the first dose is dispensed.

Review of medication orders should include:

- *Therapeutic appropriateness of a patient's medication regimen;*
- *Therapeutic duplication in the patient's medication regimen;*
- *Appropriateness of the drug, dose, frequency, route and method of administration;*
- *Real or potential medication-medication, medication-food, medication-laboratory test and medication-disease interactions;*
- *Real or potential allergies or sensitivities;*
- *Variation from organizational criteria for use; and,*
- *Other contraindications (pregnancy, breast feeding etc.)*

Note: 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 to enter the pharmacy. Policies and procedures should be consistent with Federal and State law.

When a pharmacist or doctor of medicine or osteopathy is not available and the pharmacy is closed, the hospital will define the process by a policy and procedure to ensure that following shall occur:

- *The practitioner caring for the patient must determine the urgency of administration;*
- *The medications shall be retrieved from the pharmacy or **medication** storage area only by licensed staff designated by the pharmacy service and approved by the medical staff, in accordance with principles of patient safety and Federal and State law; and,*
- *The licensed individual that obtains the medication shall have an orientation to the **medication** storage area.*

The hospital arranges for a qualified pharmacist to be available either on-call or at another location (e.g. at another organization that has 24-hour pharmacist availability) to answer questions or provide medications beyond those accessible to non-pharmacy staff;

Quality control procedures (such as an independent second check by another individual or a secondary verification built into the system, such as bar coding) are in place to prevent medication retrieval errors.

Medications can be stored in a night cabinet, automated storage and distribution device, or a limited section of the pharmacy;

*All high-risk medications in a **medication storage** area shall be segregated and unavailable;*

*There shall be a documented protocol requiring that the licensed individual **retrieving medication in the absence of a pharmacist** have access to appropriate information to process the **medication** order in a formal manner. Information shall include:*

- *Potential drug-drug interactions;*
- *Potential allergies or cross sensitivities;*
- *Proper dose ranges, and,*
- *Proper indications for administration.*

The licensed individual retrieving the medication shall follow the pharmacy protocol for identification of the drug removed for verification by the pharmacist upon next arrival at the facility.

The removal of the medication must be documented, tracked and trended and the results analyzed to determine need for additional pharmacy staff or medication storage resources and appropriateness of any pharmacy after-hour practices.

This process is continually evaluated to determine the medications accessed routinely and the causes of accessing the pharmacy after hours.

Corrective/Preventive action(s) are implemented as appropriate to reduce the amount of times non-pharmacist health care professionals are obtaining medications after the pharmacy is closed.

The effects of medication(s) on patients are monitored to assure medication therapy is appropriate and minimizes the occurrence of adverse events. That monitoring process includes:

- *Clinical and laboratory data to evaluate the efficacy of medication therapy to anticipate or evaluate toxicity and adverse effects;*
- *Physical signs and clinical symptoms relevant to the patient's medication therapy; and,*
- *Assessing the patient's own perceptions about side effects, and, when appropriate, perceived efficacy.*

Sterile products should be prepared and labeled in a suitable environment.

Surveyor Guidance:

Verify through a sampling of pharmacy records that documents the process 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.

Validate policies and procedures to determine who is designated to remove medications from the pharmacy or storage area and the amount a non-pharmacist may remove in the absence of a pharmacist. The individual(s) designated should be identified by name and have the appropriate qualifications.

Validate the system in place to ensure accurate documentation regarding the removal of medications (type and quantity) from pharmacy or the location where medications are stored after the pharmacy has closed.

Verify that a pharmacist or doctor of medicine or osteopathy reviews all medication removal activity and correlates the removal with current medication orders in the patient medication profile.

Review and validate that the pharmacy routinely reviews the contents of the after-hours supply to determine if it is adequate to meet the after-hours needs of the hospital and implements appropriate corrective/preventive action to minimize entry into the pharmacy after the pharmacy has closed.

MM.6 OVERSIGHT GROUP

- SR.1 The medical staff is responsible for developing policies and procedures that minimize drug errors. The medical staff may delegate this responsibility to an organized pharmacy oversight group.
- SR.2 There shall be procedures for reporting transfusion reactions, adverse drug reactions, and errors in prescribing, preparing, and administering of drugs, in the aggregate, for trending and analysis.
- SR.3 Drug preparation, administration, and prescribing errors, adverse drug reactions, and incompatibilities **must** be immediately reported to the attending physician and to the organization-wide quality management program.

Interpretive Guidelines:

Policies and procedures shall be developed with the involvement and approval of the medical staff in order to minimize medication errors, adverse drug reactions, and drug incompatibility.

The hospital will develop and implement procedures for reporting transfusion reactions, adverse drug reactions, and errors in prescribing, preparing, and administration of medications. These errors and reactions must be immediately reported to the patient's attending physician, or when appropriate the covering physician. When the covering physician is notified due to the attending physician not being available, the patient's attending physician must be notified as soon as he/she is available.

The hospital will document the information obtained from the errors and reactions reported and have a means for aggregating this information and related data to be trended and analyzed and continually evaluated in order to identify and implement corrective/preventive action.

The facility must have a method to measure the effectiveness of its reporting system to determine whether or not their system(s) is identifying as many medication errors and adverse drug reactions that would be expected for the size and scope of services provided by their hospital. Such methods could include use of established benchmarks or studies on reporting rates published in peer-reviewed journals.

To improve incident reporting, the facility should adopt a non-punitive system with the focus on the system and not the involved health care professionals.

Surveyor Guidance:

Verify that policies and procedures are developed in order to minimize medication errors, adverse drug reactions, and drug incompatibilities.

These policies and procedures must include the involvement and approval of the medical staff.

Validate 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.

In a sampling of records, review medication errors and adverse drug reactions to determine that they are reported immediately in accordance with written procedures, and that medications administered and/or drug reactions are promptly recorded in the patient's medical record.

Determine if the hospital's definition of an adverse drug reaction and medication error is based on established benchmarks or studies on report rate published in peer review journals and/or from other sources (i.e. ISMP).

To determine the effectiveness of the internal reporting mechanism, assess whether or not the identification of medication errors are as expected for the size and scope of services provided by the hospital. If the perception is such that medication errors are considered under-reported, determine the action(s) the hospital is taking to ensure accurate reporting of such errors. Also assess staff awareness of the internal reporting process when medication errors and adverse drug reactions are identified.

Verify the effectiveness of the reporting mechanism and the ability to retrieve data/information to be trended, analyzed, and evaluated in order to implement and determine the effectiveness of corrective/preventive action(s). Verify such information is forwarded to quality management oversight.

Assess through interviews with facility staff (nursing, pharmacy, and medicine) awareness of the facility's policy on reporting and documentation of medication errors and adverse drug reactions.

MM.7 AVAILABLE INFORMATION

Information relating to drug interactions and information on drug therapy, side effects, toxicology, dosage, indications for use, and routes of administration shall be available to the professional staff.

Surveyor Guidance:

Verify that the sources of drug information (including information relating to drug interactions and information on drug therapy, side effects, toxicology, dosage, indications for use, and routes of administration) are available to all professional staff.

SURGICAL SERVICES (SS)

SS.1 ORGANIZATION

- SR.1 If the organization provides surgical services, the services shall be well organized, appropriate to the scope of the services offered, and provided in accordance with acceptable standards of practice. National standards of practice of AORN, CDC, APIC, ASA, [AANA](#) and other professional organizations are applicable to surgical services.
- SR.2 If outpatient surgical services are offered, the services must be consistent in quality with inpatient care in accordance with the complexity of services offered.
- SR.3 Surgical care must be designed to assure the achievement and maintenance of high standards of medical practice and patient care, and must be consistent with needs and resources.

Interpretive Guidelines:

If the hospital provides any surgical services, they must be organized and staffed in such a manner to ensure the health and safety of patients and be in accordance with acceptable standards of practice. These standards of practice include the American College of Surgeons, Association of Operating Room Nurses (AORN), Centers for Disease Control (CDC), Association for Professionals in Infection Control and Epidemiology (APIC), American Society of Anesthesiologists (ASA), [American Association of Nurse Anesthetists \(AANA\)](#), and other professional organizations that are applicable to the scope and complexity of surgical services provided.

A surgery includes any procedure that is listed in any of the various coding systems used by CMS or hospital, regardless of reimbursement for the surgical procedure.

If the hospital provides outpatient surgical services, they must be in compliance with all hospital standards including the surgical services standards. These outpatient surgical services must be provided in accordance with acceptable standards of practice and in accordance with the complexity of services offered.

The hospital must design the surgical services to assure the standards of medical practice and patient care are implemented and maintained.

The hospital must develop and implement policies and procedures for providing surgical services that are in accordance with acceptable standards of medical practice and surgical patient care.

These policies and procedures shall include, at least the following:

- *Aseptic and sterile surveillance and practice, including scrub techniques;*
- *Identification of infected and non-infected cases;*
- *Housekeeping requirements/procedures;*
- *Duties of scrub and circulating nurse. These may be defined within a job descriptions, but may vary depending on the cases for which these staff members are involved;*
- *Conducting surgical counts in accordance with accepted standards of practice. The hospital will have a process in place to ensure that no foreign bodies are retained in patients following surgical procedures;*
- *The scheduling of patients for surgery;*
- *Patient care requirements:*
 - *Pre-operative testing*
 - *Clinical procedures*
 - *Patient identification procedure and site verification process*
- *Resuscitative techniques;*
- *How the DNR status is addressed when indicated in the patient's records;*
- *Handling, care and labeling procedures of surgical specimens;*
- *Malignant hyperthermia;*
- *Procedure-specific or in general protocols that are appropriate for all surgical procedures performed. This will include a list of equipment, materials, and supplies necessary to properly carry out the surgical services provided;*
- *Sterilization and disinfection procedures;*
- *Handling infectious and biomedical waste;*
- *Monitoring of temperature and humidity;*
- *Safety practices (fire safety, site marking, time-outs, etc.); and,*
- *Acceptable operating room attire.*

Surveyor Guidance:

Review and verify the extent of surgical services provided by the hospital and verify that services are in accordance with acceptable standards of practice. In order to do this appropriately, request the use of proper attire (gown, cap, and other attire as required by the hospital) to be worn during a physical tour during this review.

Review and validate policies and procedures to determine that minimum elements are addressed as specified in the Interpretive Guidelines [for SS.1](#).

Malignant hyperthermia rescue capability should be thoroughly assessed in those hospitals that perform a significant number of surgical procedures under general anesthesia.

Verify 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.

Verify 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, and that surgical costumes are designed for maximum skin and hair coverage.

Verify that the hospital has equipment available for rapid and routine sterilization of operating room materials and that the equipment used for this purpose is monitored, inspected, tested, and maintained by the hospital's biomedical equipment/clinical engineering program.

Verify that there is a process in place for handling sterilized materials and that these materials are packaged, 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.)

SS.2 STAFFING AND SUPERVISION

- SR.1 The organization of the surgical services shall be supervised by either a registered nurse with appropriate experience, or by a doctor of medicine or osteopathy.
- SR.2 Under the supervision of a registered nurse, the following personnel **may serve as "scrub nurses"**:
- SR.2a Registered nurses;
 - SR.2b Licensed practical nurses; and,
 - SR.2c Surgical technologists (operating room technicians).
- SR.3 Qualified registered nurses shall perform circulating duties in the operating room. If a qualified registered nurse is present who is immediately available to respond to emergencies, licensed practical nurses and surgical technologists may assist in circulatory duties under the supervision of that registered nurse, if State law and medical staff policies and procedures permit.

Interpretive Guidelines:

The hospital surgical services (including both inpatient and outpatient) must be supervised by an experienced RN or MD/DO. The RN or MD/DO supervising the operating room must possess appropriate education, experience working in surgical services, and specialized training in the provision of surgical services/management.

The hospital must provide the appropriate equipment and the types and numbers of qualified personnel necessary to furnish the surgical services offered by the hospital in accordance with acceptable standards of practice.

Qualified registered nurses must perform circulating duties in the operating room. If a qualified registered nurse is present in the operating suite who is immediately available to respond to emergencies, licensed practical nurses (LPN) and surgical technologists (ST) may assist in circulatory duties under the supervision of the registered nurse, if allowed by State law and medical staff policies and procedures.

Surveyor Guidance:

Review the hospital's organizational chart regarding surgical services to confirm that there are lines of authority and delegation of responsibility indicated within surgical services. Verify that an RN or a doctor of medicine or osteopathy is assigned responsibility for supervision of surgical services. Request a copy of the supervisor's position description to determine that it specifies qualifications, duties, and responsibilities of the position.

Determine and validate that an RN is available for supervision in the department or service.

Review and verify that the hospital maintains appropriate staffing schedules to provide adequate staff and RN supervision.

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.

SS.3 PRACTITIONER PRIVILEGES

- SR.1 All practitioners performing surgery shall have surgical privileges established by the organization's department of surgery and medical staff and approved by the governing body. Surgical privileges shall correspond with the established competencies of each practitioner.
- SR.2 A current roster of practitioners and their privileges shall be maintained by the department of surgery.
- SR.3 Privileges for general surgery and surgical subspecialties defined with established criteria approved by the medical staff and in accordance with MS.12.

Interpretive Guidelines:

All practitioners performing surgery shall have surgical privileges established by the organization's department of surgery and medical staff and approved by the governing body.

The medical staff bylaws must include criteria for determining the privileges to be granted to an individual practitioner and a procedure for applying the criteria to individuals requesting privileges. Core privileges for general surgery and surgical subspecialties are acceptable as long as the core is properly defined.

Surgical privileges shall correspond with the established competencies of each practitioner.

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 completed. The hospital will also be able to identify the surgeons with suspended surgical privileges or whose surgical privileges have been restricted and this information must also be retained in these areas/locations.

Surveyor Guidance:

Validate the hospital's method for reviewing practitioners' surgical privileges. This method should require verification of practitioner training, experience, health status, and performance.

Confirm that the hospital provides a current roster listing each practitioner's specific surgical privileges and that the roster is available in the surgical suite and the area where the scheduling of surgical procedures is done.

Verify that a current list of surgeons suspended from surgical privileges or who have restricted surgical privileges is retained in these areas/locations.

SS.4 HISTORY AND PHYSICAL

- SR.1 Except in emergencies, there must be a complete history and physical in the medical record of every patient prior to surgery or procedure requiring anesthesia services.
- SR.1a A complete history and physical examination must be completed and documented no more than 30 days before or 24 hours after admission or registration.
- SR.1b When the history and physical is completed within 30 days prior to admission or registration, an updated medical record entry documenting an examination for any changes in the patient's condition must be completed and documented in the patient's medical record within 24 hours after admission or registration, but prior to surgery or procedure requiring anesthesia services.
- SR.2 If the history and physical has been dictated but not yet present in the patient's medical record, the practitioner who admitted the patient shall write a statement to that effect as well as an admission note in the medical record. Such circumstance is acceptable only in a medical emergency and is not applicable for a scheduled surgery.
- SR.3 A properly executed informed consent form for the surgery shall be in the patient's medical record before surgery except in an extreme medical emergency.

Interpretive Guidelines:

There must be a complete H&P in the medical record of every patient prior to surgery, except in emergencies.

When an H&P has been conducted, but is not present on the chart prior to surgery, or in emergency situations where a complete H&P cannot be conducted prior to surgery, the practitioner who admitted the patient shall write a statement to that effect as well as an admission note in the medical record. The note should include, at a minimum, critical information about the patient's condition including pulmonary status, cardiovascular status, blood pressure, and vital signs.

The medical record must contain an H&P (as required for all inpatient and appropriate outpatient settings) and must be performed no more than 30 days prior to admission or registration or within 24 hours after admission by an authorized practitioner.

The H & P must be placed in the patient's medical record within 24 hours of admission. In the event that the H & P is completed prior to admission; the hospital must ensure that this H & P is updated to document any changes in the patient's condition.

The hospital will ensure that a properly executed informed written consent form for the surgical procedure(s) to be performed is signed by the patient or his/ her authorized representative prior to the surgical procedure. The only exception is an extreme emergency.

The informed consent form shall include at least the following: description of the proposed surgery, including anesthesia to be used, an explanation of the nature and purpose of the proposed procedures; risks and consequences of the procedures; risks and prognosis if no treatment is rendered, the probability that the proposed procedure will be successful; and, alternative methods of treatment (if any) and their associated risks and benefits. Furthermore, informed consent would include that the patient is informed as to who will actually perform the surgical procedure(s). When practitioners other than the primary surgeon will perform important components of the surgical procedure(s) the patient must be informed of the identity of these other practitioners and the components these practitioners are expected to perform. The identity of these other practitioners must be disclosed even when these practitioners are working under the primary surgeon's supervision.

The hospital's surgical informed consent policy should describe the following:

- Who may obtain the patient's informed consent*
- Which procedures require informed consent*
- The circumstances under which surgery is considered an emergency and may be undertaken without an informed consent*
- The circumstances when a patient's representative, rather than the patient, may give informed consent for surgery*
- The content of the informed consent form and instructions for completion*
- The process used to obtain informed consent, including how the informed consent is to be documented in the medical record*
- Mechanisms that ensure that the informed consent form is properly executed and is in the medical record prior to surgery (except in the case of an emergency)*

- *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*

For surgeries in which residents will perform important parts of the surgery, discussion is encouraged with the patient or their representative to include the following:

- *That it is anticipated that physicians who are in approved post graduate residency training programs will perform portions of the surgery, based upon their availability and level of competence.*
- *That it will be decided at the time of the surgery which residents will participate and their manner of participation, and that this will depend on the availability of the residents with the necessary competence; knowledge that the operating practitioner/teaching surgeon has of the resident's skill set; and the patient's condition.*
- *That residents performing surgical tasks will be under the supervision of the operating practitioner/teaching surgeon.*
- *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.*

Surveyor Guidance:

*In a sampling of medical records of surgical patients, determine if a complete history and physical examination by a doctor of medicine or osteopathy **or qualified licensed practitioner** is completed prior to surgery, except in an emergency, and in accordance with the methodology described above.*

Verify that the completion of an H&P was within the specified time frame and appropriate documentation noted.

Verify the content and completeness of the H&P per organization policy:

- *In some cases the organization may accept an H&P that has been completed in the practitioner's office. When this is allowed, verify the process for ensuring that the appropriate documentation is present and completed per the requirements of the organization and the H&P was completed within the required timeframe.*

Verify that an H&P was completed no more than 30 days before or 24 hours after admission or registration and in all cases involving surgery or procedures requiring anesthesia services or moderate/conscious sedation prior to the surgery or procedure.

*Verify **that** documentation of an H&P was placed in the medical record within 24 hours after admission or registration, and in all cases involving surgery or procedures requiring anesthesia services or moderate/conscious sedation prior to the surgery or procedure.*

Where an H&P is completed within 30 days before admission or registration and in all cases involving surgery or procedures requiring anesthesia services or moderate/conscious sedation, the hospital must ensure that this H&P is updated to document any changes in the patient's condition.

- *If there are no changes to the H&P as written, the physician **or qualified licensed practitioner** can simply document an update note stating **that**:*
 - *The H&P has been reviewed,*
 - *The patient has been examined, and,*
 - *The physician **or qualified licensed practitioner** concurs with the findings of the H&P completed on the specified date or that “no change” has occurred in the patient's condition since the H&P was completed.*

In a sampling of medical records of surgical patients, verify that informed written consent forms are present, have been properly executed, and are present in the patient's medical record prior to surgery.

Ascertain that the completed forms contain at least the information specified in the Interpretive Guidelines.

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.

SS.5 AVAILABLE EQUIPMENT

The following equipment shall be present and in operating condition and immediately available to each surgical suite:

- SR.1 Call-in system;
- SR.2 Cardiac monitor;
- SR.3 Resuscitator;
- SR.4 Defibrillator;
- SR.5 Suction equipment;
- SR.6 Provisions for emergency airway intervention; and,
- SR.7 Malignant Hyperthermia (MH) rescue materials:

SR.7a 36 vials of Dantrolene must be available for all anesthetizing locations within 10 minutes of the decision to treat for MH;

SR.7b Dantrolene must be available for all anesthetizing locations where MH trigger agents are used; and,

SR.7c Required components to safely administer Dantrolene must be readily accessible.

Interpretive Guidelines:

All facilities, including ambulatory surgery centers and offices, where MH triggering anesthetics (i.e, Isoflurane, Desflurane, Sevoflurane, Enflurane, Halothane, and Succinylcholine) are administered, should stock a minimum of 36 vials of Dantrolene, along with the other drugs and devices necessary to treat an MH reaction. If none of these agents are ever in use in the facility, then Dantrolene need not be kept on hand.

It is often not practical to have a large supply of Dantrolene in every area where anesthesia is administered. For example, anesthesia administration is now common in locations far from the operating rooms such as interventional radiology suites. Dantrolene must be available within 10 minutes.

This new guideline follows the recommendations of the Malignant Hyperthermia Association of the United States (MHAUS).

Surveyor Guidance:

Review and verify that the hospital has equipment immediately available to each surgical suite to include, at least, those items as listed in [SS.5](#), SR.1 – SR.7.

Validate that all equipment is working as intended and is maintained, inspected, and tested by the hospital's biomedical/clinical engineering department or contracted service.

Verify that a tracheotomy set is available (a cricothyroidotomy set should not be considered a substitute for this set).

SS.6 OPERATING ROOM REGISTER

The operating room register shall be complete and current.

Interpretive Guidelines:

The operating room register will include at least the following information:

- *Patient's name;*
- *Patient's hospital identification number;*
- *Date of the operation/procedure;*
- *Inclusive or total time of the operation/procedure;*
- *Name of the surgeon and any assistant(s);*

- *Name of nursing personnel (scrub and circulating);*
- *Type of anesthesia used and name of the administering practitioner;*
- *Operation/procedure performed;*
- *Pre and post-op diagnosis; and,*
- *Age of patient.*

Surveyor Guidance:

Review and validate the OR register or equivalent record to ensure that it lists all surgery performed by the surgical services and includes the elements as listed in the Interpretive Guidelines for SS.6.

SS.7 POST-OPERATIVE CARE

SR.1 There shall be adequate provision for immediate post-operative care.

SR.2 Equipment, clinical staff, and plan of care provisions as well as criteria for discharge shall be developed and adopted by the medical staff and nurse executive designees.

Interpretive Guidelines:

The hospital will make adequate provisions for immediate post-operative care. These provisions will include:

- *Post-operative care is provided in accordance with acceptable standards of practice; and,*
- *The post-operative care area or recovery room is a separate area of the hospital.*
- *Access is limited to authorized personnel.*

The hospital will provide the appropriate equipment and clinical staff to adequately address the patients' plan of care appropriate to the complexity of services provided. The hospital will develop criteria for the discharge from the post-operative care area that have been approved by the medical staff and nurse executive.

Prior to discharge, the hospital must ensure that the patient has met the appropriate criteria for discharge and that the patient has an order for discharge from the patient's surgeon or practitioner.

If patients are not transferred to the post-operative care area, there must be provisions for direct observation of the patient by a qualified nurse in the patient's room to ensure there is a comparable level of care during the recovery phase.

Surveyor Guidance:

Review and validate the process and provisions for post-operative care, including discharge criteria.

Review and verify that the hospital provides the appropriate equipment and clinical staff to adequately address the patient's plan of care appropriate to the complexity of services provided.

SS.8 OPERATIVE REPORT

- SR.1 An operative report describing techniques, findings, and tissues removed or altered shall be dictated or **documented, and authenticated** by the surgeon immediately following surgery.
- SR.2 The operative report shall be dictated or **documented and authenticated** in its entirety before the patient is transferred to the next level of care (e.g., before the patient leaves the post anesthesia care area).
- SR.3 In the event that an operative report cannot be dictated and placed on the patients chart before transfer to the next level of care, an immediate postoperative/post procedure note is required to be **documented**. **The note** shall include identification or description of:
- SR.3a The surgeon and assistants;
 - SR.3b Pre-operative and post-operative diagnosis;
 - SR.3c Procedures performed;
 - SR.3d Specimens removed;
 - SR.3e Estimated blood loss (blood administered as needed - may indicate where in chart for detail);
 - SR.3f Complications (if any encountered);
 - SR.3g Type of anesthesia administered; and,
 - SR.3h Grafts or implants (may indicate where in chart for detail).
- SR.4 If information identified in the immediate post-operative/post procedure note is available in nursing documentation; it is acceptable if authenticated as accurate by the attending surgeon

Interpretive Guidelines:

*An operative report must be dictated or **documented and authenticated** by the surgeon immediately following surgery and before the patient is transferred to the next level of care. The operative report will contain at least the following:*

- *Name and hospital identification number of the patient;*
- *Date and times of the surgery;*
- *Name(s) of the surgeon(s) and assistants or other practitioners who performed surgical tasks (even when performing those tasks under supervision);*
- *Pre-operative and post-operative diagnosis;*
- *Name of the specific surgical procedure(s) performed;*
- *Type of anesthesia administered;*
- *Complications;*
- *A description of techniques, findings, and tissues removed or altered;*
- *Surgeons or practitioners name(s) and a description of the 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); and,*
- *Prosthetic devices, grafts, tissues, transplants, or devices implanted.*

Surveyor Guidance:

*In a sampling of surgical patients' medical records, validate that the records contain an operative report that includes the information specified in the Interpretive Guidelines **for SS.8**.*

ANESTHESIA SERVICES (AS)

AS.1 ORGANIZATION

SR 1 Anesthesia services shall be provided in an organized manner, and function under the direction of a qualified doctor of medicine or osteopathy. The anesthesia service is responsible for all anesthesia services provided throughout the hospital (including all departments in all campuses and off site locations. Areas where anesthesia services are furnished may include (but are not limited to):

- Operating room suites, both in patient and out patient
- Obstetrical suites
- Radiology department
- Clinics
- Emergency department
- Psychiatry department
- Special procedure areas (endoscopy, pain management clinics, etc.)

SR 2 Anesthesia services shall be appropriate to the scope of the services offered.

Interpretive Guidelines:

The hospital may or may not offer anesthesia/sedation services. If a hospital does provide any degree of anesthesia/sedation service to its patients, these services will be provided in an organized manner. The anesthesia/sedation services will be offered under the direction of a qualified doctor of medicine or osteopathy. This individual will be responsible for all anesthesia/sedation administered throughout the hospital.

“Anesthesia” involves the administration of a medication to produce a blunting or loss of:

- *Pain perception (analgesia);*
- *Voluntary and involuntary movements;*
- *Autonomic function; and,*
- *Memory and/or consciousness, depending on where along the central neuraxial (brain and spinal cord) the medication is delivered.*

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.

“Anesthesia services” in a hospital is subject to the anesthesia administration requirements.

The additional definitions below illustrate differences among the various types of anesthesia services. Not all of the definitions are considered “anesthesia.” The definitions are generally based on American Society of Anesthesiologists definitions found in its most recent set of practice guidelines.

- *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;*
- *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 the qualified practitioner.*

The administration of medication via an epidural or spinal route for the purpose of analgesia, during labor and delivery, is not considered anesthesia and therefore is not subject to the anesthesia supervision requirements. However, if the obstetrician or other qualified physician attending to the patient determines that an operative delivery (i.e., C-section) of the infant is necessary, it is likely that the subsequent administration of medication is for anesthesia, as defined above, and the anesthesia supervision requirements would apply.

- *Monitored anesthesia care (MAC): anesthesia care that includes the monitoring of the patient by a practitioner who is qualified to administer anesthesia. 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.*
- *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 impaired. Patients may require assistance in maintaining a patent airway, and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained. An example of deep sedation would be a screening colonoscopy when there is a decision to use Propofol, so as to decrease movement and improve visualization for this type of invasive procedure. 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 qualified practitioner as specified.*

"Anesthesia services" in a hospital NOT subject to the anesthesia administration and supervision requirements:

- *Topical or local anesthesia;*

- *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. For example, a patient undergoing an MRI or CT scan may receive minimal sedation with an oral medication to decrease the anxiety while undergoing these types of radiologic examinations;*
- *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. For example, a patient undergoing the reduction of a dislocated large joint (shoulder) may require this form of sedation to tolerate the procedure.*

Rescue Capacity: Because sedation is a continuum, it is not always possible to predict how an individual patient will respond. Hence, the hospital 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 (ACLS, ATLS, PALS, etc.) 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.

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, under the direction of a qualified doctor of medicine (MD) or doctor of osteopathy (DO). 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; and*
- *Special procedures areas (e.g., endoscopy suite, pain management clinic, etc.).*

The hospital’s medical staff establishes criteria for the qualifications for the director of the anesthesia services in accordance with State laws and acceptable standards of practice. The anesthesia service is responsible for developing policies and procedures governing the provision of all categories of anesthesia services, including specifying the minimum qualifications for each category of practitioner who is permitted to provide anesthesia services that are not subject to the anesthesia administration requirements.

A well-organized anesthesia service must be integrated into the hospital's quality management system, in order to assure the provision of safe care to patients.

Surveyor Guidance:

Verify that a qualified physician is responsible for the direction of all anesthesia/sedation services offered hospital-wide. This may include, but is not limited to:

- *Surgical Services – for inpatient and outpatient surgical services (including Endoscopy and other outpatient settings);*
- *Obstetrical and Gynecological Services;*
- *Emergency Department;*
- *Medical Imaging and Nuclear Medicine Services; and,*
- *Outpatient Clinics or other settings where anesthesia/sedation services are provided.*

Review the defined scope of responsibilities or similar documentation that describes this role within the hospital. This individual will be responsible for planning, directing and monitoring all anesthesia/sedation services. The other responsibilities will encompass the implementation of staffing schedules (including on-call services).

Review the criteria and qualifications for physicians and other practitioners for attaining privileges for administering anesthesia/sedation (sample various physicians and practitioners with these privileges). This is most commonly located within the Medical Staff Bylaws or in a separate policy that governs these activities. Verify that these privileges have been granted in accordance with the physician or practitioner's scope of practice, State law, and that the criteria and qualifications include competencies, training, education and (if required) experience regarding the administration of anesthesia/sedation.

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.

Determine that there is documentation of current licensure or current certification status for all persons administering anesthesia.

Determine that there is documentation of current licensure and, as applicable, current certification for all persons administering anesthesia.

Determine if the state is an "opt-out state" and therefore permits CRNAs to administer anesthesia without supervision.

Review the hospital's policies and procedures governing supervision of CRNA's and anesthesiologist's assistants and determine whether they comply with the regulatory requirements.

Review the qualifications of individuals authorized to furnish other anesthesia services, to determine if they are consistent with the hospital's anesthesia service policies.

Verify that the anesthesia/sedation services are planned and organized in a manner in which these services are continuously monitored, and appropriate to the scope of services offered.

Verify that anesthesia/sedation services are under the direction of a doctor of medicine or osteopathy.

In most cases, the physician responsible for the direction of these services will be an anesthesiologist. In the event it is not an anesthesiologist, review the qualifications of the physician responsible for these services to see that he or she is qualified to do so and has been appointed by the medical staff and governing body.

Verify that anesthesia services are integrated into the hospital's quality management system oversight.

AS.2 ADMINISTRATION

Anesthesia shall only be administered by the following:

- SR.1 A qualified anesthesiologist or a doctor of medicine or osteopathy (other than an anesthesiologist);
- SR.2 A dentist, oral surgeon, or podiatrist who is qualified to administer anesthesia under State law;
- SR.3 A certified registered nurse anesthetist (CRNA) as defined in 42 CFR §410.69(b), who is under the supervision of the operating practitioner or of an anesthesiologist who is immediately available if needed;
- SR.4 For CRNAs [to be exempt from the CMS supervision requirement](#), the governor of the State must have received an exemption from CMS for that particular State;
- SR.5 An anesthesiologist's assistant as defined in 42 CFR §410.69(b), if approved by State law, who is under the supervision of an anesthesiologist who is immediately available if needed.
- SR.6 If anesthesia services are provided for labor and delivery, the same standard of coverage as that of operating room anesthesia will be provided and comply with the recommendations of the American Society of Anesthesiology.
- SR.7 If a patient has received epidural analgesia, there will be a [physician or other qualified licensed practitioner](#) immediately available to manage any complication for the analgesia or the specific obstetrical condition.

Interpretive Guidelines:

The hospital's medical staff will define the criteria and qualifications for those physicians who have privileges for administering anesthesia/sedation in accordance with State laws and acceptable standards of practice.

AS.2, SR.1 – SR.5 defines those physicians and other practitioners who can administer anesthesia/sedation.

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 for any type of anesthesia services, including those not subject to the anesthesia administration requirements. The hospital's governing body (or individual responsible) 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 privileges granted to the individual practitioner.

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.

Who May Administer Anesthesia, Topical/ Local Anesthetics, Minimal Sedation, or Moderate Sedation:

The requirements 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. Further, the hospital must assure that all anesthesia services are provided in a safe, well-organized manner by qualified personnel.

General anesthesia, regional anesthesia and monitored anesthesia, including deep sedation/analgesia, may only be administered by:

- *A qualified anesthesiologist;*
- *An MD or DO (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 (for CRNAs [to be exempt from the CMS supervision requirement](#), the governor of the State must have received an exemption from CMS for that particular State); or,
- An anesthesiologist's assistant under the supervision of an anesthesiologist who is immediately available if needed.

Administration by an MD/DO/dentist/oral surgeon/podiatrist

The hospitals anesthesia services policies must address the circumstances under which an MD or DO 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. The hospital should conform to generally accepted standards of anesthesia care when establishing policies governing anesthesia administration by these types of practitioners as well as MDs or DOs who are not anesthesiologists.

Administration by a CRNA

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.

The hospital should conform to generally accepted standards of anesthesia care when establishing policies for supervision by the operating practitioner. 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 suite, or in the same labor and delivery unit, or in the same procedure room, and not otherwise occupied in a way that prevents him/her from immediately conducting hands-on intervention, if needed.

If the hospital is located in a State where law or regulation permits or 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 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.aana.com/advocacy/stategovernmentaffairs/Pages/Federal-Supervision-Rule-Opt-Out-Information.aspx>

A CRNA is defined in [42 CFR §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 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 direct 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 suite, or in the same labor and delivery unit, or in the same procedure room, 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 in [42 CFR §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 non-physician 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.”

Surveyor Guidance:

Verify that a qualified physician is responsible for the direction of all anesthesia/sedation services offered hospital-wide. This may include, but is not limited to:

- *Surgical Services – for inpatient and outpatient surgical services (including Endoscopy and other outpatient settings);*
- *Obstetrical and Gynecological Services;*
- *Emergency Department;*
- *Medical Imaging and Nuclear Medicine Services; and,*
- *Outpatient Clinics or other settings where anesthesia/sedation services are provided.*

Review the defined scope of responsibilities or similar documentation that describes this role within the hospital. This individual will be responsible for planning, directing and monitoring all anesthesia/sedation services. The other responsibilities will encompass the implementation of staffing schedules (including on-call services).

Review the criteria and qualifications for physicians and other practitioners for attaining privileges for administering anesthesia/sedation (sample various physicians and practitioners with these privileges). This is most commonly located within the Medical Staff Bylaws or in a separate policy that governs these activities.

Verify that these privileges have been granted in accordance with the physician or practitioner's scope of practice, State law, and that the criteria and qualifications include competencies, training, education and (if required) experience regarding the administration of anesthesia/sedation.

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.

Determine that there is documentation of current licensure or current certification status for all persons administering anesthesia.

Determine that there is documentation of current licensure and, as applicable, current certification for all persons administering anesthesia.

Determine if the state is an "opt-out state" and therefore permits CRNAs to administer anesthesia without supervision in accordance with CMS CoP 482.52(c).

Review the hospital's policies and procedures governing supervision of CRNA's and anesthesiologist's assistants and determine whether they comply with the regulatory requirements.

Review the qualifications of individuals authorized to furnish other anesthesia services, to determine if they are consistent with the hospital's anesthesia service policies.

AS.3 POLICIES AND PROCEDURES

SR.1 Anesthesia services must be consistent with the needs and resources of the organization. Policies on anesthesia/sedation procedures must include the delineation of pre-anesthesia and post-anesthesia responsibilities.

SR.2 The policies must ensure that the following are provided for each patient:

SR.2a A pre-anesthesia evaluation must be performed for each patient who will receive general, regional or monitored anesthesia. Patients who will be receiving moderate sedation must be monitored and evaluated before, during and after a procedure by a trained practitioner, however a pre anesthesia evaluation is not required because moderate sedation is not considered to be "anesthesia" and is not subject to this requirement.

