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NATIONAL INTEGRATED ACCREDITATION FOR HEALTHCARE ORGANIZATIONS (NIAHO®)

Accreditation Requirements, Interpretive Guidelines & Surveyor Guidance for Hospitals

REVISION 25-1

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USE OF NIAHO® ACCREDITATION REQUIREMENTS, INTERPRETIVE GUIDELINES AND SURVEYOR GUIDANCE

Effective Date

NIAHO® Accreditation Requirements, Interpretive Guidelines and Surveyor Guidance, Revision 25-1

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Supersedes NIAHO® Revision 25-0 and all prior revisions (Revision numbers now align with year of publication).

National Professional Organizations – Nationally Recognized Standards of Practice and Guidelines

Nationally recognized standards of practice and guidelines of the national professional organizations referenced in these NIAHO® Accreditation Requirements, Interpretive Guidelines and Surveyor Guidance (NIAHO®) documents 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 this NIAHO® document are incorporated herein by reference and constitute NIAHO® accreditation requirements.

This NIAHO® document is based upon the Centers for Medicare and Medicaid Services (CMS) Conditions of Participation 42 CFR Section 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 (CoP). When new or revised requirements are published, hospitals are expected to demonstrate compliance in a time frame consistent with the effective date published by CMS in the Federal Register.

Life Safety Code® and Health Care Facilities Code®

The Life Safety Code® and Health Care Facilities Code® of the National Fire Protection Association referenced in this NIAHO® document is incorporated herein by reference and constitute NIAHO® accreditation requirements.

GLOSSARY

AANA	American Association of Nurse Anesthetists (AANA)
ACA	Affordable Care Act
ACS	American College of Surgeons
ACIP	CDC's Advisory Committee on Immunization Practices
ACOG	American College of Obstetricians and Gynecologists
AMA	American Medical Association
AO	Accreditation Organization
AOA	American Osteopathic Association
AORN	Association of periOperative Registered Nurses
APIC	Association of Professionals in Infection Control and Epidemiology
ASA	American Society of Anesthesiologists
ASHP	American Society of Health-System Pharmacists
AWOHNN	Association of Women's Health, Obstetric and Neonatal Nurses
CAH	Critical Access Hospital
CDC	Centers for Disease Control and Prevention
CDI	C-Difficile Infections
CNS	Clinical Nurse Specialist
CEO	Chief Executive Officer
CFR	Code of Federal Regulations
CMS	Centers for Medicare and Medicaid Services
CRNA	Certified Registered Nurse Anesthetist
DEA	Drug Enforcement Administration
DOT	United States Department of Transportation
DPU	Distinct Part Unit - Psychiatric Unit. Inpatient psychiatric services provided in a separate and distinct part unit of a CAH.
ECFMG	Educational Commission for Foreign Medical Graduates

FDA	Food and Drug Administration
HAI	Hospital Acquired or Associated Infections, as noted
HHA	Home Health Agency
HICPAC	CDC's Healthcare Infection Control Practices Advisory Committee
HVAC	Heating Ventilating and Air Conditioning
IFU	Instructions for Use
IPCP	Infection Prevention and Control Program
IRF	Inpatient Rehabilitation Facility
ISMP	Institute for Safe Medication Practices
ISO	International Organization of Standardization
IUSS	Immediate-Use Steam Sterilization
LEP	Limited English Proficiency
LPN	Licensed Practical Nurse
LP	Licensed Practitioner
LVN	Licensed Vocational Nurse
LSC	Life Safety Code® of the National Fire Protection Association
LTCH	Long-term Care Hospital
MMRC	Maternal Mortality Review Committee
NFPA	National Fire Protection Association
NP	Nurse Practitioner
NPDB	National Practitioner Data Bank
Organization	ISO vocabulary refers to entities as organizations. In NIAHO®, organization is equivalent to hospital.
OIG	Office of Inspector General, Department of Health and Human Services
OSHA	U.S. Occupational Health and Safety Administration
PA	Physician Assistant
Physician	Doctor of Medicine or Osteopathy, unless otherwise noted

PRN (prn)	Pro re nata, as the occasion arises, when necessary.
QIO	Quality Improvement Organization
QAPI	Quality Assessment and Performance Improvement
QMS	Quality Management System
Resident	Person receiving post-hospital SNF care
RU	Rehabilitation Unit. Inpatient rehabilitation services provided in a separate and distinct part unit of a CAH.
Secretary	Secretary of the Department of Health and Human Service
SGNA	Society of Gastroenterology Nurses and Associates
SHEA	Society for Healthcare Epidemiology of America
Shall	The word “shall” indicates a requirement. The intended definition of the word “shall” is “shall.”
SMDA	Safe Medical Devices Act of 1990
SNF	Skilled Nursing Facility
SOP	Standard Operating Procedure
SR	Standard Requirement
WHO	World Health Organization

QUALITY MANAGEMENT SYSTEM (QM)

QM.1 RESPONSIBILITY AND ACCOUNTABILITY

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 are responsible and accountable for ensuring the following:

SR.1a The organization develops, implements and maintains an ongoing, hospital-wide, data-driven effective quality management system (QMS) and integrates the Quality Assessment and Performance Improvement (QAPI) program into the QMS.

SR.1a(1) This system shall manage and improve performance, patient safety, and overall quality of patient care and operations.

SR.1a(2) For hospitals that offer obstetrical services, the hospital shall utilize its quality assessment and performance improvement (QAPI) program to analyze data and quality indicators collected for the QAPI program by diverse subpopulations as identified by the hospital among obstetrical patients. *(Note: This requirement shall be implemented by January 1, 2027)*

SR.1b Clear expectations for safety are established and communicated hospital-wide (see QM.8).

SR.1b(1) All staff, including contract staff and volunteers, shall adhere to the policies and procedures of the organization.

SR.1b(2) All clinical staff shall implement or clarify, as needed, patient care orders.

SR.1c Adequate resources are allocated for measuring, assessing, improving, and sustaining the hospital's performance and reducing risk to patients.

SR.1d Corrective and preventive actions are implemented, measured and monitored for effectiveness and sustainability.

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

SR.1e(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.1e(1)(i) A hospital may, as one of its projects, develop and implement an information technology system explicitly designed to improve patient safety and quality of care. This project, in its initial stage of

development, does not need to demonstrate measurable improvement in indicators related to health outcomes.

SR.1e(1)(ii) For hospitals that offer obstetrical services, the hospital shall conduct at least one measurable performance improvement project focused on improving health outcomes and disparities among the hospital's population(s) of obstetrical patients annually. *(Note: This requirement shall be implemented by January 1, 2027)*

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

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

SR.2 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).

Interpretive Guidelines:

The organization's leadership, meaning the hospital's governing body (or organized group or individual who assumes full legal authority and responsibility for operations of the hospital), medical staff, and senior leadership, are responsible and accountable for the hospital's QMS. The medical staff may delegate this leadership responsibility and accountability for the QAPI program to the medical staff executive committee if it has such a committee. Senior leadership includes, at a minimum, the hospital's chief executive officer, chief operating officer, and the chief nurse executive (or equivalent), but would also include other executives in the hospital's administration. Responsibilities include (see also QM.6, QM.7, QM.8):

- *Periodic review of the QMS*
- *Development of a plan to implement and maintain the QMS*
- *Review of the progress of QAPI projects*
- *Determination of annual QAPI projects*
- *Evaluation of the effectiveness of improvement actions that the hospital has implemented*
- *Ensuring that clear expectations for safety are established and communicated hospital-wide, as well as allocating adequate resources to carry out the functions of the QMS and QAPI program requirements.*
    - *This includes, at a minimum, informing all staff of their specific roles and*

responsibilities related to patient safety (see QM.8) and quality of patient care and operations.

- *All staff, including contract staff and volunteers, shall adhere to the policies and procedures of the organization.*
- *All clinical staff shall implement or clarify, as needed, patient care orders.*
- *Clear expectations for safety shall also be set and communicated to those providing services under arrangements or contracts and should be documented in the contracts (see GB.4).*

Quality Management System (QMS) is defined by ISO 9000 as part of a management system with regard to quality. A management system is a set of interrelated or interacting elements of an organization to establish policies, objectives, and processes to achieve those objectives. The management system elements establish the organization's structure, roles and responsibilities, planning, operation, policies, practices, rules, beliefs, objectives and processes to achieve those objectives.

The quality assessment and performance improvement (QAPI) program shall be integrated into the organization's QMS. When hospital leadership evaluate the QMS, this inherently includes the QAPI program. The terms "QMS" and "QAPI" are used interchangeably throughout the QM chapter. Where "QMS" is listed, this also includes the QAPI program.

The QAPI program shall provide a mechanism to systematically examine the quality of care delivered and implement specific improvement projects on an ongoing basis for all of the services provided by the hospital. The organization develops its program based on its unique needs, priorities, clinical programs, as well as its own considerations for the health equity needs of its patient population. There shall be processes in place to continually identify opportunities for quality and safety improvements and to implement changes that lead to improved outcomes that are sustained over time.

The resources dedicated to the QMS (and QAPI program) should be commensurate with the overall scope and complexity of the services provided by the hospital. The hospital's governing body, in collaboration with senior leadership and medical staff, should allocate adequate resources to carry out the functions specified in the QM chapter. Adequate resources would mean that the hospital provides sufficient numbers of staff (including consultants, as needed), staff time, information systems, and education and training to support all elements of the required quality and performance improvement activities and projects. In addition, adequate means that staff should be qualified to perform the functions to which they are assigned. Qualified also means staff have experience or training in the functions for which they are responsible. The hospital may choose to use qualified and experienced contractors for the day-to-day technical aspects of the program, such as data collection and analysis. However, the hospital's governing body retains the responsibility for the ongoing management of the program, even when a contractor is used for those functions. CMS does not prescribe a particular formula for determining whether the hospital has allocated adequate resources to its program. However, hospitals should be able to demonstrate inclusion of the program in its budget process and identify in detail the resources it dedicates to the program. This includes the resources that a

contracted service has allocated to support these functions. Additionally, the hospital must be able to provide evidence of the number of staff it has allocated to focus on the management and oversight of the day-to-day program functions.

Performance improvement projects are differentiated from performance improvement activities (such as that under QM.7) in that performance improvement projects require a significant amount of up-front planning, include project objectives, and have a definitive beginning and end date (time-limited). Performance improvement activities make up the continuous, ongoing functions of a hospital QMS related to quality and patient safety, such as ongoing tracking of medical errors and adverse events, analysis of data, implementation of changes with associated education and training, continuous monitoring of quality and safety in all hospital departments and service areas, etc.

CMS does not prescribe the specific types of performance improvement projects to be conducted annually. The hospital's governing body determines the number and types of annual projects based on the complexity and scope of the services provided by the hospital. No fixed ratio is required, but it is acceptable for smaller hospitals with a smaller number of distinct services to have fewer projects than a large hospital with many different services.

The hospital may choose to participate in Quality Improvement Organization (QIO) projects to fulfill the annual project requirement but are not required to do so to be compliant with the requirement at QM.1 (SR.1a). QIOs are funded by CMS to promote, through cooperative projects, improvements in services provided by Medicare-participating providers. If the hospital does not participate in a QIO project, it is expected to implement its own annual projects that are comparable in effort to a QIO project. The hospital should consider the number of patients affected, the range of services covered, and the projected magnitude of the benefit to individual patients when developing annual projects. (68 FR at 3441)

The hospital shall keep records on each performance improvement project completed within the previous survey cycle, as well as a list of projects currently underway. The documentation for each project shall, at a minimum, include an explanation of why the project was undertaken. The explanation of the project shall indicate what data was collected in the hospital, or what publicly available data and/or recommendations of nationally recognized organizations, leads the hospital to believe that the project activities will result in improvements in patient health outcomes and safety in the hospital. For projects that are in progress, the hospital shall be able to explain what activities the project entails and how the impact of the project is being monitored. The hospital will provide evidence of baseline data it is collecting (or will be collecting, in the case of projects just beginning) that will enable the hospital to assess whether the project achieved measurable outcomes. For projects that are completed, the hospital should be able to demonstrate that the project resulted in measurable progress toward improving the quality of care or patient safety.

Surveyor Guidance:

Interview leadership and review program documents (Quality Management Oversight meeting minutes, Medical Staff or MEC meeting minutes, governing body meeting minutes, etc.) to evaluate how priorities are established, how data is collected and used to monitor and improve performance, patient safety, and overall quality of patient care and operations, and to establish executive leadership's oversight of the QMS.

While these leaders are not expected to be directly involved in the day-to-day activities of the

hospital's QAPI program, they should be actively engaged in the oversight of the QAPI program through their periodic review of the program, including, but not limited to:

- *Development of a plan (e.g., Quality Plan, QAPI plan) to implement and maintain the QMS*
- *Review of the progress of QAPI projects*
- *Determination of annual QAPI projects*
- *Evaluation of the effectiveness of improvement actions that the hospital has implemented*
- *Planning for QAPI resources*

Ask to see evidence that executive leadership makes the required decisions related to planning, data collection, and projects, conducts regular reviews of information on the performance of the QMS, and makes decisions based on that review for the overall direction and management of the QMS (see also QM.2 (SR.3f), QM.6 and QM.7).

Ask the hospital to provide a list of distinct performance improvement projects the hospital is currently conducting and has conducted since the time of the last survey to verify the hospital is conducting annual QAPI projects.

Review documentation to validate why each project was conducted and as evidence to support the progress being made on each project.

- *Does the documentation include data to support "why" each project was conducted (e.g., medical error and adverse event reports indicated a need for improvement in a particular area)?*
- *Does the documentation include evidence of ongoing monitoring of the project's progress, such as periodic data collection and analysis?*
- *Ask the executive leadership to explain how the selection (number and scope) of the specific projects is in alignment with the hospital's complexity and the scope of services it provides.*
- *Consider the size of the facility and the intensity of its services, such as critical care services/units, complex surgeries, transplant services, maternal/child health services, and oncology services, including radiation and chemotherapy, etc.*

QM.2 ISO 9001 QUALITY MANAGEMENT SYSTEM

SR.1 Full conformance with the ISO 9001 standard shall occur within three (3) years after the initial deemed NIAHO® accreditation during the stage two survey (fourth visit). The Organization shall either demonstrate compliance with the ISO 9001 Quality Management System principles through a NIAHO® 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 comply with ISO 9001 in order to 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 Shall have certified or conducted a pre-assessment at a minimum of 12 hospitals.

SR.3 The organization will initiate and continue implementation toward conformance with the ISO 9001 methodology as stated in QM.1 (SR.1). At a minimum, the organization shall be able to demonstrate at the time of their stage one survey (third visit) evidence of active implementation of the following:

SR.3a Risk based thinking: an organization shall plan and implement actions to address risks and opportunities. Addressing both risks and opportunities establishes a basis for increasing the effectiveness of the quality management system, achieving improved results and preventing negative effects.

SR.3b Documented Information: the organization shall ensure that documented information (documents and records) determined to be necessary for the effectiveness of the QMS are structured and/or maintained in a manner to ensure availability and suitability of use, when and where needed.

SR.3c Internal Surveys (Internal Audits): the organization conducts internal process-based audits of its processes and resultant corrective/preventive action measures have been implemented and verified to be effective.

SR.3d Nonconformity and Corrective Action: when nonconformity occurs, the organization will have a mechanism in place to document and monitor actions taken to address improvement and changes, where appropriate.

SR.3e The organization has established measurable quality objectives, the results are analyzed and addressed.

SR.3f Management review: The organization has implemented a process for top management to review the quality management system at planned intervals, making decisions and taking actions to ensure suitability, adequacy, effectiveness and alignment with the strategic direction of the organization.

SR.3g Strategic Planning based on the context of the organization (internal and external issues, requirements of relevant interested parties, scope of the QMS and process interaction).

Interpretive Guidelines:

The ISO 9001 requirements are assessed during each survey of the organization beginning with

the stage one survey (third visit). The organization has 3 years (fourth visit) from the initial deemed NIAHO® accreditation to conform with ISO 9001. At the time of the stage one survey (third visit), active implementation shall be demonstrated, at a minimum, for the required ISO 9001 methodologies defined in QM.2 (SR.3a-SR.3g). These aspects may not be at a level of full compliance with ISO 9001, but evidence of active implementation shall be present.

Initial Survey Cycle	***NIAHO®***	***ISO 9001***
Initial visit	*Accreditation*	*N/A*
Year 1 (second visit)	*Periodic*	*N/A*
Year 2 (third visit)	*Periodic*	*Stage 1* *Active implementation required (See QM.2 (SR.3))*
Year 3 (fourth visit)	*Reaccreditation*	*Stage 2* *Full ISO 9001 conformance required*

Hospital organizations will follow a 3-year cycle thereafter of continued compliance to both NIAHO® and ISO 9001 requirements. Surveyors will continue to survey to NIAHO® and ISO 9001 compliance every year after this initial survey cycle. 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 is certified to ISO 9001 by a Registrar other than DNV Healthcare, the Registrar that currently certifies the organization shall be verified using current criteria established under SR.2a and SR.2b. This shall be verified prior to the organization's accreditation survey.

Quality management principles

ISO 9001 is based on the following quality management principles:

- *Customer focus*
- *Leadership*
- *Engagement of people*
- *Process approach*

- *Improvement*
- *Evidence-based decision making*
- *Relationship management*

When implementing ISO 9001, organizations shall consider these principles as part of their implementation process. Further information for these principles can be found in ISO 9001 0.2 and ISO 9000 Quality management systems – Fundamentals and vocabulary.

Risk-based thinking (see ISO 9001:2015; 6.1):

Though a documented process/method to determine the risks and opportunities is not required, there shall be a process for it. No formal risk management program is required. However, organizations shall be able to demonstrate how risks and opportunities are determined and evaluated. The organization is responsible for its application of risk-based thinking and the actions it takes to address risk, including whether or not to retain documented information as evidence of its determination of risks. When documented, it is common to do so in the form of risk assessments or some type of risk register where risks are documented as they are identified and ranked in terms of priority to address.

The organization shall demonstrate the application of risk-based thinking. Examples include, but are not limited to:

- *Considering processes in terms of their risks and added value (e.g., opportunities) and using that as the basis to focus efforts, plan and implement actions.*
- *Considering risk qualitatively (and sometimes quantitatively) when defining processes, policies, procedures and the level of controls needed.*
- *External and internal issues, as well as relevant interested parties, shall be considered when determining risks and opportunities. The relevant interested parties are those that provide significant risk to organization's sustainability if their needs and expectations are not met.*
- *Risks and opportunities that can cause processes and the QMS to deviate from planned results or have an impact on customer satisfaction shall be determined and addressed.*
- *Once the risks are determined, the organization shall put preventive controls in place to minimize negative effects and to make maximum use of opportunities as they arise. Not all processes in the organization carry the same level of risk in terms of how it will affect the organization's ability to meet its objectives. The organization has discretion for which risks and opportunities will receive priority.*
- *The effectiveness of actions taken related to risks and opportunities is an input to management review.*

Documented information (see ISO 9001:2015; 7.5):

Documented information that is required by the ISO 9001 standard or determined necessary by

the organization shall be controlled. Documented information such as a documented procedure, quality manual, or quality plan is referred to in The Standard by the phrase "maintain documented information." Documented information that is needed to provide objective evidence that a requirement has been fulfilled is referred to by the phrase "retain documented information."

Many organizations refer to documented information as documents and records. These terms, or any others, can be used as long as the organization understands their use. In addition to contractual and legal requirements, and as required by these NIAHO® requirements, the organization may consider the "3-C's" of necessity in determining when documented information is needed:

- *Complexity – How complex is the process, task, or activity?*
- *Criticality – The more critical the process, task, or activity, the more detail one would expect to see.*
- *Competence – What is the competency of the personnel performing the work?*

Creating and updating (see ISO 9001:2015; 7.5.2):

When developing or updating documented information, the organization shall ensure appropriate identification and description. This can be as simple as a title and date. Documented information can be in a variety of media including paper, electronic, or a combination of the two. Different formats can also be used.

The organization shall also have a system in place for review and approval of documented information. The purpose of this review is to confirm that documented information is suitable and adequate. The methods for creating and documenting information are the organization's choice.

- *Many organizations establish a system with standard templates that documented information shall follow. Depending on the type of documented information (e.g., documented procedure, form, educational material), different formats might be established. Typically, a system is used for maintaining each of the types of documented information. These vary from purchased, off-the-shelf systems with established approvals and controls, to internally developed systems like SharePoint or ShareFile. Some organizations may use more simple methods. The key is that each of the different systems shall demonstrate who can approve documented information and how approval is identified. This could be a process flow, signature on a document, or electronic sign-off.*

Control of documented information (See ISO 9001:2015; 7.5.3):

For the control of documented information, the organization shall address the following, as applicable:

- *Distribution, access, retrieval and use;*
    - *Those who need access should be able to access the information in an efficient and timely manner.*

- *Only those with a valid reason should have access to documented information in the medical record in order to maintain patient confidentiality.*

- *Protection for electronic information frequently comes in the form of employees not being able to revise documented information through read-only files. Some employees might have read-only access while other employees have revision authorities.*

- *The integrity of the documented information shall be maintained, including unintended changes to historical data.*

- *Documented information retained as evidence of conformity shall be protected from unintended alterations.*

- *Storage and preservation, including preservation of legibility;*

    - *Storage methods shall be considered. If electronic data is utilized, then the organization's IT department becomes an integral part of the control by way of backing up information. When documented information is kept in paper form, then protection should be given by ensuring restricted access to file rooms or cabinets. Consideration should also be given to whether the documented information is protected from physical damage such as fire or water. Preservation shall address legibility which could include the ability to read documented information in its printed format or the ability to view electronic documented information through a software program.*

- *Control of changes (e.g., version control); and*

    - *Changes shall be controlled, and version history maintained. This includes the potential of changes being made to documented information without going through the revision process.*

- *Retention and disposition.*

    - *The organization shall determine from interested parties (e.g., customers) and statutory and regulatory requirements what is to be retained and for how long. If the organization typically retains documented information for 10 years, but there is a regulatory or contractual requirement for 15 years retention, the organization will need to address this additional time when establishing timeframes for disposal of the documented information.*

All documented information, including the documented information that is provided from an external source and is used for planning and control of the quality management system, shall meet the intent of these requirements.

Documented information of external origin determined by the organization to be necessary for the planning and operation of the quality management system shall be identified as appropriate and be controlled. The organization shall have a method in place for obtaining revisions to this documented information, which could include using the online version or subscribing to a service.

Internal audits (see ISO 9001:2015; 9.2):

ISO 19011 defines an audit as a systematic, independent and documented process for obtaining objective evidence and evaluating it objectively to determine the extent to which the audit criteria are fulfilled.

Internal audits are the "Check" phase in the PDCA cycle. Internal audits shall be performed at planned intervals to provide information on whether the organization is meeting the requirements it has defined for its QMS (e.g., documented policies, procedures), the requirements of ISO 9001:2015, and whether the QMS is effectively implemented and maintained.

Individual audits shall examine areas or activities in a structured fashion. This includes defining the frequency, methods, responsibilities, planning requirements and reporting. The criteria and scope for the audit shall be established and communicated to the auditee. Auditors shall be selected to ensure the integrity of the audit process (objectivity and impartiality).

Audits shall be conducted according to planned intervals established by the organization. There is no requirement for audits to be performed at a certain frequency or for a minimum number of audits to be performed. Organizations shall focus their audit program on criticality of processes and consider risk and prevalence of issues, changes affecting the organization, and results of previous audits. Internal audits should add value and improve an organization's operations. The internal audit activity helps an organization accomplish its objectives by bringing a systematic, disciplined approach to evaluate and improve the effectiveness of risk management, control, and governance processes.

Additional guidance for the management of an audit program can be found in ISO 19011 Guidelines for auditing management systems although these guidelines are not mandatory unless specifically imposed by the organization.

The following definitions related to process-based auditing are informed in part by The ASQ Auditing Handbook, 4th edition.

As part of their internal audit program, organizations are required to perform process-based internal audits.

- *A process audit determines whether process requirements (methods, procedures) are being met. It examines the resources (equipment, materials, people) applied to transform inputs into outputs. The environment, the methods (procedures, instructions) followed, and the measures collected are also used to determine process performance. The adequacy and effectiveness of the process controls established by procedures, work instructions, flowcharts, and training and process specifications are evaluated.*

Process-based internal audits are not inspections and shall progress beyond a simple "compliance" or "conformance" audit. In order to reap the full benefits of an internal audit program, internal audits shall have the following characteristics in terms of objectives/purpose, strategy, and data/evidence collection:

- *Audit objectives/purpose: When an audit focuses only on collecting evidence to verify conformance or compliance to a standard or procedure, rather than taking into account*

compliance and the performance and interconnectedness of departments or processes, the audit might not reach its full benefit for the organization, which is to result in identification of risks, opportunities for improvement, and to determine effectiveness. An organization might find compliance to its procedure/process as an end result, but there may be linked or sub-processes (inputs) into the main process that are ineffective, inefficient or inconsistent (or even noncompliant), but at the end of the day still produce a compliant result.

- *Audit strategy: The American Society of Quality (ASQ) Auditing Handbook, 4th edition defines process method: "The process method, or process technique, tests the sequential steps and interaction of activities and processes…the process method is effective for identifying weaknesses within the organization's management system, breakdowns in securing appropriate inputs, and achievement of output objectives."*

- *Data/evidence collection: At a minimum, organizations shall ensure that at least two data/evidence collection methods are employed in performance of a process-based internal audit. Audit methods include:*

    - *Document/record review, staff interviews, observation of work in progress, customer feedback and environmental criteria.*

    - *An audit performed using a single method for data/evidence collection likely produces a different result than an audit that includes multiple data collection methods.*

    - *Often checklists are used to aid the auditor in the performance of the audit; this is a tool used to collect data/evidence and not an audit method. Checklists serve as a guide during the audit, ensure all key processes are covered, keep the audit on track and allow for a defined place to record audit evidence and findings.*

Management shall ensure that appropriate correction or corrective action is taken without undue delay for the deficiencies discovered during the course of the audit. A timeline for taking action should be established. When the nonconformity necessitates corrective action, the requirements in clause 10.2 Nonconformity and corrective action apply. The organization shall retain documented information that provides evidence that the actions or corrective actions related to a nonconformity have been taken. Follow-up shall be performed to verify that the actions have been implemented and whether the results are effective. For example, the recording of recently revised procedures and documenting that the training provided to personnel was deemed to be effective as substantiated through an interview process and review of relevant audit results submitted by the department.

Nonconformity and corrective action (see ISO 9001:2015; 10.2)

Nonconformities are a deviation from defined requirements. As defined by ISO 9000:2015, correction is an action to eliminate a detected nonconformity. Corrective action is an action to eliminate the cause of a nonconformity in order to prevent its recurrence. The objective of corrective action investigation and follow-up is to fully analyze the source of the problem, document it, establish ownership for the problem, assign responsibility for its resolution, and track the results. Evaluation of the need for corrective action (as opposed to just correction) should, at a minimum, cover certain areas within an organization's quality management

system:

- *Nonconformities relating to products, services, processes, and the quality management system*
- *Patient complaints*
- *Errors and adverse events*
- *Quality objectives not being met*
- *Supplier issues*
- *Actions related to internal and external audits*

Corrective action should be appropriate to the effect of the nonconformity encountered (i.e., the impact of the problem). Risk-based thinking should be used to support decisions for when corrective action may not be necessary. Not only will the organization need to determine whether corrective action is needed but also determine if any updates to the risks and opportunities (see ISO 9001:2015; 6.1) are warranted based on the analysis for the corrective action. The organization might also need to make changes to its QMS such as updating the controls in place to provide products or deliver services.

"Cause" as stated in this clause of ISO 9001 is supposed to be considered "root cause." In response to nonconformity, it is expected that any necessary immediate action is taken. When the organization subsequently determines that corrective action is necessary, causal analysis is performed, and a plan is developed to eliminate the nonconformity from happening again. It is expected that the organization consider all areas where the nonconformity exists or could potentially occur and include all affected sites in the corrective action determination and implementation.

There should be sufficient time to allow the implementation of the corrective action with a follow-up to determine if the action(s) were effective.

The organization is responsible for retaining documented information for corrective actions. This documented information includes a description of the nonconformity, actions that were taken, and results of the corrective action (the verification of effectiveness).

Quality Objectives (see ISO 9001:2015; 6.2)

The organization shall establish quality objectives at relevant functions, levels, and the processes needed for the quality management system. The quality objectives shall be documented and:

- *Consistent with the quality policy;*
- *Measurable;*
- *Take into account applicable requirements;*
- *Relevant to conformity of products and services and to enhancement of customer*

satisfaction;

- *Monitored;*
- *Communicated; and*
- *Updated as appropriate.*

The framework for the quality objectives is established in the organization's quality policy. The quantifiable objectives shall be identified at the relevant levels of the organization to support the overall intention of the policy. See QM.3 and QM.6.

Objectives may apply broadly across the organization or more narrowly to a specific site, department, or process. A methodology for communicating these objectives should be implemented to ensure that personnel responsible for their attainment are aware of them. Personnel, including newly hired, part-time, and even contracted or temporary employees, should understand the applicable objectives at their level. They should be able to translate these objectives into their everyday work duties that help achieve them (see ISO 9001:2015; 7.3 and 7.4).

Objectives shall be monitored and updated as appropriate. Improvements necessitate raising the bar on objectives already obtained, or change may be required to establish more realistic objectives if the initial objectives are not being attained.

When planning how to achieve its quality objectives, the organization shall determine:

- *What will be done;*
- *What resources will be required;*
- *Who will be responsible;*
- *When it will be completed; and*
- *How the results will be evaluated.*

Strategic Planning

The foundation for strategic planning happens with ISO 9001:2015; 4 Context of the organization.

Understanding the context of the organization is a process to determine the factors that influence the organization's purpose, objectives and sustainability. Under ISO 9001:2015; 4.1 Understanding the organization and its context, the standard requires that the organization determine external and internal issues that are relevant to its purpose and its strategic direction that affect its ability to achieve the intended result(s) of its quality management system. The organization shall monitor and review information about these external and internal issues.

Examples of internal issues include factors related to values, culture, knowledge and performance of the organization. External issues include legal, technological, competitive, market, cultural, social and economic environments. Issues may have a positive or negative

effect.

ISO 9001:2015; 4.2 Understanding the needs and expectations of interested parties requires organizations to understand the needs and expectations of interested parties. An interested party is a person or group that can affect, be affected by, or perceive themselves to be affected by a decision or activity. These are all the stakeholders, including the customer (patient) but also includes employees, investors, suppliers, external providers, business partners, regulatory agencies, etc. The relevant interested parties are those that provide significant risk to the organization's sustainability if their needs and expectations are not met.

ISO 9001:2015; 0.3 Process approach and 0.3.1 General: "The process approach involves the systematic definition and management of processes, and their interactions, so as to achieve the intended results in accordance with the quality policy and strategic direction of the organization. Management of the processes and the system as a whole can be achieved using the PDCA cycle (see ISO 9001:2015; 0.3.2) with an overall focus on risk-based thinking (see ISO 9001:2015; 0.3.3) aimed at taking advantage of opportunities and preventing undesirable results."

Surveyor Guidance:

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

The lead surveyor will describe the process to the senior leadership for 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 ISO audit 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.3g), are present in some manner and continued through the period the organization is required to conform to the full scope of the ISO 9001 requirements as stated within the timeframe under QM.2 (SR.1).

QM.3 QUALITY OUTLINE/PLAN

SR.1 The organization shall clearly outline its methodology, practice and related policies for addressing how quality and performance are measured, monitored, analyzed, and continually improved with the goal of producing positive health outcomes and reduced 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. Verify that the organization

has clearly defined their methodology for how they measure, monitor, analyze and continually improve quality and performance. The monitoring methods, data analysis, and effectiveness of action(s) taken will be verified through documentation review.

QM.4 MANAGEMENT REPRESENTATIVE

SR.1 A management representative shall be identified by senior leadership and shall have the responsibility and authority, in conjunction with senior leadership, for ensuring that the requirements of the QMS are determined, implemented and maintained.

Interpretive Guidelines:

Senior leadership is required to designate an individual or department as Management Representative. The Management Representative is responsible for ensuring that the QMS is effectively implemented and maintained and that the quality oversight processes ensure that corrective and preventive action(s) are carried out and are measured for effectiveness. It is expected that the Management Representative will report to senior leadership on the status of the QMS.

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 or department.

QM.5 CORRECTIVE ACTION

SR.1 Variations, deficiencies or non-conformities identified by the organization shall be addressed. Appropriate corrective or preventive action shall be determined, applied, and documented. Documentation of activities may take the form of a Failure Mode and Effects Analysis, Root Cause Analysis, Performance Report, Non-conformity Report, specific Performance Improvement Project analysis, etc.

SR.2 Documentation of corrective action considered by the organization as high-risk shall become part of the Quality Management Oversight.

SR.3 All implemented corrective action plans, regardless of risk, shall be validated for effectiveness.

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 shall 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 shall be able to demonstrate that planned actions were effective by quantifiable measurement subject to internal reviews (internal audits) or other means.

The organization shall have a process for elevation of high-risk corrective action that has been verified to be ineffective.

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 corrective action and follow-up to determine that the action(s) taken have been effective. If there are different means for reporting nonconformity and/or corrective action, the surveyor will determine the consistency of the process to ensure its effectiveness.

QM.6 QUALITY MANAGEMENT SYSTEM REQUIREMENTS

In establishing the QMS (see also QM.1), the organization shall be required to have the following:

SR.1 Interdisciplinary group to oversee quality performance with representation from Senior Leadership, Medical Staff, Nursing, Quality/Risk Management (Management Representative), Physical Environment/ Safety, Pharmacy Services, Ancillary Services, support services, and clinical services. A representative of outpatient services shall be present as needed. This interdisciplinary group shall conduct Quality Management Oversight regarding the effectiveness of the QMS.

SR.2 The QAPI program shall be incorporated in the QMS.

SR.3 The organization shall define and document the QMS in place, to include clinical and non-clinical services that align with QM.3 (SR.1);

SR.4 Statement of the quality policy, (e.g., mission statement and values);

SR.5 Measurable organizational quality objectives; and,

SR.6 If an organization is part of a hospital system consisting of multiple separately certified/accredited organizations using a system governing body that is legally responsible for the conduct of two or more hospitals, the system governing body can elect to have a unified and integrated Quality Assessment and Performance Improvement (QAPI) program for all of its member organizations after determining that such a decision is in accordance with all applicable state and local laws. The system governing body is responsible and accountable for ensuring that each of its separately certified/accredited organizations meets all of the requirements of this section. Each separately certified/accredited hospital subject to the system governing body shall demonstrate that:

SR.6a The unified and integrated QAPI program is established in a manner that takes into account each member organization’s unique circumstances and any significant differences in patient populations and services offered in each organization; and,

SR.6b The unified and integrated QAPI program establishes and implements policies and procedures to ensure that the needs and concerns of each of its separately certified/accredited hospitals, regardless of practice or location, are given due

consideration, and that the unified and integrated QAPI program has mechanisms in place to ensure that issues localized to particular organizations are duly considered and addressed.

Interpretive Guidelines:

The QMS includes all locations and services and departments of the hospital, whether onsite or off-site ((i.e., other inpatient campuses, inpatient units located on another hospital's campus/buildings, off-campus EDs, etc.), and all services provided directly by the hospital as well as those services provided under arrangement or contract. This means that the services at all locations of the hospital shall be taken into consideration when developing, defining, implementing, and maintaining the QMS.

The QAPI program shall be incorporated in the QMS. The QAPI program provides a mechanism to systematically examine the quality of care delivered and implement specific improvement projects on an ongoing basis for all of the services provided by the organization. The complexity of those services shall be considered when determining quality parameters of those services. The organization shall continuously study and improve their processes and service delivery and take a proactive approach to improve their performance and focus on improving patient outcomes and the prevention of medical errors (see also QM.7 and QM.8).

The program is central to establishing, advancing, and sustaining a culture of safety and quality care throughout the hospital and for the patients it serves. An effective, ongoing program includes a system for identifying problematic events, policies, or practices, taking sustainable actions to remedy these problems, and follow-up up on these remedial actions to determine if they were effective in improving performance and quality.

Through continuous collection and analysis of quality indicators and data, corrective actions are expected to be appropriate to remedy and change processes, operations, and services in ways that will ultimately improve patient care and outcomes on a sustainable basis. The expectation is to study and make improvements to existing processes and service delivery methods while, at the same time, remaining proactive in seeking innovative approaches to improving patient outcomes and preventing medical errors.

While it is not expected that all departments and services be continuously engaged in large-scale or resource intensive QAPI projects, it is still expected that the hospital will have evidence of the continuous monitoring of the quality and safety of all services provided and that it takes actions as necessary to improve the quality and safety of those services.

The Management Representative supports and facilitates the QMS; however, it is the responsibility of senior leadership to review these activities and see that appropriate actions are taken for continual improvement. The Quality Plan or other similar document outlines the process that the organization has in place. This document will include or reference the policies and procedures for the QMS, quality policy, and quality objectives. The organization shall carry out Quality Management Oversight which encompasses determination of the effectiveness of the QMS, which includes the QAPI program.