SR.2b A pre- anesthesia evaluation shall include;

SR.2b (1) A review of the medical history,

SR.2b (2) An interview and examination of the patient,

SR.2b (3) A documented airway assessment,

SR.2b (4) An anesthesia risk assessment, and

SR.2b (5) An anesthesia, drug and allergy history,

SR.2b (6) Performed by an individual, qualified, and privileged to administer anesthesia/sedation, within 48 hours prior to inpatient or outpatient surgery or procedure requiring anesthesia services. (Delivery of the first dose of medications for the purpose of inducing anesthesia marks the end of the 48 hour time frame).

SR.2c An intra-operative anesthesia record must be present for each patient who will receive general, regional or monitored anesthesia. Patients who will be receiving moderate sedation must be monitored and evaluated before, during and after a procedure by a trained practitioner, however an intra-operative anesthesia record is not required because moderate sedation is not considered to be “anesthesia” and is not subject to this requirement.

SR.2d For inpatient and outpatient surgery, a post-anesthesia evaluation for proper anesthesia recovery is completed and documented within 48 hours after surgery by the individual who administers the anesthesia or, if approved by the medical staff, by any individual qualified and credentialed to administer anesthesia

SR.2d(1) The elements of an adequate post-anesthesia evaluation should be clearly documented and conform to current standards of anesthesia care, including:

- Respiratory function, including respiratory rate, airway patency, and oxygen saturation;
- Cardiovascular function, including pulse rate and blood pressure;
- Mental status;
- Temperature;
- Pain;
- Nausea and vomiting; and
- Postoperative hydration.

Depending on the specific surgery or procedure performed, additional types of monitoring and assessment may be necessary.

SR.2d(2) A post-anesthesia evaluation for anesthesia recovery is required for each patient who will receive general, regional or monitored anesthesia.

Patients who will be receiving moderate sedation must be monitored and evaluated before, during and after a procedure by a trained practitioner, however, a post-anesthesia evaluation is not required because moderate sedation is not considered to be “anesthesia” and is not subject to this requirement.

SR.2d(3) 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 documented sooner than 48 hours. This should be addressed by hospital policies and procedures.

Interpretive Guidelines:

The hospital must develop and implement policies and procedures regarding the administration of anesthesia/sedation. This will include the responsibilities for both pre-anesthesia/sedation and post-anesthesia/sedation. These policies and procedures must address the following:

- *Pre-anesthesia/sedation responsibilities:*
 - *Physical examination of the airway (by those qualified and privileged to administer sedation) must be performed within 48 hours of administration of anesthesia/sedation;*
 - *Assessment of risk to the patient for receiving anesthesia/sedation; (within 30 days/update within 48 hours)*
 - *Drug and allergy history regarding anesthesia/sedation; (within 48 hours of induction)*
 - *Physical condition of the patient prior to induction of anesthesia/sedation; (within 48 hours of induction)*
 - *Patient consent for administration of anesthesia/sedation;*
 - *Equipment requirements, as well as the monitoring, inspection, testing and maintenance of anesthesia/sedation equipment in the hospital's biomedical equipment program;*
 - *Infection control practices in place; and,*
 - *Safety measures in place in areas where anesthesia/sedation is administered (including a protocol for supportive life functions, e.g., cardiac and respiratory emergencies.*

- *Reporting and documentation requirements*
 - *Intra-operative anesthesia/sedation/sedation record including:*
 - *Name and hospital identification number of the patient;*
 - *Name(s) of practitioner(s) who administered anesthesia/sedation, and as applicable, the name and profession of the supervising anesthesiologist or operating practitioner;*
 - *Name, dosage, route and time of administration of drugs and anesthesia/sedation agents;*
 - *Techniques used and patient position(s), including the insertion of any intravascular or airway devices*
 - *Name and amount of IV fluids;*
 - *Blood or blood products; if applicable*
 - *Time-based documentation of vital signs as well as oxygenation and ventilation parameters ;*
 - *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.*
 - *Post-anesthesia/sedation follow-up report including:*
 - *Cardiopulmonary status;*
 - *Level of consciousness;*
 - *Any follow-up care and/or observations;*
 - *Any complications occurring during post-anesthesia/sedation recovery; and,*
 - *Any follow-up care needed or patient instructions given.*

Note: This report must be completed and documented within 48 hours following the procedure in which anesthesia/sedation has been administered.

Surveyor Guidance:

Review the policies developed on anesthesia/sedation procedures.

Verify that the anesthesia/sedation services where provided incorporates that has been listed in interpretive guidelines.

Sample patient medical records to verify the following:

- *Pre-anesthesia/sedation evaluation that includes all of the defined elements*
- *An intra-operative anesthesia/sedation record documenting all pertinent events taking place during anesthesia/sedation that includes all of the defined elements*
- *A post-anesthesia/sedation follow-up report is written for each patient by an individual who is qualified to administer anesthesia, within 48 hours after surgery. Verify that this report includes all of the defined elements .*
- *A post-anesthesia/sedation evaluation for proper anesthesia/sedation recovery in accordance with hospital policies and procedures. Verify that this evaluation includes those items stated within the interpretive guidelines.*

*Verify that **the** post-anesthesia evaluation is completed by **an** individual qualified and credentialed to administer anesthesia and in accordance with State law and hospital policies and procedures approved by the medical staff.*

LABORATORY SERVICES (LS)

LS.1 ORGANIZATION

- SR.1 The organization shall maintain, or have available, adequate laboratory services, either directly or through contractual services, to meet the needs of its patients.
- SR.2 The organization shall ensure that all laboratory services provided to its patients are performed in a laboratory certified in accordance with 42 CFR §493.
- SR.3 The organization shall have the capability to perform emergency laboratory services 24 hours a day.
- SR.4 A documented scope of laboratory services shall be available to the medical staff.
- SR.5 The laboratory shall have policies and practices for proper receipt and reporting of tissue specimens.
- SR.6 The medical staff and a pathologist shall determine which tissue specimens require a macroscopic (gross) examination and which require both macroscopic and microscopic examinations.

Interpretive Guidelines:

The hospital must maintain, or have available, adequate laboratory services whenever its patients need those services. The hospital may maintain laboratory services at the hospital or may make laboratory services available through contractual agreements. All laboratory services will be provided in a laboratory that has been certified in accordance with 42 C.F.R. §493.

The hospital will have a documented scope and complexity of the laboratory services available. This will include the capability to perform necessary laboratory studies, including blood gas analysis and electrolyte determination 24 hours a day. Whether provided directly or through a contractual arrangement, these services must be provided in accordance with Clinical Laboratory Improvement Act (CLIA) requirements. The hospital shall have a current CLIA certificate appropriate to the level of services performed.

The medical staff and a pathologist shall determine which tissue specimens require a macroscopic (gross) examination for both macroscopic and microscopic examinations. There will be documented policies and practices for proper receipt and reporting of tissue specimens.

Surveyor Guidance:

Determine the total number of laboratories, the location of each laboratory, and every location where laboratory procedures are performed.

Determine which services are provided directly by the facility and which are provided through contractual arrangements. If provided under a contractual arrangement, verify that the provider has been approved by the medical staff and governing body.

Validate that the laboratory services are provided are operating under a current CLIA certificate.

Review a sampling of records and determine if the services, including emergency services, are provided in accordance with the hospital's policies.

Review a sampling of tissue records (accession records, worksheets, and test reports) to verify whether the laboratory follows the written protocol.

Review the written policies and tissue reports to assure that tissue specimens are examined in accordance with the written policies.

LS.2 POTENTIALLY INFECTIOUS BLOOD AND PRODUCTS

Potentially infectious blood (such as human immunodeficiency virus (HIV) or hepatitis C virus (HVC) and blood products (as identified in 21 CFR 610.47) can come from prior collections from a donor who: tested negative at the time of donation but tests repeatedly reactive for the antibody to the HIV or HCV on a later donation, tests positive on the FDA-licensed, more specific test or other follow up testing recommended or required by FDA, and the timing of seroconversion cannot be precisely estimated.

- SR.1 If an organization regularly uses the services of an outside blood bank, it shall have an agreement with the blood bank that governs the procurement, transfer, and availability of blood and blood products.
- SR.2 The agreement shall require that the blood bank promptly notify the organization of the following:
 - SR.2a Within three calendar days if the blood bank supplied blood and blood products collected from a donor who tested negative at the time of donation but tests repeatedly reactive for the antibody to HIV or HCV on a later donation; and,
 - SR.2b The results of the FDA licensed more specific test or other follow-up testing recommended or required by the FDA completed within 45 calendar days after the donor's repeatedly reactive screening test for HIV or HCV.
 - SR.2c Within 3 calendar days after the blood bank supplied blood and blood components collected from an infectious donor, whenever such records are available (as set forth at 21 CFR 610.48(b)(3)).
 - SR.2d Quarantine of blood and blood products pending completion of testing: If the blood bank notifies the organization of the repeatedly reactive HIV or HCV screening test results, the organization shall determine the disposition of the

blood or blood product and quarantine all blood and blood products from previous donations in inventory.

- SR.3 If the blood bank notifies the organization that the result of the FDA-licensed, more specific test or other follow up testing recommended or required by FDA is negative, absent other informative test results, the organization may release the blood and blood products from quarantine.
- SR.4. If the blood bank notifies the organization that the result of the FDA-licensed, more specific test or other follow up testing recommended or required by FDA is positive, the organization shall dispose of the blood and blood products in accordance with 21 CFR §606.40 and notify the transfusion recipients according to LS.3.
- SR.5 If the blood bank notifies the organization that the result of the FDA-licensed, more specific test or other follow up testing recommended or required by FDA is indeterminate, the organization must destroy or label prior collections of blood and blood products held in quarantine (as set forth at 21 CFR 610.46(b)(2), 610.47(b)(2), and 610.48(c)(2)).
- SR.6 The hospital must maintain adequate records which identify the source and disposition of all units of blood and blood components for no less than 10 years from the date of disposition in manner reflecting QM.2, SR.3b and are stored in such a manner they are available for prompt retrieval.
- SR.6a The organization will have a plan in place to transfer these records to another hospital or other entity if the hospital ceases its operations for any reason. The organization will have allocated adequate funding to execute this plan when necessary.

Interpretive Guidelines:

This standard requires that the hospital have a system in place to take appropriate action when notified that blood or blood products received are at increased risk of transmitting potential human immunodeficiency virus (HIV) or hepatitis C virus (HCV).

Definition: The timeframe, also referred to as the “window period”, is defined as that period early in infection when the antibody to HIV or HCV is not detectable by the screening test.

Definition: The term “repeatedly reactive” means that the initial HIV or HCV antibody screening test is reactive, re-tested in duplicate, and one or both of the duplicate tests are reactive. If repeatedly reactive, a licensed, more specific (confirmatory) test (e.g. Western Blot) is used to confirm the presence of HIV or HCV.

Definition: “Look back” is considered to include: the quarantine of products from a window period donor; notification of consignees (facilities having received such window period products) to quarantine those products; and on completion of the licensed, more specific (confirmatory) test, notification of any transfusion recipient.

Despite the best practices of blood banks, a person may have donated blood during the window period. If the donor attempts to donate blood at a later date, the screening test for the antibody to HIV or HCV may, at that time, be repeatedly reactive. Under such circumstances, previously collected blood and blood products would be at increased risk for transmitting HIV or HCV and a recipient of blood or blood products collected during the window period would not know whether the donor was infected with HIV or HCV at the time of the previous donations.

If the hospital regularly uses the services of an outside blood bank, it shall have an agreement with the blood bank to govern the procurement, transfer, and availability of blood and blood products. This applies to hospitals that receive blood and blood products from an outside source and only performs compatibility (cross match) testing in preparation for transfusion to patients.

The agreement(s) and practice policies developed between the hospital and blood bank must be consistent with applicable Federal, State, and local laws, and written with the means of addressing any changes in FDA or CMS requirements and can be incorporated into operating procedures rather than by constructing a new agreement.

Under certain circumstances, such as blood availability emergencies, hospitals may receive blood from a source other than the contracted blood bank. FDA regulations require a blood bank to notify the hospital in the event it furnished the hospital with potentially HIV or HCV infected blood.

The agreement between the notification process and procedure shall include the elements as stated in LS.2, SR.2(a) – SR.2(c).

If the blood bank notifies the organization that the result of the FDA-licensed, more specific test or other follow up testing recommended or required by FDA is negative, absent other informative test results, the organization may release the blood and blood products from quarantine.

- The hospital's policy should reflect that release (from quarantine) of potentially HIV or HCV infected blood is possible only if the more specific (confirmatory) test is negative, and the blood bank's (the facility that notified the hospital) records show the donor has no other informative test results that show evidence of HIV or HCV infection. "Other" informative tests are tests that a blood bank may voluntarily perform (e.g. HIV antigen tests, viral cultures).*

If the blood bank notifies the organization that the result of the FDA-licensed, more specific test or other follow up testing recommended or required by FDA is positive, the organization shall dispose of the blood and blood products in accordance with 21 C.F.R. §606.40.

- If these tests are positive, the blood and blood products are disposed of if still available. The blood bank will communicate this information to the hospital. If no other informative test results exist, the hospital may release the blood and blood products from quarantine. If other informative test results exist that indicate possible HIV infection, the hospital must dispose of the blood and blood products.*

Surveyor Guidance:

The hospital's laboratory will be determined to be in compliance with the requirements of LS.2 if the hospital's laboratory maintains current accreditation by the College of American Pathology (CAP) or Commission on Office Laboratory Accreditation (COLA). If the hospital laboratory is not CAP or COLA Accredited, then the following must be verified:

Validate that the written agreement with the blood bank allows for notification expectations (per LS.2, SR.2) and approval by an appropriate hospital representative.

Verify the hospital's policy for labeling and quarantining potentially HIV or HCV infected blood and blood products.

Validate the procedure for the disposal of infected blood products, when warranted.

Verify the procedure followed when the hospital is notified that it had received potentially infectious blood and blood products.

Verify that the hospital policy addresses the notification process when it receives potentially HIV or HCV infectious blood or blood products.

Verify that the hospital maintains adequate records which identify the source and disposition of all units of blood and blood components for no less than 10 years from the date of disposition in manner reflecting QM.2, SR.3b and are stored in such a manner they are available for prompt retrieval.

Verify that the organization has a plan in place to transfer these records to another hospital or other entity if the hospital ceases its operations for any reason and that the organization has allocated adequate funding to execute this plan when necessary.

LS.3 PATIENT NOTIFICATION

If the organization has administered potentially HIV or HCV infectious blood or blood products, either directly through its own blood bank or under an agreement, or released such blood or blood products to another entity or appropriate individual, the organization shall take the following actions:

- SR.1 **The organization must make reasonable attempts to promptly** notify the patient, and/ or patient's attending physician (the physician of record) or the physician who ordered the blood or blood product. (See LS.3, SR.7 regarding notification of legal representative when applicable).
- SR.2 Request that the physician immediately notify the patient, or other individual of the need for HIV testing and counseling.

SR.3 If the physician is unavailable, declines to make the notification, or later informs the organization that he or she was unable to notify the patient, promptly make at least three attempts to notify the patient, legal representative or relative of the need for HIV or HCV testing and counseling.

SR.4 Document in the patient's medical record the notification or attempts to give the required notification.

SR.5 Timeframe for notification:

For donors tested on or after February 20, 2008 – for notifications resulting from donors tested on or after February 20, 2008 as set forth in 21 CFR 610.46 and 21 CFR 610.47:

The notification effort begins when the blood bank notifies the organization that it received potentially HIV or HCV infectious blood and blood products. The organization shall make reasonable attempts to give notification for no less than twelve (12) weeks unless:

SR.5a The patient is located and notified; or

SR.5b The organization is unable to locate the patient and documents in the patient's medical record the extenuating circumstances beyond the organization's control that caused the notification timeframe to exceed 12 weeks.

For donors tested before February 20, 2008 – for notifications resulting from donors tested before February 20, 2008 as set forth in 21 CFR 610.48(b) and (c):

SR.5c The notification effort begins when the blood bank notifies the organization that it received potentially HIV or HCV infectious blood and blood products. The organization shall make reasonable attempts to give notification and must complete the actions within one year of the date on which the organization received notification from the blood bank.

Note: HCV notification requirements resulting from donors tested before February 20, 2008 as set forth in 21 CFR 610.48 is set to expire on August 24, 2015.

SR.6 Content of notification: The notification shall include the following information:

SR.6a A basic explanation of the need for HIV or HCV testing and counseling;

SR.6b Enough oral or written information so that the transfused patient can make an informed decision about whether to obtain HIV or HCV testing and counseling; and,

SR.6c A list of programs or places where the patient can obtain HIV or HCV testing and counseling, including any requirements or restrictions the program may impose.

SR.7 Policies and Procedures: The organization shall establish policies and procedures for

notification and documentation that conform to Federal, State, and local laws, including requirements for confidentiality and medical records. A notification to legal representative or relative shall address the following:

- SR.7a If the patient has been adjudged incompetent by a State court, the physician or organization shall notify a legal representative designated in accordance with State law;
- SR.7b 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 organization shall notify the patient or his/her legal representative or relative; and,
- SR.7c If the patient is deceased, the physician or organization shall continue the notification process and inform the deceased patient's legal representative or relative.
- SR.7d If the patient is a minor, the physician or organization must notify the patient's parents or legal guardian.

Interpretive Guidelines:

The hospital must develop policies and procedures in order to meet notification requirements. The physician of record should notify the patient that he or she received potentially HIV or HCV infectious blood. In the event that the physician declines for appropriate reasons, the hospital then has the responsibility to notify the patient or legal representative. The hospital may designate an appropriate, competent hospital representative to inform the patient. This may be another physician, such as the medical director of the transfusion service, an infection control officer, a nurse, a clinical laboratory scientist, a social worker, or a non-physician with a medical background.

This requirement also applies when the hospital transfusion service furnishes blood or blood products to another facility, such as an ambulatory surgery center, clinic, nursing facility, or home setting (a home health agency). The hospital retains responsibility for patient notification.

The hospital must make reasonable attempts to notify the physician (of record) or the physician who ordered the blood or blood product. If after these reasonable attempts for notification, the hospital is not able to locate the patient within the one-week notification period, it is not expected to continue its search. However, there is no limit on how much time a hospital may choose to expend on this effort.

The hospital must document information related to notification, (e.g. contacting physician, telephone log, return receipt from a certified or registered letter), and this becomes part of the patient's medical record.

The policies and procedures for the notification process must conform to all Federal, State, and local laws regarding confidentiality.

When the physician accepts the responsibility for notification, the hospital is not required to follow up with the physician to determine whether notification occurred. It is expected that the physician would inform the hospital if notification did not occur, but this is part of professional relationships and not a requirement.

When the patient is notified, the following information must be provided:

- *A basic explanation of the need for HIV or HCV testing and counseling;*
- *Enough oral or written information so that the transfused patient can make an informed decision about whether to obtain HIV testing and counseling; and,*
- *A list of programs or places where the patient can obtain HIV or HCV testing and counseling, including any requirements or restrictions the program may impose.*

Referral for testing and counseling will be made to a physician or organization that provides high quality HIV or HCV testing and has extensive experience in providing HIV or HCV counseling. In addition, the patient should be told about any requirements or restrictions the programs may impose, such as, whether the program requires a fee, a physician request form, identification or public assistance cards, or a residency requirement. The CDC National AIDS Hotline operates a toll-free number (1-800-342-2437) 24 hours a day that the hospital or physician can give to the patient for more assistance. CDC's also operates a toll-free hepatitis hotline at 1-888-4HEPCDC (1-888-443-7232). In addition, the CDC maintains a Web site with information on hepatitis for both health-care professionals and the general public, including specific materials for people who received blood transfusions in the past. The Web address is www.cdc.gov/hepatitis.

If the patient in question is incompetent or unable to comprehend the information being provided, or the physician or hospital believes the information should not be given to the patient, and State law permits a legal representative or relative to receive information on the patient's behalf, then the physician must notify the patient's representative or relative. Upon learning of the death of the transfused patient, the hospital must pursue the notification process to inform the patient's family. It would not be appropriate for a physician or hospital to determine that the patient or someone acting on his or her behalf need not be informed.

A notification to legal representative will be provided when:

- *The patient has been adjudged incompetent by a State court, the physician or organization;*
- *The patient is competent, but State law permits a legal representative or relative to receive the information on the patient's behalf; or,*
- *The patient is deceased.*

Surveyor Guidance:

The hospital's laboratory will be determined to be in compliance with the requirements of LS.3

if the hospital's laboratory maintains current accreditation by the College of American Pathology (CAP). If the hospital laboratory is not CAP Accredited, then the following must be verified:

- *Validate that, when required, the hospital documents the notification efforts in the patient's medical record, including any extenuating circumstances that prevented patient notification within the 12-week timeframe.*
- *Verify that the hospital has a process in place to assist the patient in seeking testing and counseling.*
- *Verify the process regarding physician explanation to the patient of the need for testing and counseling and in the event that the physician declines, that the process is followed by the hospital.*
- *Verify the information the hospital makes available to the patient who is transfused with potentially HIV or HCV infectious blood or blood products.*
- *Review and verify the hospital's notification procedures to ordering and/or responsible physician and the patient.*
- *Review and verify the defined circumstances when the hospital deems it necessary to notify someone other than the patient who received potentially HIV or HCV infectious blood or blood products and ensure that the hospital is aware of the State law and that the law permits a legal representative or relative to receive information on the patient's behalf.*

LS.4 GENERAL BLOOD SAFETY

For look-back activities only related to new blood safety issues that are identified after August 27, 2007, the organization must comply with FDA regulations as they pertain to blood safety issues in the following areas:

SR.1 Appropriate testing and quarantining of infectious blood and blood components.

SR.2 Notification and counseling of recipients that may have received infectious blood and blood components.

Interpretive Guidelines:

Multiple layers of safeguards, including donor screening and testing, are used to reduce the risk of transmitting infection through blood transfusion. However, a person may donate blood early in infection, during the period when the viral marker is not detectable by a screening test, but the infectious agent is present in the donor's blood (the "window period").

Definition: "Look back" is considered to include: the quarantine of products from a window period donor; notification of consignees (facilities having received such window period products) to quarantine those products; and on completion of the licensed, more specific (confirmatory) test, notification of any transfusion recipient.

- *See FDA Publication: Guidance for Industry - "Lookback" for Hepatitis C Virus (HCV): Product Quarantine, Consignee Notification, Further Testing, Product Disposition, and Notification of Transfusion Recipients Based on Donor Test Results Indicating Infection with HCV (August 2007)*
- *See FDA Publication: Guidance for Industry - Nucleic Acid Testing (NAT) for Human Immunodeficiency Virus Type 1 (HIV-1) and Hepatitis C Virus (HCV): Testing, Product Disposition, and Donor Deferral and Reentry (Draft Guidance, July 2005)*

Surveyor Guidance:

The hospital's laboratory will be determined to be in compliance with the requirements of LS.4 if the hospital's laboratory maintains current accreditation by the College of American Pathology (CAP). If the hospital laboratory is not CAP Accredited, then the following must be verified:

Verify that the organization's laboratory is following FDA regulations pertaining to blood safety issues.

Discuss the process for Notification and counseling of recipients that may have received infectious blood and blood components

Process for verification of the right blood product for the right patient.

Verify that those administering blood transfusions and intravenous medications are working within their scope of practice in accordance with State law and hospital policy.

Review transfusion records to verify the process followed is consistent with the training provided and policies and procedures are followed.

Discuss the process for addressing blood transfusion reactions and the procedure to be followed when this occurs.

RESPIRATORY CARE SERVICES (RC)

RC.1 ORGANIZATION

- SR.1 The organization of the respiratory care services shall be appropriate to the scope and complexity of the services offered.
- SR.2 Respiratory care services provided at the organization shall be delivered in accordance with medical staff directives.
- SR.3 There shall 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.
- SR.4 There shall be appropriate numbers of respiratory therapists, respiratory therapy technicians, and other qualified personnel whose training meets the qualifications specified by the medical staff and State law.

Interpretive Guidelines:

When the hospital provides respiratory care services to patients, the service will be appropriate to the scope and complexity of the services offered. Respiratory care services shall be delivered in accordance with medical staff directives and acceptable standards of practice.

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.).

Respiratory care services shall be provided under the direction of a doctor of medicine or osteopathy with the knowledge, experience, and capabilities to supervise and administer the service.

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.

The scope of diagnostic and/or therapeutic respiratory services offered by the hospital should be defined in writing, and approved by the medical staff.

Surveyor Guidance:

Verify the scope of respiratory care services provided by the organization and that they are appropriate to the scope and complexity of services provided and in accordance with acceptable standards of practice.

Review the hospital's organizational chart to determine the relationship of respiratory care services to other services provided by the hospital.

Verify that a director has been appointed by the medical staff and governing body. Verify that the director has the necessary education, experience, and specialized training and has delegated responsibility for operation of respiratory care services.

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.

Review how the appropriate staffing is determined and applied for respiratory care services.

RC.2 ORDERS FOR TREATMENT AND INTERVENTIONS

SR.1 All respiratory treatments and interventions shall 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 under State law, and has been authorized by the hospital's medical staff to order these services in accordance with the hospital's policies and procedures and State laws.

SR.2 All orders for all respiratory treatment and interventions must be documented in the patient's medical record in accordance with the requirements defined under the Medical Records [\(MR\) section](#) of these accreditation requirements.

Surveyor Guidance:

Sample medical records of patients receiving respiratory services to verify that services are provided only upon the orders of a qualified and licensed practitioner who is responsible for the care of the patient, acting within his or her scope of under State law, and has been authorized by the hospital's medical staff to order these services in accordance with the hospital's policies and procedures and State laws and that the services are provided in accordance with those orders.

Sample medical records to ensure that respiratory treatment and interventions are documented accordingly.

RC.3 POLICIES OR PROTOCOLS

Written policies or protocols shall specify:

SR.1 Which personnel are qualified to perform specific procedures; and,

SR.2 The amount of supervision required

Interpretive Guidelines:

The hospital should have policies and procedures (or protocols) for the delivery of respiratory care services that have been developed and approved by the medical staff.

The policies and procedures (or protocols) should address at least the following:

- *The qualifications, 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 services without supervision; and,*
- *The type of personnel qualified to provide the direct supervision.*

Other policies and procedures (protocols) should address the following:

- *Equipment operation and the respective preventive maintenance and calibration as required;*
- *Safety practices, including infection control measures for equipment, sterile supplies, bio-hazardous waste, posting of signs, and gas line identification;*
- *Handling, storage, and dispensing of therapeutic gases to patients;*
- *Cardiopulmonary resuscitation;*
- *Pulmonary function testing;*
- *Therapeutic percussion and vibration;*
- *Bronchopulmonary drainage;*
- *Mechanical ventilatory and oxygenation support;*
- *Aerosol, humidification, and therapeutic gas administration;*
- *Storage, access, control, administration of medications and medication errors; an*
- *Procedures for obtaining and analyzing blood samples (e.g., arterial blood gases).*

RC.4 TESTS OUTSIDE THE LABORATORY

If blood gases or other laboratory tests are performed in the areas other than the lab, including the respiratory care unit, that area shall meet the applicable requirements for laboratory services as specified in 42 CFR §482.27.

Interpretive Guidelines

Refer to the guidelines under 42 C.F.R. §482.27 for independent laboratory if blood gases and laboratory tests are performed in the respiratory care unit.

MEDICAL IMAGING (MI)

MI.1 ORGANIZATION

- SR.1 The organization shall maintain, or have readily available, diagnostic radiology services that meet professionally approved standards and Federal and State laws for radiation safety and staff qualifications and requirements according to patient needs. The medical imaging services, particularly ionizing medical imaging procedures shall be free from hazards for patients and personnel.
- SR.2 If therapeutic services are also provided, they shall meet professionally approved standards and Federal and State laws for radiation safety and staff qualifications and requirements.

Interpretive Guidelines:

The organization shall maintain, or have readily available, diagnostic radiology services that meet professionally approved standards and Federal and State laws for radiation safety and staff qualifications and requirements according to patient needs. The scope and complexity of radiological services offered should be specified in writing and approved by the medical staff and governing body. These services must be readily available at all times.

Acceptable standards of practice include maintaining compliance with applicable Federal and State laws, regulations and guidelines governing radiology services, 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.).

*All radiology services provided by the hospital (diagnostic and therapeutic, if offered) must meet acceptable standards of practice and professionally approved standards for safety and personnel qualifications.
This applies to radiology services that may be provided by the hospital or through a contractual arrangement.*

If diagnostic radiology services are provided under a contract arrangement, the services may be provided either on the hospital premises or in an adjacent or other nearby location. In all circumstances, these services must be readily accessible to the organization's facility at all times.

Surveyor Guidance:

Verify that the hospital maintains (or provides in some manner) radiology services that meet the needs of the patients.

Verify that the radiology services are provided in accordance with accepted standards of practice, and are maintained or available at all times to meet the patient needs.

If radiology services are provided through a contractual arrangement, verify that the contracted entity adheres to applicable policies and procedures of the organization and that the contracted entity and its employees or agents are properly qualified and have an evaluation method in place.

MI.2 RADIATION PROTECTION

- SR.1 Proper radiation safety precautions shall be maintained, including adequate shielding for patients, staff, and facilities, as well as appropriate storage, use, and disposal of radioactive materials.
- SR.2 Staff who work in radiation areas shall be monitored continually for the amount of radiation exposure by the use of exposure meters or badge dosimeters. This includes licensed independent practitioners who may be exposed to ionizing radiation during procedures.
- SR.3 Any high radiation readings must be investigated and reported to Quality Management Oversight.

Interpretive Guidelines:

The hospital must develop and implement policies and procedures to provide a safe environment for patients and staff.

The hospital policies and procedures must address the safety standards for the following:

- *Adequate shielding for patients, personnel and facilities;*
- *Labeling of radioactive materials, waste, and hazardous areas;*
- *Transportation of radioactive materials between locations within the hospital;*
- *Securing radioactive materials, including determining limitations of access to radioactive materials;*
- *Testing and maintenance of equipment for prevention of radiation hazards;*
- *Maintenance monitoring and measuring devices for equipment;*
- *Proper storage of radiation monitoring badges when not in use;*
- *Storage and disposal of radio nuclides and radio pharmaceuticals as well as radioactive waste; and,*
- *Methods of identifying patients who may be pregnant*
- *The hospital must implement and ensure compliance with its established safety standards*
- *The hospital shall require any staff member who may be exposed to radiation or working near radiation sources wear badges to identify levels for amount of radiation exposure. This includes certain radiology technologists, radiologists, nursing, and maintenance staff.*

Surveyor Guidance:

Review locations where radiological services are provided.

During this review, assess the following:

- *Safety measures are implemented for patients and staff;*
- *Verify that patient shielding (aprons, etc.) are properly maintained and routinely inspected by the hospital and review the records for the most recent inspection of the aprons;*
- *Review the storage of hazardous materials and process if there is any exposure and the protocol followed when this occurs;*
- *Verify that the hospital requires periodic checks on all radiology personnel and any other hospital staff exposed to radiation and how the exposure levels are communicated to staff (by month, year, and cumulative for the staff while in the employ of the hospital – review the records related to these checks; and,*
- *Verify that appropriate staff have a device to detect radiation and that it is worn appropriately without interference to detect radiation.*

MI.3 EQUIPMENT

SR.1 Periodic inspection of equipment shall be performed, at least minimally according to manufacturer's recommendations. Hazards shall be identified and promptly corrected.

SR.2 Documentation of preventative maintenance and repairs of radiology equipment shall be maintained.

Interpretive Guidelines:

The hospital must have policies and procedures in place to ensure that periodic inspections of radiology equipment are conducted. When these periodic inspections have identified that equipment is not operating or malfunctioning, this equipment is removed from service and repaired and verified prior to being put into operation for patient care. The hospital must maintain repair documentation and records for periodic maintenance.

Either the hospital staff or a qualified contract entity must ensure that equipment is inspected in accordance with manufacturer's instructions, Federal and State laws, regulations, and guidelines, and hospital policy.

Surveyor Guidance:

Review the records (often maintained in Biomedical/Clinical Engineering) to verify that periodic inspections are conducted in accordance with manufacturer's instructions, Federal and State laws, regulations, and guidelines and hospital policy.

Select the equipment numbers to trace back through the records system to verify calibration and periodic preventive maintenance performed.

Review the process for detection and correcting identified problems and the timeliness of the response.

MI.4 ORDER

Medical imaging services must be provided only on the order of practitioners with clinical privileges or, consistent with State law, of other practitioners approved by the medical staff and the governing body and authorized to order the services.

Surveyor Guidance:

Review medical records to determine that radiology services are provided only on the orders of practitioners. The practitioners ordering radiology services must have these clinical privileges. This also applies to practitioners outside the hospital who have been authorized by the medical staff and the governing body to order radiology services, consistent with State law.

MI.5 SUPERVISION

SR.1 A qualified full-time, part-time, or consulting radiologist shall supervise the ionizing radiology services and shall interpret those radiology tests that are determined by the medical staff to require a radiologist's specialized knowledge.

SR.2 For purposes of this standard, a radiologist is a doctor of medicine or osteopathy who is qualified by education and experience in radiology.

Interpretive Guidelines:

In accordance with this regulation and other Federal and State laws, regulations and guidelines, the medical staff must approve the qualifications necessary for radiologist appointment to the medical staff.

The hospital must develop and implement policies that have been approved by the medical staff to designate which radiology tests require interpretation by a radiologist.

In the event that the hospital contracts for telemedicine to be used, including the radiologist who interprets radiology tests, the hospital has a process in place to verify the radiologist interpreting the radiological test is licensed and/or meets 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 OR is subjected to the credentialing and privileging process through the medical staff to be approved for providing this service for the hospital.

A radiologist who is a member of the medical staff who supervises these services and includes the following may only perform radiology services:

- *Monitoring of radiology reports to ensure they are signed by the practitioner who interpreted them;*

- *Assigning duties to radiology personnel (duties assigned will only be appropriate to their level of training, experience, and licensure if applicable);*
- *Assures the enforcement of infection control practices within the radiology setting;*
- *Ensures that a process is in place to provide emergency care to patients who experience an adverse reaction to diagnostic agents in the radiology setting;*
- *Ensures the security of files, scans, and other image records and are readily retrievable when needed; and,*
- *Provides for training of radiology staff regarding the safe operation of equipment, performance of tests offered by the facility and on the management of emergency radiation hazards and accidents.*

Surveyor Guidance:

Review the radiologist's credentialing file to verify that he or she has met the qualifications established by the medical staff for appointment. If these services are provided by a contracted entity, the survey team will verify that the hospital has a verification process for those providing these services on behalf of the contracted entity. The radiologist may be required to go through the medical staff credentialing and privileging process of the hospital.

Review records to determine that a radiologist who interprets those tests has been credentialed and approved by the medical staff as a qualified radiologist.

Verify that a radiologist who is a member of the medical staff is the physician responsible for the supervision of radiology services.

MI.6 STAFF

Only staff designated as qualified by the medical staff, governing body, and State and/or Federal law may use the medical imaging equipment and perform medical imaging procedures.

Interpretive Guidelines:

The hospital should maintain appropriate written policies, developed and approved by the medical staff, consistent with State law, to designate which personnel are qualified to use the radiology equipment and administer procedures.

Surveyor Guidance:

Review and verify which staff are using various radiological equipment and/or administering patient procedures to ensure they have been deemed competent to use and perform as needed. This may be done through a sample review of staff personnel files to determine these individuals meet the qualifications established by the medical staff for the tasks that are performed.

MI.7 RECORDS

Records of medical imaging services must be maintained, in accordance with Nuclear Regulatory Commission requirements and any other applicable Federal and State law.

MI.8 INTERPRETATION AND RECORDS

SR.1 The radiologist or other practitioner who interprets radiology images and outcomes must sign the written reports of his/her interpretations.

SR.2 The organization must maintain the following for at least 5 years:

SR.2a copies of reports and print outs; and,

SR.2b films, scans, and other image records.

Interpretive Guidelines:

The hospital must maintain records for all radiology procedures performed in accordance with the Nuclear Regulatory Commission. At a minimum, the records should include copies of reports and printouts, and any films, scans or other image records, as appropriate.

The hospital should have written policies and procedures that ensure the integrity of authentication and protect the privacy of radiology records. Medical records, which include radiology films, image records, scans, reports, and printouts must be secure, properly stored, be accessible and retrievable in a timely manner when needed for any care, procedure, treatment, or test provided or conducted within the past 5 years.

Surveyor Guidance:

Review a sampling of radiology records to verify that reports are signed by the practitioner who reads and evaluates images or scans.

Review the hospital's policies, procedures and practices for maintaining radiology records. The documented procedure for control of records should accurately define these radiology records and the retention, storage and accessibility of these records. Verify that the hospital maintains radiology records for at least 5 years.