The management review process is to be carried out by senior leadership throughout the organization per ISO 9001 Clauses 5 and 9.3. Management review may take place separately

with the leadership team or in conjunction with another committee, such as the quality oversight committee. QM.6 (SR.1) is not a requirement for management review.

Surveyor Guidance:

The QMS will be documented in a Quality Plan, Performance Improvement Plan or similar document as identified by the organization. A part of the QMS will include or reference the quality policy, quality objectives, and how processes and services are monitored and measured.

Review QMS/QAPI program documentation and verify the program is:

- *Based on, and reflects, the size of the hospital and complexity of the hospital's scope of services*
- *Hospital-wide (including services under contract or arrangement)*
- *Inclusive of all hospital departments and services, as well as services provided under agreement or arrangement (see GB.4)*
- *Data-driven (does the documentation indicate what data is used to make QAPI program decisions?)*
- *Focused on quality indicators/measures related to improved health outcomes, as well as the prevention and reduction of medical errors (i.e., does the program focus only on non-clinical measures such as employee satisfaction data as opposed to clinical measures such as infection control incidence rates and/or nationally recognized quality indicators?)*

Determine the structure of Quality Management Oversight and Management Review, which may be separate processes and/or committees, and how they interact with each other if separate. Ensure that Quality Management Oversight is a multidisciplinary committee. Management review, if conducted separate from the Quality Management Oversight committee, should consist of at least the senior leadership team.

Verify that Quality Management Oversight reviews have taken place and there are appropriate minutes recorded.

QM.7 MEASUREMENT, MONITORING, ANALYSIS

The organization shall measure, analyze and track quality indicators and other measures of performance that assess processes of care, hospital service, and operations, including services provided by external providers.

SR.1 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 evaluate the effectiveness of actions taken to improve performance and/or reduce risks (see also QM.3 (SR.1) and QM.6 (SR.5)).

SR.2 The governing body of the organization shall define the frequency and detail for ongoing

review of the indicators and measures.

SR.3 Indicator measurement and prioritization of performance improvement activities shall include:

SR.3a Focus on high-risk, problem-prone areas, processes or functions;

SR.3b Consideration of the incidence, prevalence and severity of problems in these areas, processes or functions; and,

SR.3c Health outcomes, patient safety, and quality of care.

SR.4 Those functions to be measured, at a minimum, shall include the following:

SR.4a Threats to patient safety (e.g., falls, pt. identification, injuries);

SR.4b Medication therapy/medication use; to include medication reconciliation, high risk drugs, look alike- sound alike medications, and the use of dangerous abbreviations;

SR.4c Operative and invasive procedures, to include wrong site/wrong patient/wrong procedure surgery;

SR.4d Anesthesia/moderate sedation adverse events;

SR.4e Blood and blood components-adverse events/usage;

SR.4f Restraint use/seclusion, to include prolonged restraint (see PR.7 (SR.7));

SR.4g Effectiveness of pain management system;

SR.4h Infection prevention and control, including but not limited to:

SR.4h(1) CMS required HAI reporting; and,

SR.4h(2) Antimicrobial stewardship.

SR.4i Utilization Management System;

SR.4i(1) Readmissions; and,

SR.4i(2) Aggregate findings and trends identified by the UR Committee (see UR chapter).

SR.4j 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.4k Customer satisfaction, both clinical and support areas, including:

SR.4k(1) Grievances;

SR.4l Discrepant pathology reports;

SR.4m Unanticipated deaths;

SR.4n Adverse events/Near misses;

SR.4o Unplanned returns to surgery (as defined by the organization);

SR.4p Critical and/or pertinent processes, both clinical and supportive;

SR.4q Medical record delinquency;

SR.4r Physical Environment Management Systems; and,

SR.4s Relevant data such as data submitted to or received from Medicare quality reporting and quality performance programs including but not limited to data related to hospital readmissions, hospital acquired conditions, maternal morbidity, sepsis, and safe opioid practices.

SR.4t Hospitals which offer obstetrical care services shall develop quality indicators on patient outcomes and disparities in processes of care, services, and operations among obstetrical patients. *(Note: This requirement shall be implemented by January 1, 2027)*

SR.5 The interdisciplinary group referred to in QM.6 (SR.1), also known as the Quality Management Oversight group, shall perform an evaluation, not less than once per year, of selected high-risk/priority indicators or processes and measurement data related to those processes.

SR.5a The organization shall:

SR.5a(1) Define the mechanism and rationale used to determine the selection of high-risk/priority indicators or processes to be evaluated;

SR.5a(2) Define the minimum frequency of the evaluation(s), as well as circumstances which warrant a more frequent or detailed review.

SR.5a(3) Maintain documentation of the evaluations and (SR.5a(1)) and (SR.5a(2)).

Interpretive Guidelines:

In order for the organization to continually improve its QMS, the services and processes shall be measured to determine their effectiveness. A QAPI program should include the continuous collection and analysis of quality indicators/data and corrective actions as appropriate to remedy processes, operations, and services that will improve patient outcomes. Through an internal review 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 shall 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 QMS includes all locations and services and departments of the hospital, whether onsite or off-site and all services provided directly by the hospital as well as those services provided under arrangement or contract. Therefore, all the services at all locations of the hospital shall be taken into consideration when developing, defining, implementing, and maintaining the QMS.

While it is not expected that all departments and services be continuously engaged in large-scale or resource-intensive measurement, monitoring, and analysis, it is still expected that the hospital will have evidence of the continuous monitoring of the quality and safety of all services provided and that it takes actions as necessary to improve the quality and safety of those services.

Hospitals have many choices of indicators to use; the list above, at a minimum, is to be measured.

Indicators can be broken down into several types:

- *Outcomes Indicators: Measure results of care; typical outcomes measures include adverse events, risk-adjusted mortality rates, complication rates, healthcare-associated infection rates, length of stay, readmission rates, excess days in acute care after hospitalization, etc.*

- *Process of Care Indicators: Measure how often the standard of care was met for patients with a diagnosis related to that standard. For example, in the hospital setting, measures might focus on appropriate medication regimens for heart attack, heart failure and stroke patients, appropriate use of antimicrobials in inpatient and outpatient settings, appropriate use and discontinuation of prophylactic antibiotics for surgical cases, etc.*

- *Patient Perception Indicators: Measure a patient's experience of the care he/she received in the hospital. AHRQ sponsored development of one patient experience of care instrument, H-CAHPS, that CMS uses in reporting on hospital quality. There may be similar patient survey instruments that could be used in other departments in the hospital setting.*

Additionally, the hospital is allowed to develop its own measures and indicators that are based on the scope and complexity of its services, and on considerations for the health equity of its specific patient population.

The hospital shall evaluate its QAPI program data to ensure that it is considering the information below in establishing priority areas where it will undertake specific actions to improve its performance. The prioritization of efforts should address the effect on health outcomes, patient safety, and quality of care. Hospitals should determine these areas based on the complexity of the services they provide.

The organization is required to focus its efforts on high-risk, high volume, and problem-prone areas. It is required to consider, when selecting additional measures/indicators that will shape its improvement activities in these areas, the following:

- *High-risk areas - where the opportunity for error is higher than in other areas, for example, where there are complex processes, and/or where the consequences of poor quality or medical errors are more likely to have a serious, adverse impact on patients. Examples may include, but are not limited to, Emergency Departments, Labor and Delivery Units, ICUs, and care areas treating immunocompromised patients.*

- *High volume areas - where the number of potential patients who could be adversely affected is high due to common elements in their care. These areas may include, but are not limited to, clinical staff hand hygiene, sanitary food preparation, and general medication administration.*

- *Problem-prone areas - where the hospital's own internal QAPI data shows a history of problems, or where nationally available research or expert consensus has identified areas especially prone to problems. These areas may include, but are not limited to, hospital-acquired infections, central-venous catheter use, patient hand-off communication processes between members of the healthcare team, systems for identifying patients, and medication administration.*

- *Incidence - the rate or frequency at which problems occur in the hospital related to area measured by the indicator. The annual incidence of surgical site infections in hospital would be the rate that results when dividing the number of such infections that occurred in a calendar year by the total number of surgical cases in the hospital during that same year. The annual incidence of unplanned readmissions to a hospital would be the rate that results when dividing the number of such readmissions by the total number of acute inpatient stays during the same year.*

- *Prevalence - how widespread something is in a hospital at a given point in time in a particular place or population. For example, the prevalence of hospital acquired pressure ulcers among hospitalized patients or the prevalence of restraint utilization.*

- *Severity - The degree of seriousness or significance of an event or issue in the hospital. For example, any single instance of a wrong site surgery performed on a patient represents a serious adverse, unplanned outcome of the surgical procedure, and it would be appropriate for a hospital to track and evaluate all such cases, due to their severity, even if they are low volume incidents.*

The organization shall collect and analyze data in the respective functions listed in this standard, as well as other indicators selected by the organization, to demonstrate that these processes are closely monitored. The data gathered for quality indicators shall be used to determine if the services provided by the hospital are effective toward delivering safe, quality care to the patients it serves. There may also be considerations for cultural competence as hospitals develop these measures. The hospital shall demonstrate that the quality indicators it has selected, along with the associated data, are used to monitor quality and safety and to also identify opportunities for quality improvement.

An analysis of the data should demonstrate that the quality indicators used produce measurable improvement related to the specific quality indicator. For example, a medication error indicator included in the program must demonstrate a decrease in medication errors. The care process of proper hand hygiene (handwashing) must demonstrate increased staff compliance with hand hygiene standards of practice. A central line infection indicator must demonstrate a decrease in the incidence and prevalence of central line infections. Measurable improvement is evidenced

by quantifiable data. For example, a hospital may have identified 10 medication errors in one month in its ICU. After analysis of the errors and implementation of medication administration changes, it tracks medication errors over the next 6 months. The 6 months of data show that there was only 1 medication error in the ICU over the entire 6 months. In this example, this is measurable improvement evidenced by data. There are no prescribed thresholds for acceptable improvement; the hospital shall determine these thresholds in accordance with national standards of practice.

The governing body is responsible for specifying the frequency and the detail of the data collection, which may include, but is not limited to, what data will be collected, what the data is intended to measure, in what areas of the hospital the data will be collected, and how frequently the various types of data will be collected. This does not mean that the governing body is expected to have a high degree of technical expertise in the area of quality data collection. However, the governing body shall have information that describes the hospital's QAPI data collection program in sufficient detail so that the governing body is able to determine what program data requirements to approve. There shall be evidence that the governing body has had an active role in the development and ongoing planning of the frequency and detail of QAPI data collection. Such evidence may be documentation in the governing body meeting minutes that it has reviewed and approved the frequency and detail of the QAPI data collection program.

A preventable adverse event is an injury caused by an error. Section 482.70 defines an adverse event as "an untoward, undesirable, and usually unanticipated event that causes death or serious injury, or the risk thereof." 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.

CDC's National Healthcare Safety Network (NHSN) is the conduit for facilities to comply with CMS infection reporting requirements.

Surveyor Guidance:

The organization can demonstrate the effectiveness of its QMS through the analysis of data and follow up where variation exists in order to implement corrective/preventive action. The organization will be assessed according to its ability to effectively monitor and measure those areas listed above, as well as additional indicators selected by the organization which are reflective of the hospital's patient population.

Ask staff to provide evidence (data) of measurable improvements in the quality indicators it has selected for its program. Ask to see documented evidence of the opportunities the hospital has identified for improvement based on the collection of data.

- *Verify that improvements are ongoing (several data analyses showing improvement over time) and not just one-time events.*

- *If the evaluation did not show improvements or sustained improvements, is there evidence that the hospital implemented a revised or new solution?*

The measurement for the areas above shall be aligned with risk-based thinking, performance improvement and process approach. Look for data analysis and measures in place to determine the effectiveness of these processes.

Evaluate the process for measuring, monitoring, analysis and continual improvement to ensure alignment to organization methodology as required in QM.3 (SR.1) and structure as required in QM.6.

Evaluate the process for corrective action and follow-up, for alignment to the organization's defined process as required in QM.5.

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, reporting, investigation and response to medical errors and adverse patient events;

SR.2b Aggregation, trending, and analysis of data;

SR.2c Implementation of preventative and corrective action;

SR.2d Defined processes to reduce risk;

SR.2e On-going measurement to ensure action effectiveness;

SR.2f Feedback and learning throughout the hospital;

SR.2g Policy and procedure of informing patients and/or their families about unexpected adverse events.

SR.3 Trends in medical errors, adverse patient events, or other process errors/problems reported in the organization's incident reporting system shall be reported to the senior leadership team (through management review and/or Quality Management Oversight).

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 reporting mechanism for medical errors and adverse events is at the discretion of the hospital. The system shall permit the hospital to track and analyze medical errors and adverse events in an effective and meaningful manner. As appropriate, the hospital should educate all hospital staff and contract staff on what is considered a medical error and an adverse event, as well as when and how to report these events. All staff (including contractors) should be able to articulate their roles and responsibilities in supporting the hospital's expectations for safety, such as what safety risks or breaches they are expected to report and how they would be expected to report them. Hospitals may communicate safety expectations through education

and training, the use of posters that are constant reminders of safety requirements, staff newsletters, etc.

For purposes of this section, error means the failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim. Errors can include problems in practice, products, procedures, and systems. Medical error means an error that occurs in the delivery of healthcare services.

There are many types of medical errors, including, but not limited to:

Medication administration errors - wrong medication, wrong dosage, wrong patient, etc.;

Surgical errors - wrong patient, wrong site, retained instrument, etc.;

Equipment failure – defibrillator without working batteries, IV pump that results in inadvertent dosing, alarms not working properly, etc.;

Infection control errors – poor aseptic technique, incorrect processing of sterile instruments and equipment, incorrect isolation practices, lack of standard precautions, etc.;

Blood transfusion-related errors – wrong patient, wrong blood product administered, etc.; and

Diagnostic errors – misdiagnoses leading to incorrect choice of therapy, failure to use an indicated diagnostic test, misinterpretation of test results, failure to act properly on abnormal results.

Not every medical error results in harm to a patient; the error may be detected and addressed before a harmful effect can occur (a "near miss") or the consequence of the error may be minimal. From a patient safety perspective, a near miss is considered an error and much can be learned from the near miss in terms of system weaknesses that could, in the future, result in actual harm to patients. Therefore, hospitals must track and analyze errors that result in near misses and focus on their prevention and reduction. While the regulation also specifically calls for measuring, analyzing, and tracking of adverse events, adverse events may or may not be preventable. A preventable adverse event is an injury caused by an error. Section 482.70 defines an adverse event as "an untoward, undesirable, and usually unanticipated event that causes death or serious injury, or the risk thereof."

Analysis of Causes of Medical Errors and Adverse Events

Hospitals should analyze medical errors and adverse events to determine the cause(s) by using a systemic approach for determining the cause of the error and for implementing appropriate preventive actions.

Implementing Improvement/Preventive Strategies

After the systemic analysis of the error or adverse event has led to the identification of the cause of the event, hospitals should develop and implement preventive actions to improve the quality and safety associated with the event or the error. Preventive actions include, but are not limited to, changes in policies and procedures, repairing or replacing equipment, staff education and training, etc. Where appropriate, the hospital should make all affected staff aware of the strategies and related actions it has implemented to correct and prevent specific errors and

adverse events and also provide applicable training. Hospitals should be able to provide evidence of the implemented changes, such as documented staff education and training, documentation of new or revised policies, evidence that equipment has been repaired or replaced, etc. The organization should 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.

Where process variation and deficiencies are detected, appropriate corrective action shall be determined, applied, and documented (QM.5 (SR.1)). Implemented corrective action shall be validated for effectiveness (QM.5 (SR.3)).

Evaluating Changes and Sustaining Improvement

The hospital should also have a method to assess whether the strategies and actions it has implemented resulted in improved outcomes and that those improved outcomes are sustained over time. This means the hospital should collect data that enables the hospital to determine whether indicators, related to a specific area targeted for change, actually demonstrated an improvement after implementation of the changes. For example, the hospital should continue to periodically collect data on proper hand hygiene and then analyze the data to determine if the solution has resulted in sustained improvement in handwashing compliance. If the analysis of the periodic collection of handwashing data shows that the solution has not resulted in a sustained improvement over an appropriate period of time, a new or revised strategy/solution must be implemented, with subsequent data collection and monitoring to evaluate the effectiveness of the new solution.

Prospective hospitals applying for initial certification in Medicare

A facility seeking Medicare program initial certification as a hospital may not have been in operation long enough to demonstrate extensive internal data collection for the identification of opportunities for improvement based on the monitoring data. However, it must be able to show that it has an active data collection and analysis infrastructure in place and indicate when it expects to have sufficient data to begin analysis. In addition, because hospitals may utilize quality indicators from outside sources to prioritize QAPI program activities, an initial applicant would still be expected to provide evidence of implementing improvement actions based on selected indicators from outside sources.

When such incidents occur, a process shall 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 wrongdoing on the part of the hospital 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 hospital is acting responsibly and will promote the safest environment possible.

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 mode 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.

Ask to see evidence that the hospital tracks data for the identified indicators, which may include, but are not limited to blood product transfusion reactions, drug reactions, errors in medication administration, and infection control-related errors and events.

Ask to see evidence of the incident reporting system and related policies for reporting and responding to incidents/events. Ask for a demonstration of how to use the system and how the system is able to organize the reported data for meaningful analysis.

- *Can the system organize the data by type of error/adverse event?*
- *Can the system organize the data by dates to show trends over time?*
- *Can the system organize the data by shift, by unit where the error occurred, etc.?*

Select a sample of several (at least three) adverse events or errors the hospital has tracked and ask to see written evidence it has used a systemic approach (e.g., root cause analysis (RCA)) to analyze the cause of the events and errors), implemented changes based on the identified causes to prevent further events or errors, conducted periodic data collection to verify if the changes resulted in improvements, and analyzed the post-implementation data to assess whether the improvement (if there was an improvement) was sustained over time.

Ask the hospital leadership who oversee the patient safety system to provide evidence of improvement activities that have been initiated based on data reported through the incident reporting system.

Ask to see evidence of hospital-wide staff education and training regarding what errors and adverse events must be reported and how to report them. Look at the materials used for education and training. Are there training records to show staff received the training?

Interview staff in various units to assess their understanding of identifying and reporting medical errors and adverse events.

Review the organization's process for reporting medical errors and adverse patient events (e.g., incident reporting system). Review the process for compliance to QM.8 (SR.2a-2g and SR.3). Ensure the corrective action process for detecting process variation and deficiencies aligns with QM.5.

GOVERNING BODY (GB)

GB.1 DEFINITION OF A HOSPITAL

State licensure as a hospital does not automatically infer that an organization meets the CMS definition of a hospital. Organizations participating in Medicare as a hospital shall meet certain specified requirements. The Secretary of Health and Human Services may impose additional requirements if they are found necessary in the interest of the health and safety of the individuals who are furnished hospital services. The specified requirements serve as the basis of survey activities to determine whether an organization qualifies for a hospital provider agreement under Medicare and Medicaid.

SR.1 In order to meet the CMS definition of a hospital, the organization shall meet all the Conditions of Participation for hospitals (42 CFR Part 482), the requirements of Section 1861(e) of the Social Security Act (the Act) and:

SR.1a Be primarily engaged in providing, by or under the supervision of physicians:

SR.1a(1) Inpatient diagnostic services and therapeutic services for medical diagnosis, treatment, and care of injured, disabled, or sick persons or inpatient rehabilitation services for the rehabilitation of injured, disabled, or sick persons;

SR.1b Maintain clinical records on all patients (see MR.2);

SR.1c Have medical staff bylaws (see MS.3);

SR.1d Have a requirement that every patient with respect to whom payment may be made under Title XVIII shall be under the care of a physician except that a patient receiving qualified psychologist services (as defined in section 1861(ii) of the Act) may be under the care of a clinical psychologist with respect to such services to the extent permitted under state law (see MS.11 (SR.1));

SR.1e Provide 24-hour nursing service rendered or supervised by a registered professional nurse and has a licensed practical nurse or registered professional nurse on duty at all times (see NS.1 (SR.2));

SR.1f Have in effect a hospital utilization review plan which meets the requirements of section 1861(k) of the Social Security Act (Act) (see UR);

SR.1g Have in place a discharge planning process that meets the requirements of section 1861(ee) of the Act (see DC);

SR.1h Be licensed under state or local law or be approved by the agency of the state or locality responsible for licensing hospitals as meeting the standards established for such licensing (if located in a state in which state or applicable local law provides for the licensing of hospitals) (see GB.2);

SR.1i Have in effect an overall plan and budget that meets the requirements of section 1861(z) of the Act (see GB.3); and,

SR.1j Meet any other requirements as the Secretary finds necessary in the interest of the health and safety of individuals who are furnished services in the institution (see GB.2).

Interpretive Guidelines:

Primarily Engaged

Generally, a hospital is primarily engaged in providing inpatient services under section 1861(e)(1) of the Act when it is directly providing such services to inpatients. ***Having the capacity or potential capacity to provide inpatient care is not the equivalent of actually providing such care.*** *Inpatient hospital services are defined under section 1861(b) of the Act and in the regulations at 42 CFR Part 409, Subpart B. CMS guidance describes an inpatient as:*

"a person who has been admitted to a hospital for bed occupancy for purposes of receiving inpatient hospital services."

Generally, a patient is considered an inpatient if formally ***admitted as an inpatient with the expectation that he or she will require hospital care that is expected to span at least two midnights*** *and occupy a bed even though it later develops that the patient can be discharged or transferred to another hospital and not actually use a hospital bed overnight." (Medicare Benefit Policy Manual, Chapter 1, Section 10, (Medicare Benefit Policy Manual (cms.gov).*

The "expectation of a two midnight stay" for an inpatient is that the intent of the physician was that the patient be admitted to the hospital for an inpatient stay as opposed to that of observation status which is an outpatient service.

Therefore, an average length of stay (ALOS) of two midnights would be one of the benchmarks considered for certification as a hospital.

- *In making a determination of whether or not a facility is primarily engaged in providing inpatient services and care to inpatients, CMS considers multiple factors and will make a final determination based on an evaluation of the facility in totality. Such factors include, but are not limited to, average daily census (ADC), average length of stay (ALOS), the number of off-campus outpatient locations, the number of provider-based emergency departments, the number of inpatient beds related to the size of the facility and scope of services offered, volume of outpatient surgical procedures compared to inpatient surgical procedures, staffing patterns, patterns of ADC by day of the week, etc. Hospitals are not required to have a specific inpatient to outpatient ratio in order to meet the definition of primarily engaged.*

In order for surveyors to determine whether or not a hospital is in compliance with the statutory and regulatory requirements of Medicare participation, including the definition of a hospital, they shall observe the provision of care. Medicare requirements at 42 CFR 488.26(c)(2) state that "The survey process uses resident and patient outcomes as the primary means to establish the compliance process of facilities and agencies. Specifically, surveyors will directly observe the

actual provision of care and services to residents and/or patients, and the effects of that care, to assess whether the care provided meets the needs of individual residents and/or patients."

Because section 488.26(c)(2) and section 1861(e) of the Act refer to patients (plural) hospitals shall have at least two inpatients at the time of the survey in order for surveyors to conduct the survey. However, just because a facility has two inpatients at the time of a survey does not necessarily mean that the facility is primarily engaged in inpatient care and satisfies all of the statutory requirements to be considered a hospital for Medicare purposes. Having two patients at the time of a survey is merely a starting point in the overall survey and certification process.

If a hospital does not have at least two inpatients at the time of a survey, a survey will not be conducted at that time and an initial review of the facility's admission data will be performed by surveyors while onsite to determine if the hospital has had an ADC of at least two and an ALOS of at least two midnights over the last 12 months. Average daily census is calculated by adding the midnight daily census for each day of the 12-month period and then dividing the total number by the number of days in the year. For facilities that have multiple campuses operating under the same CMS Certification Number (CCN), the ADC is not calculated individually at each campus. All locations make up the entire facility and the ADC will be based on the total inpatient census from all campuses. This also includes PPS excluded psychiatric and rehabilitation units that are part of the facility.

In order to be considered primarily engaged in providing inpatient services, prospective hospital providers and currently participating hospitals should also be able to maintain an ALOS of two midnights or greater. The ALOS is calculated by dividing the total number of inpatient hospital days (day of admission to day of discharge, including day of death) by the total number of discharges in the hospital over 12 months. For facilities that have not been operating for 12 months at the time of the survey, an ADC calculated using 12 months as the denominator may falsely result in an ADC of less than two. Therefore, facilities that have been operating less than 12 months at the time of the survey, should calculate its ADC based on the number of months the facility has been operational but no less than three months. This does not mean that a facility shall be operational for at least three months before a survey can be completed. It merely means that the ADC cannot be calculated using a denominator of less than three months.

- *If the ADC and ALOS is two or more, the State Survey Agency (SA) or Accrediting Organization (AO) makes the determination that a second survey will be attempted at a later date.*

- *If the facility does not have a minimum ADC of two inpatients and an ALOS of two over the last 12 months (or less than 12 months for facilities that have not been operational for at least 12 months), the facility is most likely not primarily engaged in providing care to inpatients and the SA or AO may not conduct the survey. The SA or AO shall immediately contact the RO to inform them that a survey could not be completed, and the CMS Location will review additional information provided by the SA or AO to determine whether a second survey should be attempted.*

- *When the ADC and ALOS are NOT a minimum of two, the SA or AO do not make the final determination whether a second survey will be attempted. Instead, the SA or AO shall obtain further information from the facility (other factors described below), review*

the information and make a recommendation to the RO regarding whether a second survey should be attempted. The SA or AO shall provide its recommendation in writing to the RO along with the supporting information used to make the recommendation. The RO shall review the recommendation and information and make a determination on whether a second survey will be conducted and communicate its decision to the SA or AO within seven business days of receipt of the recommendation. AO communication to the RO shall be via the current established process used for all other written communication to the RO.

- *If during a second survey attempt, the facility does not have two inpatients, the survey will not be conducted, and the SA or AO shall cite condition level non-compliance with section 482.1. In addition, the SA or AO shall immediately notify the RO of the situation. The RO will then proceed with either denial of certification (for initial applicants) in the Medicare program or termination of the provider agreement (for currently participating hospitals). For currently participating hospitals, the RO will base any termination action on the totality of the situation including consideration of any access to care issues.*

Other factors that the CMS Location should consider in determining whether to (1) conduct a second survey or (2) recommend denial of an initial applicant or termination of a current provider agreement, include but are not limited to:

- *The number of provider-based off-campus emergency departments (EDs). An unusually large number of off-campus EDs may suggest that a facility is not primarily engaged in inpatient care and is instead primarily engaged in providing outpatient emergency services.*
- *The number of inpatient beds in relation to the size of the facility and services offered.*
- *The volume of outpatient surgical procedures compared to inpatient surgical procedures.*
- *If the facility considers itself to be a "surgical" hospital, are procedures mostly outpatient?*
- *Does the information indicate that surgeries are routinely scheduled early in the week, and does it appear this admission pattern results in all or most patients being discharged prior to the weekend (for example does the facility routinely operate in a manner that its designated "inpatient beds" are not in use on weekends)?*
- *Patterns and trends in the ADC by the day of the week. For example, does the ADC consistently drop to zero on Saturdays and Sundays? Therefore, suggesting that the facility is not consistently and primarily engaged in providing care to inpatients.*
- *Staffing patterns. A review of staffing schedules shall demonstrate that nurses, pharmacists, physicians, etc. are scheduled to work to support 24/7 inpatient care versus staffing patterns for the support of outpatient operations.*
- *How does the facility advertise itself to the community? Is it advertised as a "specialty" hospital or "emergency" hospital? Does the name of the facility include terms such as*

"clinic" or "center" as opposed to "hospital"?

The CMS RO should consider all of the above factors (and other factors as necessary) to make a determination as to whether or not a facility is truly operating as a hospital for Medicare purposes. A determination of non-compliance with section 482.1 will not be based on a single factor, such as failing to have two inpatients at the time of a survey.

It is important to note that CMS has the final authority to make the determination of whether or not a facility has met the statutory definition of a hospital after considering the facility's entire situation, the recommendations of the SA or AO surveyors as well as the evidence submitted by the SAs and AOs. As stated previously, a facility that meets state requirements for obtaining state status as a hospital is not automatically considered a hospital for federal survey and certification purposes without further evaluation and consideration of all relevant CMS requirements. In addition, approval by the Medicare administrative contractor of an enrollment application does not convey hospital status for CMS purposes. Hospital status is only conveyed and approved by the CMS RO after a survey has been completed and the results clearly demonstrate that the facility has met all the federal requirements, including the statutory definition.

Surveyor Guidance:

Verify there are at least two inpatients currently in the hospital at the time of survey:

- *If yes, proceed with evaluating the whether the hospital is primarily engaged in providing the requisite services of a hospital, as well as in the Conditions of Participation.*

- ***If there are currently no inpatients in the hospital, no survey is to be conducted, and the Team Leader shall contact the DNV HC Central Office immediately.*** *Following communication with the DNV HEALTHCARE HC Central Office, surveyors shall ask to see the following, in order to make the proper determination of the hospital's status and to make the proper recommendations to the RO:*

    - *ADC over the last 12 months (or less for facilities operational for less than 12 months)*

        - *Look for patterns and trends in the ADC by the day of the week.*

    - *ALOS over the last 12 months (or less for facilities operational for less than 12 months)*

    - *The number of provider-based off-campus emergency departments*

    - *The volume of outpatient surgical procedures compared to inpatient surgical procedures*

    - *Staffing schedules by day of week and shift over the last 12 months (or less for facilities operational for less than 12 months)*

    - *Verify the facility is providing the appropriate types and adequate numbers of*

staff to support 24/7 inpatient services (e.g., nursing, pharmacy, physicians, etc.).

- *Review the number of inpatient beds in relation to the size of the facility and services offered.*

- *Determine if the number of inpatient beds could support emergency or unplanned admissions from the volumes of other services offered by the facility, such as ED patients or outpatient surgery patients?*

- *If the initial review of the above information indicates that the facility is most likely not providing care to inpatients, then a second survey will not be conducted. However, if the review of the information indicates the facility has had an ADC and ALOS of two over the last 12 months (or less for facilities operational for less than 12 months) and there are no other concerns regarding facility's eligibility to be surveyed as a hospital, then a second survey will be scheduled for a future unannounced date after consulting with the RO.*

Whenever the SA or AO is unable to complete a survey because the hospital did not have a sufficient number of inpatients that is a representative sample of the different types of services and patient populations that are treated at that hospital, it shall immediately report this information to the RO.

If the survey team identifies this situation, the team leader shall contact the DNV HC Central Office immediately so that this information may be communicated to the RO.

Determine through interview, observation, and record review that the hospital meets the statutory requirements as defined by 1861(e), including the CoP. Verify the facility does the following:

- *Maintains clinical records on all patients;*

- *Has medical staff bylaws;*

- *Has a requirement that every patient with respect to whom payment may be made under this title shall be under the care of a physician except that a patient receiving qualified psychologist services (as defined in section 1861(ii) of the Act) may be under the care of a clinical psychologist with respect to such services to the extent permitted under state law;*

- *Provides 24-hour nursing service rendered or supervised by a registered professional nurse, and has a licensed practical nurse or registered professional nurse on duty at all times;*

- *Has in effect a hospital utilization review plan which meets the requirements of section 1861(k) of the Act;*

- *Has in place a discharge planning process that meets the requirements of section 1861(ee) of the Act;*

- *If located in a state in which state or applicable local law provides for the licensing of hospitals, be licensed under such law or be approved by the agency of the state or locality responsible for licensing hospitals, as meeting the standards established for such licensing;*

- *Has in effect an overall plan and budget that meets the requirements of section 1861(z) of the Act.*

GB.2 LEGAL RESPONSIBILITY

There shall 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 shall carry out the functions specified that pertain to the governing body.

SR.1 The governing body (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 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 include 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, certified, registered or otherwise meet all applicable federal, state and local laws and regulations.

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 (e.g., 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 shall provide written documentation that identifies the individual or individuals that are responsible for the conduct of hospital operations.

Surveyor Guidance:

Verify that the organization 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 organization leadership (highest level of authority in the organization that makes day to day decisions, typically CEO, COO, CNO, CMO, etc.) to determine the structure of management review per ISO 9001:2015; 9.3 and how information flows to and from the governing body.

Review documentation, such as meeting minutes, to ensure compliance to the requirements of this standard, as well as required inputs, outputs, and high-risk identified issues in accordance with ISO 9001.

The governing body or individual(s) responsible (e.g., CEO) shall take actions to assure that all services furnished by the organization through a contractor comply with the applicable NIAHO® requirements. When assessing compliance of a service provided by a contractor, deficiencies cited under other NIAHO® requirements warrant a citation of this requirement as well as CE.1, because the CEO (and governing body in those hospitals where there are both an organized governing body and CEO) has failed to assure that the contractor provides services in a manner that allows the organization to comply with the NIAHO® requirements and/or CoPs.

GB.3 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 shall provide for capital expenditures for at least a 3-year period including the year identified in GB.3 (SR.1). The plan shall 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 shall be reviewed and updated annually.

SR.4 The plan shall 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 shall 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.

For those organizations who are ISO 9001 compliant/certified, verify the alignment to the strategic direction/plan of the organization. Ensure the internal and external issues (ISO 9001:2015;4.1) and requirements of relevant interested parties (ISO 9001:2015 4.2) were considered in developing the plan. Note: 4.1 and 4.2 are not required to be documented.

GB.4 CONTRACTED SERVICES

SR.1 The governing body is responsible for all services furnished in the organization. The organization shall evaluate and select external providers (including contract services, informal arrangements, joint ventures or shared services, vendors) based on their ability to supply products and/or services in accordance with the organization's requirements.

SR.2 The organization's policy and procedure for externally provided services and products addresses, at minimum:

SR.2a Criteria for selection, evaluation, monitoring of performance, and re-evaluation to be applied. The criteria will include the requirement that the entity or individual shall provide the products/services in a safe and effective manner which complies with all applicable NIAHO® standard requirements.

SR.2b The governing body shall require reviews, performed at defined intervals, of selected indicators to ensure that external providers furnish services and products that are safe and effective and comply with all applicable requirements.

SR.3 A documented list of external providers, including their scope/nature of services and/or products shall be maintained.

Interpretive Guidelines:

The governing body is responsible for assuring that hospital services are provided in compliance with NIAHO® standard requirements and according to nationally recognized standards of practice and guidelines regardless of whether the services are provided directly by hospital employees or by an external provider. Clear expectations for safety shall also be set and communicated to those providing services under arrangements or contracts and be documented in the contracts.

When services or products are provided by an external provider, the organization shall identify the criteria for selection and procurement of services/products, and the process for evaluating the entity or individual. The criteria and process for performing the evaluation, monitoring of performance, and re-evaluation shall be established by the organization's policy.

The organization will prioritize the review of external providers based on the concept of risk-based thinking with an emphasis on those services related to patient care. Externally provided services determined to be in a high-risk category will have established evaluation processes that are based on objective evidence. All other externally provided services that do not fall into the high-risk category will be evaluated in accordance with the organization's policy as defined.

- *The governing body (or organized group or individual who assumes full legal authority and responsibility for operations of the organization) shall take actions through the organization's quality program not only to assess the services furnished directly by hospital staff, but also those services provided under arrangement, identify quality and performance problems, implement appropriate corrective or improvement activities, and to ensure the monitoring and sustainability of those corrective or improvement activities.*

- *The organization shall be able to demonstrate how it includes the services in the high-risk patient care category in its QMS. This may be done by providing evidence of the evaluation of contracted services and, when appropriate, conducting performance improvement activities or projects related to services under arrangement or contract. Evidence of this inclusion would include, but not be limited to, periodic assessment of contracted services, what resources the contractor has allocated to quality and performance improvement activities, how the contractor actively participates in QMS activities, such as providing the governing body with periodic quality reports/data, attending quality meetings, and, when appropriate, conducting performance improvement projects. For example, an organization that provides emergency services (and staffing) for its emergency department (ED) under contract or arrangement must demonstrate that it routinely receives quality data from the ED contractor, reviews the data, and takes necessary action based on the data. It is expected that the organization be able to provide evidence that the contracted services are included in the QMS in order to demonstrate compliance with the QM chapter.*

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.

The documented list of external providers shall address:

- *The service(s) or products being offered;*

- *The individual(s) or entity providing the service(s) or products;*

In addition, the organization should address:

- *Whether the services are offered on or off-site;*

- *Whether there is any limit on the volume or frequency of the services provided; and*

- *When the service(s) are available.*

Surveyor Guidance:

Determine the services that are carried out or products that are provided by an external provider

and the scope of their responsibilities (SR.3). In a sampling of these external providers, review the process to see that it complies with the organization's policies and procedures. Verify that the organization has a mechanism in place to review performance of each entity at intervals defined by the organization.