NUCLEAR MEDICINE SERVICES (NM)

NM.1 ORGANIZATION

- SR.1 If the organization provides nuclear medicine services; those services must meet the needs of the patients in accordance with acceptable standards of practice as defined by the medical staff. The nuclear medicine services shall be free from hazards for patients and personnel.
- SR.2 The organization of the nuclear medicine service shall be appropriate to the scope and complexity of the services offered.
- SR.3 There shall be a director who is a doctor of medicine or osteopathy qualified in nuclear medicine.
- SR.4 The qualifications, training, functions, and responsibilities of nuclear medicine staff shall be specified by the service director and approved by the medical staff.
- SR.5 Nuclear medicine services shall be ordered only by practitioners whose scope of Federal or State licensure and defined staff privileges allow such referrals.

Interpretive Guidelines:

If the hospital provides nuclear medicine services, directly or through a contractual arrangement, they shall be appropriate to the scope and complexity of services offered to its patients. The services must be in accordance with acceptable standards of practice as well as any standards and recommendations of nationally recognized professional organizations that have been defined by the medical staff (e.g., the American Medical Association, American College of Radiology).

Nuclear medicine services must be under the direction of a doctor of medicine or osteopathy who must be qualified in nuclear medicine.

The medical staff and physician responsible for nuclear medicine services must define the appropriate qualifications, training, functions, and responsibilities of nuclear medicine staff.

Nuclear medicine services shall be ordered only by practitioners whose scope of Federal or State licensure and defined staff privileges allow such orders.

Surveyor Guidance:

Review and validate the type(s) of services provided and the location where these services are provided.

Review and verify that the nuclear medicine service director is an MD/DO and is qualified based upon education, experience, and specialized training in nuclear medicine, appropriate to the scope and complexity of services offered.

In review of a sampling of personnel files for nuclear medicine staff, verify that they have the appropriate qualifications, as specified by the medical staff.

NM.2 RADIOACTIVE MATERIALS

- SR.1 Radioactive materials shall be prepared, labeled, used, transported, stored, and disposed of in accordance with acceptable standards of practice as defined by the medical staff.
- SR.2 The organization must maintain records of the receipt and disposition of radiopharmaceuticals.
- SR.3 In-house preparation of radiopharmaceuticals shall be by or under the direct supervision of an appropriately trained registered pharmacist or doctor of medicine or osteopathy.
- SR.4 If laboratory tests are performed in the nuclear medicine service, the service must meet the applicable requirements for laboratory services as specified in 42 CFR §482.27.

Interpretive Guidelines:

The hospital shall prepare, label, use, transport, store, and dispose of radioactive materials in accordance with acceptable standards of practice as defined by the medical staff. The hospital should define through written policies and procedures practices to include:

- *Handling of equipment and radioactive materials;*
- *Protection of patients and personnel from radiation hazards;*
- *Labeling of radioactive materials, waste and hazardous areas;*
- *Transportation of radioactive materials between locations within the hospital;*
- *Security of radioactive materials, including determining who may have access to radioactive materials and controlling access to radioactive materials;*
- *Testing of equipment for radiation hazards;*
- *Maintenance of personal radiation monitoring devices;*
- *Storage of radionuclides and radiopharmaceuticals as well as radioactive waste; and*
- *Disposal of radionuclides, unused radiopharmaceuticals, and radioactive waste.*

Records must be maintained regarding the receipt and disposition of radiopharmaceuticals and have a stated timeframe for retention of these records in accordance with Federal and State law.

An appropriately trained registered pharmacist or doctor of medicine or osteopathy must oversee the preparation of radiopharmaceuticals.

If laboratory tests are performed in the nuclear medicine service, the service must meet the applicable requirements for laboratory services as specified in 42 CFR §482.27.

Surveyor Guidance:

Review and validate that radioactive materials and waste are prepared, labeled, used, transported, stored, and disposed of in accordance with Federal and State laws and regulations and acceptable standards of practice.

Verify that safety precautions are followed in the functioning of the nuclear medicine service and those personnel and patients wear appropriate body shielding (e.g., lead aprons or lead gloves) when appropriate.

When radiopharmaceuticals are prepared in-house, verify that the preparation is performed by an appropriately trained registered pharmacist or doctor of medicine or osteopathy.

Review and verify written policies and procedures to govern the preparation, labeling, use, transporting, storage, and disposal of radioactive materials in accordance with acceptable standards of practice as defined by the medical staff.

NM.3 EQUIPMENT AND SUPPLIES

- SR.1 Equipment and supplies must be appropriate for the types of nuclear medicine services offered and must be maintained for safe and efficient performance.
- SR.2 The equipment must be maintained in safe operating condition and inspected, tested, and calibrated at least annually by qualified personnel
- SR.3 Documentation of equipment testing and preventative maintenance shall be maintained.

Interpretive Guidelines:

The hospital must develop and implement a preventive maintenance process to ensure that nuclear medicine equipment is maintained in safe operating condition to ensure accurate results and patient, staff, and public safety.

Nuclear medicine equipment must be inspected, tested and calibrated at least annually by qualified personnel in accordance with Federal and State laws, regulations and guidelines and appropriate documentation (records) maintained.

Supplies must be appropriate for the types of nuclear medicine services offered and must be maintained for the safety for the patients, staff, and public.

NM.4 INTERPRETATION

- SR.1 The practitioner approved by the medical staff to interpret diagnostic procedures must sign the interpretation of these tests.
- SR.2 The organization must maintain signed and dated reports of nuclear medicine

interpretations, consultations, and procedures.

SR.3 The organization must maintain copies of nuclear medicine reports for at least five years.

Interpretive Guidelines:

Only practitioners approved by the medical staff may interpret and sign the interpretation of diagnostic procedures and tests.

The hospital must maintain records for all nuclear medicine procedures. At a minimum, these records will include signed and dated reports of nuclear medicine interpretations, consultations, and procedures. This documentation is a part of the patient's medical record and must comply with Medical Records Services standards as stated under MR.1 – MR.7. Such records will be retained according the record retention documented procedure, but be no less than five years.

Surveyor Guidance:

Review and verify that only practitioners approved by the medical staff to interpret diagnostic procedures.

Review and verify that reports of nuclear medicine interpretation, consultations, and procedures are signed and dated only by practitioners authorized by the medical staff to perform these interpretations.

Verify that copies of nuclear medicine reports are maintained for at least 5 years.

REHABILITATION SERVICES (RS)

RS.1 ORGANIZATION

SR.1 If the organization provides rehabilitation, physical therapy, occupational therapy, audiology or speech pathology services, the service(s) shall be provided in a manner that ensures the patient's health and safety.

Interpretive Guidelines:

Rehabilitative services (including contractual services) may include physical therapy, occupational therapy, audiology and speech pathology services.

The hospital will adhere to 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).

Surveyor Guidance:

Review the extent of rehabilitation services and if these services are provided directly by the hospital or through a contractual arrangement.

Validate that these services are provided in a manner that ensures the patient's health and safety.

Verify that rehabilitation services are integrated into the hospital's quality management system oversight.

RS.2 MANAGEMENT AND SUPPORT

SR.1 The organization shall ensure that there is the appropriate management and support for this core process. These requirements shall include:

SR.1a a director/manager who has the responsibility for the management, direction and accountability for ensuring services are carried throughout the organization;

SR.1b the director/manager shall have the qualifications, experience and/or training defined by the organization and appropriate for this position;

SR.1c staff who meet the qualifications as defined by the medical staff and organization and consistent with State law shall be performed by qualified physical therapists, physical therapists assistants, occupational therapists, occupational therapist assistants, speech-language pathologists, or audiologists (as defined in 42 CFR §484.4 Personnel qualifications).

Interpretive Guidelines:

The hospital must manage and support the service(s) as necessary to maintain the level provided. In order to support these services, the appropriate equipment and qualified personnel must be in place and follow acceptable standards of practice.

The rehabilitation services offered must be under the direction of a qualified individual that will have the accountability, qualifications, and experience appropriate for this position. The staff (employed or contracted) shall meet the required qualifications, as defined by the organization to provide these services.

Surveyor Guidance:

Review the hospital's policies and procedures to verify that the scope of rehabilitation services offered is defined in writing and that these services are under the direction of a qualified individual.

Verify that staff providing rehabilitative services meet the qualifications, as defined by the medical staff and the organization and are consistent with State law and shall be performed by qualified physical therapists, physical therapists assistants, occupational therapists, occupational therapist assistants, speech-language pathologists, or audiologists. (As defined in 42 CFR § 484.4 Personnel qualifications.)

If services are provided under a contractual arrangement, determine that the agreement requires the staff to be appropriately qualified (as listed above) and scope of services provided.

Sample personnel files to verify current licensure, certifications and ongoing training, consistent with applicable State laws.

RS.3 TREATMENT PLAN/ORDERS

- SR.1 Rehabilitative services shall 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 has been authorized by the hospital's medical staff to order these services in accordance with the hospital's policies and procedures and State laws.
- SR.2 All orders for rehabilitative services, treatment plan, results, and notes must be documented in the patient's medical record in accordance with the requirements defined under the Medical Records (MR) chapter of these accreditation requirements.
- SR.3 The plan of care for rehabilitative services provided and the personnel qualifications must be in accordance with national acceptable standards of practice and must also meet the requirements of 42 CFR §409.17.

Interpretive Guidelines:

The hospital shall have an individualized plan of care, based on the patient's specific rehabilitation needs, input from family/caregivers and therapeutic treatment goals for the patient that are documented in the patient's record prior to the initiation of treatment. At a minimum, this treatment plan will include:

- *The order from the practitioner for the service(s) in collaboration with individuals qualified to provide the service(s);*
- *The type, amount, frequency and duration of services;*
- *Diagnosis and anticipated goals, results and notes; and,*
- *Reviews and revisions, as necessary, to account for changes in the patient's condition and or response to therapeutic intervention.*

Surveyor Guidance:

Sample patient records to verify that rehabilitation services are provided only in accordance with practitioner orders who are authorized by the medical staff to order these services and that those orders are documented in the medical record.

In the review of patient records, verify that there is a plan of care established in writing prior to the beginning of treatment and there are stated anticipated goals for the patient.

Verify that changes in the treatment plan are documented in the patient's medical record to include the evaluation, test results, or orders, and practitioner approvals of changes.

EMERGENCY DEPARTMENT (ED)

ED.1 ORGANIZATION

- SR.1 The organization must meet the emergency needs of its patients in accordance with acceptable standards of practice.
- SR.2 Emergency Services shall be organized and integrated with other departments under the direction and supervision of a qualified member of the medical staff.
- SR.3 The medical staff shall be responsible for developing and maintaining policies and procedures governing the medical care delivered.

Interpretive Guidelines:

The hospital's emergency services must be integrated with the other departments of the hospital (e.g. surgical services, laboratory, ICU, diagnostic services) and be accessible in the delivery of emergency care for patients.

The emergency department will be under the direction of a qualified member of the medical staff.

The medical staff will define the criteria that include the qualifications for the director of emergency service in accordance with Federal and State law.

The medical staff will ensure that policies and procedures are developed and implemented to govern the emergency services provided.

Hospitals have the responsibility and must abide by the Emergency Treatment and Labor Act (EMTALA). It is intended to reinforce that the EMTALA responsibility of the hospital with a dedicated emergency department begins when an individual arrives on hospital property (ambulance arrival) and not when the hospital "accepts" the individual from the gurney. An individual is considered to have "presented" to the hospital when her or she arrives at the hospital's dedicated emergency department or on hospital property and a request is made by the individual or on his or her behalf for examination or treatment of an emergency medical condition (42 CFR 489.24(b)). Once an individual comes to the emergency department of the hospital, whether by EMS or otherwise, the hospital has the obligation to provide an appropriate medical screening examination and, if an emergency medical condition is determined to exist, provide any necessary stabilizing treatment or an appropriate transfer. Failure to meet these requirements constitutes a potential violation of EMTALA.

EMTALA obligations would also apply to the hospital that has accepted transfer of a patient from another facility, as long as it is an "appropriate transfer" under EMTALA. An appropriate transfer is one in which the transferring hospital provides medical treatment that minimizes risks to an individual's health and the receiving hospital has the capability and capacity to accept the patient at the time the transfer is effectuated. A hospital that delays the medical screening examination or stabilizing treatment of a patient, who arrives via transfer from another facility, by not allowing EMS to leave the patient, could also be in violation of EMTALA.

A hospital policy or practice that relies on calling 9-1-1 in order for EMS to substitute its emergency response capabilities for when the hospital is required to maintain as stated above. The hospital may not rely on 9-1-1 to provide appraisal and initial treatment of medical emergencies that occur at the hospital.

Surveyor Guidance:

Verify that emergency services are organized under the direction of a qualified member of the medical staff.

Review and validate policies and procedures (including triage of patients) and that they are evaluated and updated on an ongoing basis.

Review and validate the coordination and communication between the Emergency Department and other hospital services/departments (e.g. laboratory, diagnostic services, surgical services).

Verify that the hospital is in compliance with EMTALA and has such policies, procedures and appropriate resources in place to ensure effective compliance with EMTALA in accordance with the emergency services provided.

ED.2 STAFFING

SR.1 Adequate medical and nursing staff qualified in emergency care, as outlined in the written scope of service, must be present to meet the written emergency procedures and needs determined by the organization.

SR.2 A qualified registered nurse shall perform patient triage upon presentation to the emergency department.

Interpretive Guidelines:

The hospital must ensure that a qualified member of the medical staff is on premises and available to supervise the provision of emergency services at all times.

The hospital shall also provide nursing staff qualified in emergency care, as outlined in the written scope of service, to be present when emergency services are provided.

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 when emergency services are provided.

The hospital must work with Federal, State and local agencies and officials in order to identify risks to the community (e.g., natural disasters, mass casualties, terrorist acts), to anticipate demands and resources needed by the hospital emergency services, and accordingly, develop plans and methods to address and coordinate anticipated needs.

Surveyor Guidance:

Verify that a qualified member of the medical staff is on premises and available to supervise the provision of emergency services at all times.

Verify that the appropriate numbers and types of professionals and other staff who possess the skills, education, certifications, specialized training and experience in emergency care when emergency services are provided.

Review and validate the processes in place to demonstrate that the hospital works with Federal, State and local agencies and officials in order to identify risks to the community to anticipate demands and resources needed by the hospital emergency services.

ED.3 EMERGENCY SERVICES NOT PROVIDED

If emergency services are not provided at the organization, the governing body must assure that the medical staff has written policies and procedures for appraisal of emergencies, initial treatment, and referral when appropriate.

Interpretive Guidelines:

This requirement applies hospital-wide (on-campus and off-campus locations) that do not provide emergency services.

The governing body must assure that the medical staff has written policies and procedures for appraisal of emergencies, initial treatment, and referral when appropriate.

The hospital must have appropriate policies and procedures in place for dealing with emergency care situations at the hospital. This includes emergencies that occur to hospital patients, staff, visitors, and others at any hospital location and to individuals who come to the hospital or any of its off-campus locations seeking/requiring emergency care.

Surveyor Guidance:

Review and verify that the medical staff has implemented written policies and procedures for the management of medical emergencies.

Interview staff to ensure they are aware of the policies and procedures for managing medical emergencies.

*Discuss with staff their role and responsibilities if such an emergency is encountered how they will respond and **determine** if this is consistent with the policies and procedures in place.*

Review and validate that emergency care policies and procedures address both on-campus and off-campus locations.

ED.4 OFF-CAMPUS DEPARTMENTS

The medical staff shall have written policies and procedures for appraising and referring emergencies that occur in off-campus departments where emergency services are not provided.

Interpretive Guidelines:

This requirement applies to off-campus departments that do not provide emergency services.

The hospital will implement written policies and procedures for appraising and referring emergencies that occur in off-campus departments. This includes emergencies involving patients, staff, visitors, or others or individuals who come to those locations seeking/requiring emergency care.

Initial treatment and stabilization of patients requiring emergency care must be provided within the capabilities and complexities of services provided and the staff on-site at these off-campus departments.

Surveyor Guidance:

Review and validate that written policies and procedures address the appraisal and referral of medical emergencies that occur in off-campus departments. As appropriate, when visiting the off-campus departments, validate that the staff are aware of these policies and procedures.

Interview staff to ensure they are aware of the policies and procedures for managing medical emergencies.

*Discuss with staff their role and responsibilities if such an emergency is encountered how they will respond and **determine if** this is consistent with the policies and procedures in place.*

Note: In many cases, staff will state they call 9-1-1, but the staff at these sites cannot rely upon 9-1-1 to provide appraisal and initial treatment. Discuss how the staff would handle such an emergency to ensure the staff are aware of the policies and procedures to follow if they were to encounter such an emergency.

OUTPATIENT SERVICES (OS)

OS.1 ORGANIZATION

If the organization provides outpatient services, the services shall be appropriately organized and integrated with inpatient services.

Interpretive Guidelines

If the hospital provides outpatient care to its patients, these services shall be organized and integrated with inpatient services, as appropriate.

The organization of the hospital's outpatient services must be appropriate to the scope and complexity of services offered.

All outpatient services provided by the hospital must meet the needs of the patients, in accordance with acceptable standards of practice. The hospital must ensure that services, equipment, staff, and infrastructure are adequate to provide the outpatient services offered at each location in accordance with acceptable standards of practice.

Outpatient services must be integrated into the hospital's quality management system oversight.

Surveyor Guidance:

Verify the extent of outpatient services provided; and,

Verify that the outpatient services are organized in a manner appropriate to the scope and complexity of services offered.

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.

Verify that outpatient services are integrated into the hospital's quality management system oversight.

OS.2 STAFFING

SR.1 The organization shall assign one or more individuals to be responsible for outpatient services.

SR.2 Have appropriate professional and non-professional personnel available at each location where outpatient services are offered, based on the scope and complexity of outpatient services.

OS.3 SCOPE OF SERVICE

A documented scope of service shall be available for each patient care site that includes core staffing for each site with associated staff responsibilities.

Interpretive Guidelines:

The hospital must designate one or more individuals responsible for the overall operation of the hospital's entire outpatient services (all outpatient services). The hospital should define in writing the qualifications and competencies necessary to direct the outpatient services.

Adequate types and numbers of qualified professional and nonprofessional personnel must be available to provide patients with the appropriate level of care and services.

Surveyor Guidance:

Verify that the hospital has designated one or more appropriately qualified individuals to manage and be responsible for outpatient services.

Review and validate the application of policies and contracts, if services provided are under an arrangement.

Review the scope of services for patient care and document core staffing for each area.

DIETARY SERVICES (DS)

DS.1 ORGANIZATION

- SR.1 Dietary Services are organized processes that shall be carried out internally or through a contract with a nutrition management company that interacts on a regular basis with the medical staff on dietetic policies affecting patient care.
- SR.2 The organization shall ensure that there is the appropriate management and support for this core process. These requirements shall include a full-time person responsible for the management, direction and accountability for ensuring food and dietetic services are carried out daily throughout the organization. This full-time person shall have the qualifications, experience and training defined by the organization and appropriate for the position.
- SR.3 The full-time person responsible for the management of Food and Dietetic Services shall ensure that the appropriate administrative and technical personnel are competent and adequate to carry out this process for the organization.
- SR.4 The organization shall have a qualified dietitian in the organization **that** is available to address issues, concerns, and patient care planning. This dietitian shall be employed by the organization on a full-time or part-time basis or contracted as a consultant for the organization and available as needed.

Interpretive Guidelines:

The nutritional needs of the patients are met in accordance with practitioners' orders, acceptable standards of practice, and the hospital being in compliance with Federal and State licensure requirements for food and dietary personnel as well as food service standards, laws and regulations. These activities are carried out by food and dietetic services. This can be completed with qualified hospital staff or through a contractual basis with a nutrition management company.

The full-time individual responsible for Food and Dietetic Services will be authorized and have the delegated responsibility for these services from the hospital's governing body and medical staff. The responsibilities of the responsible individual in this role will include operational management, implementing training and education for dietary staff, and assuring that there are policies and procedures developed and implemented to address at least the following:

- *Orientation, work assignments, supervision of work and personnel performance;*
- *Safety practices for food handling;*
- *Provision for emergency food supplies; and,*
- *Supervision of the menu planning function, purchasing of foods and supplies, and retention of required records.*

The hospital should have written policies and procedures that address at least the following:

- *Availability of a diet manual and therapeutic diet menus to meet patients' nutritional needs;*
- *Frequency of meals served;*
- *Process for ordering and delivery of food to respective patient areas;*
- *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.); and,*
- *Guidelines for acceptable hygiene practices of food service personnel and the sanitation protocols for the preparation and cleaning areas.*

The full-time individual responsible for Food and Dietetic Services must demonstrate he or she has the qualifications necessary to manage the service to include education, experience, and/or training appropriate to the scope and complexity of the food service operations.

The hospital must have a qualified dietitian to supervise the nutritional aspects of patient care. This individual shall have met the required education, experience, and training defined by the hospital and medical staff, and, where applicable, the State licensure or registration when applicable.

The qualified dietitian will be responsible for:

- *Approving menus and nutritional supplements provided to patients;*
- *Provide dietary counseling to patients and those responsible for the patient upon discharge;*
- *Performing and documenting nutritional assessments;*
- *Evaluating patient tolerance to therapeutic diets as 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 to meet the nutritional needs of the patients;*
- *Maintaining pertinent patient data necessary to recommend, prescribe, and/or modify therapeutic diets as needed to meet the nutritional needs of the patients; and,*
- *Maintaining professional standards of practice.*

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.

Surveyor Guidance:

Verify that the director of the food and dietetic services is a full-time employee and has an appropriate job description to verify that his or her responsibility and authority for the direction of the food and dietary service has been clearly delineated. The personnel file for this individual should be reviewed.

Review the dietitian's personnel file to determine that he or she is qualified for this role and has an appropriate job description to verify he or she has the experience, specialized training, and required licensure or certification (as required by State law).

If the dietitian is not full-time, determine the frequency in which the nutritional needs of the patients are assessed, and that the hospital makes adequate provisions for qualified consultant coverage when this dietitian is not available. This would include evening and weekend coverage.

DS.2 SERVICES AND DIETS

Dietary Services shall be provided and menus/diets offered that meet the needs of the patients. The following criteria shall be applied:

- SR.1 All menus/diets offered must meet the needs of the patients
- SR.2 All therapeutic diets shall be prescribed by a practitioner or practitioners responsible for the care of the patient; and,
- SR.3 All nutritional needs of patients shall be met in accordance with recognized dietary practices that are consistent with the orders of the practitioner or practitioners responsive for the care of the patients.

Interpretive Guidelines:

Menus provided by the hospital must be nutritionally balanced and meet the special needs of the patients. Current menus available to patients will be posted or readily available in the food preparation area.

Review the screening criteria to identify patients at nutritional risk and how the process is carried out from assessment and re-assessment to ensure that their nutritional needs are being met.

The following represent examples of patients who require nutritional assessment. The organization may define additional criteria for the provision of nutritional assessments:

- *All patients requiring artificial nutrition by any means (i.e., parenteral nutrition (tube feeding), total parenteral nutrition, or peripheral parenteral nutrition);*
- *Patients whose medical condition or physical status (current or future status based upon care plan) 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, mal-absorption, end stage organ diseases, etc.); and,*
- *Patients whose medical condition is directly impacted by their nutritional intake (e.g., diabetes, congestive heart failure, food/drug interactions, etc.).*

For all therapeutic diets provided to patients as a result of a nutritional assessment or as prescribe, such diets should be:

- *Prescribed in writing by a qualified practitioner or a qualified dietitian;*
- *Documented in the patient's medical record (include the patient's tolerance to the diet); and,*
- *And evaluated for nutritional adequacy to meet the patient's needs.*

In the event a patient refuses the food served, the patient should be offered an appropriate substitute that is of equal nutritional value in order to meet their nutritional needs. Religious beliefs should also be taken into consideration if applicable.

Current national standards for recommended dietary allowances will be referenced (i.e., the current Recommended Dietary Allowances (RDA) or the Dietary Reference Intake (DRI) of the Food and Nutrition Board of the National Research Council).

Surveyor Guidance:

Review medical records to verify where therapeutic diet orders are prescribed and authenticated by the practitioner(s) responsible for the care of the patient. In the sampling of medical records reviewed, verify that:

- *The patient's nutritional needs have been met;*
- *The appropriate therapeutic diets have been ordered; and,*
- *The patient's dietary intake and nutritional status is being monitored and re-assessed as appropriate.*

The hospital should be able to demonstrate what national standard they are following to be applied to their menus to meet the nutritional needs of their patients.

DS.3 DIET MANUAL

- SR.1 The organization shall maintain a dietary manual (hardcopy or electronic) that defines the current therapeutic diets used by the organization.
- SR.2 The dietary manual shall be approved by a dietitian (full-time, part-time or contracted) and the medical staff at least every five years.

SR.3 The dietary manual shall be a document that is communicated, controlled and available to all staff and practitioners who are directly or indirectly responsible for ensuring that appropriate nutritional services are implemented.

Interpretive Guidelines:

A therapeutic diet manual must be approved by the dietitian and the medical staff. This therapeutic diet manual should be reviewed and under no circumstance should the publication or revision date be more than five years old. The therapeutic diet manual must be readily available to all medical, nursing and food service personnel.

Surveyor Guidance:

Review the therapeutic diet manual to determine that it is current and readily available to all appropriate staff. The therapeutic diet manual should include the diets currently available to patients and meet current national standards, such as RDA or DRI. The therapeutic diet manual should be referenced as necessary when such diets are prescribed.

Verify that the therapeutic diet manual has been approved by the medical staff and a qualified dietitian.

PATIENT RIGHTS (PR)

PR.1 SPECIFIC RIGHTS

The organization shall protect and promote each patient's rights. The organization shall inform, whenever possible, each patient and/or legal representative of the patient's rights in advance of providing or discontinuing care. The written listing of these rights shall be provided to the patient and /or family and shall include policies and procedures that address the following:

- SR.1 Beneficiary Notice of non-coverage and right to appeal premature discharge;
- SR.2 Patient participation and means for making informed decisions regarding his/her plan of care;
- SR.3 Information to the patient or family of patient care and to involve the patient and family to make informed decisions regarding their care planning and treatment, including the requesting and/or refusing treatment, their health status, not to be construed as a demand for the provision of treatment or services deemed medically unnecessary or inappropriate;
- SR.4 Prompt notification of the patient and his/her representative of patient choice and to promptly notify the patient's physician of admission;
- SR.5 Personal privacy;
- SR.6 Provision of care in a safe setting;
- SR.7 Freedom from all forms of abuse or harassment;
- SR.8 Confidentiality of clinical records;
- SR.9 Patient access to clinical records as quickly as record keeping system permits; and,
 - SR.9(a) The hospital must not impede the legitimate efforts of individuals to gain access to their own clinical records and must actively seek to meet these requests as quickly as the record keeping system permits.
- SR.10 Procedure for submission of a written or verbal grievance. (See PR.5 Grievance Procedure)
- SR.11 Pain Management
- SR.12 Patient visitation rights
 - SR.12(a) The 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.

- SR.12(b) The hospital must: Inform each patient (or representative, 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 42 CFR 482.13(a).
- SR.12(c) Inform each patient (or representative, 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.
- SR.12(d) Not restrict, limit, or otherwise deny visitation privileges on the basis of race, color, national origin, religion, sex, sexual orientation, gender identity, or disability.
- SR.12(e) Ensure that all visitors designated by the patient (or representative, where appropriate) enjoy visitation privileges that are no more restrictive than those that immediate family members would enjoy.

SR.13 Other rights defined within the Patient Rights requirements (PR.1 – PR.8)

Interpretive Guidelines:

This standard requires that whenever possible, the hospital informs each patient and/or legal representative of the patient's rights in advance of providing or discontinuing care. The hospital will inform both inpatients and outpatients of their rights to include the elements as described in PR.1, SR.1 – SR.10.

Each Medicare beneficiary who is an inpatient is provided with a standardized notice, the "Important Message from Medicare, within two days of their admission. The Important Message (IM) template provided by CMS is to be used by the hospital, signed and dated by the patient when it is delivered to the beneficiary. In addition a copy of the IM is to be presented to the beneficiary within two days before discharge.

The hospital has the responsibility to establish and implement policies and procedures that effectively ensure that patients and/or legal representative have the information necessary to exercise their rights under the Federal law. This responsibility includes, and is not limited to, providing all notices required by statute and regulation regarding patients' rights. The hospital may decide it is most effective to bundle the patients' rights and advance directives notice with these existing notices.

The hospital will provide for interpretation for certain individuals who speak languages other than English, use alternative communication techniques or aides for those who are deaf or blind, or take other steps as needed to effectively communicate with the patient.

The hospital's obligation to inform requires that the hospital present information in a manner and form that can be understood (e.g., the use of large print materials, specialized programs to inform individuals who are deaf or blind, use of interpreters).

The hospital must include the patient or their legal representative in the development, implementation and revision of his/her plan of care.

A patient may elect to delegate his or her right to make informed decisions to another person. To the degree permitted by State law, and to the maximum extent practical, the hospital must respect the patient's wishes and follow these accordingly. If the patient is unconscious or otherwise incapacitated and unable to make a decision, the hospital must consult the patient's advance directives, medical durable power of attorney or patient representative, if any of these individuals are available. In the advance directive or the medical power of attorney, the patient may provide guidance as to his or her wishes in certain situations, or may delegate decision-making to another individual as permitted by State law. If such an individual has been selected by the patient, or if a person willing and able under applicable State law is available to make treatment decisions, relevant information should be provided to the representative so that informed health care decisions can be made for the patient. However, as soon as the patient is able to be informed of his or her rights, the hospital should provide such information to the patient.

The patient's (or patient's representatives, as allowed by law) right to participate in the development and implementation of his or her plan of care includes at a minimum, the right to: information regarding the patient's health status, diagnosis and prognosis, participate in the development and implementation of his/her inpatient treatment/care plan or outpatient treatment/care plan, including providing consent to, or refusal of, medical or surgical interventions,; participate in the development and implementation of his/her discharge plan; and, participate in the development and implementation of his/her pain management plan. The patient or his or her representative should receive information provided in a manner that it is understood and to assure that the patient can effectively exercise the right to make informed decisions.

The patient and/or legal representative has the right to request or refuse treatment. This standard stresses, however, that the patient's right to make decisions about health care is not equivalent to an ability to demand treatment or services that are deemed medically inappropriate or unnecessary.

The right to personal privacy includes, at a minimum, that patients have privacy during personal hygiene activities (e.g., toileting, bathing, dressing), during medical/nursing treatments, and when requested by the patient as appropriate. The right to personal privacy would also include limiting the release or disclosure of patient information such as the patient's presence in the facility or location in the hospital, or personal information such as name, age, address, income, health information without prior consent from the patient. The hospital should have procedures in place, in accordance with State law, to provide appropriate information to patient families or significant others in those situations where the patient is unable to make their wishes known.

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.

Privacy should be afforded when the MD/DO or other staff visits the patient to discuss clinical care issues or conduct any examination.

A patient's right to privacy may be limited in situations where a person must be continuously observed, such as when restrained or in seclusion when immediate and serious risk to harm him/ herself (such as when the patient is under suicide precautions or special observation status) or others exists.

The 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.

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.

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 Federal law.

Definition: 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. 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.

The hospital must have sufficient safeguards in place to ensure that access to all information regarding patients is limited to those individuals designated by law, regulation, and policy; or duly authorized as having a need to know. No unauthorized access or dissemination of clinical records is permitted. Clinical records are kept secure and are only viewed when necessary by those persons having a part in the patient's care.

Confidentiality applies to both central records and clinical record information that may be kept at other locations in the hospital, such as, patient units, radiology, laboratories, patient clinics, record storage areas, data systems, etc.

Patient visitation rights:

The hospital must have developed 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.

A hospital must (1) Inform each patient (or representative, 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 42 CFR 482.13(a).

(2) Inform each patient (or representative, 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. (3) Not restrict, limit, or otherwise deny visitation privileges on the basis of race, color, national origin, religion, sex, sexual orientation, gender identity, or disability. (4) Ensure that all visitors designated by the patient (or representative, where appropriate) enjoy visitation privileges that are no more restrictive than those that immediate family members would enjoy.

Surveyor Guidance:

Verify the hospital's policy for notifying all patients of their rights, both inpatient and outpatient.

Review the information that is provided to patients by the hospital.

Verify the method(s) used to inform patients of their rights.

Interview patients (with hospital and patient permission) to determine how the hospital has informed them about their rights.

Verify that the hospital has alternative means, such as written materials, signs, or interpreters, to communicate patients' rights, when necessary.

Validate that the hospital initiates activities that involve the patient or the patient's legal representative in the patient's care and the process for assuring that the patients have this information.

Verify that the hospital respects a patient's request for or refusal of certain treatments and the process followed when this occurs and how this is handled.

Verify that there is a policy that addresses how patient requests for treatment are handled and the circumstances under which a patient request for treatment may be denied.

Verify that the hospital provides adequate information to patients and their representatives regarding the patient's health status, diagnosis and prognosis, and then how the patient is allowed to make informed decisions about their care planning and treatment.

Review and verify that the hospital has a system in place to assure that a patient's family and MD/DO are contacted as soon as can be reasonably expected after the patient is admitted (unless the patient requests that this not be done).

In the review of patient care areas, verify that patients are provided privacy during examinations, procedures, treatments, surgery, personal hygiene activities, and discussions about their health status/care and other appropriate situations.

Review and validate patient and staff incident and accident reports to identify any incidents or patterns of incidents concerning a safe environment.

In review of areas where infants and children are inpatients, verify the security protections (such as alarms, arm banding systems) in place. Determine how these protections are tested and where corrective/preventive action(s) have been implemented.

Review and validate the system in place to protect patients from abuse, neglect and harassment of all forms, whether from staff, other patients, visitors or other persons. Review and verify that the hospital has a written procedure for investigating allegations of abuse and neglect including methods to protect patients from abuse,

Verify that the hospital has a process in place to notify appropriate agencies, including reporting requirements, as applicable, regarding incidents involving abuse, neglect or harassment, in accordance with State and Federal Laws as well as notification to any law enforcement or other agency (i.e. Child/Adult Protective Services)

In review of patient care areas, verify that medical records are not accessible to people not involved with the patient's care.

Verify that the hospital promotes and protects the patient's right to access information contained in his/her clinical records and provides these records to patients within a reasonable timeframe.

Patient visitation rights.

Review the hospital policies on visitation and validate that the policies delineate any reasonable clinical restrictions or limitations, if needed.

Verify that the hospital has developed an active process for informing each patient (or representative, where appropriate) of his or her visitation rights, including any clinical restriction or limitation on such rights.

Verify that all patients (or representative, where appropriate) are informed that they can 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.

Verify that patients have been able to receive all of the visitors that were designated by the patient (or representative, where appropriate) and that visitation privileges have been no more restrictive than those that immediate family members would enjoy.

PR.2 ADVANCE DIRECTIVE

The organization must allow the patient to formulate advance directives and to have organization staff and practitioners comply with the advance directives in accordance with Federal and State law, rules and regulations. The organization must maintain written policies in accordance with 42 CFR §489.102 requirements for providers and 42 CFR §489.104 regarding the effective dates for this requirement.

- SR.1 The organization will 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.
- SR.1a The organization shall document in the patient's medical record whether or not the patient has executed an advance directive for all inpatients, emergency room patients, observation status patients, and day surgery patients.
- SR.2 The organization shall not condition the provision of care or otherwise discriminate based on the execution of the advance directive.
- SR.3 The organization shall ensure compliance with State law regarding the provision of an advance directive.
- SR.4 The organization shall provide education for staff concerning its policies and procedures regarding the advance directives.
- SR.5 When an advance directive exists and is not in the patient's medical record, a written policy for follow-up and compliance shall exist.

Definitions:

An advance directive means 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.

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. State laws regarding the use of psychiatric advance directives vary.

Interpretive Guidelines:

The patient (inpatient or outpatient) has the right to formulate advance directives and to have hospital staff implement and comply with their advance directive in accordance with Federal and State law, rules and regulations. 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.

The hospital should also provide the advance directive notices to outpatients (or their representatives) that 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.

The hospital must communicate its policies regarding the implementation of advance directives, including 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:

- *Clarify any differences between institution-wide conscience objections and those that may be raised by individual MD/DOs;*
- *Identify the State legal authority permitting such an objection; and,*
- *Describe the range of medical conditions or procedures affected by the conscience objection.*

The hospital must document in a prominent part of the patient's medical record whether or not the patient has executed an advance directive.