Verify the process for development of contracts and/or agreements meets the following:

- *The organization shall communicate to external providers its requirements for:*

  a) the processes, products and services to be provided;

  b) acceptable methods for products and services being provided, to include equipment being used;

  c) required competency to be completed by either the hospital organization or the external provider, or both;

  d) the expectations for external providers' interactions with the organization (e.g., incident reporting process, any access to software programs);

  e) control (policies/procedures) and monitoring of the external providers' performance to be applied by the hospital organization.

For those services the organization provides under arrangement or contract that are in the high-risk patient care category, ask to see evidence that the external provider is actively involved in the QMS:

- *Do the governing body, medical staff, and administrative officials periodically receive and review quality data from the external provider?*
- *Is the external provider involved in any current or past hospital QAPI projects?*
- *Does the contract or agreement include the organization's expectations regarding the external provider's roles and responsibilities regarding the QMS?*
- *Does the data from the external provider demonstrate positive outcomes related to the services provided?*
- *Do written contracts include QAPI requirements and roles and responsibilities of the contractor?*

Review the list of external providers and verify that there is a delineation of the scope/nature of services and/or products.

CHIEF EXECUTIVE OFFICER (CE)

CE.1 QUALIFICATIONS

SR.1 The governing body shall appoint a chief executive officer who is qualified through education and experience to be responsible for managing the organization.

CE.2 RESPONSIBILITIES

SR.1 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 as applicable.

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 ORGANIZATION, ACCOUNTABILITY, AND RESPONSIBILITY

SR.1 The medical staff shall be organized in a manner approved by the governing body (see MS.2). The medical staff shall operate under bylaws approved by the governing body and is responsible for the quality of medical care provided to patients by the hospital.

SR.2 The responsibility for organization and conduct of the medical staff shall be assigned to an individual Doctor of Medicine or Osteopathy or, when permitted by state law of the state in which the organization is located, a Doctor of Dental Surgery or Dental Medicine or Doctor of Podiatric Medicine.

SR.3 The governing body shall consult directly with the individual assigned the responsibility for the organization and conduct of the hospital's medical staff, or his or her designee. At a minimum, this direct consultation shall occur periodically throughout the fiscal or calendar year and include discussion of matters related to the quality of medical care provided to patients of the organization. For a multi-hospital system using a single governing body, the single multi-hospital system governing body shall consult directly with the individual responsible for the organized medical staff (or his or her designee) of each hospital within its system in addition to the other requirements of 42 CFR Section 482.12(a).

SR.4 If a hospital is part of a hospital system consisting of multiple separately certified hospitals and the system elects to have a unified and integrated medical staff for its member hospitals, after determining that such a decision is in accordance with all applicable state and local laws, each separately certified hospital shall demonstrate that:

SR.4a The medical staff members of each separately certified hospital in the system (that is, all medical staff members who hold specific privileges to practice at that hospital) have voted by majority, in accordance with medical staff bylaws, either to accept a unified and integrated medical staff structure or to opt out of such a structure and to maintain a separate and distinct medical staff for their respective hospital;

SR.4b The unified and integrated medical staff has bylaws, rules, and requirements that describe its processes for self-governance, appointment, credentialing, privileging, and oversight, as well as its peer review policies and due process rights guarantees, and which include a process for the members of the medical staff of each separately certified hospital (that is, all medical staff members who hold specific privileges to practice at that hospital) to be advised of their rights to opt out of the unified and integrated medical staff structure after a majority vote by the members to maintain a separate and distinct medical staff for their hospital;

SR.4c The unified and integrated medical staff is established in a manner that takes into account each member hospital's unique circumstances and any significant differences in patient populations and services offered in each hospital; and

SR.4d The unified and integrated medical staff establishes and implements policies and procedures to ensure that the needs and concerns expressed by members of the medical staff, at each of its separately certified hospitals, regardless of practice or location, are given due consideration, and that the unified and integrated medical staff has mechanisms in place to ensure that issues localized to particular hospitals are duly considered and addressed.

SR.5 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.5a 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.

Interpretive Guidelines:

The hospital shall have one medical staff for the entire hospital (including all campuses, provider-based locations, satellites, remote locations, etc.). For example, a multi-campus hospital may not have a separately organized medical staff for each campus. On the other hand, in the case of a hospital system, it is permissible for the system to have a unified and integrated medical staff (hereafter referred to as a "unified medical staff") for multiple, separately certified hospitals. The medical staff shall be organized and integrated as one body that operates under one set of bylaws approved by the governing body. These medical staff bylaws shall 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 medical staff is responsible for the quality of medical care provided to patients by the hospital.

The medical staff shall be accountable to the organization's governing body for the quality of medical care provided to patients. The responsibility for organization and conduct of the medical staff shall be assigned to an individual Doctor of Medicine or Osteopathy or, when permitted by state law of the state in which the organization is located, a Doctor of Dental Surgery or Dental Medicine or Doctor of Podiatric Medicine.

All patients shall 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. The hospital CoPs do permit the patient to be under the care of a treating LIP other than a physician. Section 482.12(c)(1) requires every Medicare patient to be under the care of a Doctor of Medicine or Osteopathy; or, within the scope of their respective licenses, a Doctor of Dental Surgery or Dental Medicine, a Doctor of Podiatry, chiropractor, or clinical psychologist. The individual overseeing the patient's care may be the attending physician or a health professional practicing with the delegated authority or supervision of a Doctor of Medicine or Osteopathy as permitted by State law and hospital policy.

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.

If the hospital uses a unified medical staff, only one individual may be responsible for the organization and conduct of the unified medical staff; that individual may or may not hold privileges and practice at the hospital being surveyed.

The governing body is expected to determine the number of consultations needed based on various factors specific to the hospital, or to each of the hospitals within a multi-hospital system. These factors include, but are not limited to, the scope and complexity of hospital services offered, specific patient populations served by a hospital, and any issues of patient safety and quality of care that a hospital's quality assessment and performance improvement program might periodically identify as needing the attention of the governing body in consultation with its medical staff. The organization shall also provide evidence that the governing body is appropriately responsive to any periodic and/or urgent requests from the leader of the medical staff or designee for timely consultation on issues regarding the quality of medical care provided to patients of the hospital. (79 FR 27112, May 12, 2014).

Per the Interpretive Guidelines of 42 CFR Section 482.12(a)(10), "it is expected that consultations occur at least twice during either a calendar or fiscal year."

A hospital that is part of a system consisting of multiple separately certified hospitals may use a single unified and integrated medical staff (hereafter referred to as a "unified medical staff") that is shared with one or more of the other hospitals in the system. In other words, as long as the requirements of 482.22(b)(4) are met, it is not necessary for each separately certified hospital within the system to have its own distinct medical staff organization and structure, including hospital-specific medical staff bylaws, rules and requirements, hospital-specific medical staff leadership, hospital-specific credentialing and peer review, etc. Instead, it may use one medical staff organization and structure for multiple hospitals, so long as all of the requirements of this section are met. However, separately certified hospitals which share a single unified and integrated medical staff shall also share a system governing body, in accordance with the provisions of 482.12, since only one governing body may carry out the governing body's medical staff responsibilities for a unified medical staff.

Note that a multi-campus hospital that has several inpatient campuses that are provider-based, remote locations of the hospital is not a multi-hospital system. A multi-campus hospital is one certified hospital, not several separately certified hospitals. A multi-campus hospital may not have separate medical staffs at each campus, since each hospital shall have no more than one medical staff. A multi-campus hospital with one medical staff separate from that of other certified hospitals is not employing a unified medical staff as that term is used in this regulation. However, a multi-campus hospital that is part of a hospital system consisting of multiple separately certified hospitals may share a unified medical staff with other separately certified hospitals within the system.

It should also be noted that a hospital system that includes certain types of hospitals, e.g., Hospitals-within-Hospitals or Hospital Satellites, that are being paid under a Medicare payment system other than the Hospital Inpatient Prospective Payment System (IPPS) might jeopardize the Medicare payment status of those excluded hospitals if it owns both the tenant and host hospitals and uses a unified medical staff for both. This is the case even if the requirements of §482.22(b)(4) are met. However, surveyors do not assess compliance with or enforce the Medicare payment regulations that govern Hospitals-within-Hospitals or Hospital Satellites.

When granting practitioners privileges to provide patient care, an organization's governing body shall specify those hospitals in the system where the privileges apply, since, in addition to the qualifications of individual practitioners, the services provided at each hospital shall be considered when granting privileges. For example, psychiatric hospitals do not offer surgical services, labor and delivery services, nuclear medicine, etc., so it would not be appropriate for practitioners practicing in these areas to hold privileges at psychiatric hospitals in a multi-hospital system that uses a unified medical staff.

Likewise, if a multi-hospital system covers a wide geographic area, many of its practitioners may have no interest in practicing on site at hospitals that are distant from their usual practice location(s). In addition, in order for the acceptance or opt-out provisions of 482.22(b)(4)(i) and (ii) to be workable, privileges shall be granted on a hospital-specific basis to practitioners who actually practice or are likely to practice at the hospital.

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

- *This does not relieve the governing body of the responsibility to conduct a review of all applicable state and local laws, including regulations, and make a determination that use of a unified medical staff that is shared by multiple hospitals does not conflict with those laws. The hospital shall maintain documentation of this determination by its governing body.*

- *Nor does it relieve the governing body of the obligation to inform the medical staff of the right to vote to opt out of a unified medical staff arrangement. (See discussion of 482.22(b)(4)(ii), which requires notification of all members of this right. Failure to comply would be cited under the tag for 482.22(b)(4)(ii).)*

If a hospital is part of a multi-hospital system that wishes to establish a unified medical staff for some or all of its separately certified hospitals after the July 11, 2014 effective date of the final rule at 482.22(b)(4), then the hospital's system governing body shall document in writing its decision to elect to use the unified medical staff option, conditioned upon acceptance of a unified medical staff by the hospital's medical staff in accordance with 482.22(b)(4)(i).The governing body shall also document its determination that such election does not conflict with state or local laws, including regulations.

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

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.

Validate that the governing body consulted directly with the individual assigned the responsibility for the organization and conduct of the hospital's medical staff, or his or her designee periodically through the fiscal or calendar year.

Verify that if the organization has an executive committee, 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.

Verify that any individual providing patient care services is a member of the medical staff or is accountable to a member of the medical staff qualified to evaluate the quality of services provided, and in turn, is responsible to the governing body for the quality of services provided.

MS.2 ELIGIBILITY

SR.1 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.2 The governing body shall determine, in accordance with state law, which categories of practitioners are eligible candidates for appointment to the medical staff.

SR.3 The medical staff shall include Doctors of Medicine or Osteopathy. In accordance with state law, including scope-of-practice laws, the medical staff may also include other types of practitioners included in the definition of a physician in Section 1861(r) of the Social Security Act and categories of non-physician practitioners determined as eligible for appointment by the governing body.

SR.4 When the hospital utilizes non-physician practitioners who are assigned patient care responsibilities (which may or may not include formal medical staff privileges, but excluding nursing care services), there shall be established policies and procedures, approved by the medical staff and governing body, for overseeing and evaluating their clinical activities. The policies and procedures shall address:

SR.4a Specific type of clinical activities that each class of practitioner will be eligible to perform, consistent with scope of practice under applicable State law;

SR.4b Oversight process by the medical staff over each class of practitioner;

SR.4c Physician supervision or collaboration, as defined by the hospital and in accordance with State law;

SR.4d Process and criteria for reviewing qualifications of each individual practitioner before he/she is permitted to provide patient care; and

SR.4e The process, criteria and frequency for evaluating the performance in providing clinical services by practitioners other than physicians.

SR.5 A candidate who has been recommended by the medical staff and who has been appointed by the governing body for medical staff membership and/or clinical privileges is subject to all medical staff bylaws, rules, and regulations, in addition to the requirements contained in the MS chapter.

Interpretive Guidelines:

The bylaws, rules and regulations shall describe the organization of the medical staff and define the duties and privileges of each category for the medical staff.

The hospital shall have an organized medical staff that is composed of fully licensed Doctors of Medicine or Osteopathy. In accordance with state law and the hospital's medical staff bylaws, the medical staff may also include other types of practitioners included in the definition of a physician in Section 1861(r) of the Social Security Act, including Doctors of Dental Medicine Surgery or Dental Medicine, Doctors of Podiatric Medicine, Doctors of Optometry and chiropractors. The governing body has the option and authority, in accordance with state law, to grant medical staff privileges and membership to these physician practitioners or non-physician practitioners or other licensed healthcare professionals (referred to collectively as "practitioners") (see Section 1842(b)(18)(C) of the Act). Non-physician practitioners may include physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists (CRNA), certified nurse-midwives, clinical social workers, clinical psychologists, anesthesiologist assistants, or registered dietitians/nutrition professionals.

Other types of licensed healthcare professionals have a more limited scope of practice and usually are not eligible for hospital medical staff privileges, unless their permitted scope of practice in their State makes them more comparable to the above listed types of non-physician practitioners. Some examples of types of such licensed healthcare professionals who might be eligible for medical staff privileges, depending on State law and medical staff bylaws, rules and regulations include, but are not limited to Physical Therapists, Occupational Therapists, Speech Language Therapists. Furthermore, some States have established a scope of practice for certain licensed pharmacists who are permitted to provide patient care, services that make them more like the above types of non-physician practitioners, including the monitoring and assessing of patients and ordering medications and laboratory tests. In such States, a hospital may grant medical staff privileges to such pharmacists and/or appoint them as members of the medical staff. There is no standard term for such pharmacists, although they are sometimes referred to as "clinical pharmacists."

It is generally expected that all practitioners granted privileges are also appointed as members of the medical staff. However, if State law limits the composition of the hospital's medical staff to certain categories of practitioners, e.g., only MDs or DOs, or only physician practitioners, there is nothing that prohibits hospitals and their medical staffs from establishing certain practice privileges for those specific categories of practitioners excluded from medical staff membership under State law, or from granting those privileges to individual practitioners in those categories, as long as such privileges are recommended by the medical staff, approved by the governing

body, and in accordance with State law. All practitioners granted medical staff privileges shall function under the bylaws, rules and regulations of the hospital's medical staff. The privileges granted to an individual practitioner shall be consistent with State scope-of-practice laws.

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

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

When the hospital uses licensed practitioners other than physicians to provide patient care, other than nursing care, the hospital's medical staff and governing body shall approve written policies and procedures that establish a system for overseeing and evaluating the quality of the clinical services provided by these non-physician practitioners.

Surveyor Guidance:

Review the bylaws, rules and regulations to verify that the governing body has determined and stated the duties and scope of medical staff privileges for each category of medical staff.

Confirm that the governing body appoints all members to the medical staff and grants privileges 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.

If the hospital grants medical staff privileges and/or membership to physicians who are not MDs/DOs or to non-physician practitioners, ask the hospital and medical staff leadership to describe the process the hospital uses to ensure that any privileges granted are consistent with State law. Ask for documentation that supports their response.

Determine whether the hospital uses licensed practitioners other than physicians to provide care, other than nursing care, within the hospital. If it does, verify that the medical staff and governing body have approved a policy governing the oversight and evaluation of practitioners other than physicians that addresses all required elements of the standard.

Review the credentialing files for each licensed practitioner who is not a physician providing patient care in the hospital to validate that it includes evidence of the practitioner's qualifications, consistent with the hospital's policy, as well as evidence of periodic evaluation of the practitioner's performance.

Ask the hospital and medical staff leadership to describe the process by which they exercise oversight of physician practitioners granted privileges only without medical staff membership.

MS.3 MEDICAL STAFF BYLAWS, RULES AND REGULATIONS

SR.1 Each practitioner who is a member of the medical staff or who holds clinical privileges 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.

Interpretive Guidelines:

The governing body and medical staff shall 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. All practitioners granted clinical privileges (which may or may not include medical staff membership) shall function under the bylaws, rules and regulations of the hospital's medical staff.

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.

MS.4 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 (see also GB.2 (SR.1c)).

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 organization 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 solely based upon certification, fellowship, or membership in a specialty body or society.

MS.5 MEDICAL STAFF PARTICIPATION

The medical staff shall participate in a manner to ensure the effective oversight of:

SR.1 Medication management practices;

SR.2 Infection prevention and control;

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.6 APPOINTMENT, REAPPOINTMENT, AND CLINICAL PRIVILEGING

SR.1 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. Members of the medical staff, as well as practitioners granted clinical privileges without membership, shall be legally and professionally qualified for the positions to which they are appointed and for the performance of any privileges granted.

SR.2 The medical staff shall examine the credentials of all eligible candidates for medical staff membership/appointment 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 This process for examination of credentials and recommendation by the medical staff to the governing body shall also be extended to non-physician practitioners and licensed healthcare professionals who are applying for clinical privileges but are not eligible for medical staff membership.

SR.4 Initial appointment to the medical staff and granting of initial clinical privileges:

SR.4a Primary source verification of licensure, education, specific training, experience, (AMA Master Profile or Osteopathic Physician Profile Report from American Osteopathic Information Association is acceptable) and current competence, including any required certifications;

SR.4a(1) Verification of ECFMG (as applicable);

SR.4b Primary source verification of current Federal Narcotics Registration Certificate (DEA) number (if required);

SR.4c Two peer recommendations;

SR.4d Review of involvement in any professional liability action; and,

SR.4e Receipt of database profiles from/through professional sources (e.g., AMA, AOA, NPDB, OIG, Medicare/Medicaid Exclusions).

SR.5 Reappointment to the medical staff and renewal, revision or amendment of clinical privileges:

SR.5a Primary source verification of current licensure and current competence (AMA Master Profile or Osteopathic Physician Profile Report from American Osteopathic Information Association is acceptable) and any required certifications;

SR.5b Federal Narcotics Registration Certificate (DEA) number (if required);

SR.5c Review of involvement in any professional liability action; and,

SR.5d Receipt of database profiles from NPDB, OIG Medicare/Medicaid Exclusions.

SR.6 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 (initial, renewal, and revision/amendment).

SR.6a Initial privileging:

SR.6a(1) In addition to other privileging criteria defined in the medical staff bylaws or policy/procedure/delineation, the hospital shall determine and document any identified needs for further training or proctoring and/or modification/amendment to initial privileges granted.

SR.6b Renewal and revision/amendment:

SR.6b(1) In addition to other privileging criteria established in the medical staff bylaws or policy/procedure/delineation, as part of the process for determining whether existing clinical privileges will be renewed or require modification/amendment, a review of individual performance data (see MS.8) shall be performed and documented in order to identify variation from defined criteria/benchmarks established by the medical staff.

SR.6b(2) The hospital shall document its process for addressing any identified variation, to include medical staff determination of validity, written explanation of findings and, if appropriate, an action plan to include improvement strategies, the need for further training or proctoring, or amendment to privileges.

SR.7 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 (see also SS).

SR.7a As part of the process for determining the privileges to be granted, the medical staff and governing body consider whether the activity/task/procedure is one that the hospital can support when it is conducted within the hospital.

SR.7b Privileges shall not be granted for tasks/procedures/activities that are not conducted within the hospital, regardless of the individual practitioner's ability to perform them.

SR.8 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.9 The recommendations provided by the medical staff for initial appointments, reappointments, and privileging shall be in writing and include the supporting rationale.

SR.9a If the governing body appoints a candidate or makes a privileging decision contrary to the recommendation of the qualified medical personnel, its rationale for doing so shall be clearly documented.

SR.10 Appointment or reappointments to the medical staff and the granting, renewal, or revision/amendment of clinical privileges shall be made for a period defined by state law or if permitted by state law, not to exceed three years. Reappraisal shall also occur:

SR.10a When a practitioner seeks to perform procedures outside the scope of those originally granted and;

SR.10b As defined in the medical staff bylaws.

SR.11 The medical staff bylaws shall include indications and procedures for automatic and summary suspension of medical staff membership or clinical privileges in any of the following instances:

SR.11a Revocation/restriction of professional license;

SR.11b Revocation/suspension/probation of Federal Narcotics Registration Certificate (DEA);

SR.11c Termination or revocation of the practitioner's Medicare or Medicaid status;

SR.11d Failure to maintain the specified amount of professional liability insurance; or,

SR.11e Non-compliance with written medical record delinquency or deficiency requirements.

SR.12 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 hospital's governing body shall assure that medical staff privileges are granted only to legally and professionally qualified practitioners. "Legally qualified" means the practitioner has a current license to practice within the State where the hospital is located, and that the privileges to be granted fall within that State's permitted scope of practice. The hospital shall verify that each practitioner has a current professional license and document the license in the practitioner's file. "Professionally qualified" means that the practitioner has demonstrated competence in the area for which privileges are sought. Competence is demonstrated through evidence of specialized training and experience, e.g., certification by a nationally recognized professional board.

The medical staff shall develop criteria for the qualifications to be met by a candidate in order to be recommended to the governing body for appointment to the medical staff, as well as criteria

for determining the privileges to be granted to individual practitioners. These criteria shall be included in the bylaws. There shall also be a procedure in place to ensure that these criteria have been met prior to membership or 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.

SR.6: In addition to the minimum criteria outlined at SR.4 and SR.5, the medical staff and governing body shall define the qualifications and criteria to be met in order to grant clinical privileges. These criteria shall be documented in the medical staff bylaws or reference to the corresponding medical staff policies, procedures, or delineations of privileges which have also been approved by the medical staff and governing body. This includes qualifications and criteria for both core and non-core privileges and a process to validate that the criteria have been met prior to granting of the privileges. Core privileges are a defined grouping of privileges for a particular specialty or sub-specialty that include patient care services or procedures that are generally accepted as fundamental and routinely taught in residency and/or fellowship training for that specialty or sub-specialty. However, this does not mean that each individual practitioner within that category/specialty can automatically be granted the full range of privileges included under the core and it cannot be assumed that every practitioner can perform every task/procedure/activity that is included in the core or within the scope of practice for that specialty of practitioner. The organization shall have a mechanism to modify an individual's core privileges if the applicant is deemed not qualified or competent, as well as a process for ensuring that applicants are aware of how to "opt out" of requesting a particular privilege, even if it is included in the core.

When non-core privileges (commonly referred to as "additional" or "special" privileges) are granted, the medical staff and governing body shall define the specific criteria (i.e., additional training, experience, and competency) that shall be met to grant the non-core privileges. "Special" privileges often involve the use of advanced technology or those that cross specialties. Common non-core privileges include, but are not limited to administration of sedation, use of fluoroscopy equipment, robotic surgery, ultrasound, stereotactic radiosurgery, and insertion of central venous catheters. It is possible for a privilege to be considered a core privilege for a particular specialty, but non-core for others.

Privileges cannot be granted for tasks/procedures/activities not conducted within the hospital despite the practitioner's ability to perform the requested tasks/procedures/activities.

All members of the hospital's medical staff and all practitioners granted medical staff privileges shall be appointed to their position by the hospital's governing body. They shall be granted privileges by the governing body, in writing, that specify in detail the types of procedures they may perform. It is not sufficient for the governing body to grant privileges to "perform surgery" or even to perform "orthopedic surgery." For example, a hospital that offers orthopedic surgery of various types shall specify which types of procedures each surgeon is privileged to perform.

The governing body is required to solicit the opinion of qualified medical personnel on the competence of applicants for privileges. The recommendation provided shall be in writing and include a supporting rationale. The qualified medical personnel may be current members of the hospital's medical staff but may also be physicians not practicing in the hospital. The organization should consider seeking the recommendations of qualified outside physicians when they do not have appropriate expertise in-house to evaluate the competency of an applicant for privileges. The hospital's governing body is not required to accept the recommendation provided by the qualified medical personnel to grant, deny, or restrict

privileges to a practitioner. However, if the governing body makes a decision contrary to the recommendation, it is expected to document its rationale for doing so.

Based on review of the qualifications addressed for reappointment, the governing body shall decide whether to continue the practitioner's current privileges without change, or to amend those privileges by contracting or expanding them, or by withdrawal of the practitioner's privileges entirely. The hospital shall also reappraise a practitioner any time the practitioner seeks to perform procedures, treatments, etc. outside the scope of privileges previously granted. The hospital shall also develop triggers for reappraisal of privileges outside the periodic reappraisal schedule.

The medical staff shall 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;*
- *Termination or revocation of the practitioner's Medicare or Medicaid status;*
- *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.*

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:

Sample records of medical staff appointments to determine that the governing body is involved in the initial appointment and reappointment of medical staff members, as well as any privileging decisions. Verify that there are written criteria for appointments/reappointments to the medical staff and for clinical privileges granted to individual practitioners (initial, renewal, revision/amendment) and that a procedure exists for applying these criteria.

Review and verify the mechanism to examine credentials of individual prospective members (new appointments, reappointments, and clinical privileging) by the medical staff, including evidence that data on the practitioner's practice is considered along with the practitioner's credentials.

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

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.7 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.7 (SR.3) will apply for granting temporary privileges.

Surveyor Guidance:

Review and verify that the organization 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.8 PERFORMANCE DATA

Practitioner specific performance data for physicians and other practitioners who have been granted clinical privileges 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 defined by medical staff policy/procedure.

SR.1 Performance data will be collected:

SR.1a Periodically within the reappointment period, as defined by medical staff policy/procedure;

SR.1b As required as a part of the peer review process; and,

SR.1c Be utilized for reappointment, reappraisal, and renewal of privileges.

SR.1d In order to monitor the clinical performance of physicians with clinical privileges, the areas required to be measured (as applicable to the practitioner's specialty and privileges granted) shall include:

SR.1d(1) Utilization data;

SR.1d(2) Timely and legible completion of patients' medical records;

SR.1d(3) Prescribing of medications: prescribing patterns, trends, errors and appropriateness of prescribing for Drug Use Evaluations;

SR.1d(4) Blood use (may include AABB transfusion criteria);

SR.1d(5) Readmissions/unplanned returns to surgery (as defined);

SR.1d(6) Appropriateness of care for non-invasive procedures/interventions;

SR.1d(7) Surgical Case Review: appropriateness and outcomes for procedures as defined by the medical staff, including but not limited to:

SR.1d(7)(i) Post-surgical infection rates;

SR.1d(7)(ii) Surgical complications;

SR.1d(8) Anesthesia/Moderate Sedation Adverse Events;

SR.1d(9) Mortalities;

SR.1d(10) Specific department indicators that have been defined by the medical staff;

SR.1d(11) Significant deviations from nationally recognized standards of

practice and guidelines; and,

SR.1d(12) Any variant that should be analyzed for statistical significance.

SR.2 Performance data shall include comparative and/or national data when available. In the absence of available comparative and/or national data, the medical staff shall determine the appropriate thresholds which would indicate the need for further analysis.

SR.3 The governing body and medical staff shall approve written policies and procedures that address the process, criteria, and frequency for evaluating the clinical performance and competency of other practitioners (non-physicians) with clinical privileges.

Interpretive Guidelines:

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

"Physician" is defined in §1861(r) of the Social Security Act as:

- *Doctor of Medicine or Osteopathy;*
- *Doctor of Dental Surgery or of Dental Medicine;*
- *Doctor of Podiatric Medicine;*
- *Doctor of Optometry with respect to services legally authorized to be performed in the State; and*
- *Chiropractor with respect to treatment by manual manipulation of the spine (to correct subluxation diagnosed by x-ray).*

The organization shall define and measure the respective elements under MS.8 (SR.2) to generate a quality profile for each physician to be used for evaluation as a part of the appointment and reappointment process, as well as periodically during the reappointment period for reappraisals as defined by medical staff policy/procedure.

Specialty-specific indicators to be defined by the medical staff may be informed by the American College of Surgeons, National Quality Forum, Agency for Healthcare Research and Quality and other professional bodies, societies, and associations. Consideration may also be given to those measures required by the CMS Quality Reporting and Value-Based Programs and Initiatives.

The governing body and medical staff shall approve written policies and procedures that address the process, criteria, and frequency for evaluating the clinical performance of other practitioners (non-physicians) with clinical privileges in the hospital.

Surveyor Guidance:

Verify that the governing body is periodically apprised of the evaluation of patient care services provided by both physicians and other practitioners.

Verify that the governing body and medical staff have developed and approved written policies and procedures that address the process, criteria, and frequency for evaluating the clinical performance and competency of other practitioners (non-physicians) with clinical privileges.

Sample quality profiles or other documentation for physicians and other practitioners to validate that this data is being measured and a part of the appointment and reappointment process, as well as periodically during the reappointment period as defined by medical staff policy/procedure.

The required performance data can come from a variety of different places in the hospital (e.g., medical record review, incident or adverse event reports, customer feedback).

The hospital can determine thresholds and report performance data by exception if desired. However, the performance profile should indicate that an assessment of those applicable elements was completed.

MS.9 REQUIRED EDUCATION AND TRAINING

All individuals with delineated clinical privileges shall meet the training and education requirements for state licensure renewal, maintenance of registration or certification, and of the organization in order to be eligible for clinical privileges.

SR.1 The organization shall have a process to validate that education and/or training required by the organization is met prior to the granting or renewal of affected clinical privileges (see also MS.6 (SR.6)).

SR.1a Documentation shall be made available and considered in decisions for appointment, reappointment, and clinical privileging.

SR.1b Action on an individual's application for appointment, reappointment, initial and subsequent clinical privileges is withheld until the information is available and verified.

SR.2 The organization shall have a process for ensuring that training and/or education required by the organization, federal and state law or regulation, or otherwise imposed by standard requirements (OR fire safety, OSHA bloodborne pathogens, restraint and seclusion, etc.) has been completed.

Interpretive Guidelines:

When the hospital has defined requirements for training and/or education that must be met in order for certain clinical privileges to be granted, especially for special privileges (see MS.6), there shall be a process for validating that the training and education requirements have been met prior to granting or renewing the affected clinical privileges. This criteria may be addressed in the medical staff bylaws, on a delineation of privileges form, or accompanying special privilege request form. Documentation (e.g., training/education records) supporting that the criteria has been met is required for this process.

The organization shall also have a process to validate completion of:

- *Any other training/education requirements imposed by the hospital as part of orientation or on an ongoing basis, such as annual (or other frequency) required education.*

- *Training/education required by federal and state law or regulation or standard requirements (OR fire safety, OSHA bloodborne pathogens, restraint and seclusion, etc.).*

Hospitals are not required by this standard to maintain documentation for CMEs required for state licensure renewal or maintenance of registration or certification, since these are already subject to audit from those licensing or certification bodies. However, the hospital shall comply with any requirements included in the medical staff bylaws, rules and regulations, and hospital policy/procedure.

MS.10 CORRECTIVE OR REHABILITATIVE ACTION

SR.1 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 shall 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 organization 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.11 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 Section 410.71 and only to the extent permitted by state law.

SR.2 If a Medicare or Medicaid patient is admitted by a practitioner not specified in SR.1 (SR.1a-SR.1f) above, that patient is under the care of a Doctor of Medicine or Osteopathy.

SR.3 The governing body shall ensure that:

SR.3a A Doctor of Medicine or Osteopathy is on duty or on call at all times; and,

SR.3b 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.11 (SR.1b-1f) as that scope of practice is defined by the medical staff and state law.

Interpretive Guidelines:

All patients shall 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. The hospital CoPs do permit the patient to be under the care of a treating LIP other than a physician. Section 482.12(c)(1) requires every Medicare patient to be under the care of a Doctor of Medicine or Osteopathy; or, within the scope of their respective licenses, a Doctor of Dental Surgery or

Dental Medicine, a Doctor of Podiatry, chiropractor, or clinical psychologist. The individual overseeing the patient's care may be the attending physician or a health professional practicing with the delegated authority or supervision of a Doctor of Medicine or Osteopathy as permitted by State law and hospital policy.

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.

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 a licensed practitioner (as defined by MS.11 (SR.1)).

CMS hospital regulations do permit licensed practitioners (i.e., Doctors of Dental surgery, Dental Medicine, podiatric medicine, or optometry; chiropractors; or clinical psychologists), as allowed by the State, to admit patients to a hospital. However, CMS does require that Medicare and Medicaid patients who are admitted by a Doctor of Dental Surgery, Dental Medicine, podiatric medicine, or optometry; a chiropractor; or clinical psychologist be under the care of a MD/DO with respect to any medical or psychiatric problem that is present on admission or develops during hospitalization that is outside the scope of practice of the admitting practitioner. If a hospital allows a Doctor of Dental Surgery, Dental Medicine, podiatric medicine, or optometry, a chiropractor or a clinical psychologist to admit and care for patients, as allowed by State law, the governing body and medical staff shall establish policies and bylaws to ensure that the requirement for Medicare and Medicaid patients to be under the care of an MD/DO with respect to any medical or psychiatric problem that is present on admission or develops during hospitalization that is outside the admitting practitioner's scope of practice is met. As applicable, the patient's medical record shall demonstrate MD/DO responsibility/care.

CMS hospital regulations do permit licensed non-physician practitioners (e.g., nurse practitioners, physician assistants, etc.), as allowed by the State, to admit patients to a hospital, and CMS does not require these practitioners be employed by a MD/DO. However, CMS regulations do require that Medicare and Medicaid patients admitted by these practitioners be under the care of an MD/DO. Evidence of being under the care of an MD/DO shall be in the patient's medical record. If a hospital allows these non-physician practitioners to admit and care for patients, as allowed by State law, the governing body and medical staff would have to establish policies and bylaws to ensure that the requirement for Medicare and Medicaid patients to be under the care of an MD/DO, when admitted by a non-physician practitioner, is met.

CMS requires ONLY Medicare patients of a midwife be under the care of a Doctor of Medicine or Osteopathy. CMS DOES NOT require Medicaid or other non-Medicare patients admitted by a midwife to be under the care of a Doctor of Medicine or Osteopathy.

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 shall 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 (e.g., 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.

Verify that an assigned Doctor of Medicine or Osteopathy is responsible for and is monitoring the care of each Medicare or Medicaid patient with respect to all medical or psychiatric problems during the hospitalization.

If non-MD/DOs admit patients, verify that every Medicare/Medicaid 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. All Medicare and Medicaid patients (only Medicare patients for midwives) that are admitted to the hospital by a practitioner not defined under SR.1b-1f shall be under the care of an MD/DO.

MS.12 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 shall be defined policies and procedures for dealing with medical record delinquencies.

The process for medical records completion and the actions taken shall be enforced by organization policy.

In order to ensure that there is an effective process in place, the medical staff shall 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 by laws, 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.13 HISTORY AND PHYSICAL OR OUTPATIENT ASSESSMENT

SR.1 The medical staff bylaws shall include a requirement that a medical history and physical examination (H&P) for each patient shall be completed and documented in the medical record no more than 30 days before or 24 hours after an admission or registration, and prior to surgery, or procedures requiring anesthesia services, and placed in the patient's medical record within 24 hours after admission. The H&P shall be in the medical record prior to surgery or other procedure requiring anesthesia services.

SR.1a An H&P completed within 30 days prior to admission or registration shall include an update 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, oral and maxillofacial surgeon or other LP who has been granted these privileges by the medical staff in accordance with state law.

SR.1b Any H&P update of the patient's current medical condition shall document:

SR.1b(1) That the patient has been examined;

SR.1b(2) That the H&P has been reviewed;

SR.1b(3) Any changes in the patient's condition; or,

SR.1b(4) That ''no change'' has occurred in the patient's condition since the H&P was completed.

SR.1c 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, and prior to surgery or other procedure requiring anesthesia services.

SR.2 A Doctor of Medicine or Osteopathy, or oral and maxillofacial surgeon shall perform the H&P described above. Alternatively, a LP 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.13 (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 shall be in the medical record prior to any surgery, or other procedure requiring anesthesia services and within 24 hours of admission or registration as stated in MS.13 (SR.1).

SR.4 Outpatient assessment: The medical staff may elect to permit an outpatient assessment rather than an H&P for patients receiving specific outpatient surgical or procedural services. If the medical staff chooses to allow assessments for specific outpatient surgical or procedural services, the medical staff shall:

SR.4a Develop and maintain a policy that identifies specific patients as not requiring a comprehensive medical history and physical examination, or any update to it, prior to specific outpatient surgical or procedural services. The policy shall:

SR.4a(1) Demonstrate evidence that the policy applies only to those patients receiving specific outpatient surgical or procedural services: and,

SR.4a(2) Demonstrate evidence that the policy is based on:

SR.4a(2)(i) Patient age, diagnoses, the type and number of surgeries and procedures scheduled to be performed, comorbidities, and the level of anesthesia required for the surgery or procedure;

SR.4a(2)(ii) Nationally recognized standards of practice and guidelines for assessment of specific types of patients prior to specific outpatient surgeries and procedures; and,

SR.4a(2)(iii) Applicable state and local health and safety laws.

SR.4b Ensure that the outpatient assessment is:

SR.4b(1) Completed and documented by a Doctor of Medicine or Osteopathy (as defined in section 1861(r) of the Act), an oral and maxillofacial surgeon, or other LP in accordance with state law and hospital policy;

SR.4b(2) Completed and documented after registration, but prior to the outpatient surgery or procedure requiring anesthesia services.

Interpretive Guidelines:

The medical record shall be completed by an authorized practitioner and contain an H&P as required for all inpatients and applicable outpatients. The H&P shall be performed no more than 30 days prior to admission (or procedure or service that requires a H&P) or within 24 hours after admission, and prior to any surgery or procedures requiring anesthesia services unless the medical staff has approved outpatient assessments for specific outpatient surgical or procedural services.