The hospital must not condition the provision of care or otherwise discriminate against an individual on the basis of whether or not the patient has executed an advance directive.

*The hospital must ensure compliance with State law regarding the provision of an advance directive and inform individuals that complaints **that concern** the advance directive requirements may be filed with the State survey agency and this accreditation body.*

When the advance directive exists and is not in the patient's medical record, a written policy must be in place to address the follow-up and compliance. When necessary, the hospital will take the appropriate steps to secure a copy of the patient's advance directives.

Surveyor Guidance:

In a sampling of patient records, review and verify that the hospital has complied with the patient's advance directive notice requirements.

Review and verify the hospital has a procedure in place to allow patients to formulate an advance directive or to update their current advance directive.

*Verify that the hospital educates its staff regarding advance directives, **including psychiatric advance directives, as indicated by hospital policy and state law.***

Determine how the hospital advises inpatients, applicable outpatients, or their representatives, of the patient's right to formulate an advance directive and to have hospital staff comply with the advance directive in accordance with State law.

PR.3 LANGUAGE AND COMMUNICATION

The organization shall inform the patient and/or legal representative of their rights in language or format that the patient and/or legal representative understand.

SR.1 Organization policy and practice provides for competent individuals to interpret the patient's language for individuals who do not speak English or provide alternative communication aids for those who are deaf, blind, or otherwise impaired.

Interpretive Guidelines:

The hospital will provide for interpretation for certain individuals who speak languages other than English, use alternative communication techniques or aides for those who are deaf or blind, or take other steps as needed to effectively communicate with the patient.

The hospital's obligation to communicate with patients requires that the hospital present information in a manner and form that can be understood (e.g., the use of large print materials, specialized programs to inform individuals who are deaf or blind, use of interpreters, etc.).

Surveyor Guidance:

Verify that the hospital has alternative means, such as written materials, signs, or interpreters, to communicate patients' rights, when necessary.

Verify how the hospital meets the needs of these diverse patients.

PR.4 INFORMED CONSENT

The organization shall obtain an informed written consent from each patient or authorized representative for the provision of medical and/or surgical care except in medical emergencies. The consent shall include an explanation of risks, benefits, and alternatives for high-risk procedures, sedation, and participation in research projects, as defined by the medical staff and State law.

Interpretive Guidelines:

All patients receiving either inpatient and outpatient care must complete an informed written consent form for all procedures and treatments specified by the hospital's medical staff, or State or Federal laws or regulations. In the event of a medical emergency, the hospital is not required to obtain a written consent, but timely efforts should be made to obtain an informed written consent from the patient's authorized representative.

The procedures/treatments which will require the hospital to obtain patient written consent will at least include: high-risk procedures (including blood transfusions); sedation; participation in research projects; and, filming or videotaping.

Definition elements: Informed consent means the patient or patient representative is given (in a language or means of communication he/she understands) the information, explanations of risks, benefits and alternatives, needed in order to consent to a procedure or treatment. Informed consent would include that the patient is informed as to who will actually perform planned surgical interventions.

When practitioners other than the primary surgeon will perform important parts of the surgical procedures, even when under the primary surgeon's supervision, the patient must be informed of who these other practitioners are, as well as, what important tasks each will carry out. We recognize that at the time of the surgery, unforeseen circumstances may require changing which individual practitioners actually are involved in conducting the surgery.

A properly executed informed consent form contains at least the following:

- *Name of patient, and when appropriate, patient's legal guardian;*
- *Name of hospital;*
- *Name of specific procedure(s) or medical treatment);*
- *Name of the responsible practitioner who is performing the procedure(s) or administering the medical treatment;*
- *Signature of patient or legal representative;*
- *Date and time consent form is signed by the patient or the patient's legal representative;*
- *Statement that procedure/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.)*
- *Name of person who explained the procedure to the patient or guardian.*

Situations where the patient consents to a procedure and information was withheld from the patient, where if the patient had been informed of that information, the patient may not have consented to the procedure or made the same decisions would not be considered informed consent.

Surveyor Guidance:

Verify that the medical staff has specified which procedures or treatments require a written informed consent.

Verify that medical records contain consent forms for all procedures or treatments as required by hospital policy.

In a sampling of patient records, review and validate that consent forms are properly executed and contain at least the information identified above.

PR.5 GRIEVANCE PROCEDURE

The organization shall develop and implement a formal grievance procedure that provides for the following:

- SR.1 A list of whom to contact;
- SR.2 The governing body's review and resolution of grievances or the written delegation of this function to an appropriate person or committee;
- SR.3 A referral process for quality of care issues to the Utilization Review, Quality Management or Peer Review functions, as appropriate; and,
- SR.4 Specification of reasonable timeframes for review and prompt response and resolution to patient grievances.
- SR.5 Grievance resolutions must be in writing and directed to the patient. The grievance resolution shall include the following:
 - SR.5a Organization contact person;
 - SR.5b Steps taken to investigate;
 - SR.5c Results of the grievance process; and,
 - SR.5d Date of completion.

Interpretive Guideline:

The hospital must develop and implement a formal grievance procedure to identify the process that will be followed and the required correspondence, including grievance resolution, to be provided to the patient.

Definition elements: 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, when a patient issue cannot be resolved promptly by staff present. If a complaint cannot be resolved promptly by staff present or is referred to a complaint coordinator, patient advocate, or hospital management, it is to be considered a grievance.

The patient should have reasonable expectations of care and services and the facility should address those expectations in a timely, reasonable, and consistent manner. 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. A written response is required for the initial acknowledgement of the grievance (which may or may not include the resolution) within the timeframe of 7 to 10 days. If the grievance is not resolved, the investigation is not complete, or if the corrective action is still being evaluated, the hospital's response should address that the hospital is still working to resolve the complaint and states that the hospital will follow-up with another written response within a specified timeframe (depending on what actions the hospital may have to take). Not all grievances must be in writing if the hospital is addressing a relatively minor request from a patient and that it can be immediately resolved. When appropriate, the grievance resolution will include:

- *Identification of the organization's contact person;*
- *Steps taken to investigate;*
- *Results of the grievance process; and,*
- *Date of completion.*

The hospital must inform the patient and/or the patient's legal guardian/representative of the internal grievance process, including whom to contact to file a grievance (complaint). As part of its notification of patient rights, the hospital must inform the patient that he/she may submit 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. The hospital must provide the patient or the patient's representative a phone number and address for submitting a grievance with the State agency.

The hospital is required to have procedures for referring Medicare beneficiary concerns to the assigned Quality Improvement Organization (QIO) at the beneficiary's request if they have a complaint regarding quality of care, disagree with a coverage decision, or they wish to appeal premature discharge; additionally, hospitals must inform all beneficiaries of this right.

Surveyor Guidance:

Review and verify the hospital's policies and procedures to assure that its grievance process encourages all personnel to alert appropriate staff concerning any patient grievance and that the hospital's governing body has approved the grievance process.

Verify that the hospital's process assure that grievances involving situations or practices that place the patient in immediate danger, are resolved in a timely manner.

Verify that information is provided to patients to explain the hospital's grievance procedures.

Verify that time frames are established to review and respond to patient grievances.

Verify that the hospital provides written notices (responses) to patients as required.

Review the time frames established to review and respond to patient grievances and that these are being met.

Verify that these time frames are clearly explained in the information provided to the patient and explains the hospital's grievance process.

PR.6 RESTRAINT OR SECLUSION

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, that is not medically necessary, or that is imposed by staff as a means of coercion, discipline, convenience, or retaliation. Each patient should be treated with respect and dignity.

SR.1 The patient has 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.

SR.1a A restraint is 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 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.

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).

SR.1b A restraint includes a drug or medication 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.

SR.1c Seclusion is the involuntary confinement of a patient alone in a room or area from which the patient is physically prevented from leaving. A situation where a patient is restricted to a room or area alone and staff are physically intervening to prevent the patient from leaving the room or area is also considered seclusion.

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.

Interpretive Guidelines:

An object may be a restraint by functional definition. Anything that prevents the patient access to his or her body, moving their arms, legs, or ambulating in a normal manner is a restraint.

A device is considered a restraint if it is applied to someone who is physically able to get up and they are prevented from doing so. Under this definition, many commonly used hospital devices and practices could meet the definition of a restraint, including:

- *Tucking a patient's sheets in so tightly that he or she cannot move; or*
- *Wrist holders, highly padded mitts or other types of devices would be considered a restraint. Using a side rail to prevent a patient from voluntarily getting out of bed.*

- *A restraint such as a soft wrist restraint, an arm restraint, wrapping or bundling, or some similar type of intervention to prevent an infant or toddler from removing invasive lines or reopening a surgical site, meets the definition of physical restraint and the requirements apply.*
- *Placing hand mitts on infants would not be considered restraint but pinning or otherwise attaching those same mitts to bedding would meet the definition of physical restraint and the requirements would apply.*
- *Devices that serve multiple purposes such as Geri chair or side rails, when they have the effect of restricting a patient's movement and cannot be easily removed by the patient, constitute a restraint.*
- *Physical holding of a patient for the purpose of conducting routine physical examination or tests is permitted. However, patients do have the right to refuse treatment. This includes the right to refuse physical examinations or tests. Holding a patient in a manner that restricts the patient's movement against his or her will would be considered a restraint. This includes therapeutic holds.*

Siderails

It is standard practice to raise 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.

Devices that protect the patient from falling out of bed are not restraints. However, raising all four side rails in order to restrain a patient, (as this may immobilize or reduce 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 rule applies. A patient's history of falls without current evidence of falling is not a reason to use restraints.

A disoriented patient may see the side rail as a barrier to be climbed over or may attempt to wriggle through split rails or to the end of the bed to exit the bed. As a result, this 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.

Raising fewer than four side rails when the bed has more than two side rails, would not necessarily immobilize or reduce the ability of a patient to move

A functional definition does not name each device and situation that can be used to inhibit an individual's movement, and promotes looking at situations on a case-by-case basis. Therefore, if the effect of using an object fits the definition of restraint for that patient at that time, then for that patient at that time, the device is a restraint.

Regardless of whether a restraint is voluntarily or involuntarily, this standard applies. 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.

Exemptions from requirements of the restraint or seclusion standards include:

- *The use of handcuffs or other restrictive devices applied by law enforcement officials who are not employed by or contracted by the hospital when the use of such devices is for custody, detention, and public safety reasons, and is not involved in the provision of health care. The application, monitoring, and removal of forensic devices are the responsibility of the law enforcement officers. The hospital and its staff are responsible for providing safe and appropriate care to the patient.*
- *A voluntary 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. Some patients lack the ability to walk without the use of leg braces, to sit upright without neck, head, or back braces.*
- *A medically necessary and voluntary positioning or securing device used to maintain the position, limit mobility, or temporarily immobilize during medical, dental, diagnostic, or surgical procedures is not considered a restraint.*
- *Physically holding a patient during a forced psychotropic medication procedure is considered physical restraint and is not included in this exception.*
- *Recovery from anesthesia that occurs when the patient is in the intensive care unit or recovery room is considered part of the surgical procedure; therefore, medically necessary restraint use in this setting would not need to meet the requirements of this standard. 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 the standard(s) must be followed.*
- *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 standard. The use of these safety interventions needs to be addressed in the hospital's policies or procedures.*

Drugs Used as a Restraint

If the use of the medication for the patient meets the definition of a drug used as a restraint, the assessment, monitoring and documentation requirements apply. The use of PRN orders is prohibited for drugs or medications that are being used as restraints.

The standard is not intended to interfere with the clinical treatment of patients who need medication in appropriate doses that are standard medical or psychiatric treatment for the patient's condition. Medications such as the following are not considered restraints when based on the assessed needs of the particular patient with careful monitoring to minimize adverse effects:

- *Therapeutic doses of psychotropic medication for patients who are suffering from serious mental illness to improve their level of functioning so that they can more actively participate in their treatment.*

- *Therapeutic doses of anti-anxiety medications to calm the patient who is anxious.*
- *Appropriate doses of sleeping medication prescribed to treat insomnia.*
- *Appropriate doses of analgesic medication ordered for pain management.*

Therefore, a notation that certain medications are a standard treatment for a patient's medical or psychiatric conditions and are NOT subject to the requirements of the restraint standard is acceptable in the following circumstances:

- *The medication is used within the pharmaceutical parameters approved by the Food and Drug Administration (FDA) and the manufacturer for the indications it is manufactured and labeled to address, including listed dosage parameters.*
- *The use of the medication follows national practice standards established or recognized by the medical community and/or professional medical association or organization.*
- *The use of the 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 LIP's knowledge of that patient's expected and actual response to the medication.*

An additional component of "standard treatment" for a medication is the expectation that the standard use of a 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 of the medication. If the overall effect of a medication is to reduce the patient's ability to effectively or appropriately interact with the world around the patient, then the medication is not being used as a standard treatment for the patient's condition.

Example: "A patient has Sundowner's Syndrome, a syndrome in which a patient's dementia becomes more apparent at the end of the day than 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 unit's staff find the patient's behavior bothersome, and ask the physician to order a high dose of a sedative to keep him in bed. The patient has no medical symptoms or condition that indicates that he needs a sedative. In this case, for this patient, the sedative is being used as a restraint for staff convenience. Such use is not permitted by the regulation. The regulation does not allow a drug to be used to restrain the patient for staff convenience, to coerce or discipline the patient, or as a method of retaliation."

The standard 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.

Seclusion

Seclusion can only be used in emergency situations if needed to ensure the immediate safety of the patient exhibiting violent or self-destructive behavior (and others) and less restrictive interventions have been determined to be ineffective.

In a therapeutic time out, the staff and patient collaboratively determine when the patient has regained self-control and is able to return to the treatment milieu. In seclusion, this judgment

is made by the clinicians—that is, an agitated patient may feel that he or she should be released, even though the patient’s behavior continues to be violent or self-destructive. A situation where a patient is restricted to a room or area alone and staff are physically intervening to prevent the patient from leaving the room or area is also considered seclusion

SR.2 The hospital will keep the patient safe and protect their rights when restraints or seclusion are applied.

SR.2a The hospital will have policies and procedures designed to protect patient rights and dignity with regards to the use of restraint and seclusion, and ensure safety of the patient, staff and others. These policies and procedures guide staff in the safe use of restraint or seclusion, and incorporate all elements of the Federal and State regulations.

SR.2b Restraint or seclusion may only be imposed to ensure the immediate physical safety of the patient, staff, or others and must be discontinued at the earliest possible time.

SR.2c Restraint or seclusion may only be used when less restrictive interventions have been determined to be ineffective to protect the patient or others from harm.

SR.2d The type or technique of restraint or seclusion used must be the least restrictive intervention that will be effective to protect the patient or others from harm.

SR.2e The use of restraint or seclusion must be in accordance with a written modification to the patient’s plan of care, and implemented in accordance with safe and appropriate restraint and seclusion techniques as determined by hospital policy in accordance with State law.

SR.2f Restraint and seclusion may not be used simultaneously, unless the patient is continually monitored, face-to-face, by an assigned, trained staff member; or continually monitored by trained staff using both video and audio equipment.

SR.2f(1) This monitoring must be in close proximity to the patient.

SR.2f(2) For the purposes of this provision, “continually” means ongoing without interruption.

Interpretive Guidelines:

Restraint or seclusion must not be used unless it is to meet the patient’s individual clinical needs. The uses of restraint or seclusion should be discontinued as soon as possible.

Restraint use associated with non-violent or non-self-destructive behavior may be indicated, but only when it directly supports medical healing.

When a patient's violent or self-destructive behavior presents an immediate and serious danger to the patient or others, immediate action is needed. While staff should be mindful of using the least intrusive intervention, it is critical that staff considers all interventions available to them and that the intervention selected be effective in protecting the patient or others from harm.

A patient may experience a severe medication reaction that causes him or her to become violent or a patient may be withdrawing from alcohol and having delirium tremors (DTs). The patient is agitated, combative, verbally abusive, and attempting to hit staff. Regardless of facility type, such emergencies generally pose a significant risk for patients and others. For the safety of the patient and others, the use of restraint or seclusion may be necessary to manage the patient's violent or self-destructive behavior that jeopardize the immediate physical safety of the patient, a staff member, or others when less restrictive interventions have been determined to be ineffective to protect the patient, staff, or others from harm. It is not targeted only at patients on psychiatric units or those with behavioral/mental health care needs. The patient protections contained in this standard apply to all patients when the use of restraint or seclusion becomes necessary.

The use of restraint or seclusion is a last resort when alternatives or less restrictive measures have been determined ineffective to protect the patient or others from harm, not a standard response to a behavior or patient need.

Further, the decision to use a restraint is implemented following a comprehensive individual assessment that concludes that for this patient at this time, the use of less intrusive measures pose a greater risk than the risk of using a restraint or seclusion.

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 can cause confusion, agitation, and combative behaviors. Addressing these medical issues can often eliminate or minimize the need for the use of restraints.

When assessing and planning the care for the patient, the hospital should consider whether he/she 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. A restraint must not serve as a substitute for adequate staffing to monitor patients.

Comprehensive assessment of the patient and the environment, in conjunction with individualized patient care planning, should be used to determine those interventions that will best ensure the patient's safety and well-being with the least risk.

The most appropriate intervention that will ensure the safety of the patient is to be selected following a comprehensive assessment of the patient, the environment, and the patient's individualized treatment plan.

Hospital policies should address the frequency of assessment and the assessment parameters (for example, vital signs, circulation checks, hydration needs, elimination needs, level of distress and agitation, mental status, cognitive functioning, skin integrity).

Hospital policies should guide staff in how to determine an appropriate interval for assessment and monitoring based on the individual needs of the patient, the patient's condition, and the type of restraint used. It may be that a specific patient needs continual face-to-face monitoring; or that the patient's safety, comfort, and well-being are best assured by periodic checks.

The hospital is responsible for providing the level of monitoring and frequency of reassessment that will ensure the patient's safety.

The use of a restraint or seclusion intervention is documented in the patient's plan of care or treatment plan based on an assessment and evaluation of the patient.

The plan of care or treatment plan should be reviewed and updated in writing within a timeframe specified by hospital policy. The plan should reflect an individualized approach that is in the best interest of the patient and promotes the patient's health, safety, dignity, self-respect, and self-worth.

The risks associated with any intervention must be considered within the context of an ongoing process of assessment, intervention, evaluation, and re-evaluation.

The use of restraint or seclusion interventions must never act as a barrier to the provision of safe and appropriate care, treatments, and other interventions to meet the needs of the patient.

Surveyor Guidance:

Review hospital policies relative to the use of restraint or seclusion to verify that they have been designed to protect patient rights and all elements of Federal and State regulations are included:

- *These policies should conform to State law and indicate which [QLP's](#) are permitted to order restraints.*
- *Verify that the hospital has defined who has the authority to discontinue restraints (based on State law and hospital policies) and under what circumstances restraints are to be discontinued.*

In a sampling of medical records of patients where restraint or seclusion has been applied, review and validate that restraint or seclusion was appropriately used based upon the patient's physical or mental condition before the application of restraint or seclusion.

Verify that the rationale for restraint is described and the least restrictive technique was selected.

Verify that staff attempted other less restrictive measures before applying restraint or seclusion.

Interview hospital staff to identify how they assess the patient and determine that the least restrictive interventions would be ineffective to protect the patient, staff, and others from harm.

Review and validate if the hospital has applied the same type of restraint to other patients regardless of their respective medical condition.

Verify that the plan of care is updated according to hospital policy and reflects continuous assessment, intervention, evaluation, and reassessment as required.

SR.3 Order for Restraint or Seclusion:

SR.3a The use of restraint or seclusion must be in accordance with the order of a physician or other **qualified licensed practitioner (QLP)** who is responsible for the care of the patient as specified under § 482.12(c) and is authorized to order restraint or seclusion by hospital policy in accordance with State law.

SR.3b An order for restraint or seclusion must be obtained prior to the application of restraints, except in emergency situations when the need for intervention may occur quickly;

SR.3c An order for restraint or seclusion is never to be written as a standing order or on an as needed basis (PRN).

SR.3d The attending physician must be consulted as soon as possible if restraint or seclusion is not ordered by the patient's attending physician.

SR.3e Each order for restraint or seclusion used to manage violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others based on the age of the patient.

SR.3e(1) Orders are limited to 4 hours for adults 18 years of age or older; 2 hours for children and adolescents 9 to 17 years of age; and 1 hour for children under 9 years of age.

SR.3e(2) The restraint or seclusion order may only be renewed in accordance with these limits for up to a total of 24 hours unless superseded by State law that is more restrictive.

SR.3e(3) After 24 hours, and 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 QLP (if allowed by State law) must see and assess the patient.

SR.3e(4) If the restraint or seclusion is discontinued prior to the expiration of the order, a new order must be obtained prior to re-initiation of the restraint or seclusion.

SR.3f 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.

Interpretive Guidelines:

*A **qualified licensed practitioner (QLP)** is any individual permitted by State law and hospital policy to order restraints and seclusion for patients independently within the scope of the individual's license and consistent with the individually granted clinical privileges. This provision is not to be construed to limit the authority of a physician to delegate tasks to other qualified healthcare personnel, that is, physician assistants and advanced practice nurses, to the extent recognized under State law or a State's regulatory mechanism, and hospital policy.*

When the restraint or seclusion is not ordered by the patients attending physician, the order must be followed by consultation with the patient's treating physician as soon as possible.

Consultation ensures that the physician who has overall responsibility and authority for the management and care of the patient is aware of and involved in the intervention. This also promotes continuity of care and elicits information from the attending physician that might be relevant in choosing the most appropriate intervention for the patient.

Medical staff policies determine who is considered the treating (attending) physician.

Hospital policies and procedures should address the definition of "as soon as possible" based on the needs of their particular patient population.

*When the attending physician is unavailable, responsibility for the patient must be delegated to another physician, who would **then be** considered the attending physician.*

The attending practitioner must be able to conduct both a physical and psychological assessment of the patient in accordance with State law, their scope of practice, and hospital policy

When implementing a protocol that includes the use of an intervention that meets the definition of a restraint, a separate order must be obtained for the restraint.

The patient's medical record must include documentation of an individualized patient assessment indicating that the patient's symptoms and diagnosis meet the-triggering criteria identified in the protocol. Restraint or seclusion use is an exception, not a routine response to a certain condition or behavior.

Hospitals that utilize protocols would be expected to provide evidence that there has been medical staff involvement in the development, review, and quality monitoring of their use.

A registered nurse can initiate restraint in an emergency situation:

- *In emergency situations, an order must be obtained either during the emergency application of the restraint or seclusion, or immediately after the restraint has been applied. The hospital should address this process in its restraint policies and procedures.*
- *Hospital procedures shall specify who can initiate the use of restraint or seclusion in an emergency prior to obtaining an order from a physician or other QLP.*

Time limits on the length of each order only apply when restraint or seclusion are used to manage violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others.

- *The length-of-order requirement identifies critical points at which there is mandatory contact with a physician or QLP responsible for the care of the patient.*
- *A trained RN can reassess the patient when the original order is about to expire, and then contact the physician or other QLP to obtain direction as to whether to renew the order (for up to 4 hours, 2 hours, or 1 hour, as permitted by the regulation) and whether other steps are to be taken.*
- *If a patient remains in restraint or seclusion for the management of violent or self-destructive behavior 24-hours after the original order,, a face-to-face assessment by a physician or other QLP must occur before a new order for the continued use of restraint or seclusion is written.*

The regulation does not require the ordering QLP to be physically present to re-evaluate the need for continuing restraint for non-violent and non-self-destructive behaviors. Hospitals have the flexibility to determine time frames for the restraint of the non-violent, non-self-destructive patient. These time frames should be addressed in policies and procedures.

Surveyor Guidance:

Review the medical records of patients that required restraint or seclusion to verify that:

- *The attending physician was consulted of the need for restraint or seclusion, as soon as possible, according to hospital policy*
- *The attending physician was contacted prior to the expiration of orders for restraint or seclusion*

SR.4 One Hour Face-to-Face Evaluation.

The condition of the patient must be continuously assessed, monitored, and reevaluated.

SR.4a When restraint or seclusion is used to manage violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others, a physician or other QLP, or a RN or PA trained in accordance with the requirements specified under PR.7 must see the patient face-to-face within 1-hour after the initiation of the intervention to evaluate:

SR.4a(1) The patient's immediate situation;

SR.4a(2) The patient's reaction to the intervention;

SR.4a(3) The patient's medical and behavioral condition; and,

SR.4a(4) The need to continue or terminate the restraint or seclusion.

SR.4b If the 1-hour face-to-face evaluation is conducted by a trained RN or PA, the attending physician or other QLP responsible for the care of the patient must be consulted as soon as possible after completion of the evaluation.

Interpretive Guidelines:

The 1-hour face-to-face evaluation includes both a physical and behavioral assessment of the patient. Therefore, the practitioner who conducts this evaluation must be able to complete both a physical and behavioral assessment of the patient in accordance with State law, his or her scope of practice, and hospital policy. 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 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.

When a trained RN or PA conducts the 1-hour evaluation, the physician is consulted, but is not required to come to the hospital to see and evaluate the patient 1-hour after the initiation of the restraint or seclusion.

The physician can determine the need for immediate or further onsite evaluation based upon the patient's symptoms, condition, and history.

Telephone consultation may be acceptable for this consultation.

The 1-hour face-to-face evaluation only applies when restraints, use of a medication as a restraint, or seclusion are used to manage violent or self-destructive behavior.

If a patient's violent or self-destructive behavior is resolved and the restraint or seclusion is discontinued before the practitioner arrives to perform the one hour face to face evaluation, a practitioner is still required to see the patient face to face within one hour after the initiation of the intervention. Ending the intervention prior to the 1-hour point does not mean that the mandated assessment and consultation are no longer necessary. The patient's behavior warranted the use of a restraint or seclusion which indicates a serious change in a patient's condition and must be assessed.

State law (by statute or regulation) regarding the 1-hour face-to-face evaluation should be followed if more restrictive than these requirements.

Surveyor Guidance:

Validate the competency of personnel conducting the 1-hour face-to-face evaluation. The 1-hour face-to-face evaluation includes both a physical and behavioral assessment of the patient. Therefore, the practitioner who conducts this evaluation must be able to complete both a physical and behavioral assessment of the patient in accordance with State law, his or her scope of practice, and hospital policy

Generally, practitioners such as social workers, psychologists and other mental health workers are not qualified to conduct a physical assessment, nor is it in their scope of practice.

Review a sampling of medical record for patients where restraint or seclusion was applied and review documentation to confirm that:

- *The patient received a face-to-face medical and behavioral evaluation within 1 hour of the intervention by an appropriate person identified in hospital policy*
- *Consultation with the attending physician has taken place as soon as possible following the 1-hour face-to-face evaluation*
- *The patient's condition and reaction to the intervention was documented.*

SR.5 Assessment, Monitoring, and Evaluation of the Restrained or Secluded Patient

SR.5a The condition of patients in restraint or seclusion is monitored and assessed by a physician, other licensed independent practitioner or trained staff at an interval determined by hospital policy, at least every 24 hours.

SR.5a(1) Hospital policies address the frequency of assessment and the assessment parameters (for example, vital signs, circulation checks, hydration needs, elimination needs, level of distress and agitation, mental status, cognitive functioning, skin integrity).

SR.5a(2) Hospital policies guide staff in how to determine an appropriate interval for assessment and monitoring based on the individual needs of the patient, the patient's condition, and the type of restraint used (for example, every 15 minutes).

SR.5b Restraint or seclusion must be discontinued at the earliest possible time, regardless of the length of time identified in the order.

SR.5c If restraint and seclusion are used simultaneously, the patient must be continually monitored, face-to-face, by an assigned, trained staff member; or continually monitored by trained staff using both video and audio equipment.

SR.5c(1) This monitoring must be in close proximity to the patient.

SR.5c(2) For the purposes of this provision, “continually” means ongoing without interruption

Interpretive Guidelines:

All restraint interventions must be based on the individual clinical needs of a particular patient at a particular time as demonstrated by documented ongoing assessments of that patient.

Ongoing assessment and monitoring of the patient's condition are crucial for prevention of patient injury

The selection of an intervention and determination of the necessary frequency and level 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 chosen intervention, and other relevant factors.

Staff determines the appropriate level of monitoring and frequency of assessment based on hospital policy, an individualized patient assessment, and type of intervention used.

The attending physician should be kept informed about the patient's status.

After 24 hours, a face-to-face assessment by a physician or other QLP must occur before a new order is written for restraints or seclusion for the violent or self-destructive patient

Restraint or seclusion must be ended at the earliest possible time, regardless of the length of time identified in the order.

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.

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:

- *Staff cannot discontinue an order and then restart it because that would constitute a PRN order.*
- *A temporary release that occurs for the purpose of caring for a patient's needs, for example, toileting, feeding, and range of motion, is not considered a discontinuation of the intervention.*
- *Example: When a trial period of observation out of restraints is initiated and the patient again exhibits the symptoms that prompted the prior use of restraints, and the patient is placed in restraint again, a new order would be required. This episode cannot be considered as part of the original episode/order as it would be considered a PRN order which is not permitted.*
- *Example: A patient is released from restraint or seclusion. If this patient later exhibits violent or self-destructive 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.

- *Example: When patient's behavior responds to the intervention in 20 minutes, the restraint or seclusion should be discontinued, even if the order was given for up to 4 hours.*

All requirements specified under this standard apply in the simultaneous use of restraint and seclusion:

- *Continual face-to-face monitoring (that is, moment to moment) is only required when restraint and seclusion are used simultaneously to address violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others.*
- *Monitoring in "close proximity" to the patient is intended to ensure that staff is immediately available to intervene and render appropriate interventions to meet the patient's needs.*

The use of PRN orders for drugs or medications is only prohibited when a drug or medication is being used as a restraint.

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 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.*

Surveyor Guidance:

In a sampling of medical records of patients where restraint or seclusion has been applied review and validate that:

- *The patient was monitored and reassessed according to timeframes defined by hospital policy*
- *The patient was reassessed according to criteria established by hospital policy*

SR.6. Documentation in the Medical Record

SR.6a When restraint or seclusion is used, there must be documentation in the patient's medical record of the following:

SR.6a(1) A description of the patient's behavior and the intervention used;

SR.6a(2) Alternatives or other less restrictive interventions attempted (as applicable);

SR.6a(3) The patient's condition or symptom(s) that warranted the use of the restraint or seclusion; and,

SR.6a(4) The patient's response to the intervention(s) used, including the rationale for continued use of the intervention

SR.6a(5) The 1-hour face- to-face medical and behavioral evaluation and assessment findings if restraint or seclusion is used to manage violent or self- destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others;

SR.6a(6) Monitoring and assessment activities

SR.6a(7) Written modification to the patient's plan of care or treatment plan based on an assessment and evaluation of the patient.

SR.6a(8) The plan of care or treatment plan should be reviewed and updated in writing within a timeframe specified by hospital policy.

SR.6a(9) Additional elements of documentation, such as name, title, and credentials of staff members involved in the procedure, should be specified in hospital policy.

SR.6b In addition, staff must document in the patient's medical record the date and time any death associated with restraint or seclusion use was reported to CMS. (see section on Report of Death)

Interpretive Guidelines:

Patient care staff must be able to demonstrate that the restraint or seclusion intervention is the least restrictive intervention that protects the patient's safety. Patient care staff must demonstrate through their documentation that the use of restraint or seclusion is based on individual assessment of the patient the assessments and documentation of these assessments must be ongoing in order to demonstrate a continued need for restraint or seclusion.

Surveyor Guidance:

Verify and validate that there is documentation of ongoing patient assessment (e.g. skin integrity, circulation, respiration, intake, and output, weight, hygiene, injury).

In a sampling of patient records, where restraint or seclusion was applied during their hospital stay, review and validate that the record contains:

- *A description of the patient's behavior and the intervention used.*
- *Alternative/less restrictive interventions attempted, as applicable*
- *The patient's response to interventions used, including rationale for continued use*
- *The one-hour face-to-face medical and behavioral evaluation when restraint or seclusion is used to manage violent or self-destructive behavior*
- *Monitoring and assessment activities*

SR.7 Quality Monitoring

SR.7a The use of restraint and seclusion is to be monitored and evaluated on a continual basis as part of the organization's Quality Management System (See also QM.7.SR.6).

SR.7b Evidence of prolonged restraint, as defined by the organization, and, if possible, actions taken to reduce or eliminate the use of restraints must be analyzed by the treatment team,

SR.7c Aggregate data regarding the use of restraint must be collected and analyzed for the identification of patterns and trends. Intensive analysis must be implemented in the event a patient is injured through the use of restraint or a staff member is injured through the application of a restraint.

Interpretive Guidelines:

The data collected will be aggregated and analyzed to ensure that only clinically necessary restraints are used with a focus on patient safety.

Actions are to be implemented to ensure that standards for restraint or seclusion are applied appropriately as they relate to the patient with non-violent/ non-self-destructive behavior and the patient with violent/self-destructive behavior.

As a means of documenting this assessment and monitoring, the use of restraints must be recorded within a log or other data collection mechanism for monitoring. The documentation must include identification of:

- *Shift;*
- *Date, time of order;*
- *Staff who initiated the process;*

- *The length of each episode;*
- *Date and time each episode was initiated;*
- *Day of the week each episode was initiated;*
- *Type of restraint or seclusion used (including physical restraint or drug used as restraint);*
- *Compliance with requirements defined in the standards;*
- *Whether injuries were sustained by the individual or staff;*
- *Age of individual; and,*
- *Gender of individual.*

Data must be analyzed for the identification of patterns and trends including:

- *Patterns of excessive use*
- *Use of physical restraint or drugs used as restraint to substitute for adequate staffing, monitoring, assessment, or investigation of the reasons behind patient behavior such as wandering or getting up in the night, which may be indicative of unmet patient care needs*
- *Opportunities for improving compliance with the requirements of the standards*

Twenty-four hours of restraint or seclusion for the management of violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others is an extreme measure which could potentially seriously harm the patient. When there is evidence of prolonged restraint, as defined by the organization, and, if possible, actions taken to reduce or eliminate the use of restraints must be analyzed and presented for management review.

Intensive analysis must be implemented in the event a patient is injured through the use of restraint or a staff member is injured through the application of a restraint.

Surveyor Guidance:

Review the aggregate data regarding the use of restraints and seclusion to see if the hospital has identified patterns and trends.

Confirm that the organization can demonstrate implementation of corrective or preventive action where analysis of data reflects variation.

Verify the hospital had conducted an intensive analysis in the event a patient is injured through the use of restraint or a staff member is injured through the application of a restraint.

PR.7 RESTRAINT OR SECLUSION: STAFF TRAINING REQUIREMENTS

The patient has the right to safe implementation of restraint or seclusion by trained staff.

- SR.1 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
 - SR.1a. Training must occur before performing any of these actions, as part of orientation, and subsequently on a periodic basis consistent with hospital policy.
- SR.2 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:
 - SR.2a. Techniques to identify staff and patient behaviors, events, and environmental factors that may trigger circumstances that require restraint or seclusion;
 - SR.2b. The use of non-physical intervention skills, including de-escalation and dealing with aggressive behavior;
 - SR.2c. Choosing the least restrictive intervention based on an individualized assessment of the patient's medical or behavioral status or condition;
 - SR.2d. 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);
 - SR.2e. Clinical identification of specific behavioral changes that indicate that restraint or seclusion is no longer necessary;
 - SR.2f. 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; and;
 - SR.2g. The use of first aid techniques and certification in the use of cardiopulmonary resuscitation, including recertification requirements.
- SR.3 At a minimum, physicians, and other QLP's authorized to order restraint or seclusion by hospital policy in accordance with State law must have a working knowledge of the hospital policy regarding the use of restraint or seclusion.
 - SR.3a. Physician and other QLP training requirements must be specified in hospital policy
- SR.4 Individuals providing staff training must be qualified as evidenced by education, training, and experience in techniques used to address patients' behaviors.
- SR.5 The hospital must document in the staff personnel records that the training and demonstration of competency were successfully completed.
- SR.6 Registered Nurses and Physician Assistants that are selected to perform face-to-face evaluations of patients that exhibit violent or self-destructive behaviors are identified and trained in the expectations of this role, specifically how to evaluate and document

the:

- SR.6a Patient's immediate situation;
- SR.6b Patient's reaction to intervention
- SR.6c Patients medical and behavioral condition including a review of systems, patient history, medications, and lab results; and
- SR.6d Need to continue or terminate the restraint or seclusion.