Surveyor Guidance:

Determine that the medical records contain an H&P or outpatient assessment.

MS.14 CONSULTATION

SR.1 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.15 TELEMEDICINE

SR.1 The governing body shall ensure that, when telemedicine services are furnished to the hospital's patients through an agreement with a distant-site telemedicine entity, the written agreement specifies that the distant-site telemedicine entity is a contractor of services to the hospital and as such, in accordance with GB.4, 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 (SR.2), MS.4 (SR.1 and SR.3)) with regard to the distant-site telemedicine entity's physicians and practitioners providing telemedicine services.

SR.1a The distant-site entity shall meet the following requirements:

SR.1a(1) Determine, in accordance with state law, which categories of practitioners are eligible candidates for appointment to the medical staff.

SR.1a(2) Appoint members of the medical staff after considering the recommendations of the existing members of the medical staff.

SR.1a(3) Assure that the medical staff has bylaws.

SR.1a(4) Approve medical staff bylaws and other medical staff rules and regulations.

SR.1a(5) Ensure that the medical staff is accountable to the governing body for the quality of care provided to patients.

SR.1a(6) Ensure the criteria for selection are individual character, competence, training, experience, and judgment.

SR.1a(7) Ensure that under no circumstances is the accordance of staff membership or professional privileges in the hospital dependent solely

upon certification, fellowship or membership in a specialty body or society.

SR.1b 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.6, 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. The hospital's governing body shall also ensure, through its written agreement with the distant-site telemedicine entity, that all of the following provisions are met:

SR.1b(1) 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)(1) through (a)(7) and 482.22(a)(1) through (a)(2).

SR.1b(2) 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.1b(3) 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.1b(4) 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 shall 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.1c The distant-site telemedicine entity may or may not be a Medicare- participating provider or supplier. This is at the discretion of the organization to require this as a condition of the agreement with the distant-site entity.

SR.2 The governing body shall ensure that, when telemedicine services are furnished to the hospital's patients through an agreement with a distant-site hospital, the agreement is written and that it specifies that it is the responsibility of the governing body of the distant-site hospital to meet the requirements in Medical Staff (MS.2, MS.3 (SR.2),

MS.4 (SR.1 and SR.3)) and Governing Body (GB.2 (SR.1c)) with regard to the distant-site hospital's physicians and practitioners providing telemedicine services:

SR.2a The distant-site hospital shall meet the following requirements:

SR.2a(1) Determine, in accordance with state law, which categories of practitioners are eligible candidates for appointment to the medical staff.

SR.2a(2) Appoint members of the medical staff after considering the recommendations of the existing members of the medical staff.

SR.2a(3) Assure that the medical staff has bylaws.

SR.2a(4) Approve medical staff bylaws and other medical staff rules and regulations.

SR.2a(5) Ensure that the medical staff is accountable to the governing body for the quality of care provided to patients.

SR.2a(6) Ensure the criteria for selection are individual character, competence, training, experience, and judgment.

SR.2a(7) Ensure that under no circumstances is the accordance of staff membership or professional privileges in the hospital dependent solely upon certification, fellowship or membership in a specialty body or society.

SR.2b 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.6, 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.2b(1) The distant-site hospital providing the telemedicine services is a Medicare-participating hospital.

SR.2b(2) 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.2b(3) 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.2b(4) 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 shall 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 CoP and NIAHO® accreditation requirements, particularly those requirements related to the credentialing and privileging of practitioners providing telemedicine services to the patients of a hospital.*

The hospital's governing body shall grant privileges to each telemedicine physician or practitioner providing services at the hospital under an agreement with a distant-site hospital or telemedicine entity before they may provide telemedicine services. The scope of the privileges in the hospital shall reflect the provision of the services via a telecommunications system. For example, a surgeon at a distant-site hospital may provide telemedicine consultation services at a hospital under agreement but obviously would not be able to perform surgery by this means

and shall not have surgical privileges in the hospital as part of his/her telemedicine services privileges. If the surgeon also periodically performed surgery on-site at the hospital, then he or she would have to have privileges to do so, granted in the traditional manner provided for at §482.12(a)(1) through §482.12(a)(7) and §482.22(a)(1) and §482.22(a)(2).

In granting privileges to telemedicine physicians and practitioners, the hospital's governing body has the option of considering hospital medical staff recommendations that rely, in accordance with §482.22(a)(3) and §482.22(a)(4), upon the credentialing and privileging decisions of the distant-site hospital or telemedicine entity.

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

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

Surveyor Guidance:

Review agreements with any distance-site telemedicine providers to validate that the agreements contain the required elements concerning credentialing and privileging of the telemedicine physicians and practitioners.

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.

Verify that the hospital has documentation indicating that it granted privileges to each telemedicine physician and practitioner. Does the documentation indicate that for each telemedicine physician and practitioner there is a medical staff recommendation, including an indication of whether the medical staff conducted its own review or relied upon the decisions of the distant-site hospital or telemedicine entity?

Validate that the hospital has a mechanism to review the services provided by the telemedicine physicians and practitioners, including any adverse events and complaints, and provides feedback to the distant-site hospital or entity.

NURSING SERVICES (NS)

NS.1 NURSING SERVICE

SR.1 The organization shall 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 shall supervise and evaluate the nursing care for all patients. A registered nurse shall be on duty at all times except in facilities that have been granted a waiver in accordance with 42 CFR Section 488.54(c), federal law, rules or regulations.

SR.3 The nursing service shall develop and maintain a procedure to ensure that nursing personnel for whom licensure is required have a valid and current licensure. Nursing services shall 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 shall 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 All licensed nurses and clinical staff who provide services in the hospital shall adhere to the policies and procedures of the hospital.

SR.6a All licensed clinical staff will follow orders for care and treatment of the patient.

SR.6a(1) If a clinician is unable to implement an order as written, the order shall be clarified and/or changed and the communication with the provider shall be documented.

SR.6b All staff providing clinical care services under the direction and delegation of nursing staff will adhere to the policies and procedures of the hospital.

SR.7 The director of nursing service shall provide for the adequate supervision and evaluation of the clinical activities of all nursing personnel that occur within the responsibility of the nursing service, regardless of the mechanism through which those personnel are providing services (that is, hospital employee, contract, lease, other agreement, or volunteer).

SR.8 The hospital shall have policies and procedures in place establishing which outpatient departments, if any, are not required under hospital policy to have a registered nurse present. The policies and procedures shall:

SR.8a Establish the criteria such outpatient departments shall meet, taking into account the types of services delivered, the general level of acuity of patients

served by the department, and the established nationally recognized standards of practice and guidelines for the services delivered;

SR.8b Establish alternative staffing plans;

SR.8c Be approved by the director of nursing; and,

SR.8d Be reviewed at least once every 3 years.

Interpretive Guidelines:

The hospital shall have an organized nursing service and shall 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.

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).

The nursing service must ensure that patient needs are met by ongoing assessments of patients' needs and provides nursing staff to meet those needs. There must be sufficient numbers, types and qualifications of supervisory and staff nursing personnel to respond to the appropriate nursing needs and care of the patient population of each department or nursing unit.

A registered nurse shall 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 nurse executive shall 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 shall provide nursing services 24 hours a day, 7 days a week. An LPN/LVN can provide nursing services if an RN supervises that care. The RN shall be immediately available for the bedside care of those patients.

Every inpatient unit/department/location within the hospital-wide nursing service must have adequate numbers of RNs physically present at each location to ensure the immediate availability of a RN for the care of any patient.

A RN would not be considered immediately available if the RN were working on more than one unit, building, floor in a building, or provider (distinct part SNF, RHC, excluded unit, etc.) at the same time.

Exception for small and rural hospitals: CMS Conditions of Participation Section 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 Location. The hospital shall 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:

- *Organization chart(s) for nursing services for all locations where the hospital provides nursing services;*
- *Job descriptions or descriptions 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.

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.

Review samples of the following documentation:

- *Staffing schedules;*
- *Unit assignment sheets;*
- *Nursing policies and procedures; and (verify the DON has involvement with or approved the nursing policies and procedures. See NS.2 (SR.3)*
- *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.*

When contracted (non-employee) personnel are used by the organization, these individuals shall 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.

Verify that all staff under the direction and delegation of licensed professionals adhere to hospital policies and procedures.

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. See also GB.4 (SR.1).

(Exception for small and rural hospitals: CMS Conditions of Participation 42 CFR Section 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 Location.)

The following shall 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.

NS.2 NURSE EXECUTIVE

SR.1 The nurse executive shall be a licensed registered nurse with either a master's degree, actively pursuing a master's degree or equivalent experience in comparable positions as defined by the organization.

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 shall be appropriately qualified. The nurse executive shall have a nursing master's degree, or is actively pursuing a nursing master's degree, or can demonstrate the equivalent experience in comparable positions as defined by the organization. The hospital may have only one nursing service hospital-wide and one single nurse executive.

Operation of service:

The nursing service shall 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 shall 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 shall 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.

Surveyor Guidance:

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 organization 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 PLAN OF CARE

SR.1 The hospital shall ensure that the nursing staff develops, and keeps current, a nursing care plan for each patient that reflects the patient's goals and the nursing care to be provided to meet the patient's needs.

SR.2 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.

SR.3 Hospital policy determines the process for adding nursing diagnosis and co-morbidities to the nursing care plan.

SR.4 The patient's plan of care is reviewed and revised, and updated at regular intervals, as necessary and as defined in hospital policy.

SR.5 The patient and/or patient representative shall have the right to be involved in the development and implementation of the plan of care. The nursing care plan may be part of an interdisciplinary care plan.

Interpretive Guidelines:

Nursing care planning starts upon admission. It includes planning the patient's nursing care to meet the patient's needs and interventions toward meeting patient treatment goals while in the hospital as well as planning for discharge to meet post-hospital needs. A nursing care plan is based on assessing the patient's nursing care needs (not solely those needs related to the admitting diagnosis). The assessment considers the patient's treatment goals and, as appropriate, physiological and psychosocial factors and patient discharge planning. The plan develops appropriate nursing interventions in response to the identified nursing care needs. The nursing care plan is kept current by ongoing assessments of the patient's needs and of the patient's response to interventions, assessment of patient treatment goals, and updating or revising the patient's nursing care plan in response to assessments. The nursing care plan is part of the patient's medical record and shall comply with the medical records requirements at §482.24.

The hospital CoP governing patients' rights at §482.13(b) provides that "The patient has the right to participate in the development and implementation of his or her plan of care." (CMS views discharge planning as part of the patient's plan of care). A patient's goals and preferences may be, in the hospital's view, unrealistic. Identifying divergent hospital and patient assessments of what is realistic enables a discussion of these differences and may result in an assessment and subsequent development of a discharge plan that has a better chance of successful implementation.

Hospitals have the flexibility of developing the nursing care plan as part of a larger, coordinated interdisciplinary plan of care. This method may serve to promote communication among disciplines and reinforce an integrated, multi-faceted approach to a patient's care, resulting in better patient outcomes. The interdisciplinary plan of care does not minimize or eliminate the need for a nursing care plan. It does, however, serve to promote the collaboration between

members of the patient's health care team.

Surveyor Guidance:

Select a sample of nursing or interdisciplinary care plans. Approximately 6-12 plans should be reviewed. For each plan reviewed, with respect to the nursing care component:

- *Was the plan initiated as soon as possible after admission for each patient?*
- *Does the plan describe and reflect patient goals as part of the patient's nursing care assessment and, as appropriate, physiological and psychosocial factors and patient discharge planning?*
- *Is the plan consistent with the plan for medical care of the practitioner responsible for the care of the patient?*
- *Is there evidence of reassessment of the patient's nursing care needs and response to nursing interventions and, as applicable, revisions to the plan?*
- *Was the plan implemented in a timely manner?*

NS.4 ASSESSMENT-REASSESSMENT

SR.1 Nursing staff shall complete an assessment of a patient's condition within twenty-four hours of admission to an inpatient setting.

SR.1a The hospital will determine where the elements of this assessment are documented.

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

SR.2a Allergies;

SR.2b Admitting problem;

SR.2c History of pain and current status;

SR.2d Preexisting or other condition (e.g., Pregnancy, COPD, Diabetes);

SR.2e Current medications (including any illicit drugs);

SR.2f ADL needs; and,

SR.2g Dietary Requirements.

SR.3 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.4 Nursing staff will reassess the patient at regularly defined intervals and if the patient's condition changes.

Surveyor Guidance:

Select a sample of medical records to review the following:

- *Nursing assessments;*
- *Nursing re-assessments;*
- *Nursing notes; and,*
- *Medication administrations records (MARs).*

STAFFING MANAGEMENT (SM)

SM.1 LICENSURE OR CERTIFICATION

SR.1 The organization shall have a policy and practice for outlining and verifying that each staff member possesses a valid and current license or certification, along with training, education, and minimum qualifications as required by the organization and federal and state law. This written policy shall be strictly enforced, with compliance data reported and escalated per the organization's policy and process.

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.

Verify there is a process in place for determining minimum qualifications, along with any education or training that may be required by federal and state law or the organization. Validate through a sample of personnel files that required criteria has been met.

Review the practice for reporting compliance data and ensuring escalation of expired licensure and/or certification per the organization's policy and process.

SM.2 PROFESSIONAL SCOPE

SR.1 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 shall be strictly enforced and include a documented process for reporting variations to Quality Management Oversight.

Surveyor Guidance:

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 there is a documented process for communicating identified variations to Quality Management Oversight. Review any variation that the organization has identified over the past year to validate the process for reporting to Quality Management Oversight is implemented. Ensure that the process aligns with the organization's process for compliance to QM.5.

SM.3 DEPARTMENT SCOPE OF SERVICE

Each department, whether clinical or supportive, including offsite locations 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 shall be reviewed and updated (e.g., 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, to include offsite locations 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;*
- *Description of assessment and reassessment, including timeframes. The intent is primarily that of departments, locations or units performing patient assessments/reassessments.*

The hospital will describe and illustrate the sequence and interaction of these processes (services). See ISO 9001:2015; 4.4 Quality management system and its processes / 4.4.1.

Surveyor Guidance:

Verify that the hospital has a description of the scope of services, provided for all services including clinical or supportive and encompasses all offsite locations and 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 hospital shall document its method for determining and modifying staffing in order to ensure that staffing is sufficient to care for individual patients' needs and to provide the services essential to the operation of the organization.

SR.2 The hospital shall:

SR.2a Document variance from core staffing;

SR.2b Outline justification for variance; and

SR.2c Link that justification with patient and process outcomes, including any untoward patient events or process failures.

SR.3 Reporting of variances to Quality Management Oversight and other appropriate committees shall occur as defined by organization policy/procedure.

Interpretive Guidelines:

The hospital will document a method for determining and modifying staffing. Adequate staffing will be validated through reporting of variance from core staffing, outline the justification for variance, and link for that justification with patient and process outcomes, including any untoward patient events or process failures. Variances will be reported to Quality Management Oversight and other appropriate committees, as defined by organization policy/procedure. At a minimum, trends in variances and untoward patient events or process failures will be reported to Quality Management Oversight.

Surveyor Guidance:

Review and verify the documented method(s) used by the hospital for determining and modifying staffing, ensuring there is a process to document variance from core staffing, justify and link those variances to patient and process outcomes, including but not limited to, untoward patient events or process failures.

Validate that there is a means in place for reporting variances and other associated information to Quality Management Oversight and other appropriate committees as required by organization policy/procedure. Validate that the organization is, at a minimum, reporting trends in variances to Quality Management Oversight.

SM.5 JOB DESCRIPTION

SR.1 All employed staff, whether clinical or supportive, shall have a current job description available that contains the required experience and/or education, any physical requirements, supervision (as indicated), duties, responsibilities and performance expectations for that position, as required by federal and state law or by the organization.

SR.2 The organization shall document the requirements to be met by relevant contracted staff, students, and volunteers. At a minimum, the following will be addressed:

SR.2a Required experience and education, supervision (as indicated), duties, responsibilities, and performance expectations;

SR.2b A means to communicate the above requirements to the contracted service, learning institution, or volunteer organization; and

SR.2c The method to be used by the hospital to validate that any relevant requirements (e.g., license, certification) are met by individuals prior to providing services to the hospital's patients.

Interpretive Guidelines:

Contracted staff, students, and volunteers are not required to have an individual job description. However, the organization shall document the requirements to be met by these entities and establish a means to communicate those requirements to the contracted service, learning institution, or volunteer organization. The organization shall establish a method to ensure that any relevant requirements are validated as met prior to these entities providing services on behalf of the hospital. The organization may choose to provide these individuals with a job description, but this is not required.
For purposes of this standard, the definition of contracted staff does not include vendors who are providing products or supplies alone. Contracted staff include individuals providing direct patient care or integral patient services such as dietary services, housekeeping, treatment services, diagnostic services, medical equipment or facility equipment servicing, etc.).

Surveyor Guidance:

Review and verify a sampling of employee job descriptions to verify that the organization has identified the following:

- *Required experience and/or education*
- *Any physical requirements*
- *Supervision (as indicated)*
- *Duties and responsibilities of the position*
- *Performance expectations for the position*

Validate that the organization has defined (documented) the requirements to be met by relevant contracted staff, students, and volunteers and addresses the minimum content at (SR.2a-SR.2c). In a sampling of relevant files, validate that the requirements defined by the organization have been met according to their process.

SM.6 ORIENTATION AND CONTINUING EDUCATION

SR.1 All staff, whether clinical or supportive, including contract staff, students and volunteers, shall receive a general orientation prior to providing care or services to the hospital or its patients.

SR.2 All staff, whether clinical or supportive, including contract staff and volunteers shall:

SR.2a 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.2b Participate in annual education as required by federal and state law and regulation and the organization.

SR.3 Each staff member, including contract staff, shall participate in continuing education as required by individual licensure/certification, professional association, law or regulation, or organization policy.

SR.4 Members of the medical staff shall:

SR.4a Receive a general orientation developed and approved by the organization that includes general safety practices, emergency procedures, infection control, confidentiality and other issues as required by federal and state law and regulation and the organization.

SR.4b Participate in annual education as required by federal and state law and regulation and the organization.

SR.4c Meet the continuing education and training requirements of MS.9.

Interpretive Guidelines:

The hospital will require that all staff, including contract staff, students and volunteers receive a general orientation prior to providing care or services to the hospital or its patients.

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

- *Organization 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 shall be addressed within the department or service where the individual is assigned and completed prior to working independently. Orientation to specific job duties is not required for students, since students will be providing services or care under supervision/instruction and are not working independently.

Members of the medical staff shall complete a general orientation as noted within SM.6 (SR.4a).