Interpretive Guidelines

Staff who have direct contact with patients must be trained and able to demonstrate competency before applying restraints, implementing seclusion, providing care for a patient in restraint or seclusion, or with assessing and monitoring the condition of the restrained or secluded patient:

- *The facility identifies the appropriate clinical staff that must be trained in the application, monitoring, patient care, and discontinuation of restraint or seclusion.*
- *Non-nursing staff must be included to the extent that they are involved with restraint use.*
- *Application of restraint or seclusion by an untrained staff member, including contract staff, would constitute a violation of this requirement.*

Training must be comprehensive and must involve demonstration and return demonstration

The written training curriculum reflects the defined competency skill sets defined for each level of clinical personnel:

- *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.*
- *Hospital policies and emergency procedures for managing violent or self-destructive behaviors in included in the training curriculum.*
- *It is appropriate to have different levels of training for different individuals depending upon their involvement with restraints.*

The training curriculum is reviewed annually and revised as indicated, incorporating relevant findings from QA/PI activities.

Accurate recordkeeping of training sessions, including titles of the employees who attend must be stored onsite where the actual documents will be easily accessible for review. In order to ensure that the employee training is complete, all the required components of the program must be covered.

Surveyor Guidance:

Review hospital policy and training records to verify:

- *Competency skill sets for clinical staff are identified.*
- *Training content and frequency are identified to meet the standard.*
- *Trainers are qualified as evidenced by education, training, and experience.*
- *All staff that applies or monitors restraint or seclusion, including Physical Therapy, Radiology, and Respiratory Care staff receive training and have demonstrated competency related to use of restraint and seclusion.*
- *Policy describes training requirements for physicians and licensed independent practitioners.*
- *Training has been provided for the medical staff, [QLP's](#) and hospital staff as defined.*

Review and validate that the hospital has documented instructional training for the use of all restraint techniques used and the alternatives to the use of restraint and seclusion.

Review selected personnel files to verify that clinical staff have demonstrated appropriate competency.

PR.8 RESTRAINT OR SECLUSION: REPORT OF DEATH

- SR.1 Hospitals must report deaths associated with the use of restraint or seclusion directly to CMS in accordance with 42 CFR 482.13(g), the Conditions of Participation, and the State Operations Manual.
- SR.2 Staff must document in the patient's medical record the date and time the death was reported to CMS.

Interpretive Guidelines

The CMS regional office must be informed 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 of each reportable death.

The CMS regional office will determine if an investigation is warranted.

The following information should be available when notifying the CMS regional office:

1. *Provider information*
 - a. *Hospital name, address, and NPI provider number*
2. *Patient information*

- a. *Patient name, date of birth*
 - b. *Admitting diagnosis*
 - c. *Date of admission*
 - d. *Date and time of death*
 - e. *Cause of death*
 - f. *Circumstances surrounding the death*
3. *Associated restraint reporting criteria*
- a. *Death occurred while the patient was in restraint or in seclusion*
 - b. *Death occurred within 24 hours after restraint or seclusion was removed*
 - c. *Death occurred 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.*
 - d. *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. *Any death that occurs while a patient is in such restraints.*
 - ii. *Any death that occurs within 24 hours after a patient has been removed from such restraints.*
 - e. *The staff must document in the patient's medical record the date and time the death was:*
 - i. *Reported to CMS for deaths or*
 - ii. *Recorded in the internal log or other system for deaths described in paragraph 3(d).*
 - f. *For deaths described in paragraph 3(d), entries into the internal log or other system must be documented as follows:*

- i. *Each entry must be made not later than seven days after the date of death of the patient.*
- 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 Sec. 482.12(c), medical record number, and primary diagnosis(es).*
- iii. *The information must be made available in either written or electronic form to CMS immediately upon request.*

4. *Hospital care information*

- a. *Reason for use of restraint or seclusion and alternatives attempted*
- b. *Type: physical restraint, seclusion, or drug used as restraint*
- c. *Restraint type details*
- d. *For drugs used as restraint; drug name, dosage, number of doses given*
- e. *Total length of time in restraint or seclusion*
- f. *Date and time originally ordered and applied*
- g. *Most recent order date and time*
- h. *Monitoring methods including: face to face evaluation, date and time of last face-to-face evaluation, documented frequency of monitoring, date and time last monitored*

5. *Results of any facility investigation*

Surveyor Guidance:

Review the hospital policy on reporting deaths that occur while a patient is restrained or in seclusion, within 24 hours of removal, or where it is reasonable to assume that a restraint or seclusion contributed to a patient's death.

Confirm that deaths associated with use of restraint or seclusion were reported in compliance with CMS Conditions of Participation and the State Operations Manual.

INFECTION PREVENTION AND CONTROL (IC)

IC.1 INFECTION PREVENTION and CONTROL SYSTEM

- SR.1 The organization shall have a process in place, as required and/or recommended by the Centers for Disease Control (CDC) and related professional organizations, to maintain a sanitary environment for organization patients, staff, and others
- SR.2 The organization shall have a documented process, policies and procedures to define how infections and communicable diseases are prevented, controlled and investigated throughout the organization.
- SR.3 The Infection Prevention and Control System shall be evaluated at least annually. This evaluation shall be forwarded to Quality Management oversight group.
- SR.4 The documented process shall define the following:
- SR.4a 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. The designated infection control officer or officers shall have the appropriate qualifications and experience as defined by the organization and shall govern the policies for controlling infections and communicable diseases.
 - SR.4b Any designated practitioner shall have completed a course in basic surveillance by a recognized body or show evidence that they have supervision by a qualified infection control practitioner. If in the role five years or longer there must be evidence of pertinent continuing education related to infection control, minimally every two years;
 - SR.4c The infection control officer or officers must develop a system for identifying, reporting, investigating, and controlling infections and communicable diseases of patients and personnel and,
 - SR.4d The maintaining and control of records to account for incidents related to infections and communicable diseases.
- SR.5 Infections and communicable diseases shall be measured and analyzed to identify any patterns or trends.
- SR.6 The organization, through its chief executive officer, medical staff and nurse executive shall ensure that the Infection Control System and associated activities adequately address issues identified throughout the organization and there are prevention, correction, improvement and training programs to address these issues and provide adequate resources to accomplish the associated activities of the infection control program.

- SR.7 Significant infection control data/information shall be disseminated no less than quarterly to the organization oversight group responsible for the infection control function.
- SR.8 Surveillance methodology shall be appropriate for the population(s) served and approved no less than annually by the Infection Control oversight. The inpatient and outpatient populations shall be reported to this oversight group as an annual summary of reported illnesses.

Interpretive Guidelines:

The hospital must maintain an infection control program for the prevention, control, and surveillance of infections (which includes, but is not limited to hospital acquired infections) and communicable diseases of patients and personnel (which includes, but is not limited to patient care staff).

Definitions:

Infectious disease – 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.

Infectious agent – a living or quasi-living organism or particle that causes an infectious disease, and includes bacteria, viruses, fungi, protozoa, helminthes, and prions.

Communicable disease – a disease associated with an agent that can be transmitted from one host to another.

Infection control professional – a person whose primary training is in either nursing, medical technology, microbiology, or epidemiology and who has acquired specialized training in infection control.

The infection control surveillance program will include specific measures for prevention, detection, control, intervention, education, collection of data and investigation of infections and communicable diseases in the hospital that covers patients and hospital staff. The infection control program must be continually evaluated for effectiveness and when necessary, corrective and/or preventive action taken to reduce risks of infections.

The infection control program will encompass nationally recognized systems of infection control guidelines to reduce the risk and transmission of infections and communicable diseases (e.g., the Centers for Disease Control and Prevention (CDC) Guidelines for Prevention and Control of Nosocomial infection, the CDC Guidelines for Preventing the Transmission of Tuberculosis in Health Care Facilities 2005, CDC 2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings, World Health Organization (WHO), the Society for Healthcare Epidemiology of America (SHEA), the Association of periOperative Registered Nurses (AORN), the Occupational Health and Safety Administration (OSHA) regulations, and the Association for Professionals in Infection Control and Epidemiology (APIC) infection control guidelines).

The hospital must provide for and maintain a sanitary environment to avoid the sources and transmission of infections and communicable diseases. All areas of the hospital must be regularly cleaned and sanitary including all hospital units, campuses and off-site locations (as applicable). The infection control surveillance program will include monitoring of housekeeping and maintenance (including when applicable areas of the hospital are under repair, renovation, or construction) as well as any other activities to ensure the hospital maintains a sanitary environment.

The hospital must provide adequate resources to accomplish the activities of the infection control program – when assessing the need for resources; the organization should consider the patient population and complexity of services provided as a part of the process for evaluation and provision of resources.

The organization shall have a documented process, policies and procedures to define how infections and communicable diseases are prevented, controlled and investigated throughout the organization. These policies and procedures will include:

- *Maintenance of a sanitary physical environment, including;*
 - *Ventilation and water quality control issues*
 - *Safe air handling systems in areas of special ventilation, such as operating rooms, intensive care units, and isolation rooms*
 - *Food sanitation, storage and handling*
 - *Cleaning and disinfecting surfaces, carpeting, and furniture*
 - *Textiles reprocessing, storage and distribution*
 - *Disposal of regulated and non-regulated waste*
 - *Pest control*

No items shall be stored under any sink in a Healthcare Facility except where the organization has developed a written policy that specifically identifies the items that are permissible to be stored under sinks. Procedures to identify and maintain areas under sinks used for storage must be part of the Infection Control Management Plan. No patient care items are permitted to be stored under sinks in any policy.

Note: The accepted NIAHO definition of healthcare facilities:

NFPA 99: “buildings or portions of buildings in which medical, dental, psychiatric, nursing, obstetrical, or surgical care are provided.”

NFPA 70 and 70E adds more to this definition: “Health care facilities include, but are not limited to hospitals, nursing homes, limited care facilities, clinics, medical and dental offices, and ambulatory care centers.”

NFPA 45 and 5000 include in addition: “whether permanent or movable”

- *Measures related to hospital staff*
 - *Evaluation of immunization status for designated infectious diseases*
 - *Circumstances when screens are to be conducted of staff for infections or other risks when individuals may be exposed*
 - *When restrictions will be imposed on staff from providing direct patient care and/or required to remain away from the healthcare facility entirely*
 - *Measures to evaluate staff and volunteers exposed to patients with infections and communicable diseases*
 - *orientation and on-going training regarding the prevention and control of infections and communicable diseases*

- *Mitigation of risks associated with patient infections present upon admissions to include:*
 - *Early identification of patients who require isolation and techniques for precaution in accordance with CDC guidelines*
 - *Appropriate use of personal protective equipment (i.e. gowns, masks, gloves, eye protection)*

- *Mitigation of risks contributing to healthcare-acquired infections:*
 - *Surgery-related infection risk mitigation measures*
 - *Implementing appropriate prophylaxis to prevent surgical site infections such as a protocol to assure that antibiotic prophylaxis is administered to prevent surgical site infections for appropriate procedures and discontinued appropriately after surgery*
 - *Addressing aseptic technique practices used in surgery and invasive procedures outside the operating room, including sterilization of instruments*
 - *Other hospital-acquired infection risk mitigation measures*
 - *Promotion of hand washing hygiene among all staff and employees, including use of alcohol-based hand sanitizer*
 - *measures specific to prevention of infections caused by Multi-Drug - resistant organisms (MDRO). This applies to, but is not limited to, organisms such as methicillin-resistant staphylococcus aureus (MRSA), clostridium difficile (C.dif), vancomycin-resistant enterococci (VRE), carbapenem-resistant entobacteriaceae (CRE) and multidrug-resistant gram-negative bacteria.*
 - *Measures specific to prevention of central-line associated bloodstream infection (CLABSI), such as a bundle or protocol for reducing infections of central venous catheters specifying aseptic precautions for line insertions, care of inserted lines, and prompt removal when the line is no longer needed.*

- *Measures specific to prevention of other device-associated infections such as those associated with ventilators, tube feeding, urinary catheters, etc. (VAP, CAUTI)*
- *Isolation procedures and requirements for immuno-suppressed patients*
- *Safe Injection Practice Program*
- *Care techniques for tracheostomy care, respiratory therapy, burns and other situations that reduce a patient's resistance to infection*
- *Use of disinfectants, antiseptics and germicides as instructed*
- *Appropriate use of facility and medical equipment including negative and positive pressure room equipment, portable air filtration equipment, enclosed beds, UV lights, and other equipment used to control the spread of infectious agents*
- *Adherence to CDC and other nationally recognized guidelines for infection prevention and control precautions*
- *Education of patients, visitors, caregivers, and staff about infections and communicable diseases and methods to reduce transmission in the hospital and community*
- *Active Surveillance methods for:*
 - *Obtaining and review data on infections and communicable diseases selected for monitoring*
 - *Monitoring and evaluating practices of asepsis*
 - *Authority and indications for obtaining microbiological cultures from patients and the environment, as indicated*
- *A designated Infection Control Officer and his or her scope of responsibilities:*
 - *Development and implementation of infection control measures*
 - *Mitigation of risks associated with patient infections and risks contributing to healthcare-acquired infections*
 - *Program evaluation and revisions (as necessary)*
 - *Coordination as required by law with Federal, State, and local emergency preparedness and health authorities to address communicable disease threats, bioterrorism, and outbreaks*
 - *Compliance with the requirements for reporting to local health authorities*
 - *Roles and responsibilities for infection control within the hospital and how various committees and departments interface with the infection control program*
 - *The hospital leaders are responsible for implementing and ensuring corrective/preventive action(s) are implemented and effective in addressing infection control issues.*
 - *A process for identifying, reporting, investigating preventing, controlling infections and communicable diseases; to include both inpatient and outpatient populations as well as hospital staff;*

- *Records to be maintained and controlled to account for incidents related to infections and communicable diseases;*
 - *Log of incidents related to infections and communicable diseases is maintained (safe and secure from unauthorized access, up-to-date, and readily accessible and retrievable) and documents infections and communicable diseases in patients and staff (patient care staff and non-patient care staff, including employees, contract staff and volunteers).*
 - *To protect privacy, the hospital may use codes instead of names in the log with a separate reference document to interpret codes to address these incidents*
 - *Although not required, the hospital is encouraged to categorize the types of incidents such as:*
 - *Healthcare-associated infection including surgical site infections following inpatient or outpatient procedures*
 - *Patients or staff identified by laboratory cultures as colonized or infected with multi drug-resistant organisms (MDROs), as defined by the hospital*
 - *Patients who meet CDC criteria for requiring isolation precautions during their hospitalization*
 - *Patients or staff 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*
- *How infections and communicable diseases are measured and analyzed to identify any patterns or trends;*
- *A process for adequately addressing issues identified throughout the organization and for the prevention, correction, improvement and training programs to address these issues;*
- *A means of reporting data/information at least quarterly to the organization oversight group responsible for the infection control function (i.e. Infection Control Committee);*
- *How education of patients, family members and caregivers about infections and communicable diseases is conducted;*
- *Orientation of all new hospital personnel, including contract staff, students and volunteers, to infections, communicable diseases, and to the infection control program; and,*
- *A procedure for meeting the reporting requirements of the local health authority as required.*

Surveyor Guidance:

Interview the infection control officer to verify the scope and activities of the hospital's infection control program and hospital issues regarding infection control.

Review the personnel file of the infection control officer(s) to verify that he or she is qualified through education, training, experience, and certification or licensure to oversee the infection control program.

Review and validate that appropriate policies and procedures have been developed and implemented to identify, prevent, monitor, report, investigate and measure the control of infections and communicable diseases;

- *Mitigation of risks associated with patient infections present on admission*
- *Mitigation of risks contributing to healthcare-associated infections*

Determine whether the infection control program is hospital-wide and identifies all hospital locations and take these various locations into account under the program and there is active surveillance in place.

Review how areas of the hospital are monitored to include: areas where food is stored, prepared and served, refrigerators, ice machines, air handlers, autoclave rooms/areas, ventilation systems, inpatient rooms, patient care areas, laboratory, surgical areas, supply storage and where equipment is stored and cleaned.

During the survey, all surveyors should observe the sanitary condition of the physical environment, cleanliness of rooms, surfaces, patient equipment, air inlets, mechanical rooms, food service activities, treatment and procedure areas, surgical areas, central supply and storage areas, etc.

Review the (Infection Control Committee) meeting minutes to evaluate compliance with requirements and follow-up on corrective and preventive actions taken.

Review a sampling or records for incidents related to infections and communicable diseases, including those identified through employee health services to ensure that corrective and/or preventative actions were taken to minimize risks. Review compliance with reporting requirements to the local health authority.

Verify that a log is maintained of incidents related to infections and communicable diseases and is easily accessible and retrievable by the infection control officer and other appropriate staff.

Verify that there is coordination with Federal, State and local emergency preparedness and health authorities as required by law to address communicable disease threats, bioterrorism, and outbreaks.

Verify that the infection control program is under the scope of the hospital quality management system and that infection control issues are reported to the Medical Staff, Leadership and Nursing to ensure that corrective and/or preventative action (s) are implemented and effective.

Review the on-going evaluation of the infection control program and revisions made to the program based in part on this evaluation.

MEDICAL RECORDS SERVICE (MR)

MR.1 ORGANIZATION

- SR.1 Administrative responsibility for medical records shall rest with the medical record service of the organization.
- SR.2 The organization shall provide these services in accordance with the scope and complexities of services offered and allocate the appropriate resources to ensure efficient functioning.

Interpretive Guidelines:

The hospital must have administrative responsibility for all medical records- both inpatient and outpatient. The medical record service shall reflect the scope and complexities of services offered.

Definition: "Medical records" refers to the 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.

Surveyor Guidance:

Verify that the medical records service is designed to meet the needs of the hospital and the patients with respect to the scope and complexities of services.

MR.2 COMPLETE MEDICAL RECORD

- SR.1 The organization shall maintain an accurately written, promptly completed medical record for each inpatient and outpatient.
- SR.2 The organization shall have a process for providing services for the completion, filing, and retrieval of the medical record. The process for completion of the medical record must address timeframes.
- SR.3 Authenticity and security of all record entries shall be safeguarded.

Interpretive Guidelines:

The hospital must maintain a medical record for each inpatient and outpatient evaluated or treated in any part or location of the hospital.

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.

The hospital will define the process for providing medical record services to encompass the completion, filing and retrieval of medical records. In the event records are stored outside of the medical records office or off-premises through a contractual arrangement, the hospital must ensure there is a process in place to protect and retrieve these records in a timely manner.

The record must be completed promptly after discharge in accordance with State law and hospital policy but no later than 30 days following discharge.

Surveyor Guidance:

Review the area(s) where medical records are maintained by the hospital.

Verify that a medical record is maintained for each person treated or receiving care.

Verify that medical records are stored and maintained in area(s) that ensure the records are secure, protected from damage by flood, fire, and other casualties, and access is limited to authorized staff.

Verify that the hospital has a process to ensure that records are accurate, completed promptly, easily retrieved and readily accessible in all area(s) where medical records are maintained.

MR.3 RETENTION

SR.1 Medical records (original or legally reproduced form) shall be retained for a period of at least five (5) years, or more if required by state or local laws.

SR.2 The coding and indexing system shall be designed in such a way that allows for timely retrieval by diagnosis and procedure, in order to support medical care evaluation studies.

Interpretive Guidelines:

Medical records shall be retained in their original or legally reproduced form and maintained for minimum five (5) years, or more if required by state or local laws. These records may be in the form of a hard copy, microfilm, computer memory, or other electronic storage media. The hospital must have a process to promptly retrieve the complete medical record of every individual evaluated or treated in accordance with Federal and State law and regulations. Certain medical records may have retention requirements that exceed five (5) years (e.g.: FDA, OSHA, and EPA).

Surveyor Guidance:

Verify that the control of medical record is in place and these records are retained for at least 5 years, or more if required by State or local laws.

Verify that the hospital uses a coding and indexing system that allows for timely retrieval of patient records by diagnosis and procedures.

MR.4 CONFIDENTIALITY

- SR.1 Confidentiality of patient records shall be assured.
- SR.2 Individuals who are authorized by the patient to receive information from or copies of records shall follow processes designed to protect improper or inadvertent release of private information to unauthorized individuals.
- SR.3 The organization shall also ensure that the medical record cannot be altered or accessed by unauthorized individuals.
- SR.4 Original medical records shall be released by the organization only in accordance with Federal or State laws, court orders, or subpoenas.

Interpretive Guidelines:

The hospital must have a means of ensuring that access to all information regarding patient's records is limited to those individuals designated by law, regulation, and policy or duly authorized as having a need to know.

The process must be designed to protect improper or inadvertent release of private information to unauthorized individuals.

Patient information will include; patient paper records, video, audio, and/or computer stored information.

The hospital will maintain a compliance program as required under the Health Insurance Portability and Accountability Act (HIPAA).

Surveyor Guidance:

Verify that the hospital has a means of ensuring that access to patients' records is limited to those individuals designated by law, regulation, and policy or duly authorized as having a need to know.

Validate the policy and procedure for release of patient information and verify that copies of medical records and other confidential patient information are released outside the hospital only upon written authorization of the patient, legal guardian, or person with an appropriate "power of attorney" to act on the patient's behalf, or only if there is a properly executed subpoena or court order, or as mandated by Federal and State law.

Verify the methods in place to prevent unauthorized persons from gaining physical access or electronic access to information in patient records.

Validate the hospital's current practices in place for protecting and securing the confidentiality of patient records.

Verify the elements of the hospital's compliance program as required under (HIPAA).

MR.5 RECORD CONTENT

SR.1 The medical record shall contain information to:

SR.1a Justify admission and continued hospitalization;

SR.1b Support the diagnosis; and,

SR.1c Describe the patient's progress and response to medications and services.

SR.2 All entries shall be:

SR.2a Legible, complete, dated and timed; and,

SR.2b Authenticated by the person responsible for providing or evaluating the services provided consistent with hospital policy.

SR.3 Authentication may include written signatures or initials. Electronic authentication is permissible.

SR.4 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.

SR.4a Practitioners 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 document may not reflect when the entry was authenticated.

SR.4b If a preprinted order set is used, the ordering practitioner must date, time, and authenticate the last page of the order set, with the last page also identifying the total number of pages in the order set.

SR.4c Changes, such as additions, deletions, or strike-outs of components that do not apply, that have been made in the body of the preprinted order set are initialed and all internal pages have been signed or initialed by the ordering practitioner.

SR.5 Verbal orders must be in accordance with Federal and State law and authenticated as required by State law.

SR.5a Telephone or verbal orders are to be used infrequently and when used must be accepted only by personnel authorized by the medical staff and in accordance with Federal and State law.

SR.5b Verbal orders must be authenticated in accordance with Federal and State law by the ordering practitioner or a practitioner responsible for the care of the patient. If there is not State law that designates a specific timeframe for the

authentication of verbal orders, the orders must be authenticated within timeframe in accordance with hospital policy.

- SR.5c For the limited time period defined in 42 CFR §482.24(c)(1)(ii), all such orders may be dated, timed and authenticated by another practitioner who is responsible for the patient's care as specified in 42 CFR §482.12(c) and who is authorized to write orders in accordance with hospital policy and State law.

Interpretive Guidelines:

The medical record must contain information such as notes, documentation, records, reports, recordings, test results, and assessments to:

- *Justify admission and continued hospitalization;*
- *Support the diagnosis; and,*
- *Describe the patient's progress and response to medications and services*

All entries in the patient's medical record (information/documentation regarding evaluations, interventions, care provided, services, care plans, discharge plans, and the patient's response to those activities, laboratory reports, test results, consults, assessments, radiology reports, 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.

These entries must be legible, complete, dated, timed and authenticated by the person responsible for prescribing the services or by another practitioner who is responsible for the patient's care . This individual must be authorized to write orders in accordance with hospital policy and State law.

When a practitioner is using a preprinted order set, the ordering practitioner may be in compliance with the requirement to date, time, and authenticate an order if the practitioner accomplishes the following:

- *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.*
- *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, 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.*

In the case of a pre-established electronic order set, the same principles would apply. 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.

Although verbal and telephone orders should be minimized when possible, for such orders, these must be in accordance with Federal and State law and authenticated as required by State law. Verify the process for authentication of verbal orders to ensure these are within the timeframes as stated according to Federal or State law. If there is not a State law in place, verify that these orders are authenticated per hospital policy.

The expectation is that hospital policies and procedures for verbal orders will include a read-back and verify process, in addition to specifying a timeframe for authentication of the orders.

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.

Verify the process for handling of verbal orders and that there have been measures put in place to effectively reduce these, when possible.

Surveyor Guidance:

Review a sample of medical records during the survey. Validate that that MR.5 is consistently applied throughout the hospital.

Verify that the hospital has policies and procedures in place for addressing verbal orders including a process for read-back and verification to ensure accuracy of such orders.

Interview staff and review examples of verbal orders to verify this process for authentication and the read-back and verification process.

Verify that within each medical record reviewed, the appropriate information is stated, timed, dated and authenticated by the appropriate individual(s) and supports the diagnosis, treatment and other services provided to the patient.

Verify that the last page of the orders on standing order sets identifies the total number of pages in the order set and that they are timed, dated and authenticated.

Verify that internal pages of an order set where selections or changes have been made, have been initialed or signed by the practitioner (top or bottom) and initialed in each place in the preprinted order set where changes, such as additions, deletions, or strike-outs of components that do not apply, have been made.

MR.6 IDENTIFICATION OF AUTHORS

The organization shall have a system to identify the author of each entry into the medical record.

Interpretive Guidelines:

The organization shall have a system to identify the author of each entry in the medical record. Entries may be made only by individuals as specified in hospital and medical staff policies.

If the hospital, through the approval of the medical staff and leadership allow rubber stamps, the individual whose signature the stamp represents shall place in the administrative offices of the hospital a signed statement to the effect that he/she is the only one who has the stamp and is the only individual allowed to use it. No other individual can be authorized to use the stamp under any circumstance.

All entries in the medical record must be legible. Any entry in the medical record that is not legible can be misread or misinterpreted and could lead to medical errors or other adverse patient events.

Surveyor Guidance:

Verify that the hospital has a means of identifying authors for each entry in the patient medical record. The organization shall have a policy in place that states who is allowed to document in the medical record and the means for identifying the author. Review a sampling of records to verify the consistency of this process.

In the event that the medical staff and leadership allow stamps to be used, verify that the stamps have been approved and are only used by the individual identified on the stamp.

In the sample of records, validate that all entries in the medical record are legible.

MR.7 REQUIRED DOCUMENTATION

All records must document the following, as appropriate:

SR.1 [All medical records of inpatients and all outpatient medical records for patients having same day surgery or a procedure requiring anesthesia must contain evidence of a physical examination, including a health history, must be performed no more than thirty \(30\) days prior to admission or registration or within twenty four \(24\) hours after admission:](#)

SR.1a The history and physical completed and documented no more than 30 days before [admission or registration](#) or 24 hours after admission, but prior to surgery or procedure requiring anesthesia services; [must be](#) placed in the patient's medical record within 24 hours after admission or registration, but prior [to any](#) surgery or procedure requiring anesthesia services.

- SR.1b When the history and physical is completed within 30 days prior to admission or registration, an updated medical record entry documenting an examination for any changes in the patient's condition must be completed and documented in the patient's medical record within 24 hours after admission or registration, but prior to any surgery or procedure requiring anesthesia services.
- SR.2 Admitting diagnosis,
- SR.3 Results of all consultative evaluations of the patient and appropriate finding by clinical and other staff involved in the care of the patient,
- SR.4 Documentation of complications, organization acquired infections, and unfavorable reactions to drugs and anesthesia,
- SR.5 Properly executed informed written consent forms for procedures and treatments specified by the medical staff, or by Federal or State law if applicable, signed by the patient or his/her authorized representative,
- SR.6 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,
- SR.7 Discharge summary with outcome of hospitalization, disposition of case, and provisions for follow up care,
- SR.8 Final diagnosis with completion of medical records within thirty, (30) days following discharge.

Interpretive Guidelines:

The medical record must contain an H&P for all inpatients and outpatient [medical records for patients having same day surgery or a procedure requiring anesthesia and/or as indicated](#). The H&P must be performed by an authorized practitioner no more than 30 days prior to admission or within 24 hours after admission.

The H&P must be placed in the patient's medical record within 24 hours after admission. In the event the H&P is completed within 30 days prior to admission, the hospital must ensure that the H&P is updated to document any changes in the patient's condition.

The patient's medical record must document the following:

- *Admitting diagnosis;*
- *Results of all consultative evaluations of the patient and appropriate finding by clinical and other staff involved in the care of the patient,*
- *Documentation of complications, organization acquired infections, and unfavorable reactions to drugs and anesthesia;*

- *Properly executed informed written consent forms for procedures and treatments specified by the medical staff, or by Federal or State law if applicable, signed by the patient or his/her authorized representative;*
- *A properly executed consent form should reflect the patient consent process. All inpatient and outpatient medical records must contain a properly executed informed consent prior to conducting any procedure or other type of treatment when informed consent is required. A properly executed consent form must be consistent with hospital policy as well as applicable State and Federal law or regulation and at a minimum contain the following elements:*
 - *Hospital name where procedure or treatment is to take place*
 - *Description of the procedure or treatment for which consent is being given*
 - *Name of the responsible practitioner performing the procedure or administering treatment*
 - *Statement that the procedure or treatment, including the benefits, risks, and alternative therapies, was explained to the patient or the patient's legal representative*
 - *Signature of the patient or patient's legal representative*
 - *Date and time the informed consent is signed by the patient or patient's legal representative*

If there is applicable State law governing the content of the informed consent, then the hospital must comply with those requirements.

Additional information may be considered to include as a part of the informed consent form:

- *Name of the practitioner who conducted the consent.*
- *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;*
- *Discharge summary with outcome of hospitalization, disposition of case, and provisions for follow up care; and,*
- *Final diagnosis with completion of medical records within thirty, (30) days following discharge.*

Surveyor Guidance:

Determine that medical records contain a physical examination and medical history completed for each patient by an authorized practitioner.

In a sampling of patient medical records, verify that the completion of the H&P was within the specified time frame and appropriate documentation noted.

Verify the content and completeness of the H&P per organization policy.

In some cases the organization may accept an H&P that has been completed in the practitioner's office, when this is allowed, verify the process for ensuring that the appropriate documentation is present and completed per the requirements of the organization and the H&P was completed within the required timeframe.

Verify that the H&P was completed no more than 30 days before or 24 hours after admission or registration and in all cases involving surgery or procedures requiring anesthesia services or moderate/conscious sedation prior to the surgery or procedure.

Verify this documentation of the H&P was placed in the medical record within 24 hours after admission or registration, and in all cases involving surgery or procedures requiring anesthesia services or moderate/conscious sedation prior to the surgery or procedure.

Where the H&P is completed within 30 days before admission or registration and in all cases involving surgery or procedures requiring anesthesia services or moderate/conscious sedation, the hospital must ensure that this H&P is updated to document any changes in the patient's condition.

If there are no changes to the H&P as written, the physician can simply document an update note stating [that the](#):

- *H&P has been reviewed,*
- *Patient has been examined, and*
- *Physician concurs with the findings of the H&P completed on the specified date or that "no change" has occurred in the patient's condition since the H&P was completed.*

Review a sample of medical records (inpatient and outpatient) to verify conformance to the appropriate elements specified in the Interpretive Guidelines [for MR.7](#).

Verify that the medical staff has specified which procedures and treatments require informed consent.

Ascertain that the completed forms contain at least the information specified in the Interpretive Guidelines [for MR.7](#).

Compare the hospital standard informed consent form to the hospital's policy regarding informed consent to verify that the form is consistent with the policy. If there is applicable State law, verify that the form is consistent with the requirements of that law.

DISCHARGE PLANNING (DC)

DC.1 WRITTEN POLICIES

- SR.1 Written policies shall be in place to establish a system for discharge planning that applies to all patients.
- SR.2 At an early stage of hospitalization, all patients who would be at risk for adverse health consequences or negative outcomes without benefit of appropriate discharge planning shall be identified and a plan developed to map a course of treatment aimed at minimizing the likelihood of having any patient re-hospitalized for reasons that could have been prevented.
- SR.2a Patients at high-risk of requiring post-hospital services must be identified through a screening process.
- SR.3 A discharge planning evaluation is provided for or upon the request of:
- SR.3a The patients identified in [DC1](#), SR.2;
- SR.3b Any patients upon their request;
- SR.3c A person acting on the patient's behalf; or,
- SR.3d The patient's physician.

Interpretive Guidelines:

The hospital must define the discharge planning process and communicate it to all appropriate areas of the hospital. This process is imperative in the patient care delivery system to ensure that patients' needs are being met. This 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 does not apply to patients who appear in a hospital emergency department but are not admitted as hospital inpatients. The hospital must identify all patients who are at risk for adverse health consequences or negative outcomes so that the discharge planning process and an educational plan may be developed.

There is no set time frame for identification of patients requiring a discharge planning evaluation other than it must be done as early as possible. The timing is left up to the hospital, its staff, and attending MD/DO.

The discharge planning process can be initiated at the request of the patient, an individual acting on the patient's behalf or the physician caring for the patient.

Surveyor Guidance:

Review hospital policies and procedures regarding the discharge planning process. These

policies and procedures should address:

- *Scope of the discharge planning process.*
- *The hospital's high-risk screening procedure.*
- *Initiation of the discharge planning process;*
- *Individual(s) who may initiate this process;*
- *When the process is initiated as a part of the plan of care;*
- *Reassessment of discharge plans; and,*
- *Preparations for post-hospital care and how patients or those responsible for the patient are kept informed of the progress.*

Sample patient records to see that the patient care plan includes the discharge planning process and associated interventions.

Interview hospital staff who are involved in direct patient care to verify that discharge planning is an inherent part of patient care delivery process.

DC.2 DISCHARGE PLANNING EVALUATION

SR.1 A registered nurse, social worker, or other appropriately qualified personnel must develop, or supervise the development of the evaluation.

SR 1a The responsible personnel should have experience in discharge planning, knowledge of social and physical factors that affect functional status at discharge, and knowledge of community resources to meet post-discharge clinical and social needs.

SR.2 The discharge planning evaluation shall include:

SR.2a An evaluation of the likelihood of a patient needing post-hospital services and of the availability of the services; and,

SR.2b 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 organization.

SR.2c A means to 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.

SR.3 The discharge planning evaluation shall be completed on a timely basis so that appropriate arrangements are made before discharge, and unnecessary delays in discharge are avoided.

SR.4 The discharge planning evaluation shall be a part of the patient's medical record and be used when forming the discharge plan with the patient or individual acting on his or her behalf.

SR.5 If the results of the discharge evaluation so indicate, or at the request of the patient's physician, a registered nurse, social worker, or other appropriately qualified personnel shall develop, or supervise the development of, a discharge plan and associated educational materials.

SR.5a The results of the discharge planning evaluations must be discussed with the patient or individual acting on their behalf.

Interpretive Guidelines:

The discharge planning process will identify the following factors when patients are leaving the hospital setting: functional status, cognitive ability of the patient and family support.

The hospital should have a screening process in place to identify patients who are at risk of requiring post-hospital service. The hospital needs to ensure the availability of services that the patient may need and determine the patient's ability for self-care or care to be provided by another party when necessary.

The discharge planning process will be initiated in a timely manner in order for arrangements to be made for the patient prior to discharge.

The documentation associated with the discharge planning process will be included as a part of the patient's medical record as a means of coordinating communication with other providers involved in the patient's care throughout the hospital. The patient's physician, a registered nurse, social worker, and/or other qualified staff member will be responsible for the development of information and materials to implement the discharge plan for the patient.

Surveyor Guidance:

Verify that the discharge planning is effective and an inherent part of the patient care delivery system through the following means:

- Interview staff to determine how patients are identified and require discharge planning;*
- Review the hospital's policy and procedures to verify that at-risk patients are provided discharge planning;*
- Sample records to see when the discharge planning process is initiated, the roles of individuals involved in the process, reassessments as needed and the implementation of the discharge plan.*

DC.3 PLAN IMPLEMENTATION

- SR.1 The initial implementation of the patient's discharge plan shall be performed by the organization.
- SR.2 Patients shall be transferred or referred with necessary medical information, to appropriate facilities, agencies, or outpatient services, as needed.
- SR.3 When the discharge planning evaluation determines a referral is medically appropriate, the organization shall give the patient a list of Medicare-participating providers (home health agencies, skilled nursing facilities and other providers as applicable) (this will include those qualified to receive the patient from the patient's managed care organization where applicable) that are available and serve the geographical area where the patient resides. The organization shall document in the medical record that the patient (or authorized representative) received a copy of the list and was advised of his/her freedom of choice.

Note: Home Health Agencies must request to be listed by the hospital as available.

SR.3a The organization must respect the choice of the patient or authorized representative except in unusual circumstances. The organization may not lead, direct, specify, or otherwise limit the selection of qualified Medicare-participating providers.

SR.3b The organization must identify in writing any Medicare-participating providers to which the patient is referred in which the organization has a disclosable financial interest and any Medicare-participating providers that has a disclosable financial interest in the organization. Disclosable financial interests are defined by 42 CFR §420, Subpart C.

SR.4 When the organization must transfer or refer patients, the necessary medical information and other supporting documentation must be provided to appropriate facilities, agencies or outpatient services as needed, for follow-up or ancillary care.

Interpretive Guidelines:

The hospital must initiate the implementation of the discharge plan for the patient. When patients are transferred or referred to another provider, the necessary medical information must be communicated to these providers as needed. This includes arranging for necessary post-hospital services and care, and educating patient/family/caregivers/community providers about post-hospital care plans.

The hospital must ensure that patients receive proper post-hospital care within the abilities of a hospital's authority under State law. The patient has the right to refuse discharge-planning services, but the hospital may still make these services available to the patient. If a patient does exercise his or her right to refuse discharge planning, written documentation of the refusal should be completed.

The hospital will maintain a list of Medicare-participating home health agencies (HHA) or skilled nursing facilities (SNF) (including those qualified to receive the patient from the patient's managed care organization where applicable) that are available and serve the geographical area).

This list will be provided to patients when the discharge planning evaluation has determined that a referral is medically appropriate for the patient. The patient has the freedom of choice for the providers on the list and the hospital can take no part in leading, directing, or otherwise limit the selection of a qualified HHA or SNF.

If the hospital has a financial interest in any HHA or SNF or vice versa to which the patient is referred, it is the responsibility of the hospital identify and define such financial interest in writing.

Surveyor Guidance:

Sample patient records to verify that there objective evidence regarding the implementation of the discharge plan, including communication of information to the patient (when possible) and the next provider.

Interview staff that are responsible for the patient's care to determine the discharge planning process and how it has been implemented. The following may be asked of the staff regarding this process:

- *How are the patient's rights, confidentiality, refusal, and preference considered?*
- *Is there documentation that care instructions have been communicated to the post hospital care setting where the patient is being referred?*
- *Is there documentation that the HHA/SNF list is being provided to patients?*

DC.4 EVALUATION

SR.1 The discharge plan shall be periodically reevaluated on an on-going basis to provide for changes in the patient's condition or circumstances. The reassessment must include a review of the discharge plans to ensure that they are responsive to discharge needs.

SR.2 As needed, the patient and family members or interested persons shall be **counseled** to prepare them for post-hospital care.

Interpretive Guidelines:

The purpose of a discharge planning evaluation is to determine continuing care needs after the patient leaves the hospital setting. The hospital will determine the frequency and scope of the evaluation. Ideally, discharge planning will be an interdisciplinary process, involving disciplines with specific expertise, as dictated by the needs of the patient. It is important that this address the changes in the patient condition and other circumstances of the patient.

The hospital must have a mechanism in place for ongoing reassessment of its discharge planning process. The hospital should assure the following factors in the reassessment process:

- *Effectiveness of criteria to identify patients needing discharge plans;*
- *The quality and timeliness for discharge planning evaluations and discharge plans;*
- *The hospital discharge personnel to maintain complete and accurate information to advise patients and their representatives of appropriate options; and*
- *The hospital has a coordinated discharge planning process that integrates discharge planning with other functional departments, including the quality management and utilization review activities of the institution and involves various disciplines.*

Surveyor Guidance:

Sample patient records and other appropriate documentation to verify that the hospital is reevaluating the needs of the patients on an ongoing basis, and prior to discharge, as they may need to change the discharge plan based on the individual's status. The discharge plan evaluation can be in the clinical notes if there is no separate form.

The surveyor may interview patients and their family members who are expecting discharge with approval from the hospital. Feedback from this interview should address:

- *If the hospital staff assisted in planning for post-hospital care;*
- *Involvement of the patient and family to assess their preparation(s) for discharge*
- *How ready do they feel they are prepared for discharge,*
- *How the patient/family was **counseled** by the staff regarding post-hospital care.*
- *Were they given the pamphlet, "Important Message from Medicare?"*
- *Were they aware that they could request assistance with discharge planning?*

Verify that the hospital includes the discharge planning process within the quality management system and this process is effective.

Discuss with staff the extent and frequency the discharge planning process is reassessed and how this process is evaluated for effectiveness.

UTILIZATION REVIEW (UR)

UR.1 DOCUMENTED PLAN

The organization shall maintain a documented utilization review plan that provides for review of organizational and medical staff services to patients, particularly those patients entitled to benefits under both Medicare and Medicaid. The plan shall include:

SR.1 Responsibilities and authority for those involved in utilization review activities in a Utilization Review (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 osteopathy. The other members may be any of the other types of practitioners as defined in MS.15 (SR.1)

SR.1a A staff committee of the institution; or

SR.1b A group outside the institution established by the local medical society and some or all of the hospitals in the locality; or

SR.1c Established in a manner approved by CMS.

SR.1d 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 such that;

SR.1d(1) The committee or group's reviews may not be conducted by any individual who;

SR.1d(1)(a) Has a direct financial interest (for example, an ownership interest) in the hospital; or

SR.1d(1)(b) Was professionally involved in the care of the patient whose case is being reviewed.

SR.2 Requirement for all review findings in the aggregate to be reported to Quality Management Oversight.

SR.3 Provision for avoidance of conflict by prohibiting any individual with any financial or professional involvement in the case from participating in the review. This shall be strictly enforced.

SR.4 Review of:

SR.4a Medical necessity of admissions and extended stays;

SR.4b Appropriateness of setting; and,

SR.4c Medical necessity of professional services.

Interpretive Guidelines:

The hospital UR plan should include a delineation of the responsibilities and authority for those involved in the performance of UR activities, define the requirement for all review findings to be reported to the Quality Management Oversight body, and ensure that there is no conflict of interest (financial or otherwise) by those individuals participating in the review.

Surveyor Guidance:

Verify that the hospital has a utilization review plan for those services furnished by the hospital and its medical staff to patients, particularly those patients entitled to benefits under both Medicare and Medicaid.

Sample records and reports, and supporting documentation that UR activities are being performed as described in the hospital UR plan.

Verify the composition of the UR committee.

Review for any conflicts of interest or hospital ownership and that individuals, when applicable, in these circumstances to ensure that these individuals are not included as a part of the Utilization Review process, as appropriate.

Interview the chairperson of the UR Committee and/or other representative members of the committee to validate their role in carrying out the UR plan.

- *This may also include a review of the minutes of the UR committee to verify: members in attendance; dates and times of the meetings; documentation of extended stay reviews with approval or disapproval noted in a status report of any actions taken.*

Note: Do **not** apply these UR requirements if any of the following situations apply:

- *A Quality Improvement Organization (QIO) has assumed binding review for the hospital;*
- *The State has entered into a contract with a QIO that is deemed under 42 CFR §431.630, or*
- *CMS has determined that the UR procedures established by the State under Medicaid are superior to these requirements and has required hospitals in that State to meet them. In these cases, the State requirements are applied to both Medicare and the Medicaid patients. The State requirements will then be used for survey in those States.*

UR.2 SAMPLING

The review may be done before, at or after admission and may be conducted by sampling. The review shall include medical necessity for the following:

SR.1 Admissions;

SR.2 Length of stay; and,

SR.3 Professional services furnished, including medications.

Surveyor Guidance:

Review the UR plan and other supporting documentation to determine that the medical necessity for patients is reviewed with respect to admission, length of the stay, and professional services (including medications).

Note: This requirement does not apply to PPS-excluded hospitals or units.

UR.3 MEDICAL NECESSITY DETERMINATION

SR.1 The committee must review professional services, to determine medical necessity and to promote the most efficient use of available health facilities and services.

SR.2 The determination that an admission or continued stay is not medically necessary may be made by two members of the Quality Management Oversight group after the practitioner(s) caring for the patient has (have) been notified and given an opportunity to present his/her views.

SR.2a Practitioner(s), the organization and the patient must receive written notification of a decision that admission or continued stay is determined to be not medically necessary.

SR.2b The notification must be given no later than two (2) days after such decision is made.

Interpretive Guidelines:

The UR committee (or subgroup of the Quality Management Oversight Group) must include a physician and at least two members of the Quality Management Oversight group. Cases that are determined to have not met medical necessity will be reviewed. If the committee or subgroup agrees after reviewing the case where admissions, or extended stay is not medically necessary or appropriate, the attending physician is notified and allowed an opportunity to present his or her views and any additional information relating to the patient's needs for admissions or extended stay.

The attending physician and the patient must receive notification within two days of the decision where the admission or continued stay has been determined to be not medically necessary. If the attending physician 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 deemed to be final.

In the event that the attending physician contests the committee or subgroup findings, or if he or she 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 is deemed to be final.

A written notification of this decision must be sent to the attending physician and patient and the chief executive officer within two days after such final decision.

Under no circumstance may a non-physician make a final determination that a patient's stay is not medically necessary or appropriate.

If, after a case that has been reviewed by the committee or subgroup thereof, the physician reviewer has determined 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.

Surveyor Guidance:

Sample case reviews of where decisions involving admissions or extended stay that were deemed to be not medically necessary and verify the decision-making and notification process to all respective parties as indicated in the interpretive guidelines.

Definition: "Professional" services include the aspects of care rendered by laboratory personnel, physical therapists, nurses, and others, as well as services provided by MD/DOs.

UR.4 EXTENDED STAY REVIEW

The utilization review plan must include a process to periodically review all patients who receive services during a continuous period of extended duration.

SR.1 For organizations paid under the prospective payment system, all patients whose length of stay is considered an outlier must be reviewed.

SR.2 All reviews must be conducted no later than seven (7) days after the day required in the utilization review plan.

Interpretive Guidelines:

In accordance with 42 CFR 482.30 (e)(1)(i) and e(1)(ii) - The scheduling of the periodic reviews may:

- (i) Be the same for all cases; or*
- (ii) Differ for different classes of cases.*

Surveyor Guidance:

Review the facility's definition of stay of extended duration in the UR plan.

Verify that the hospital's UR plan requires a periodic review of each current inpatient receiving hospital services of extended duration and that the review is carried out as specified in the hospital's UR plan.

Review minutes of the UR committee to determine that the periodic reviews of extended stay are carried out no later than seven days after the day required in the hospital's UR plan.

PHYSICAL ENVIRONMENT (PE)

PE.1 FACILITY

The facility shall be constructed, arranged, and maintained to ensure patient safety, and to provide areas for diagnosis and treatment and for special organization services appropriate to the needs of the community.

- SR.1 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 are assured.
- SR.2 The hospital must maintain adequate facilities for its services.
 - SR.2a Diagnostic and therapeutic facilities must be located for the safety of patients.
 - SR.2b Facilities, supplies, and equipment must be maintained to ensure an acceptable level of safety and quality.
 - SR.2c The extent and complexity of facilities must be determined by the services offered.
- SR.3 The organization shall have policies, procedures and processes in place to manage staff activities, as required and/or recommended by local, State, and national authorities or related professional organizations, to maintain a safe environment for the organization's patients, staff, and others.
- SR.4 The organization shall have a documented process, policies and procedures to define how unfavorable occurrences, incidents, or impairments in the facility's infrastructure, Life Safety, Safety, Security, Hazardous Material/Waste, Emergency, Medical Equipment, and Utilities Management Systems are prevented, controlled investigated, and reported throughout the organization.
- SR.5 The organization shall evaluate the facility's physical environment management systems at least annually. This evaluation shall be forwarded to Quality Management oversight.
- SR.6 Occurrences, incidents, or impairments shall be measured and analyzed to identify any patterns or trends.
- SR.7 The organization, through its senior leadership shall ensure that the physical environment and associated management systems adequately address issues identified throughout the organization and there are prevention, correction, improvement and training programs to address these issues.
- SR.8 Significant physical environment data/information shall be disseminated regularly to Quality Management oversight.
- SR.9 The organization, through its senior leadership shall ensure that a tobacco-free policy be developed and enforced campus-wide. Substantial progress toward complete conformity shall be demonstrated over time.

Interpretive Guidelines:

Facilities

The hospital must ensure that the condition of the physical plant and overall hospital

environment is developed and maintained in a manner that provides an acceptable level of safety and well-being of patients, staff and visitors.

Supplies

The hospital must ensure that supplies are maintained to provide an acceptable level of safety and quality for patients. Among other things, this means that the hospital identifies the supplies required to meet its patients' needs for both day-to-day operations as well as 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. Further, the hospital must make adequate provisions to ensure the availability of those supplies when needed.

Supplies must be stored in such a manner to ensure their safety (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.).

Equipment

In order to ensure an acceptable level of safety and quality, the hospital must identify the equipment required to meet its patients' needs for both day-to-day operations and in a likely emergency/disaster situation, such as mass casualty events resulting from natural disasters, mass trauma, disease outbreaks, internal disasters, etc. In addition, the hospital must make adequate provisions to ensure the availability and reliability of equipment needed for its operations and services. Equipment includes both facility equipment, which supports the physical environment of the hospital (e.g., elevators, generators, air handlers, medical gas systems, air compressors and vacuum systems, etc.) and medical equipment, which are devices intended to be used for diagnostic, therapeutic or monitoring care provided to a patient by the hospital (e.g., IV infusion equipment, ventilators, laboratory equipment, surgical devices, etc.).

All equipment must be inspected and tested for performance and safety before initial use and after major repairs or upgrades.

All equipment must be inspected, tested, and maintained to ensure their safety, availability and reliability. Equipment maintenance activities may be conducted using hospital personnel, contracted services, or through a combination of hospital personnel and contracted services. Individual(s) responsible for overseeing the development, implementation, and management of equipment maintenance programs and activities must be qualified. The hospital maintains records of hospital personnel qualifications and is able to demonstrate how it assures all personnel, including contracted personnel, are qualified.

All equipment maintenance policies, procedures and programs, as well as specific equipment maintenance inventories, activities and schedules fall under the purview of the hospital's clinical maintenance personnel, safety department personnel or other personnel who have been assigned responsibility for equipment maintenance by hospital leadership.

Hospitals comply with this regulation when they follow the manufacturer-recommended

maintenance activities and schedule. Hospitals may choose to perform maintenance more frequently than the manufacturer recommends, but must use the manufacturer-recommended maintenance activities in such cases. When equipment is maintained in accordance with the manufacturer's recommendations, the hospital must maintain documentation of those recommendations and the hospital's associated maintenance activity for the affected equipment.

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. 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 or medical equipment. The AEM program must be based on generally accepted standards of practice for facility or medical equipment maintenance. An example of guidelines for a medical equipment maintenance program may be found in the American National Standards Institute/ Association for the Advancement of Medical Instrumentation document: ANSI/AAMI EQ 56: 1999/ (R) 2013, Recommended Practice for a Medical Equipment Management Program. Likewise, an example of guidelines for physical plant equipment may be found in the American Society for Healthcare Engineering (ASHE) 2009 document: Maintenance Management for Health Care Facilities. There may be similar documents issued by other nationally recognized organizations which hospitals might choose to reference.

Decision to Place Equipment in an AEM Program

The determination of whether it is safe to perform facility or 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. Highly specialized or complex equipment may require specialized knowledge or training in order for personnel to be considered qualified to make a decision to place such equipment in an AEM program.

In the case of facility equipment, a Healthcare Facility Management professional (facility manager, director of facilities, vice president of facilities) would be considered qualified.

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.

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.

A hospital is expected to identify any equipment in its AEM program which is “critical equipment,” i.e., biomedical or physical plant equipment for which there is a risk of serious injury or death to a patient or staff person should the equipment fail. Surveyors must focus their review of a hospital’s AEM program on critical equipment in that program and the hospital’s documentation of the factors and evidence it considered in developing an AEM strategy for that equipment.

Factors for a hospital to consider when evaluating the risks associated with a particular type of equipment include, but are not limited to:

- How the equipment is used and the likely consequences of equipment failure or malfunction - would failure or malfunction of the equipment hospital-wide or in a particular setting be likely to cause harm to a patient or a staff person?*
- How serious is the harm likely to be? For example, a slightly miscalibrated scale in an adult internal medicine outpatient clinic might not present significant risk of harm. However, a miscalibrated scale in a neonatal intensive care unit could have very serious consequences for patient care.*
- How widespread is the harm likely to be? For example, are many patients exposed to the equipment, resulting in harm due to failure impacting more patients or staff? If harm would be widespread, even if the harm to each affected individual is not serious, this would be a cause for concern.*

Information, if available, on the manufacturer’s equipment maintenance recommendations, including the rationale for the manufacturer’s recommendations;

- Maintenance requirements of the equipment:*
 - Are they simple or complex?*
 - Are the manufacturer’s instructions and procedures available in the hospital, and if so can the hospital explain how and why it is modifying the manufacturer’s instructions?*
 - If the manufacturer’s instructions are not available in the hospital, how does the hospital assess whether the AEM uses appropriate maintenance strategies?*
 - How readily can the hospital validate the effectiveness of AEM methods for particular equipment? For example, can the hospital explain how it ensures there is no reduction in the quality of the performance of biomedical equipment subjected to alternate maintenance methods?*
 - The timely availability of alternate devices or backup systems in the event of equipment failure or malfunction; and*
 - Incident history of identical or very similar equipment – is there documented evidence, based on the experience of the hospital (or its third party contractor), or on evidence publicly reported by credible sources outside the hospital, which:*
 - Provides the number, frequency and nature of previous failures and service requests?*
 - Indicates use of an AEM strategy does not result in degraded performance of the equipment?*

Generally 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.

Equipment not Eligible for Placement in the AEM Program:

Some equipment may not be eligible for placement in the AEM program, for one or more of the following reasons:

- *Other Federal law (for example, regulations promulgated by another Federal agency) or State law may require that facility or medical equipment maintenance, inspection and testing be performed strictly in accordance with the manufacturer's recommendations, or may establish other, more stringent maintenance requirements. In these instances, the hospital must comply with these other Federal or State requirements, but State Surveyors conducting Federal surveys assess compliance only with the hospital Conditions of Participation (CoPs).*
- *Other CoPs require adherence to manufacturer's recommendations and/or set specific standards which preclude their inclusion in an AEM program. For example:*
 - *The National Fire Protection Association Life Safety Code (LSC) requirements incorporated by reference at 42 CFR 482.41(b) has some provisions that are pertinent to equipment maintenance, and compliance with these requirements are assessed on Federal surveys. Further, §482.41(b)(9)(v) requires hospitals to adhere to the manufacturer's maintenance guidelines for alcohol-based hand-rub dispensers. Compliance with these requirements is assessed on Federal surveys.*
 - ***Imaging/radiologic equipment, whether used for diagnostic or therapeutic purposes, is governed by 42 CFR 482.26(b)(2) and must be maintained per manufacturer's recommendations.***
- *The equipment is a medical laser device. It should be noted that for medical lasers the U.S. Food and Drug Administration requires manufacturers to provide a schedule of maintenance and adequate instructions for service adjustments and service procedures to purchasers and, at cost, to any other parties requesting them.*
- *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. New equipment must be maintained in accordance with manufacturer recommendations until a sufficient amount of maintenance history has been acquired to determine whether the alteration of maintenance activities or frequencies would be safe. If a hospital later transitions the equipment to a risk-based maintenance regimen different than the manufacturers' recommendations, the hospital must maintain evidence that it has first evaluated the maintenance track record, risks, and tested the alternate regimen.*

Alternative Maintenance Frequencies or Activities

Maintenance strategies are various methodologies used for determining the most efficient and effective maintenance activities and frequencies. Manufacturers' recommendations may be based on one or more such strategies. A hospital may also use one or more maintenance strategies for its AEM program in order to determine the appropriate maintenance, inspection, and testing 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 recommendations and other materials, nationally recognized expert associations, and/or the hospital's (or its third party contractor's) own experience. Maintenance strategies may be applied to groups or to individual pieces of equipment.

The hospital is expected to adhere strictly to the AEM activities or strategies it has developed.

Background Information on Types of Maintenance Strategies

- **Preventive Maintenance (Time-based Maintenance)** – a maintenance strategy where maintenance activities are performed at scheduled time intervals to minimize equipment degradation and reduce instances where there is a loss of performance. Most preventive maintenance is “interval-based maintenance” performed at fixed time intervals (e.g., annual or semi-annual), but may also be “metered maintenance” performed according to metered usage of the equipment (e.g., hours of operation). In either case, the primary focus of preventive maintenance is reliability, not optimization of cost-effectiveness. Maintenance is performed systematically, regardless of whether or not it is needed at the time. Example: Replacing a battery every year, after a set number of uses or after running for a set number of hours, regardless.
- **Predictive Maintenance (Condition-based Maintenance)** – a maintenance strategy that involves periodic or continuous equipment condition monitoring to detect the onset of equipment degradation. This information is used to predict future maintenance requirements and to schedule maintenance at a time just before equipment experiences a loss of performance. Example: Replacing a battery one year after the manufacturer's recommended replacement interval, based on historical monitoring that has determined the battery capacity does not tend to fall below the required performance threshold before this extended time.
- **Reactive Maintenance (Corrective, Breakdown or Run-to-Failure Maintenance)** – a maintenance strategy based upon a “run it until it breaks” philosophy, where maintenance or replacement is performed only after equipment fails or experiences a problem. This strategy may be acceptable for equipment that is disposable or low cost, and presents little or no risk to health and safety if it fails. Example: Replacing a battery after equipment failure when the equipment has little negative health and safety consequences associated with a failure and there is a replacement readily available in supply.

- **Reliability-Centered Maintenance** – a maintenance strategy that not only considers equipment condition, but also considers other factors unique to individual pieces of equipment, such as equipment function, consequences of equipment failure, and the operational environment. Maintenance is performed to optimize reliability and cost effectiveness. Example: Replacing a battery in an ambulance defibrillator more frequently than the same model used at a nursing station, since the one in the ambulance is used more frequently and is charged by an unstable power supply.

Maintenance Tools

Tools (e.g., hand tools, test equipment, software, etc.) necessary for performing equipment maintenance must be available and maintained to ensure that measurements are reliable. Tools used for maintenance are not required to be those specifically recommended by the manufacturer, but tools utilized must be capable of providing results equivalent to those required by the equipment manufacturer.

AEM Program Documentation

For each type of equipment subject to the AEM program, there must be documentation indicating:

- The pertinent types and level of risks to patient or staff health and safety;
- Alternate maintenance activities, and the maintenance strategy and any other rationale used to determine those activities; the differences from the manufacturer's recommended maintenance activities are made explicit, unless the hospital is unable to obtain the manufacturer's maintenance recommendations, due to the age of the equipment or the manufacturer's restricting the availability of its recommendations;
- Alternate maintenance frequencies to be used, if any, and the maintenance strategy and any other rationale used to determine those frequencies. For equipment identified as presenting a very low risk to patient or staff safety, it could be acceptable to not set a particular frequency but instead indicate a less specific approach, for example, an interval range, such as "every 12 – 24 months." It could also be acceptable to employ periodic "departmental sweeps" for such very low risk equipment, where equipment functioning is sampled and operators are polled about its functionality.
- The date when AEM program maintenance activities were performed and, if applicable, further actions required/taken; and
- Documentation of any equipment failures (not including failures due to operator error), including whether there was resulting harm to an individual. (Note: equipment failure that is due to operator error and which results in an adverse event or near miss must be documented in accordance with the QAPI CoP, as part of the hospital's required tracking of patient safety-related incidents. However, there is no requirement to include operator failures in equipment maintenance documentation.)

When the hospital has multiple identical equipment items, the documentation may be generic to that type of equipment, except that documentation of maintenance activities performed must be specific to each item of equipment.

Evaluating Safety and Effectiveness of the AEM Program

The hospital must have policies and procedures which address the effectiveness of its AEM program. In evaluating the effectiveness of the AEM program the hospital is expected to address factors including, but not limited to:

- *How equipment is evaluated to ensure there is no degradation of performance, particularly for equipment where such degradation may not be readily apparent to staff using the equipment, e.g., miscalibration.*
- *How incidents of equipment malfunction are investigated, including:*
 - *whether or not the malfunction could have been prevented, and 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 from service of equipment determined to be unsafe or no longer suitable for its intended application; and*
- *The use of performance data to determine if modifications in the AEM program procedures are required.*

Equipment Inventory

All hospital facility and medical equipment, regardless of whether it is leased or owned, and regardless of whether it is maintained according to manufacturer recommendations or is in an AEM program, is expected to be listed in an inventory which includes a record of maintenance activities. For low cost/low risk equipment, such as housekeeping cleaning equipment, it is acceptable for the inventory to indicate under one item the number of such pieces of equipment in the hospital, e.g., "15 vacuum cleaners for cleaning patient rooms and common areas."

If the hospital is using an AEM program, the equipment managed through that program must be readily separately identifiable as subject to AEM. Critical equipment, whether in an AEM program or not, must also be readily identified as such.

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.

- *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 (for equipment generally kept in a fixed location);*
- *The identity of the department considered to "own" the equipment;*
- *Identification of the service provider;*

- *The acceptance date; and*
- *Any additional information the hospital believes may be useful for proper management of the equipment.*

This standard shall apply to all locations of the hospital, all campuses, and all off-site facilities. The hospital's department that is responsible for the hospital's buildings and equipment (both facility equipment and patient care equipment) must be evaluated for maintaining the appropriate work environment and related infrastructure to be safe for all staff, patients and visitors.

Certain areas of the hospital may be required to have external sources responsible for maintaining treatment areas and the hospital will ensure that these services are provided to provide a safe environment for all staff, patient and visitors.

The organization leadership shall require that a tobacco-free policy be developed and enforced campus-wide. Substantial progress toward complete conformity shall be demonstrated over time.

Surveyor Guidance:

The survey team will delegate one surveyor to review and evaluate the physical environment of the hospital. However, each surveyor, during their respective review of areas within the hospital, should assess the hospital's compliance with the physical environment standards. If warranted, based upon the size and complexity of services provided, the Life Safety Code may be reviewed and evaluated separately by a qualified surveyor.

Verify that the condition of the hospital is maintained in a manner to assure the safety and wellbeing of patients (e.g., condition or ceilings, walls, and floors, presence of patient hazards, etc.).

Review the hospital's routine and preventive maintenance schedules to determine that ongoing maintenance inspections are performed and that necessary repairs are completed.

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.

Observe the facility layout and determine if the patient's needs are met. Toilets, sinks, specialized equipment, etc. should be accessible.

Interview personnel in charge of facility, supplies and equipment maintenance to verify:

- *supplies are maintained in such a manner as to ensure an acceptable level of safety and quality.*
- *supplies are stored as recommended by the manufacturer.*
- *supplies are stored in such a manner as not to endanger patient safety.*
- *the hospital has identified supplies and equipment that are likely to be needed in emergency situation.*
- *the hospital has made adequate provisions to ensure the availability of those supplies and equipment when needed.*
- *Interview equipment users when surveying the various units/departments of the hospital to determine if equipment failures are occurring and causing problems for patient health*

or safety.

- Determine if there is a complete inventory of equipment required to meet patient needs, regardless of ownership.
- Is critical equipment readily identified?
- If the hospital employs an AEM program, is equipment in this program readily identified?
- Determine if the hospital has documentation of the qualifications (e.g., training certificates, certifications, degrees, etc.) of hospital personnel responsible for the AEM program (if one is being used by the hospital) as well as for those performing maintenance.
- Determine if the hospital is able to demonstrate how it assures contractors use qualified personnel.

If the hospital is following the manufacturer-recommended equipment maintenance activities and frequencies:

- In addition to reviewing maintenance records on equipment observed while inspecting various hospital locations for multiple compliance assessment purposes, select a sample of equipment from the hospital's equipment inventory to determine whether the hospital is following the manufacturer's recommendations. Critical equipment which poses a higher risk to patient safety if it were to fail, such as ventilators, defibrillators, robotic surgery devices, etc. should make up the sample majority.

For the sample selected, determine if:

- The hospital has available manufacturer's recommendations (e.g., manufacturer's operation and maintenance manual, standards, studies, guidance, recall information, service records, etc.);
- Maintenance is being performed in accordance with manufacturer's recommendations.

If a hospital is using an AEM for some equipment:

- Does the hospital's inventory include equipment, for example, any diagnostic imaging or therapeutic radiologic equipment, which is not eligible for AEM?
- Determine if the hospital's development of alternate maintenance activities and frequencies for equipment in the AEM program as well as AEM activities are being performed by qualified personnel
- Verify 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.
- If there is equipment on the inventory the hospital has identified 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. Does it seem reasonable?

Select a sample of equipment in the AEM program. The majority of the sample must include critical equipment which poses a higher risk to patient safety if it were to fail, such as ventilators, defibrillators, robotic surgery devices, etc. For the sample selected:

- *Ask the responsible personnel to explain how the decision was made to place the equipment in an AEM program. Does the methodology used consider risk factors and make use of available evidence?*
- *Ask the responsible personnel to describe the methodology for applying maintenance strategies and determining alternative maintenance activities or frequencies for the sampled equipment. Can they readily provide an explanation and point to sources of information they relied upon?*
- *Determine if maintenance is being performed in accordance with the maintenance activities and frequencies defined in the AEM program.*
- *Verify the hospital is evaluating the safety and effectiveness of the AEM maintenance activities for this equipment and taking corrective actions when needed.*

PE.2 LIFE SAFETY MANAGEMENT SYSTEM

SR.1 The organization shall meet the applicable provisions of the 2000 edition of the Life Safety Code® of the National Fire Protection Association.

Note: A hospital may no longer continue to keep in service existing roller latches even when those roller latches are demonstrating the ability to keep the door closed against 5 lbf, Chapter 19.3.6.3.2, exception number 2.

Note: A hospital must have replaced 1 hour batteries with 1 ½ hour batteries in emergency lighting systems that use batteries as power sources, Chapter 19.2.9, Emergency Lighting.

SR.2 *RESERVED (original standard deleted)*

SR.3 After consideration of the State survey agency findings, CMS may waive specific provisions of the Life Safety Code®, which, if rigidly applied, would result in unreasonable hardship upon the facility, but only if the waiver does not adversely affect the health and safety of patients.

SR.3a 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 protect patients.

SR.4 The organization 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 firefighting authorities.

The fire control plan shall provide for the following (NFPA 101-2000, 18.7.2.2 & 19.7.2.2):

SR.4a Use of alarms

- SR.4b Transmission of alarm to fire department
- SR.4c Response to alarms
- SR.4d Isolation of fire
- SR.4e Evacuation of immediate area
- SR.4f Evacuation of smoke compartment
- SR.4g Preparation of floors and building for evacuation
- SR.4h Extinguishment of fire
- SR.5 The organization shall maintain written evidence of regular inspection and approval by State or local fire control agencies.
- SR.6 Health care occupancies shall conduct unannounced fire drills, but not less than one (1) drill per shift per calendar quarter that transmits a fire alarm signal and simulates an emergency fire condition. When fire drills are conducted between 9:00 p.m. (2100 hours) and 6:00 a.m. (0600 hours), a coded announcement shall be permitted to be used instead of audible alarms. (NFPA 101-2000, 18.7.1.2. & 19.7.1.2). False alarms may be used (up to 50% of total drills) if all elements of the fire plan are exercised.
Business occupancies shall conduct at least one unannounced fire drill annually per shift.
SR.6 a Fire drills must be thoroughly documented and evaluate the organization's knowledge to the items listed in PE.2, SR.4.
SR.6 a (1) At least annually, the organization shall evaluate the effectiveness of the fire drills, The report of effectiveness shall be forwarded to Quality Management oversight.
- SR.7 The Life Safety Management System shall address applicable Alternative Life Safety Measures (ALSM) that shall be implemented whenever life safety features, systems, or processes are impaired or deficiencies are created or occur. Thorough documentation is required.
SR.7a All alternative life safe measures must be approved by the authority having local jurisdiction.
- SR.8 The Life Safety Management System shall require that Life Safety systems (e.g., fire suppression, notification, and detection equipment) shall be tested and inspected (including portable systems).
- SR.9 The Life Safety Management System shall require a process for reviewing the acquisition of bedding, draperies, furnishings and decorations for fire safety.
- SR.10 Construction, Repair, and Improvement operations shall involve the following activities:
 - SR.10a During construction, repairs, or improvement operations, or otherwise affecting the space, *the Guidelines for Design and Construction of Hospitals and Health Care Facilities, 2010* edition, published by the American Institute of Architects shall be consulted for designing purposes.
 - SR.10b The organization shall assess, document, and minimize the impact of construction, repairs, or improvement operations upon occupied area(s). The assessment shall include, but not be limited to, provisions for infection control, utility requirements, noise, vibration, and alternative life safety measures (ALSM).

- SR.10c In occupied areas where construction, repairs, or improvement operations occur, all required means of egress and required fire protection features shall be in place and continuously maintained or where alternative life safety measures acceptable to the authority having local jurisdiction are in place.
NFPA 241-1996, *Standard for Safeguarding Construction, Alteration, and Demolition Operations* shall be referenced in identifying and implementing alternative life safety measures.
- SR.10d All construction, repairs, or improvement operations, shall be in accordance with applicable NFPA 101-2000 standards, and State and local building and fire codes. Should standards and codes conflict, the most stringent standard or code shall prevail.

Interpretive Guidelines:

The hospital, regardless of size or number of beds, shall meet the applicable provisions of the 2000 edition of the Life Safety Code® of the National Fire Protection Association for all inpatient care locations, emergency departments, and outpatient care locations.

Additionally, the hospital must be in compliance with all applicable codes referenced in the Life Safety Code®, such as, NFPA-99: Health Care Facilities.

Note: In order for SR.3 to be applicable, the appropriate supporting documentation must be in place.

The hospital will maintain and update, as necessary, a fire control plan that includes the elements of SR.4. The hospital will also have supporting documentation to verify the regular inspection and approval by State or local fire control agencies.

The Life Safety Management System shall:

- *include in the elements of SR.4d a written plan for the protection of the integrity of hospital smoke and fire barriers. The plan should include:*
- *Name(s) of Responsible hospital staff for barrier protection program*
 - *Requirement for written permission for anyone (including all hospital staff, contractors and vendors) to penetrate a smoke or fire barrier wall, ceiling or floor*
 - *Input from Infection Control and Prevention Practitioner on critical clinical areas prior to issuance of written permit for performing work on barriers*
 - *Establishment of monitoring process to ensure all work is completed correctly*
 - *address applicable Alternative Life Safety Measures to be implemented whenever life safety systems, processes, or deficiencies are created or occur;*
 - *require that Life Safety systems (e.g., fire alarm and detection equipment) shall be is tested and inspected (including portable systems);*
 - *require a process for reviewing bedding, draperies, furnishings and decorations for fire safety; and,*

When construction, repairs, or improvement operations affect the space where hospital processes are carried out, the Guidelines for Design and Construction of Hospitals and Health Care Facilities, 2006 edition (or newer revision if in publication), NFPA 101-2000 standards, and State and local building and fire codes shall be used.

When construction, repairs, or improvement operations impacts occupied areas, the hospital will also make provisions to include, as appropriate, infection control practices to be followed, utility requirements, and account for noise and vibration. The hospital may have also implemented appropriate alternative life safety measures which are required to be approved by the authority having local jurisdiction.

Surveyor Guidance:

When applicable, verify the consideration, assessment, and recommendation for waivers of specific Life Safety Code® provisions have been handled by the Fire Authority surveyor as part of the Life Safety Code® survey process.

Review and validate the hospital's written fire control plans to verify they contain the required provisions of the Life Safety Code® or State law.

Review and verify that hospital staff has a process in place to report all fires as required to State officials.

In the review of respective areas of the hospital, interview staff throughout the facility to verify knowledge of their role and responsibilities during a fire.

Review and validate the documentation of inspection and approval reports from State and local fire control agencies.

Review and validate that the Life Safety Management System addresses the elements as described within the Interpretive Guidelines.

The surveyor should validate compliance with the inspection, testing, and maintenance of fire detection, notification, and suppression equipment and systems.

Review areas where current construction, repairs, or improvement operations are taking place and validate that the Guidelines for Design and Construction of Hospitals and Health Care Facilities, NFPA 101-2000, standards, and State and local building and fire codes are being followed.

If construction, repairs, or improvement operations are taking place and affects occupied areas, verify that the hospital has made provisions for the respective elements as described in the Interpretive Guidelines (above).

If there is no renovation or construction taking place within the hospital, verify that the hospital follows a process to follow the Guidelines for Design and Construction of Hospitals and Health Care Facilities, implements alternative life safety measures and includes the infection control practitioner and has the resources to account for utility requirements, and eliminating, to the extent possible, noise and vibration.

Validate there was documentation:

- *That the means of egress were checked daily.*

- *That the means of egress were continuously maintained free from obstructions or impediments.*
- *That an assessment was performed of work relating to the impact on the occupied area(s) shall be conducted and include provisions for infection control, utility requirements, noise, vibration, and alternate life safety measures.*
- *That the authority having local jurisdiction approved the alternate life safety measures.*

PE.3 SAFETY MANAGEMENT SYSTEM

- SR.1 The organization shall provide a Safety Management System that shall maintain safe and adequate facilities for its services. Diagnostic and therapeutic facilities must be located for the safety of patients.
- SR.2 The Safety Management System shall require that facilities, supplies and equipment be maintained and ensure an acceptable level of safety and quality. The extent and complexity of facilities shall be determined by the services offered.
- SR.3 The Safety Management System shall require proper ventilation, light and temperature controls in pharmaceutical, food preparation, and other appropriate areas.
- SR.4 The Safety Management System shall require that the organization maintain an environment free of hazards and manages staff activities to reduce the risk of occupational related illnesses or injuries.
- SR.5 The Safety Management System shall require periodic surveillance of the hospital grounds to observe and correct safety issues that may be identified.
- SR.6 The Safety Management System shall address safety recalls and alerts.

Interpretive Guidelines:

The hospital will maintain safe and adequate facilities that are designed and maintained in accordance with Federal, State and local laws, regulations and guidelines and reflect the scope and complexity of the services it offers in accordance with accepted standards of practice. The Safety Management System will require:

- *That facilities, supplies, and equipment be maintained and ensure an acceptable level of safety and quality;*
- *The hospital maintains an environment free of hazards and manages staff activities to reduce the risk of occupational related illnesses or injuries; and,*
- *A process for addressing safety recalls and alerts.*

The hospital shall require periodic surveillance of the hospital grounds to observe safety issues that may be identified and make corrective/preventive action(s) as needed.

Surveyor Guidance:

Review and verify that diagnostic, treatment, and other specialized services are provided in areas appropriate for the service provided.

Review and verify that the physical facilities are large enough and properly equipped for the scope of services provided and the number of patients served.

Where corrective/preventive action(s) have been taken, review and verify the documentation in place to ensure the effectiveness of action(s) taken.

PE.4 SECURITY MANAGEMENT SYSTEM

- SR.1 The organization shall develop a Security Management System that provides for a secure environment.
- SR.2 The Security Management System shall provide for identification of patients, employees and others.
- SR.3 The Security Management System shall address issues related to abduction, elopement, visitors, workplace violence, and investigation of property losses.
- SR.4 The Security Management System shall establish emergency security procedures to include all hazard events
- SR.5 The Security Management System shall require vehicular access to emergency service areas.
- SR.6 The Security Management System shall require a process for reporting and investigating security related issues.

Interpretive Guidelines:

The organization should have a written, comprehensive workplace violence control and prevention program based on guidelines from national authorities such as the OSHA Publication 3148-01R 2004 Guidelines for Preventing Workplace violence for Healthcare and Social Workers.

Elements of a Workplace Violence Prevention Program should include but not limited to:

- *A Clearly Written Company Workplace Violence Policy Statement*
- *Establishment of a Threat Assessment Team*
- *Hazard Assessments*
- *Workplace Hazard Control and Prevention*
- *Training and Education*

- *Incident Reporting, Investigation, Follow-up and Evaluation*
- *Recordkeeping*

Surveyor Guidance:

Review and validate the Security Management System to ensure that it addresses the respective elements as stated within PE.4, SR.1 – SR.6.

PE.5 HAZARDOUS MATERIAL (HAZMAT) MANAGEMENT SYSTEM

- SR.1 The organization shall provide a Hazmat Management System to manage hazardous materials and waste.
- SR.2 The HAZMAT Management System shall provide processes to manage the environment, selection, handling, storing, transporting, using, and disposing of hazardous materials and waste.
- SR.3 The HAZMAT Management System shall provide processes to manage reporting and investigation of all spills, exposures, and other incidents.
- SR.4 The organization monitors staff exposure levels in hazardous environments and report the results of the monitoring to the Quality Management System.
- SR.5 Notwithstanding any provisions of the 2000 edition of the Life Safety Code to the contrary, a hospital may install alcohol-based hand rub dispensers in its facility if:
- SR.5a Use of alcohol-based hand rub dispensers does not conflict with any State or local codes that prohibit or otherwise restrict the placement of alcohol-based hand rub dispensers in health care facilities;
- SR.5b The dispensers are installed in a manner that minimizes leaks and spills that could lead to falls;
- SR.5c The dispensers are installed in a manner that adequately protects against inappropriate access
- SR.5d The dispensers are maintained in accordance with dispenser manufacturer guidelines.
- SR.5e If dispensers are stored in corridors, the corridor must be a minimum of 72 inches.
- SR.5f The maximum individual dispenser fluid capacity shall be:
- 1.2 liters (0.3 gallons) for dispensers in rooms, corridors, and areas open to corridors.
 - 2.0 liters (0.5 gallons) for dispensers in suites of rooms.
- SR.5g The dispensers shall have a minimum horizontal spacing of 4 ft. (1.2m) from each other.
- SR.5h Not more than an aggregate 37.8 liters (10 gallons) of ABHR solution shall be in use in a single smoke compartment outside of a storage cabinet.
- SR.5i Storage of quantities greater than 18.9 liters (5 gallons) in a single smoke compartment shall meet the requirements of NFPA 30, *Flammable and Combustible Liquids Code*.

- SR.5j The dispensers shall not be installed over or directly adjacent to an ignition source.
- SR.5k In locations with carpeted floor coverings, dispensers installed directly over carpeted surfaces shall be permitted only in sprinklered smoke compartments.
- SR.5l Where minimum corridor width is 72 inches (1830 mm), projections of maximum 6 inches (152 mm) from the corridor wall, above the handrail, shall be permitted for the installation of hand-rub dispensing units.
- SR.6 RESERVED
- SR.7 In anesthetizing locations, which use alcohol-based skin preparations, have implemented effective fire risk reductions measures which include:
 - SR.7a The use of unit dose skin prep solutions.
 - SR.7b Application of skin prep follows manufacture/supplier instructions and warnings.
 - SR.7c Sterile towels are used to absorb drips and runs during the application and then removed from the anesthetizing location prior to draping.
 - SR.7d Verifying that all of the above has occurred prior to initiating the surgical procedure.
- SR.8 Verify that nonflammable medical gas stored outside of an enclosure does not exceed 300 cubic feet per smoke compartment.

Interpretive Guidelines:

The term waste refers to common garbage, hazardous material as well as biohazardous wastes. 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 Conditions of Participation for Radiology and Nuclear Medicine Services address handling and storage of radioactive materials.

There must be proper ventilation in at least the following areas: Areas using ethylene oxide, nitrous oxide, gluteraldehydes, xylene, pentamidine, or other potentially hazardous substances;

Information regarding storage requirements for small quantities of medical gas and determination of "in use" status can be found in NFPA 99, 2005, 9.4.3

Surveyor Guidance:

Verify that the hospital has developed and implemented policies and processes for the selection, handling, storing, transporting, using, and disposing of hazardous materials and waste in accordance with Federal, State and local laws and regulations (e.g. EPA, OSHA, CDC, State environmental, health and safety regulations).

Review and verify that processes are in place for the reporting and investigation of all spills, exposure and other incidents involving hazardous materials.

Review documents to ensure employee and environmental monitoring is being conducted.

PE.6 EMERGENCY MANAGEMENT SYSTEM

- SR.1 The organization must provide a comprehensive Emergency Management System to respond to emergencies in the organization or within the community and region that may impact the organization's ability to provide services.
- SR.2 The organization shall meet the requirements set forth in NFPA 99 (2005), Chapter 12, Emergency Management.
- SR.3 The Emergency Management System shall require that the organization conduct a hazard vulnerability analysis to identify potential emergencies in the organization and the community.
- SR.4 The Emergency Management System shall establish an emergency process to address the potential hazards to the organization and the community. The hospital shall conduct an organization-wide emergency management exercise, including the triage and disposition of patients. The organization-wide emergency management exercises, including the triage and disposition of patients, shall be conducted no less frequently than twice per year.
- SR.4a Emergency management exercises shall test the most threatening hazard(s) identified in the HVA and tax the resources of the organization.
- SR.4b At least every other emergency management exercise shall be conducted with the community to evaluate surge capacity, the integration of Incident Command and interoperability of communications.
- SR.4c The organization shall formulate an After Action Report of all emergency management exercises to identifying opportunities for improvements and revise its emergency management plan according to the identified opportunities for improvement.
- SR.5 The Emergency Management System processes shall address alternative means to support essential building functions such as electricity, water, ventilation, fuel, medical gas and vacuum systems, and other identified utilities.
- SR.6 The Emergency Management System shall include memorandums of understanding for utilization of resources (space, personnel, and equipment) with local and regional healthcare facilities and public health agencies in cases of organizational, community, or regional crisis.
- SR.7 The organization shall have policies, procedures, and decision criteria for the determination of protection in place or evacuation of patients in the event of a disaster.

Interpretive Guidelines:

Assuring the safety and wellbeing of patients would include developing and implementing appropriate emergency preparedness plans and capabilities. The organization must develop and implement a comprehensive plan to ensure that the safety and wellbeing of patients are assured during emergency situations.

The organization must coordinate with Federal, State, regional, and local emergency preparedness and health authorities to identify likely risks for their area (e.g., natural disasters, bioterrorism threats, disruption of utilities such as water, sewer, electrical communications, fuel; nuclear accidents, industrial accidents, and other likely mass casualties, etc.) and to develop appropriate responses that will assure the safety and wellbeing of patients. The following issues should be considered when developing the comprehensive emergency plans(s):

- *The differing needs of each location where the certified hospital operates;*
- *The special needs of patient populations treated at the hospital (e.g., patients with psychiatric diagnosis, patients on special diets, newborns, etc.);*
- *Security of patients and walk-in patients;*
- *Security of supplies from misappropriation;*
- *Pharmaceuticals, food, other supplies and equipment that may be needed during emergency/disaster situations;*
- *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 transfer of patients is necessary, etc.);*
- *Communication among staff within the hospital itself;*
- *Qualifications and training needed by personnel, including healthcare staff, security staff, and maintenance staff, to implement and carry out emergency procedures;*
- *Identification, availability and notification of personnel that are needed to implement and carry out the hospital's emergency plans;*
- *Identification of community resources, including lines of communication and names and contact information for community emergency preparedness coordinators and responders;*
- *Transfer or discharge of patients to home, other healthcare settings, or other hospitals; • Transfer of patients with hospital equipment to another hospital or healthcare setting; and*
- *Methods to evaluate repairs needed and to secure various likely materials and supplies to effectuate repairs.*
- *Provisions if gas, water, electricity supply is shut off to the community;*

The hospital must provide for a comprehensive Emergency Management System in order to respond to emergencies in the organization or that occur in the community that impact the hospital's ability to provide services.

The hospitals must comply with the applicable provisions of the Life Safety Code®, National Fire Protection Amendments (NFPA) 101, 2000 Edition and applicable references, such as, NFPA-99: Health Care Facilities, Chapter 12, Emergency Management.

In order to prepare for such an emergency, the hospital must conduct a hazard vulnerability analysis to identify potential emergencies or other circumstances that may impact the hospital and the community. The hospital must maintain documentation that this analysis has been conducted and that the hospital has prioritized activities to address and prepare for these vulnerabilities.

Emergency management exercises shall be based upon the most probable emergencies or other circumstances that may impact the hospital and the community. A report, After Action Report, shall be created after each exercise documenting opportunities for improvement.

The organization's emergency management plan shall be revised based upon the identified opportunities for improvement.

In PE,6, SR.4b, the "community" represents local, regional, State, Federal public safety forces and/or public health agencies.

Surveyor Guidance:

Review and 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. This plan must address the elements listed above within the Interpretive Guidelines.

Review and validate that the hospital has conducted a hazard vulnerability analysis to identify potential emergencies in the organization and the community. Determine the method used to prioritize and made preparations to address the potential hazards to the organization and community.

Review and validate:

- *That the organization has conducted appropriate and timely emergency management exercises.*
- *That after action reports identified opportunities for improvements.*
- *That the organization revised its emergency management plan according to the identified opportunities for improvement.*

PE.7 MEDICAL EQUIPMENT MANAGEMENT SYSTEM

- SR.1 The organization shall establish a Medical Equipment Management System that provides processes for the acquisition, safe use, and the appropriate selection of equipment.
- SR.2 The Medical Equipment Management System shall address issues related to the organization's initial service inspection, the orientation, and the demonstration of use for rental or physician owned equipment.
- SR.3. The Medical Equipment Management System shall address criteria for the selection of equipment.
- SR.4 The Medical Equipment Management System shall address incidents related to serious injury or illness or death (See SMDA 1990).
- SR.5 The Medical Equipment Management System shall have a process for reporting and investigating equipment management problems, failures, and user errors.
- SR.6 The Medical Equipment Management System shall address a process for determining timing and complexity of medical equipment maintenance.
- SR.7 The Medical Equipment Management System shall address the process of receiving and responding to recalls and alerts.

Interpretive Guidelines:

Medical Equipment must be maintained to ensure an acceptable level of safety and quality.

In order to ensure an acceptable level of safety and quality, the hospital must identify the equipment required to meet its patients' needs for both day-to-day operations and in a likely emergency/disaster situation, such as mass casualty events resulting from natural disasters, mass trauma, disease outbreaks, internal disasters, etc. In addition, the hospital must make adequate provisions to ensure the availability and reliability of equipment needed for its operations and services. Equipment includes both facility equipment, which supports the physical environment of the hospital (e.g., elevators, generators, air handlers, medical gas systems, air compressors and vacuum systems, etc.) and medical equipment, which are devices intended to be used for diagnostic, therapeutic or monitoring care provided to a patient by the hospital (e.g., IV infusion equipment, ventilators, laboratory equipment, surgical devices, etc.).

All equipment must be inspected and tested for performance and safety before initial use and after major repairs or upgrades.

All equipment must be inspected, tested, and maintained to ensure their safety, availability and reliability. Equipment maintenance activities may be conducted using hospital personnel, contracted services, or through a combination of hospital personnel and contracted services. Individual(s) responsible for overseeing the development, implementation, and management of equipment maintenance programs and activities must be qualified. The hospital maintains records of hospital personnel qualifications and is able to demonstrate how it assures all personnel, including contracted personnel, are qualified.

All equipment maintenance policies, procedures and programs, as well as specific equipment maintenance inventories, activities and schedules fall under the purview of the hospital's clinical maintenance personnel, safety department personnel or other personnel who have been assigned responsibility for equipment maintenance by hospital leadership.

Hospitals comply with this regulation when they follow the manufacturer-recommended maintenance activities and schedule. Hospitals may choose to perform maintenance more frequently than the manufacturer recommends, but must use the manufacturer-recommended maintenance activities in such cases. When equipment is maintained in accordance with the manufacturer's recommendations, the hospital must maintain documentation of those recommendations and the hospital's associated maintenance activity for the affected equipment.

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. 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 or medical equipment. The AEM program must be based on generally accepted standards of practice for facility or medical equipment maintenance.

An example of guidelines for a medical equipment maintenance program may be found in the American National Standards Institute/ Association for the Advancement of Medical Instrumentation document: ANSI/AAMI EQ 56:1999/ (R) 2013, Recommended Practice for a Medical Equipment Management Program. Likewise, an example of guidelines for physical plant equipment may be found in the American Society for Healthcare Engineering (ASHE) 2009 document: Maintenance Management for Health Care Facilities. There may be similar documents issued by other nationally recognized organizations which hospitals might choose to reference.

Decision to Place Equipment in an AEM Program

The determination of whether it is safe to perform facility or 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. Highly specialized or complex equipment may require specialized knowledge or training in order for personnel to be considered qualified to make a decision to place such equipment in an AEM program.

In the case of facility equipment, a Healthcare Facility Management professional (facility manager, director of facilities, vice president of facilities) would be considered qualified.

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.

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.

A hospital is expected to identify any equipment in its AEM program which is "critical equipment," i.e., biomedical or physical plant equipment for which there is a risk of serious injury or death to a patient or staff person should the equipment fail. Surveyors must focus their review of a hospital's AEM program on critical equipment in that program and the hospital's documentation of the factors and evidence it considered in developing an AEM strategy for that equipment.

Factors for a hospital to consider when evaluating the risks associated with a particular type of equipment include, but are not limited to:

- *How the equipment is used and the likely consequences of equipment failure or malfunction - would failure or malfunction of the equipment hospital-wide or in a particular setting be likely to cause harm to a patient or a staff person?*

- *How serious is the harm likely to be? For example, a slightly miscalibrated scale in an adult internal medicine outpatient clinic might not present significant risk of harm. However, a miscalibrated scale in a neonatal intensive care unit could have very serious consequences for patient care.*
- *How widespread is the harm likely to be? For example, are many patients exposed to the equipment, resulting in harm due to failure impacting more patients or staff? If harm would be widespread, even if the harm to each affected individual is not serious, this would be a cause for concern.*
- *Information, if available, on the manufacturer's equipment maintenance recommendations, including the rationale for the manufacturer's recommendations;*

Maintenance requirements of the equipment:

- *Are they simple or complex?*
- *Are the manufacturer's instructions and procedures available in the hospital, and if so can the hospital explain how and why it is modifying the manufacturer's instructions?*
- *If the manufacturer's instructions are not available in the hospital, how does the hospital assess whether the AEM uses appropriate maintenance strategies?*
- *How readily can the hospital validate the effectiveness of AEM methods for particular equipment? For example, can the hospital explain how it ensures there is no reduction in the quality of the performance of biomedical equipment subjected to alternate maintenance methods?*
- *The timely availability of alternate devices or backup systems in the event of equipment failure or malfunction; and*
- *Incident history of identical or very similar equipment – is there documented evidence, based on the experience of the hospital (or its third party contractor), or on evidence publicly reported by credible sources outside the hospital, which:*
 - *Provides the number, frequency and nature of previous failures and service requests?*
 - *Indicates use of an AEM strategy does not result in degraded performance of the equipment?*

Generally 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.

Equipment not Eligible for Placement in the AEM Program:

Some equipment may not be eligible for placement in the AEM program, for one or more of the following reasons:

- *Other Federal law (for example, regulations promulgated by another Federal agency) or State law may require that facility or medical equipment maintenance, inspection and testing be performed strictly in accordance with the manufacturer's recommendations, or may establish other, more stringent maintenance requirements.*

- *In these instances, the hospital must comply with these other Federal or State requirements, but State Surveyors conducting Federal surveys assess compliance only with the hospital Conditions of Participation (CoPs).*
- *Other CoPs require adherence to manufacturer's recommendations and/or set specific standards which preclude their inclusion in an AEM program. For example:*
 - *The National Fire Protection Association Life Safety Code (LSC) requirements incorporated by reference at 42 CFR 482.41(b) has some provisions that are pertinent to equipment maintenance, and compliance with these requirements are assessed on Federal surveys. Further, §482.41(b)(9)(v) requires hospitals to adhere to the manufacturer's maintenance guidelines for alcohol-based hand-rub dispensers. Compliance with these requirements is assessed on Federal surveys.*
 - *Imaging/radiologic equipment, whether used for diagnostic or therapeutic purposes, is governed by 42 CFR 482.26(b)(2) and must be maintained per manufacturer's recommendations.*
- *The equipment is a medical laser device. It should be noted that for medical lasers the U.S. Food and Drug Administration requires manufacturers to provide a schedule of maintenance and adequate instructions for service adjustments and service procedures to purchasers and, at cost, to any other parties requesting them.*
- *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. New equipment must be maintained in accordance with manufacturer recommendations until a sufficient amount of maintenance history has been acquired to determine whether the alteration of maintenance activities or frequencies would be safe. If a hospital later transitions the equipment to a risk-based maintenance regimen different than the manufacturers' recommendations, the hospital must maintain evidence that it has first evaluated the maintenance track record, risks, and tested the alternate regimen.*

Alternative Maintenance Frequencies or Activities

Maintenance strategies are various methodologies used for determining the most efficient and effective maintenance activities and frequencies. Manufacturers' recommendations may be based on one or more such strategies. A hospital may also use one or more maintenance strategies for its AEM program in order to determine the appropriate maintenance, inspection, and testing 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 recommendations and other materials, nationally recognized expert associations, and/or the hospital's (or its third party contractor's) own experience. Maintenance strategies may be applied to groups or to individual pieces of equipment.

The hospital is expected to adhere strictly to the AEM activities or strategies it has developed.

Background Information on Types of Maintenance Strategies

- **Preventive Maintenance (Time-based Maintenance)** – a maintenance strategy where maintenance activities are performed at scheduled time intervals to minimize equipment degradation and reduce instances where there is a loss of performance. Most preventive maintenance is “interval-based maintenance” performed at fixed time intervals (e.g., annual or semi-annual), but may also be “metered maintenance” performed according to metered usage of the equipment (e.g., hours of operation). In either case, the primary focus of preventive maintenance is reliability, not optimization of cost-effectiveness. Maintenance is performed systematically, regardless of whether or not it is needed at the time. Example: Replacing a battery every year, after a set number of uses or after running for a set number of hours, regardless.
- **Predictive Maintenance (Condition-based Maintenance)** – a maintenance strategy that involves periodic or continuous equipment condition monitoring to detect the onset of equipment degradation. This information is used to predict future maintenance requirements and to schedule maintenance at a time just before equipment experiences a loss of performance. Example: Replacing a battery one year after the manufacturer’s recommended replacement interval, based on historical monitoring that has determined the battery capacity does not tend to fall below the required performance threshold before this extended time.
- **Reactive Maintenance (Corrective, Breakdown or Run-to-Failure Maintenance)** – a maintenance strategy based upon a “run it until it breaks” philosophy, where maintenance or replacement is performed only after equipment fails or experiences a problem. This strategy may be acceptable for equipment that is disposable or low cost, and presents little or no risk to health and safety if it fails. Example: Replacing a battery after equipment failure when the equipment has little negative health and safety consequences associated with a failure and there is a replacement readily available in supply.
- **Reliability-Centered Maintenance** – a maintenance strategy that not only considers equipment condition, but also considers other factors unique to individual pieces of equipment, such as equipment function, consequences of equipment failure, and the operational environment. Maintenance is performed to optimize reliability and cost effectiveness. Example: Replacing a battery in an ambulance defibrillator more frequently than the same model used at a nursing station, since the one in the ambulance is used more frequently and is charged by an unstable power supply.

Maintenance Tools

Tools (e.g., hand tools, test equipment, software, etc.) necessary for performing equipment maintenance must be available and maintained to ensure that measurements are reliable. Tools used for maintenance are not required to be those specifically recommended by the manufacturer, but tools utilized must be capable of providing results equivalent to those required by the equipment manufacturer.

AEM Program Documentation

For each type of equipment subject to the AEM program, there must be documentation indicating:

- *The pertinent types and level of risks to patient or staff health and safety;*
- *Alternate maintenance activities, and the maintenance strategy and any other rationale used to determine those activities; the differences from the manufacturer's recommended maintenance activities are made explicit, unless the hospital is unable to obtain the manufacturer's maintenance recommendations, due to the age of the equipment or the manufacturer's restricting the availability of its recommendations;*
- *Alternate maintenance frequencies to be used, if any, and the maintenance strategy and any other rationale used to determine those frequencies. For equipment identified as presenting a very low risk to patient or staff safety, it could be acceptable to not set a particular frequency but instead indicate a less specific approach, for example, an interval range, such as "every 12 – 24 months." It could also be acceptable to employ periodic "departmental sweeps" for such very low risk equipment, where equipment functioning is sampled and operators are polled about its functionality.*
- *The date when AEM program maintenance activities were performed and, if applicable, further actions required/taken; and*
- *Documentation of any equipment failures (not including failures due to operator error), including whether there was resulting harm to an individual.) (Note: equipment failure that is due to operator error and which results in an adverse event or near miss must be documented in accordance with the QAPI CoP, as part of the hospital's required tracking of patient safety-related incidents. However, there is no requirement to include operator failures in equipment maintenance documentation.)*

When the hospital has multiple identical equipment items, the documentation may be generic to that type of equipment, except that documentation of maintenance activities performed must be specific to each item of equipment.

Evaluating Safety and Effectiveness of the AEM Program

The hospital must have policies and procedures which address the effectiveness of its AEM program. In evaluating the effectiveness of the AEM program the hospital is expected to address factors including, but not limited to:

- *How equipment is evaluated to ensure there is no degradation of performance, particularly for equipment where such degradation may not be readily apparent to staff using the equipment, e.g., miscalibration.*
- *How incidents of equipment malfunction are investigated, including:*
- *whether or not the malfunction could have been prevented, and 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 from service of equipment determined to be unsafe or no longer suitable for its intended application; and*
- *The use of performance data to determine if modifications in the AEM program procedures are required.*

Equipment Inventory

All hospital facility and medical equipment, regardless of whether it is leased or owned, and regardless of whether it is maintained according to manufacturer recommendations or is in an AEM program, is expected to be listed in an inventory which includes a record of maintenance activities. For low cost/low risk equipment, such as housekeeping cleaning equipment, it is acceptable for the inventory to indicate under one item the number of such pieces of equipment in the hospital, e.g., "15 vacuum cleaners for cleaning patient rooms and common areas."

If the hospital is using an AEM program, the equipment managed through that program must be readily separately identifiable as subject to AEM. Critical equipment, whether in an AEM program or not, must also be readily identified as such.

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.

- *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 (for equipment generally kept in a fixed location);*
- *The identity of the department considered to "own" the equipment;*
- *Identification of the service provider;*
- *The acceptance date; and*
- *Any additional information the hospital believes may be useful for proper management of the equipment*

The hospital will develop and implement a Medical Equipment Plan that addresses the following:

- *Issues related to use of demonstration or rental equipment and how appropriate training is provided to ensure safe operation;*
- *Defined criteria for the selection of equipment;*
- *The process of reporting and investigating incidents related to serious injury or illness or death (See SMDA 1990);*
- *A process for reporting and investigating equipment management problems, failures, and user errors;*
- *A process for determining timing and complexity of medical equipment maintenance; and,*
- *A process of receiving and responding to recalls and alerts.*

This shall apply to all locations of the hospital, all campuses, and all off-site facilities.

Surveyor Guidance:

Interview personnel in charge of equipment maintenance:

- *Select a sample of equipment for which the facility uses the manufacturer's recommendations for maintenance frequency. Sample selection should be based on:*
- *Risk to patient safety from equipment failure (e.g., sample high/medium/low risk).*

- *Critical equipment (e.g., life support devices, key resuscitation devices, critical monitoring devices, equipment used for radiologic imaging etc.) with higher risk should make up the sample majority.*
- *Service Requests (e.g., sample equipment with high service requests)*
- *Failure Records (e.g., sample high failure rates)*
- *Equipment Usage (e.g., sample high use)*
- *Type of Equipment (e.g., sample medical equipment & facility components)*
- *Maintenance is being performed in accordance with manufacturer's recommendations*

For the sample selected, review maintenance records to determine if:

- *Maintenance, inspection, and testing records are complete and accurate;*
- *Maintenance records include equipment failures and down-time;*
- *Equipment failures are corrected (through repair or replacement) in a timely manner;*
- *Equipment failure patterns are investigated and addressed.*
- *Records contain the qualifications (e.g., training certificates, certifications, degrees, etc.) of hospital personnel responsible for performing maintenance and/or the hospital is able to demonstrate how they assure contracted personnel are qualified. In the case of medical equipment, qualified personnel would be clinical or biomedical technicians or engineers.*
- *Records contain documents required to support maintenance activities (e.g., manufacturer's operation and maintenance manual, standards, studies, guidance, recall information, service records, etc.)*

Review the hospital's routine and preventive maintenance schedules to determine that ongoing maintenance inspections are performed and that necessary repairs are completed.

Verify that the hospital has developed and implemented a comprehensive plan to ensure that the safety and well-being of patients are assured during emergency situations.

Observe the facility layout and determine if the patient's needs are met. Toilets, sinks, specialized equipment, etc. should be accessible.

Interview personnel in charge of facility, supplies and equipment maintenance to verify:

- *the hospital has identified supplies and equipment that are likely to be needed in emergency situation.*
- *the hospital has made adequate provisions to ensure the availability of those supplies and equipment when needed.*
- *Interview equipment users when surveying the various units/departments of the hospital to determine if equipment failures are occurring and causing problems for patient health or safety.*
- *Determine if there is a complete inventory of equipment required to meet patient needs, regardless of ownership.*
- *Determine if the inventory is periodically reviewed and updated.*
- *Is critical equipment readily identified?*
- *If the hospital employs an AEM program, is equipment in this program readily identified?*
- *Determine if the hospital has documentation of the qualifications (e.g., training certificates, certifications, degrees, etc.) of hospital personnel responsible for the AEM program (if one is being used by the hospital) as well as for those performing maintenance.*
- *Determine if the hospital is able to demonstrate how it assures contractors use qualified personnel.*

If the hospital is following the manufacturer-recommended equipment maintenance activities and frequencies:

In addition to reviewing maintenance records on equipment observed while inspecting various hospital locations for multiple compliance assessment purposes, select a sample of equipment from the hospital's equipment inventory to determine whether the hospital is following the manufacturer's recommendations. Critical equipment, which poses a higher risk to patient safety if it were to fail, such as ventilators, defibrillators, robotic surgery devices, etc., should make up the sample majority.

For the sample selected, determine if:

- *The hospital has available manufacturer's recommendations (e.g., manufacturer's operation and maintenance manual, standards, studies, guidance, recall information, service records, etc.);*
- *Maintenance is being performed in accordance with manufacturer's recommendations.*

If a hospital is using an AEM for some equipment:

- *Does the hospital's inventory include equipment, for example, any diagnostic imaging or therapeutic radiologic equipment, which is not eligible for AEM?*
- *Determine if the hospital's development of alternate maintenance activities and frequencies for equipment in the AEM program as well as AEM activities are being performed by qualified personnel.*
- *Verify 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.*
- *If there is equipment on the inventory the hospital has identified 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. Does it seem reasonable?*

Select a sample of equipment in the AEM program. The majority of the sample must include critical equipment which poses a higher risk to patient safety if it were to fail, such as ventilators, defibrillators, robotic surgery devices, etc.

For the sample selected:

- *Ask the responsible personnel to explain how the decision was made to place the equipment in an AEM program. Does the methodology used consider risk factors and make use of available evidence?*
- *Ask the responsible personnel to describe the methodology for applying maintenance strategies and determining alternative maintenance activities or frequencies for the sampled equipment. Can they readily provide an explanation and point to sources of information they relied upon?*

- *Determine if maintenance is being performed in accordance with the maintenance activities and frequencies defined in the AEM program.*
- *Verify the hospital is evaluating the safety and effectiveness of the AEM maintenance activities for this equipment and taking corrective actions when needed.*
- *If there is equipment on the inventory the hospital has identified 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. Does it seem reasonable?*

PE.8 UTILITY MANAGEMENT SYSTEM

- SR.1 The organization shall require a Utility Management System that provides for a safe and efficient facility that reduces the opportunity for organization-acquired illnesses.
- SR.2 The Utility Management System shall provide for a process to evaluate critical operating components.
- SR.3 The Utility Management System shall develop maintenance, testing, and inspection processes for critical utilities.
- SR.4 The Utility Management System shall contain a process to address medical gas systems and HVAC systems (e.g., includes areas for negative pressure).
- SR.5 The Utility Management System shall provide for emergency processes for utility system failures or disruptions.
- SR.6 The Utility Management System shall provide for reliable emergency power sources with appropriate maintenance as required.
- SR.7 The Safety Management System shall require proper ventilation, light and temperature controls in operating rooms, sterile supply rooms, special procedures, isolation and protective isolation rooms, pharmaceutical, food preparation, and other appropriate areas.
- SR.8 There shall be emergency power and lighting in at least the operating, recovery, intensive care, emergency rooms, and in other areas where invasive procedures are conducted, stairwells, and other areas identified by the organization (e.g., blood bank refrigerator, etc.). In all other areas not serviced by the emergency supply source, battery lamps and flashlights shall be available.
- Emergency lighting standards shall comply with Section 7.9 of Life Safety Code, 101-2000, and applicable references, such as, NFPA-99: Health Care Facilities, for emergency lighting and emergency power.
- SR.9 There shall be facilities for emergency gas and water supply.
- SR.10 All relevant utility systems shall be maintained inspected, and, tested.

Interpretive Guidelines:

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 wellbeing of patients, visitors, and staff. The hospital will ensure that routine and preventive maintenance and testing activities are performed as necessary, in accordance with Federal and State laws, regulations, and guidelines and manufacturer's recommendations, by establishing maintenance schedules and conducting ongoing maintenance inspections to identify areas in need of repair.

There should be proper ventilation, light and temperature controls in pharmaceutical, food preparation, and other appropriate areas.

There must be proper ventilation in at least the following areas:

- *Areas using ethylene oxide, nitrous oxide, gluteraldehydes, xylene, pentamidine, formaldehyde, or other potentially hazardous substances;*
- *Locations where oxygen is transferred from one container to another;*
- *Isolation rooms and reverse isolation rooms (both must be in compliance with Federal and State laws, regulations, and guidelines such as OSHA, CDC, NIH);*
- *Pharmaceutical preparation areas (hoods, cabinets);*
- *Laboratory locations: and*
- *Anesthetizing locations.*

According to NFPA 99, anesthetizing locations are "Any area of a facility that has been designated to be used for the administration of nonflammable inhalation anesthetic agents in the course of examination or treatment, including the use of such agents for relative analgesia." NFPA 99 defines relative analgesia as "A state of sedation and partial block of pain perception produced in a patient by the inhalation of concentrations of nitrous oxide insufficient to produce loss of consciousness (conscious sedation)."

(Note that this definition is applicable only for LSC purposes and does not supercede other guidance that has been given on anesthesia and analgesia.)

Temperature, humidity, and airflow in the anesthetizing locations must be maintained within acceptable standards to inhibit microbial growth, reduce the risk of infection, control odor and promote patient comfort.

Hospitals must maintain relative humidity (RH) levels at 35 percent or greater in each anesthetizing location, unless the hospital elects to use the CMS categorical waiver, which permits it to maintain a RH of at least 20 percent. Hospitals must maintain records that demonstrate they have achieved the required levels. Although not required, CMS recommends that hospitals maintain the upper range of RH at 60 percent or less, as excessive humidity is conducive to microbial growth and compromises the integrity of wrapped sterile instruments and supplies.

Each operating room should have separate temperature control. Acceptable standards such as from the Association of Operating Room Nurses (AORN) or the Facilities Guidelines Institute (FGI) should be incorporated into hospital policy.

The hospital will maintain, and regularly test and inspect, emergency power and lighting in at least the operating, recovery, in other areas where invasive procedures are conducted, intensive care, and emergency rooms, stairwells, and other areas identified by the organization (e.g. blood bank refrigerator) to comply with the applicable Life Safety Code (101).

Where areas are not supplied with an emergency supply source, the hospital will make provisions for battery lamps and flashlights.

The hospital must have systems for emergency gas and water needs to provide care to inpatients and other persons who may come to the hospital in need of care. This includes making arrangements with local utility companies and others for the provision of emergency sources of water and gas. The hospital should consider nationally accepted references or calculations made by qualified staff when determining the need for at least water and gas. For example, one source for information on water is the Federal Emergency Management Agency (FEMA).

Emergency gas includes fuels such as propane, natural gas, fuel oil, liquefied natural gas, as well as any gases the hospital uses in the care of patients such as oxygen, nitrogen, nitrous oxide, etc.

The hospital should have a plan to protect these limited emergency supplies, and have a plan for prioritizing their use until adequate supplies are available. The plan should also address the event of a disruption in supply (e.g., disruption to the entire surrounding community).

Surveyor Guidance:

Review and validate the hospital's Utility Management System to ensure that there is a process in place to provide for a safe and efficient facility that reduces the opportunity for hospital-acquired illnesses.

Review and validate the condition of the hospital and that it is maintained in a manner to assure the safety and wellbeing of patients (e.g. condition of ceilings, walls, and floors, presence of patient hazards).

Review and validate the hospital's routine and preventive maintenance schedules to determine that ongoing maintenance inspections are performed and that necessary corrective/preventive action(s) are taken.

Review and verify that the facility layout is appropriate to meet patient's needs. Toilets, sinks, specialized equipment should be accessible.

The hospital will maintain, test and inspect their utility systems and have adequate facilities for emergency gas and water supply, to provide safe care for patients.

Verify that the Utility Management System provides for:

- A process to evaluate critical operating components;*
- A means of addressing medical gas systems and HVAC systems;*
- A means for providing emergency processes for utility system failures or disruptions; and,*
- A means for providing for reliable emergency power sources with appropriate maintenance.*
- Verify that the quality of the water supply and distribution system has been deemed acceptable for its intended use (drinking water, irrigation water, lab water, dialysis);*
- Emergency gases have been deemed acceptable and can be adequately supplied as needed;*
and,

- *Review the system used by hospital staff to determine the hospital's emergency needs for gas and water.*
- *Verify that the system accounts for not only inpatients, but also staff and other persons who come to the hospital in need of care during emergencies.*
- *Determine the source of emergency gas and water supplies, Review the quantity and availability of these supplies to the hospital, and that they are available within a short time through period additional deliveries.*
- *Verify that arrangements have been made with utility companies and others for the provision of emergency sources of critical utilities, such as water and gas.*
- *Verify that the utility systems have been tested, inspected and maintained for the safety of patient care and applicable to the services provided.*

Review and verify that adequate lighting is in place in all the patient care areas, and food and medication preparation areas.

Review and verify that humidity levels (RH) at 35 percent or greater in each anesthetizing location.

Review and verify that each surgical suite has separate temperature control.

Review and 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.

Review and verify that pharmaceuticals are stored at temperatures recommended by the product manufacturer and according to hospital policy.

- *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.*

ORGAN, TISSUE AND EYE PROCUREMENT (TO)

TO.1 PROCESS

SR.1 The organization shall have a process in place for the procurement of organs, tissue, and eyes. The organization shall have an agreement with at least one tissue bank and 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;

TO.2 ORGAN PROCUREMENT ORGANIZATION (OPO) WRITTEN AGREEMENT

The organization shall have a written agreement with an OPO designated under 42 CFR §486This agreement shall:

- SR.1 Contain procurement protocols that have been approved by the organization's governing body and medical staff,
- SR.2 Ensure that timely notification is provided to the OPO, or a third party designated by the OPO, for all individuals whose death is imminent or who have died in the hospital,
- SR.3 Ensure communication of the policy for organ, tissue and eye procurement to all appropriate areas of the organization, in addition to any revisions or modifications under a controlled document,
- SR.4 Acknowledge that it is the OPO's responsibility for the determination of medical suitability for organ donation, and, in the absence of alternative arrangements by the organization, 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 organization for this purpose.
- SR.5 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. If a designated requestor is responsible for initiating this request, this individual must have completed a course offered or approved by the OPO that has been designed in conjunction with the tissue and eye bank community in the methodology for approaching potential donor families and requesting organ or tissue donation.
- SR.6 Ensure that it 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 takes place.

Interpretive Guidelines:

The hospital has a process in place for the procurement of organs, tissue, and eyes.

The hospital must have a written agreement with an Organ Procurement Organization (OPO), designated under [42 CFR Part 486](#). At a minimum, the written agreement must address the following:

- Procurement protocols approved by the governing body and medical staff and criteria for referral, including the referrals of all individuals whose death is imminent or who have died in the hospital and ensure timely notification;*
- Specifications as to how the tissue and/or eye bank will be notified about potential donors using notification protocols developed by the OPO in consultation with the hospital-designated tissue and eye bank(s);*
- The OPO's responsibility for the determination of medical suitability in lieu of any alternative arrangement with a different tissue and/or eye bank;*
- Provisions 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;*
- Documentation 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;*
- Procedures that permit 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;*
- Policies that confirm 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,*
- The interventions the hospital will utilize to maintain potential organ donor patients so that the patient organs remain viable.*

The hospital must implement a mechanism for communication of the policy for organ, tissue and eye procurement to all appropriate area of the organization, in addition to any revisions or modifications under a controlled document.

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. 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.

Definition elements: “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*
- *MD/DOs are evaluating a diagnosis of brain death or*
- *An MD/DO has ordered that life-sustaining therapies be withdrawn, pursuant to the family’s decision.*

Note: 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.

Definition: “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.

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.

Definition: 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.

Waivers: A hospital may obtain a waiver of the above requirements from the Secretary under certain specified conditions. A waiver allows the hospital to have an agreement with an OPO other than the one initially designated by CMS, if the hospital meets certain conditions specified in section 1138(a)(2)(A) of the Social Security Act.

In addition, the Secretary may review additional criteria described in section 1138(a)(2)(B) of the Act to evaluate the hospital's request for a waiver.

Section 1138(a)(2)(A) of the Act states that in granting a waiver, the Secretary must determine that the waiver.

- (1) Is expected to increase organ donations; and*
- (2) Will ensure equitable treatment of patients referred for transplants within the service area served by the designated OPO and within the service area served by the OPO with which the hospital seeks to enter into an agreement under the waiver.*

In making a waiver determination, section 1138(a)(2)(B) of the Act provides that the Secretary may consider, among other factors:

- (1) Cost-effectiveness;*
- (2) Improvements in quality;*
- (3) Whether there has been any change in a hospital's designated OPO due to the changes made in definitions for metropolitan statistical areas; and*
- (4) The length and continuity of a hospital's relationship with an OPO other than the hospital's designated OPO.*

Surveyor Guidance:

Verify that the hospital has a written agreement, approved by the governing body, and that it addresses all required information or if they have obtained a waiver approved by the Secretary.

In a sampling of records, verify that the hospital has implemented its organ procurement policies.

Verify that that all designated requestors have completed the required training.

Verify that the hospital ensures that only OPO, tissue bank, or eye bank staff or designated requestors are approaching families to ask them to donate.

When possible, interview a hospital-designated requestor regarding his or her approach to donation requests.

Validate that the hospital ensures that all appropriate staff have attended an educational program regarding donation issues and how to work with the OPO, tissue bank, and eye bank.

Review and verify that there are policies and procedures in place to ensure the coordination between facility staff and OPO staff in maintaining the potential donor.

Verify that the organ, tissue, and eye procurement program is integrated into quality management system oversight.

TO.3 ALTERNATIVE AGREEMENT

In the event the organization has an alternative agreement with a tissue and/or eye bank, this agreement shall:

- SR.1 Specify the criteria for referral of all individuals who have died in the organization, and,
- SR.2 Acknowledge the OPO's responsibility for the determination of medical suitability in lieu of any alternative arrangement with a different tissue and/or eye bank.

Surveyor Guidance:

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.

Verify that the OPO is responsible for the determination of medical suitability for tissue and eye donation, unless the hospital has an alternative agreement with a different tissue and/or eye bank.

TO.4 RESPECT FOR PATIENT RIGHTS

The organ, tissue and eye procurement policies, procedures and practices shall demonstrate the respect for individual patient and family rights that reflect their views, religious beliefs and other special circumstances that have been communicated by the patient and/or family to the organization personnel.

TO.5 DOCUMENTATION

Documents and records of organ procurement will be maintained in the manner directed by the OPO.

Surveyor Guidance:

Review a sampling of documents and records regarding organ procurement

TO.6 ORGAN TRANSPLANTATION

If the organization performs organ transplantation, the organization shall:

- SR.1 Be a member in the Organ Procurement and Transplantation Network (OPTN), which is established and operated in accordance with section 372 of the Public Service Act (42. U.S.C 274) and abide by its rules,
- SR.2 Define the term "organ" as to what transplantation is done. The consistency in terms shall apply to a kidney, liver, heart, lung or pancreas, and,
- SR.3 Provide data related to the performance of organ transplantation as requested by the OPTN, the Scientific Registry of Transplant Recipients and the OPO. The organization shall be required to provide this data to CMS as requested by the Secretary.

Surveyor Guidance:

If the hospital performs organ transplantation, verify that the hospital is a member in the Organ Procurement and Transplantation Network (OPTN), and they have defined the term "organ" as to what transplantation is done. The consistency in terminology shall apply to a kidney, liver, heart, lung or pancreas, and,

Verify by review, the reports submitted by the facility to the OPTN, the Scientific Registry, the OPOs, and any data submitted to the Department of Health and Human Services per request of the Secretary.

TO.7 TRANSPLANT CANDIDATES

- SR.1 The organization shall ensure the appropriate candidates for receipt of transplanted organs have been screened, matched, and medically cleared prior to receipt of any organs.
- SR.2 Candidate information shall be documented, accurate and available at the time of the organ transplantation.
- SR.3 Authority for transplantation shall be co-signed by the patient or designated representative of the patient and the practitioner(s) performing the transplantation.

Interpretive Guidelines:

The hospital shall ensure that appropriate candidates for receipt of transplanted organs have been screened, matched, and medically cleared prior to receipt of any organs. The hospital will take all appropriate steps to verify that this has occurred prior to the transplantation process is started and this has been appropriately communicated and documented accordingly to the transplantation team.

The hospital will accurately document the time of the organ transplantation. The hospital will take such steps to ensure that there are no unnecessary delays when this process is initiated.

The hospital will ensure that authority for transplantation is co-signed by the patient or designated representative of the patient and the practitioner(s) performing the transplantation.

Surveyor Guidance:

In a review of patient records and/or policies and procedures, regarding the transplantation of organs, verify that candidates receiving organs are screened, matched, and medically cleared prior to receipt of any organs.

In the review of records or policies and procedures in place, verify that the time of the organ transplantation is documented as appropriate when this process is initiated and required by policy.

Verify that the hospital ensures that authority for transplantation is co-signed by the patient or designated representative of the patient and the practitioner(s) performing the transplantation.

APPENDIXES

APPENDIX NUMBER	TITLE
1	RESERVED
2	STERILE COMPOUNDING FOR PHARMACIES: OPTIONAL
3	SAFETY RISK MANAGEMENT: PROPOSED

APPENDIX 2: STERILE COMPOUNDING FOR PHARMACIES: OPTIONAL

If a State Board of Pharmacy accepts accreditation for meeting requirements/regulations for sterile compounding, the following requirements must be met. The purpose of these requirements is to ensure standards of pharmaceutical care; the preparation, labeling, and distribution of sterile pharmaceuticals, and product quality and characteristics.

MM.8 STERILE COMPOUNDING

- SR.1 All drug products for compounding will require receipt of a valid order by the Pharmacy for an individual patient where the prescriber has approved use of a compounded drug product either verbally or in writing. When the approval has been provided verbally, this will be documented on the order prior to compounding.
- SR.1a The ingredients and the compounding process for each preparation must be determined in writing before compounding begins and must be reviewed by a pharmacist.
- SR.2 The Pharmacy may prepare and store a limited quantity of a compounded drug product in advance of receipt of a patient-specific order. Compounded drug products shall only be in the quantity as is necessary to ensure continuity of care for an identified population of patients of the pharmacy based on a documented history of compounded drug products dispensed for that patient population.
- SR.3 A “reasonable quantity” of compounded drug product may be furnished to a specific patient care unit for use upon prescriber order and approved by the Pharmacy, where “reasonable quantity” is that amount of compounded drug product that:
- SR.3a Is sufficient for administration or application to patients on the patient care unit, or for dispensing of not more than a 72-hour supply to patients located on the patient care unit, as estimated by the prescriber and approved by the Pharmacy; and
- SR.3b Is reasonable considering the intended use of the compounded medication; and
- SR.3c For any individual prescriber and for all prescribers taken as a whole, is an amount which the Pharmacy is capable of compounding in compliance with pharmaceutical standards for integrity, potency, quality and strength of the compounded drug product.
- SR.4 A drug product shall not be compounded until the Pharmacy has first prepared a written master formula record that includes at least the following elements:
- SR.4a Active ingredients to be used.
- SR.4b Inactive ingredients to be used.
- SR.4c Process and/or procedure used for preparation of the drug product.

SR.4d Monitoring through quality assurance reviews required at each step in preparation of the drug product.

SR.4e Post-compounding process or procedures required, as applicable.

SR.4f Dates of expiration/use by dates as required.

Note: Where a pharmacy does not routinely compound a particular drug product, the master formula record for that product may be recorded on the order itself.

- SR.5 The pharmacist performing or supervising compounding is responsible for the integrity, potency, quality, and appropriate labeling of compounded drug products until they are dispensed.
- SR.6 All chemicals, bulk drug substances, drug products, and other components used for drug compounding shall be stored and used according to applicable requirements to maintain their integrity, potency, quality, and labeled strength.
- SR.7 Every compounded drug product shall be given an expiration date representing the date beyond which, in the professional judgment of the pharmacist performing or supervising the compounding, it should not be used. This “use by date” of the compounded drug product shall not exceed 180 days from preparation or the shortest expiration date of any component in the compounded drug product, unless a longer date is supported by stability studies of finished drugs or compounded drug products using the same components and packaging. Shorter dating may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist in accordance with the requirements.
- SR.8 In order to ensure compliance and consistency, prior to preparation of any drug product to be compounded in a Pharmacy, the pharmacist in-charge shall complete the required documentation for compounding pharmacies. This will be applicable to all compounding, and applicable to sterile injectable compounding. The documentation shall be completed by the pharmacist-in-charge before any compounding and/or any sterile injectable compounding is performed in the Pharmacy. The required documentation will be completed in accordance with State law/regulation and in accordance within the timeframes as defined by the State Board of Pharmacy.
- SR.9 For each compounded drug product, the pharmacy records shall include:
- SR.9a The master formula record.
 - SR.9b The date the drug product was compounded.
 - SR.9c The name of the pharmacy personnel who compounded the drug product.
 - SR.9d The name of the pharmacist reviewing the final drug product.

- SR.9e The quantity of each component used in compounding the drug product.
 - SR.9f The manufacturer and lot number of each component. If the manufacturer name is not readily available, the name of the supplier may be substituted. Exempt from this requirement are sterile products compounded on a one-time basis for administration within twenty-four hours to an inpatient in a health care facility licensed by the State.
 - SR.9g The equipment used in compounding the drug product.
 - SR.9h A Pharmacy assigned reference or lot number for the compounded drug product.
 - SR.9i The expiration date of the final compounded drug product.
 - SR.9j The quantity or amount of drug product compounded.
- SR.10 Pharmacies shall maintain records of the proper acquisition, storage, and wastage/destruction of chemicals, bulk drug substances, drug products, and components used in compounding. Records shall be readily available and retained for at least three years from the date the record was created or as otherwise required by State law/regulation.
- SR.11 Chemicals, bulk drug substances, drug products, and components used to compound drug products shall be obtained from reliable suppliers. The Pharmacy shall acquire and retain any available certificates of purity or analysis for chemicals, bulk drug substances, drug products, and components used in compounding. Certificates of purity or analysis are not required for products that are approved by the Food and Drug Administration (FDA).
- SR.12 In addition to the labeling information required in accordance with State law/regulation, the label of a compounded drug product shall contain the generic name(s) of the principal active ingredient(s).
- SR.13 Objective evidence (documented/indicated) that the drug has been compounded by the Pharmacy shall be included on the container and/or on the MAR or other documentation when administered to the patient.
- SR.14 Drug products compounded in unit-dose packaging that are too small or otherwise impractical to demonstrate full compliance as indicated in MM.8; SR.12 and SR.13 shall be labeled with at least the name(s) of the active ingredient(s), concentration of strength, volume or weight, pharmacy reference or lot number, and expiration date.
- SR.15 The Pharmacy shall maintain a written policy and procedure manual for compounding that establishes procurement procedures, methodologies for the formulation and compounding of drugs, facilities and equipment cleaning, maintenance, operation, and other standard operating procedures related to compounding. The policy and procedure manual shall be reviewed on an annual basis by the pharmacist-in-charge and shall be

updated whenever changes in processes are implemented.

The policy and procedure manual shall include the following:

- SR.15a Procedures for notifying staff assigned responsibilities for compounding to address any changes in processes or to the policy and procedure manual.
 - SR.15b Documentation for handling recalls of dispensed compounded drug products where subsequent verification demonstrates the potential for adverse effects with continued use of a compounded drug product.
 - SR.15c The procedures for maintaining, storing, calibrating, cleaning, and disinfecting equipment used in compounding, and for training on these procedures as part of the staff training and competency assessment/evaluation process.
 - SR.15d Documentation of the methodology used to test integrity, potency, quality, and labeled strength of compounded drug products.
 - SR.15e Documentation of the methodology used to determine appropriate expiration dates for compounded drug products.
- SR.16 The Pharmacy shall maintain written documentation regarding the facilities and equipment necessary for safe and accurate compounded drug products. Where applicable, this shall include records of certification(s) of facilities or equipment.
- SR.16a Any equipment used to compound drug products shall be stored, used, and maintained in accordance with manufacturers' specifications/recommendations.
 - SR.16b Equipment used to compound drug products where calibration or adjustment is necessary to ensure the accuracy of dispensing shall be calibrated prior to use to ensure accuracy. Documentation of calibration of equipment shall be documented and records of calibration are maintained and retained in the Pharmacy.
- SR.17 The Pharmacy shall maintain documentation sufficient to demonstrate that Pharmacy personnel have demonstrated the required skills and received the appropriate training to properly and accurately perform their assigned responsibilities, including processes and procedures, for the compounding of drug products.
- SR.17a The Pharmacy shall develop and maintain an on-going competency assessment/evaluation process for Pharmacy personnel involved in compounding of drug products, and shall maintain documentation of all training/education related to compounding performed by Pharmacy personnel.

- SR.18 The Pharmacy shall maintain a documented quality assurance plan/program designed for monitoring and ensuring the integrity, potency, quality, and labeled strength of compounded drug products.
- SR.18a The quality assurance plan/program shall include written procedures for verification, monitoring, and review of the adequacy of the compounding processes and shall also include documentation of review of those processes by qualified Pharmacy personnel.
 - SR.18b The quality assurance plan/program shall include written standards for qualitative and quantitative analysis of integrity, potency, quality, and labeled strength of compounded drug products. All qualitative and quantitative analysis reports for compounded drug products shall be retained by the Pharmacy and collated with the compounding record and master formula. The information attained from the analysis shall be shared with the Pharmacy oversight group.
 - SR.18c The quality assurance plan/program shall include a documented procedure for corrective/preventive action required when any compounded drug product is identified to be below minimum standards for integrity, potency, quality, or labeled strength.
- SR.19 The Pharmacy shall conform to the parameters and requirements in accordance with State law/regulation as applicable to all compounding and sterile injectable compounding.
- SR.20 A Pharmacy performing sterile injectable compounding shall have a designated area for the preparation of sterile injectable products which shall meet the following standards in accordance with State law/regulation:
- SR.20a Clean Room and Work Station Requirements.
 - SR.20b Construction of walls, ceilings, and floors.
 - SR.20c Maintain appropriate ventilation of the preparation area.
 - SR.20d Be certified annually by a qualified technician who is familiar with the methods and procedures for certifying laminar air flow hoods and clean room requirements, in accordance with standards adopted by the United States General Services Administration. Certification records must be retained for at least 3 years or as otherwise required.
 - SR.20e The compounding area of the Pharmacy shall be appropriately arranged. Items related to the compounding of sterile injectable products within the compounding area shall be stored in such a way as to maintain the integrity of an aseptic environment.

- SR.20f A sink shall be in place and maintained within the compounding area of the Pharmacy.
- SR.20g The Pharmacy shall maintain a refrigerator and/or freezer of sufficient capacity to meet the storage requirements for all material requiring refrigeration.

During preparation and prior to administration, critical surfaces and ingredients within the compounding area are not to be directly exposed to contact contamination such as human touch, particulates, blood human body substances (excretions and secretions, e.g., nasal or oral) and non-sterile inanimate sources.

- SR.21 The Pharmacy performing compounding of sterile injectable products from one or more non-sterile ingredients shall also comply with any related State law or other related codes/regulations as required. The Pharmacy shall ensure that sterile injectable compounding is not carried out when the designated area does not meet criteria to ensure safe compounding.
- SR.22 Pharmacies compounding sterile injectable products for future use shall maintain records in readily retrievable form for a minimum of 3 years, or as otherwise required stating the name, lot number, amount, and date on which the products were provided to a prescriber in accordance with State law/regulation.
 - SR.22a For sterile products compounded from one or more non-sterile ingredients, the following records must be maintained by the Pharmacy to include documentation of:
 - SR.22a(1) Training and competency evaluation of employees in sterile product procedures.
 - SR.22a(2) Monitoring of refrigerator and freezer temperatures.
 - SR.22a(3) Certification of the sterile compounding environment.
 - SR.22a(4) Other facility quality control logs specific to the Pharmacy policies and procedures (e.g., cleaning logs for facilities and equipment).
 - SR.22a(5) Inspection for expired or recalled pharmaceutical products or raw ingredients.
 - SR.22a(6) Preparation records including the master work sheet, the preparation work sheet, and records of end-product evaluation results.
- SR.23 In addition to the other indicated labeling information required, a Pharmacy which compounds sterile products shall include the following information on the labels for those products:

- SR.23a Telephone number of the pharmacy, except for sterile injectable products dispensed for inpatients of a hospital pharmacy.
 - SR.23b Name and concentrations of ingredients contained in the sterile injectable product.
 - SR.23c Instructions for storage and handling.
 - SR.23d All cytotoxic agents shall be clearly labeled to indicate "Chemotherapy-Dispose of Properly."
- SR.24 A Pharmacy performing compounding of sterile injectable drug products shall maintain a documented policy and procedure manual for compounding in accordance with State law/regulation that includes:
- SR.24a Compounding, filling, and labeling of sterile injectable compounds.
 - SR.24b Labeling of the sterile injectable product based on the intended route of administration and recommended rate of administration.
 - SR.24c Equipment and supplies used.
 - SR.24d Training of staff regarding the preparation of sterile injectable products.
 - SR.24e Procedures for handling cytotoxic agents (including disposal of infectious materials and/or materials containing cytotoxic residues and protocols for cleaning of spills in conformity with local health jurisdiction standards).
 - SR.24f Documented quality assurance plan/program and appropriate records maintained for monitoring and ensuring the compounding of sterile injectable drug products
- SR.25 A Pharmacy compounding sterile injectable products from one or more non-sterile ingredients shall have documented policies and procedures in place to include:
- SR.25a Competency evaluation.
 - SR.25b Storage and handling of products and supplies.
 - SR.25c Storage and delivery of final products.
 - SR.25d Process validation of processes.
 - SR.25e Personnel access and movement of materials into and near the controlled area.

- SR.25f Use and maintenance of environmental control devices used to create the critical area for manipulation of sterile products (e.g., laminar-airflow workstations, biological safety cabinets, class 100 clean rooms, and barrier isolator workstations).
- SR.25g Regular cleaning schedule for the controlled area and any equipment in the controlled area and the alternation of disinfectants in accordance with the Infection Control Program.
- SR.25h Disposal of packaging materials, used syringes/needles, and containers to ensure the sanitation and avoidance of accumulation of such materials in the controlled area..
- SR.25i For sterile batch compounding, written policies and procedures must be established for the use of master formulas and work sheets and for appropriate documentation.
- SR.25j Sterilization.
- SR.25k End-product evaluation and testing.

Pharmacy personnel shall have and maintain knowledge of all documented policies and procedures shall be immediately available to all personnel involved in these activities before compounding sterile injectable products. These policies and procedures shall be made available to State inspectors and other applicable regulatory agencies when requested.

SR.26 A Pharmacy compounding sterile injectable products from one or more non-sterile ingredients shall have documented policies and procedures for the preparation area to include at a minimum:

- SR.26a Means for limiting access to the designated area or clean room to those individuals wearing the required personal protective attire.
- SR.26b Ensuring that all equipment used in the designated area or clean room be made of a material that can be easily cleaned and disinfected.
- SR.26c Maintaining a schedule for cleaning and disinfecting exterior workbench surfaces and other hard surfaces in the designated area, such as walls, floors, ceilings, shelves, tables, and stools at least weekly and after any unanticipated event that may increase the risk of contamination.
- SR.26d Current and appropriate reference materials regarding the compounding of sterile injectable products be located in or immediately available to the Pharmacy.

SR.27 Pharmacies preparing parenteral cytotoxic agents shall do so in accordance with State law/regulation, requiring a laminar air flow hood. The hood must be certified annually by

a qualified technician who is familiar with the methods and procedures for certifying laminar air flow hoods and clean room requirements, in accordance with currently revision of the National Sanitation Foundation Standard 49 for Class II (Laminar Flow) Biohazard Cabinetry, or manufacturer's specifications, Certification records must be retained for at least three years.

SR.28 When compounding sterile products from one or more non-sterile ingredients the following standards shall be met:

- SR.28a Clean room attire consisting of a low-shedding coverall, gloves, head cover, face mask, and shoe covers must be worn inside the designated area at all times. When preparing cytotoxic agents, gowns and gloves shall also be worn.
- SR.28b Clean room attire must be donned and removed outside the designated area.
- SR.28c Prohibiting wearing any hand, finger, and wrist jewelry. In the event jewelry cannot be removed then it must be thoroughly cleaned and covered with a sterile glove.
- SR.28d Head and facial hair must covered and be kept out of the critical area.

(The requirements of SR.30 do not apply if a barrier isolator is used to compound sterile injectable products from one or more non-sterile ingredients).

SR.29 The pharmacist-in-charge shall be responsible to ensure all Pharmacy personnel involved in compounding sterile injectable drug products shall have and maintain the required training and demonstrated competence regarding the safe handling and compounding of sterile injectable products, including cytotoxic agents (as applicable). Consultation shall be available to the patient and/or primary caregiver concerning proper use of sterile injectable products and related supplies furnished by the pharmacy.

SR.30 A Pharmacy that compounds sterile products from one or more non-sterile ingredients must comply with the following training requirements:

SR.30a The pharmacy must establish and follow a written program of training and performance evaluation to ensure that each person working in the designated area has the knowledge and skills necessary to perform their assigned tasks properly before being allowed to prepare sterile injectable products. This program of training and performance/competency evaluation must address at least the following:

SR.30a(1) Use of aseptic preparation technique and procedures.

SR.30a(2) Appropriate use of personal protective attire and conduct in the controlled area.

- SR.30a(3) Accuracy of pharmaceutical calculations and terminology.
- SR.30a(4) Documentation of Sterile product compounding.
- SR.30a(5) Appropriate use of sterilization techniques.
- SR.30a(6) Cleaning, sanitizing, and maintaining equipment used in the controlled area.
- SR.30a(7) Selection of containers, equipment, and closure system.
- SR.30a(8) Quality assurance procedures and measures.

Each individual assigned to the controlled area must successfully complete practical skills training in aseptic technique and aseptic area practices. Evaluation must include written testing and a written protocol of periodic routine performance monitoring/evaluation to ensure adherence to aseptic area policies and procedures.

Demonstration of individual competency and continuing training needs must be reassessed at least every 12 months or whenever the quality assurance program yields an unacceptable result, when the compounding process changes, equipment used in the compounding of sterile injectable drug products is repaired or replaced, the facility is modified in a manner that affects airflow or traffic patterns, or whenever improper aseptic techniques are observed. Documentation of individual competency shall be documented and retained in the Pharmacy for three years.

- SR.31 The Pharmacy shall have a process in place to ensure the effectiveness of processes in the same manner as normal preparation except that an appropriate microbiological growth medium is used in place of the actual product used during sterile preparation.
 - SR.31a The validation process shall be representative of all types of manipulations, products and batch sizes the individual is expected to prepare. Completed medium samples must be incubated. If microbial growth is detected, then the sterile preparation process must be evaluated, corrective action taken, and the validation process repeated. Revalidation must be documented.
 - SR.31b The same personnel, procedures, equipment, and materials are must be involved.
- SR.32 A Pharmacy performing compounding sterile injectable drug products shall maintain, as part of its written policies and procedures, a written quality assurance plan/program for monitoring personnel performance, equipment, and facilities and shall include at least the following: The Quality Assurance Program shall include at least the following:
 - SR.32a Cleaning and sanitization of the parenteral medication preparation area.
 - SR.32b Storage of compounded sterile injectable products in the Pharmacy

- SR.32c Periodic documentation of refrigerator temperatures.
- SR.32d Corrective/Preventive actions to be taken in the event of a drug recall.
- SR.32e Written justification of the indicated expiration dates for compounded sterile injectable products.
- SR.32f Process for periodic sampling as determined by the pharmacist-in-charge to assure required specifications are met.

SR.32f (1) Batch produced sterile injectable drug products compounded from one or more non-sterile ingredients shall be subject to documented end product testing for sterility and pyrogens and shall be quarantined until the end product testing confirms sterility and acceptable levels of pyrogens.

SR.32f(2) Batch-produced sterile to sterile transfers shall be subject to periodic testing through process validation for sterility as determined by the pharmacist-in-charge and described in the written policies and procedures.

Interpretive Guidelines:

Definitions:

Compounding: means any of the following activities occurring in a licensed pharmacy, by or under the supervision of a licensed pharmacist, pursuant to a prescription:

- *Altering the dosage form or delivery system of a drug*
- *Altering the strength of a drug*
- *Combining components or active ingredients*
- *Preparing a drug product from chemicals or bulk drug substances*

“Compounding” does not include:

- *Reconstitution of a drug pursuant to a manufacturer’s direction(s) for oral, rectal topical, or injectable administration, nor does it include tablet splitting or the addition of flavoring agent(s) to enhance palatability.*
- *Except in small quantities under limited circumstances as justified by a specific, documented, medical need, preparation of a compounded drug product that is commercially available in the marketplace or that is essentially a copy of a drug product that is commercially available in the marketplace.*

Integrity: means retention of potency until the expiration date noted on the label.

Potency: means active ingredient strength within +/- 10% of the labeled amount.

Quality: means the absence of harmful levels of contaminants, including filth, putrid, or decomposed substances, and absence of active ingredients other than those noted on the label.

Strength: means amount of active ingredient per unit of a compounded drug product.

Anteroom: means an area where personnel perform hand hygiene and garbing procedures, staging of components, order entry, CSP labeling, and other high-particulate generating activities. It is also a transition area that provides assurance that pressure relationships are constantly maintained so that air flows from clean to dirty areas. The Anteroom area is to be maintained within ISO Class 8 level of particulate contamination.

Beyond-use-date: means the date after which a compounded preparation should not be used and is determined from the date the preparation was compounded.

Bulk Compounding: means the compounding of CSPs in increments of 25 or more doses from a single source.

Clean room: An area where the activities of CSP take place; it shall not contain sinks or drains. In High-Risk compounding this must be a separate room. The Buffer area is to be maintained within ISO Class 7 level of particulate contamination.

Class 100 environment: means an atmospheric environment which contains no more than one hundred particles of 0.5 microns in diameter or larger per cubic foot of air. A class 100 environment is equivalent to ISO Class 5 level of particulate contamination.

ISO Class 7 guidelines are met when particulate contamination is measured at “not more than 352,000 particles 0.5 micron size or larger per cubic meter of air for any buffer area (room).”

ISO Class 8 guidelines are met when particulate contamination is measured at “not more than 3,520,000 particles 0.5 micron size or larger per cubic meter of air for any anteroom (area).”

Surveyor Guidance:

Review sampling of orders to ensure the prescriber has approved use of a compounded drug product either verbally or in writing to the Pharmacy.

Verify that compounded drug products are only available in quantities as necessary to ensure continuity of care for an identified population of patients.

Validate that there is a process in place for the supervision of compounding to ensure integrity, potency, quality, and appropriate labeling of compounded drug products until they are dispensed.

Review a sampling of records to ensure that a written master formula record has been prepared.

Review documentation completed by the pharmacist-in-charge before any compounding and/or any sterile injectable compounding is performed in the Pharmacy.

Verify that records of the proper acquisition, storage, and wastage/destruction of chemicals, bulk drug substances, drug products, and components used in compounding are maintained.

Review the written policies and procedures for:

- *Compounding of drugs*
- *Compounding sterile injectable products from one or more non-sterile ingredients*
- *Preparation area*

Validate that documentation of Pharmacy personnel records show demonstration of the required skills and appropriate training to properly and accurately perform their assigned responsibilities, including processes and procedures, for the compounding of drug products.

Assess the designated area for the preparation of sterile injectable products.

Evaluate the documented quality assurance plan/program to verify that appropriate measures and actions are in place to ensure the effectiveness of the drug compounding process.

APPENDIX 3: SAFETY RISK MANAGEMENT: PROPOSED

This requirement is being proposed for review. This standard will not be surveyed to note any findings of nonconformity until January 2015. DNVHC will be providing additional guidance to the accredited hospitals regarding this process and further outline the expectations of the organization in meeting these requirements.

SAFETY RISK MANAGEMENT (RM)

RM.1 PLANNING AND RESOURCES

- SR.1 The hospital shall ensure that a risk management system is established that addresses patient safety as well as other safety risks that may impact on patients, staff or other visitors to the hospital. The risk management system shall be implemented and maintained and the performance of the system reported to senior management for review and as a basis for improvement.
- SR.2 The organization shall ensure the approach to risk assessment is defined with respect to its scope, nature and timing so that it is proactive rather than reactive.
- SR.3 The hospital shall identify resource requirements and provide adequate resources for risk management, including the assignment of trained personnel for management, performance of work, and verification activities, including internal review.

Interpretive Guidelines:

The roles and responsibilities of personnel who perform and verify work affecting risk management should be defined and documented, particularly for people who need authority to do one of the following:

- 1. Initiate action to prevent or reduce the adverse effects of risk;*
- 2. Control further treatment of risks until the level of risk becomes acceptable;*
- 3. Identify and record any problems relating to the management of risks;*
- 4. Initiate, recommend or provide solutions through designated channels; and*
- 5. Communicate and consult internally and externally as appropriate.*

The following may trigger either a new risk assessment or review of an existing one:

- 1. Commencement of new work or changes to care that may alter or introduce new risks to patient staff or visitors;*
- 2. New construction / modifications to hospital facilities;*
- 3. Introduction of altered and unplanned staffing arrangements personnel);*
- 4. Significant alterations to Standard Operating Procedures (SOPs) or working practices;*
- 5. When unexpected events that may have relevance for the management of patient care or staff or visitor safety are observed;*
- 6. When actual or potential non-conformity with internal / external rules and regulations is identified (e.g. introduction of new legislation or following major accidents or incidents);*
- 7. When considering emergency response and contingency planning requirements; and*

8. *As part of the existing management system review process (e.g. annually or at another appropriate and predetermined frequency).*

RM.2 RISK ASSESSMENT

- SR.1 The hazards associated with proposed work shall be identified and documented.
- SR.2 The organization shall ensure that suitable methodologies for assessing and recording risks are identified, implemented, and maintained.

Interpretive Guidelines:

There are many defined methodologies and approaches available for conducting hazard identification, risk assessment and control and the approach taken will vary depending upon the nature of the situation and the level of detail required.

RM.3 RISK MANAGEMENT

- SR.1 The organization shall ensure suitable methodologies for the allocation of actions resulting from risk assessments, including time lines, responsible persons and associated reporting and approval mechanisms are identified, implemented and maintained.
- SR.2 Management shall establish the controls and put in place documented procedures for monitoring the effectiveness of the controls being applied to reduce or eliminate the hazards identified in the risk assessment process.

RM.4 REPORTING

- SR.1 The hospital shall have documented procedures to define record, analyze and learn from incidents that impact safety. This shall include medical errors and adverse patient events.
- SR.2 The hospital shall have a policy and procedure for informing patients and/or their families about unexpected adverse events.

Interpretive Guidelines:

The hospital shall be able to demonstrate that they have a hospital wide approved document which as a minimum shall include:

- A. *Roles and responsibilities for the management of risk throughout the hospital;*
- B. *Training requirements related to risk management and adverse event reporting;*
- C. *Processes for assessing all risks throughout the hospital;*
- D. *Process for ensuring systematic management of all identified risks throughout the hospital;*
- E. *Process for informing patient and or their families about unexpected adverse event; and*
- F. *Process for ensuring where deficiencies are identified (e.g. through risk assessment, adverse incidents, litigation, and customer satisfaction) action plans are developed and implemented to ensure continual management/improvement.*

Surveyor Guidance:

The organization shall provide a documented process which as a minimum shall include:

- A. Roles and responsibilities for the management of risk throughout the hospital*
- B. Processes for assessing all risks throughout the hospital*
- C. Process for ensuring systematic management of all identified risks throughout the hospital*
- D. Process for informing patient and or their families about unexpected adverse events*
- E. Process for ensuring where deficiencies are identified (e.g. through risk assessment, adverse incidents, litigation, and customer satisfaction) action plans are developed and implemented to ensure continual management/improvement.*

Evidence of implementation of the above shall be available.