The hospital will require that all staff, including contract staff and volunteers, and medical staff receive annual education per federal and state law and as required by the organization.

In order to continually improve the fulfillment of their job responsibilities, 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. Medical staff shall meet the continuing education and training requirements as defined in the MS chapter.

Contract Staff

The requirement for contract staff to have a general orientation and orientation to specific job duties, responsibilities, and their work environment is intended to apply only to those contract staff who are working independently and providing direct patient care or an integral support service that is comparable to services that would be provided by the organization's employed staff such as dietary services, housekeeping, treatment services, diagnostic services, medical equipment maintenance, etc. Independently means that the contract staff member does not have direct supervision by hospital staff. The definition of contracted staff does not include vendors who provide products or supplies alone.

In situations where the hospital outsources an entire service, such as medical equipment maintenance, it is not the expectation that the hospital will provide the orientation to specific job duties and responsibilities, since these duties are inherent with the contractual agreement and would be provided by the external provider. In these situations, the hospital is expected to provide general orientation and orientation to the relevant or unique aspects of the work environment only (this may be brief). The hospital and external provider should communicate with each other for any annual education or continuing education requirements, including who is responsible for providing the education and maintaining records. In the event that the hospital does not maintain these records on-site, records shall be available from the external provider upon request.

The organization has the option to provide some level of orientation for other types of contract staff that do not meet the above criteria but provide frequent services to the organization. However, this is not explicitly required. In determining whether it is necessary to provide orientation-type information to these individuals, the organization should consider the type of service being provided, frequency of service, the impact to operations or patient care, and risk to the organization.

Surveyor Guidance:

Verify the process in place for providing a general orientation to employed staff, relevant contract staff, students, volunteers and medical staff as noted within SM.6. Verify through a sample of employed and relevant contract staff files that both general orientation and orientation to specific job duties and responsibilities was completed prior to the staff working independently.

Verify through discussion with staff responsible for internal education and a sample of employed staff, relevant contract staff, and medical staff files that the annual education process is

implemented and compliant with SM.6.

Verify that the organization 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 organization policy.

SM.7 COMPETENCY ASSESSMENT AND PERFORMANCE APPRAISAL

SR.1 The organization shall conduct a performance appraisal to objectively measure the ability of staff to perform all job duties and responsibilities as outlined in the job description.

SR.1a The organization shall have a policy and procedure for sharing results of individual appraisals with staff members that allows for staff feedback within a timeframe defined by the organization, not to exceed one calendar year.

SR.2 The organization shall perform competency assessments initially and on an ongoing basis as defined by organization policy.

SR.2a The assessment shall evaluate the current key competencies necessary for the job position as determined by the organization.

SR.2b Additional focus areas or topics may be considered from one or more of the following:

SR.2b(1) Variations and problem processes identified through the analysis of outcomes measurement as required by the QMS;

SR.2b(2) High-risk, low volume procedures;

SR.2b(3) New technology/equipment/processes;

SR.2b(4) Customer satisfaction feedback;

SR.2b(5) Scheduled training session outcomes;

SR.2b(6) Staff learning needs assessments that include variations identified through prior staff competency assessment performance measurement;

SR.2b(7) Staff feedback;

SR.2b(8) Medical staff feedback;

SR.2b(9) Requirements of federal or state law; and,

SR.2b(10) Other indicators as determined by the organization.

SR.3 Competency assessment and performance appraisal processes for contract staff may be modified based on organization outcomes and frequency of service of individuals. Modification of these processes will be made when needed, shall be justified by data analysis, and defined in organization policy/procedure.

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 defined by organization policy/procedure to monitor staff performance improvement.

Interpretive Guidelines:

Performance appraisal refers to the overall employee evaluation where the ability of staff to perform all job duties and responsibilities in their job description is measured. A competency assessment evaluates the current key competencies required for the individual to perform the technical aspects of their job duties safely and effectively; this is an assessment of the technical knowledge and capability of staff. Performance appraisal and competency assessments together comprise the employee evaluation process.

The organization may elect to maintain documentation of the performance appraisal and competency assessments together or separately. However, in all cases, the organization shall evaluate both the performance and competency of staff at the required frequencies.

In addition to key competencies, additional focus areas or topics may be considered from one or more of the following:

- *Variations and problem processes identified through the analysis of outcomes measurement as required by the QMS;*
- *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 organization will have a policy and procedure for sharing results of individual performance appraisals with staff members that allows for staff feedback within a timeframe defined by the organization, not to exceed one calendar year.

The organization may modify the competency assessment and performance appraisal process for contract staff based on organization outcomes and frequency of service of individuals. This modification will be made when needed, shall be justified by data analysis, and defined in organization policy/procedure.

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 that require further training, coaching, and mentoring. This data can be used to identify opportunities for individuals, across departments, units, etc., or organization wide. Organizations may use this data to identify opportunities to adjust annual, ongoing or just-in-time education requirements/assignments.

Surveyor Guidance:

In a sampling of personnel records, verify that the organization has a performance appraisal and competency assessment process that is compliant with the standard requirements and as stated within the Interpretive Guidelines for SM.7.

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

Verify the organization's process for aggregating objective performance data from sources that may include; individual evaluations, incident reports, risk management, staff and patient feedback, and/or data analysis and how data is used to identify variations that require further training, coaching, and mentoring. Verify that the aggregated data has been reported to Quality Management Oversight as required by the organization's policy/procedure.

MEDICATION MANAGEMENT (MM)

MM.1 MANAGEMENT PRACTICES

SR.1 The organization shall have a pharmacy service with written policies and procedures to ensure effective medication management practices that meet the needs of the patients. These policies shall address ordering, storage, handling, dispensing, and administration including, but not limited to the timing of the administration of drugs and biologicals within the organization. Medications will be prepared and administered in accordance with accepted professional principles.

SR.2 The pharmacy service shall 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 shall have an adequate number of qualified personnel to ensure effective medication management services, including emergency services.

SR.3 Drugs and biologicals shall be prepared and administered in accordance with federal, state and local requirements, recommendations of professional organizations and accepted nationally recognized standards of practice and guidelines (e.g., ASHP, USP, ISMP), and the orders of the practitioner or practitioners responsible for the patient's care, and,

SR.3a Drugs and biologicals shall be prepared and administered in accordance with federal and state laws, the orders of other practitioners not specified under 42 CFR Section 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.3b 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 42 CFR Section 482.24(c)(3) (see MR.7).

SR.3c All drugs and biologicals shall 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.4 Sterile compounding: All compounding, packaging, and dispensing of medication shall be under the supervision of a pharmacist.

SR.4a All personnel involved in the compounding of pharmaceuticals shall receive training and evaluation based upon the complexity of the compounding performed.

SR.4b The hospital shall develop a written training program that describes the required training, frequency, and the process for evaluating the performance of individuals involved in sterile compounding.

SR.4c The hospital shall establish and follow written Standard Operating Procedures (SOPs) for compounded sterile preparation (CSP). The SOPs shall ensure that the entire compounding operation is well designed, functions as designed and will yield CSPs that are safe for administration to patients.

SR.5 All drugs and biologicals shall be controlled, secured and distributed in accordance with applicable nationally recognized standards of practice and guidelines and consistent with federal and state law at all times.

SR.5a Drugs listed as Schedule II, III, IV, and V of the Comprehensive Drug Abuse Prevention and Control Act of 1970 shall be kept locked within a secure area.

SR.5b Only personnel authorized by the pharmacy service shall have access to locked medication areas.

SR.6 Outdated, mislabeled, or otherwise unusable medications shall not be available for patient use.

SR.7 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.8 Blood transfusions and intravenous medications shall be administered in accordance with state law and approved medical staff policies and procedures.

Interpretive Guidelines:

The organization shall have a system that ensures that drugs and biologicals are managed in a manner that is safe and appropriate, and that its pharmacy system provides all drugs and biologicals prescribed by the organization's practitioners in a timely manner for administration to its patients.

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 shall 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 biologicals shall meet the requirements of MM.4.

Accepted Nationally Recognized Standards of Practice and Guidelines:

Hospital policies and procedures for the preparation and administration of all drugs and biologicals shall not only comply with all applicable federal and state laws but also shall be consistent with accepted nationally recognized standards of practice based on guidelines or recommendations issued by nationally recognized organizations with expertise in medication preparation and administration (e.g., ASHP, USP, ISMP).

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.

Accepted professional principles include compliance with applicable federal and state law and adherence to standards or guidelines for pharmaceutical services and medication administration issued by nationally recognized professional organizations, including, but not limited to: U.S. Pharmacopeia (www.usp.org), the American Society of Health-System Pharmacists (http://www.ashp.org/), the Institute for Safe Medication Practices (http://www.ismp.org/default.asp), the National Coordinating Council for Medication Error Reporting and Prevention (www.nccmerp.org); the Institute for Healthcare Improvement (http://www.ihi.org/ihi); or the Infusion Nurses Society (http://www.ins1.org).

Direction of pharmaceutical services may not require continuous on-premises 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 shall 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 shall 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.

Only the pharmacy compounds or admixes all sterile medications, intravenous admixtures, or other drugs except in emergencies or when not feasible (for example, when there is a need for emergency or immediate patient administration of a compounded sterile preparation).

Staff that participate in the compounding of pharmaceuticals will be trained and exhibit competence in understanding the standard operating procedures (SOPS). Procedures will include access to the compounding area, decontamination procedure for supplies, cleaning of carts and the environment, use of personnel protective equipment, materials allowed in compounding areas, cleaning of work surfaces, certification and proper use of primary engineering controls, proper disposal of supplies, and safe handling of hazardous supplies.

Use of Compounding Pharmacies

Compounding pharmacies, not registered as an outsourcing facility with the FDA, are popularly referred to as "503A pharmacies" and generally are subject to oversight only by their state

pharmacy board. If a hospital obtains compounded medications from a compounding pharmacy rather than a manufacturer or a registered outsourcing facility, then the hospital shall demonstrate how it assures that the compounded medications it receives under this arrangement have been prepared in accordance with accepted professional principles for compounded drugs as well as applicable State or Federal laws or regulations. For example, does the contract with the vendor include provisions:

- *Ensuring that the hospital has access to quality assurance data verifying that the vendor is adhering to current standards of practice for compounding medications and the hospital document that it obtains and reviews such data*

- *Requiring the vendor to meet the requirements of Section 503A of the FDCA concerning pharmacy compounding of human drug products*

Nonconforming outputs

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

A drug or biological is outdated after its "beyond-use date" (BUD), which may be reached before the expiration date, but never later. The BUD takes into account the specific conditions and potential for deterioration and microbial growth that may occur during or after the original container is opened, while preparing the medication for dispensing and administration, and/or during the compounding process if it is a compounded medication. There may be instances when the manufacturer may allow for a medication to be used beyond its expiration date; if the hospital elects to use a medication under concession, they shall maintain documentation of such (ISO 9001:2015; 8.7.1(d)).

Medication security:

All medications (listed as Schedule II, III, IV, and V of the Comprehensive Drug Abuse Prevention and Control Act of 1970) shall 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 shall 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.

- *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 shall approve policies and procedures for medication administration, consistent with the requirements of federal and state law and accepted nationally recognized standards of practice and guidelines. 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 shall address key issues related to medication administration, which include but are not limited to:

- *Personnel Authorized to Administer Medication.*

- *Policies and procedures shall 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 shall 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; and,*

    - *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 e.g. nitroglycerine tablets and inhalers). The provision for patient self-administration would also include other nonprescription medications at the bedside (e.g., 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 nationally recognized standards of practice and guidelines 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; and*
    - *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 shall be sufficient to properly order, prepare, dispense, administer and monitor medications as appropriate;*

- *Identification of when weight-based dosing is required (e.g., pediatric dosing, chemo, contrast, etc.);*

- *Other relevant performance improvement activities*

Basic safe practices for medication administration:

The hospital's policies and procedures shall reflect accepted nationally recognized standards of practice and guidelines 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 shall 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 shall 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 (e.g., 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 shall 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 workarounds that jeopardize patient safety due to the imposition of unrealistic or unnecessary time constraints for medication administration. Instead, hospital policies and procedures shall 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 shall address at least the following:

- *Medications not eligible for scheduled dosing times;*
- *Medications eligible for scheduled dosing times; and*
- *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 shall 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 shall 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 shall ensure timely administration of such medications. In addition, they shall 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 shall 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 shall 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 shall 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 shall 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; and,*
- *Medications prescribed for administration within a specified period of time of the medication order; Medications that shall 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 shall 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 shall also outline guidelines for the administration and timing of new medications which are initiated between standardized dosing times.

These policies and procedures shall 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 shall be reported to the attending physician immediately in accordance with requirements (see MM.6 (SR.3)).

Evaluation of medication administration timing policies:

Hospitals shall 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 shall 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 shall consider whether there is a need to revise the policies and procedures governing medication administration timing.

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 hours, 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 nationally recognized standards of practice and guidelines, 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 biological 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 (e.g., 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; and,*
- *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; and,*
- *Verify that the staff are able to describe requirements for the timing of administration of time critical and nontimed critical medications in accordance with the hospital's policies.*

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

SR.1 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.

SR.2 The hospital shall have processes to address medication shortages and outages, including the following:

SR.2a Communicating with appropriate prescribers and staff;

SR.2b Developing approved substitution protocols;

SR.2c Educating appropriate LIPs, appropriate health care professionals, and staff about these protocols; and

SR.2d Obtaining medications in the event of a disaster.

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 organization maintains or that are readily available. In accordance with accepted nationally recognized standards of practice and guidelines, 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 organization's information management system or in a hardcopy form. The organization will ensure a means of notifying the hospital staff and medical staff when changes are made to the formulary.

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

- *Communicating with appropriate prescribers and staff;*
- *Developing approved substitution protocols; and*
- *Educating appropriate LPs, appropriate health care professionals, and staff about these protocols; and obtaining medications in the event of a disaster.*

The organization 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 organization 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 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 the organization 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 shall 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 shall 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 shall 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 shall develop and implement policies and procedures to minimize abuses and losses of controlled substances. These procedures shall 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 Be in accordance with acceptable standards practice and include at least the following:

SR.1a Name of the patient;

SR.1b Age and weight of the patients, or other dose calculation requirements, where applicable;

SR.1c Date and time of the order;

SR.1d Drug name;

SR.1e Dose, frequency, and route;

SR.1f Exact strength or concentration, when applicable;

SR.1g Quantity and/or duration, when applicable;

SR.1h Specific instructions and indications for use:

SR.1h(1) PRN administration and/or multiple uses and one time use of medication; and,

SR.1h(2) Which medication to administer or offer first when applicable (e.g., more than one medication for same use such as pain, nausea, constipation); and

SR.1i Name of the prescriber.

SR.2 Be in writing and signed, including date and time, by the practitioner or practitioners responsible for the care of the patient 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 organization policy after an assessment of contraindications, orders for drugs and biologicals shall be documented and signed by a practitioner who is authorized to write orders in accordance with state law and organization policy, and who is responsible for the care of the patient.

SR.3 A licensed pharmacist shall review all medication orders prior to administration of the first dose to a patient, except in emergency situations, or when the ordering provider is also administering the medication (i.e., urgent or emergent procedural or surgical setting).

SR.4 A process is established for resolving questions with the prescribing practitioner and the discussion and outcome are documented in the patient's medical record or pharmacy copy of the prescriber's order. This review shall include:

SR.4a Therapeutic appropriateness of a patient's medication regimen;

SR.4b Therapeutic duplication in the patient's medication regimen;

SR.4c Appropriateness of the drug, dose, frequency, and route of administration;

SR.4d Real or potential medication-medication, medication-food, medication-laboratory test and medication-disease interactions;

SR.4e Real or potential allergies or sensitivities; and

SR.4f Other contraindications.

SR.5 Telephone or verbal orders are to be used infrequently and when used shall be accepted only by personnel authorized by the medical staff and in accordance with federal and state law.

SR.6 Verbal orders shall be signed or initialed by the prescribing practitioner and 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 shall be authenticated within a time specified by organization policy.

SR.7 Orders for drugs and biologicals may be documented and signed by other practitioners only if such practitioners are acting in accordance with state law, including scope-of practice laws, organization 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 (including orders for PRN administration and/or multiple uses for the same medication).*
- *Specific instructions for use, including but not limited to which medication to offer or administer first when more than one medication is ordered for the same indication and by the same route. Examples include but are not limited to, multiple medications ordered for pain, nausea, constipation;*
- *Name of prescriber.*

Hospitals shall 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 an organization 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. These protocols or standing orders will also comply with requirements in MR.7.

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 shall 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 organization 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 required elements 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 organization policy.

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

MM.5 AFTER HOURS ACCESS TO PHARMACY

SR.1 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 a policy approved by the pharmacy service and by the medical staff, in accordance with principles of patient safety and federal and state law.

SR.2 The licensed individual that obtains the medication shall have an orientation to the storage area for the medication.

SR.2a Only designated prescribers and trained, licensed staff are permitted access to medications.

SR.3 All high-risk medications in the pharmacy or medication storage area shall be segregated and unavailable. 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.

SR.4 The hospital arranges for a qualified pharmacist to be available either on-call or at another location (for example, at another organization that has 24-hour pharmacy service) to answer questions or provides medications beyond those accessible to non-pharmacy staff.

SR.5 The removal of the medication shall 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:

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-pharmacists to enter the pharmacy. Policies and procedures should be consistent with federal and state law.

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

- *The practitioner caring for the patient shall 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,*
- *Proper indications for administration; and*
- *Other contraindications (pregnancy, breast feeding, etc.).*

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.

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 number of times non-pharmacist health care professionals are obtaining medications after the pharmacy is closed.

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 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 shall be immediately reported, if appropriate, to the attending physician.

SR.4 All medication related errors shall be tracked and analyzed to determine their causes (see QM.7 (SR.4b), (SR.4d), (SR.4e), (SR.4m), and (SR.4n)).

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 shall 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 shall 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 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.*

The facility shall 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 shall include the involvement and approval of the medical staff.

Validate that the organization 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 organization'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 (e.g., ISMP).

To determine the effectiveness of the internal reporting mechanism, assess whether or not the identification of medication errors is 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

SR.1 Information relating to drug interactions and information on drug therapy, side effects, toxicology, dosage, indications for use, and routes of administration shall be current and available to the professional staff. See also QM.2 (SR.3b).

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 current and available to all professional staff.

MM.8 ANTIMICROBIAL STEWARDSHIP

The organization shall have a program in place to enhance antimicrobial stewardship, an activity that includes appropriate selection, dosing, route, and duration of antimicrobial therapy. There shall be pharmacy involvement in the program that includes monitoring, prescribing and resistance patterns, education and reporting to the antibiotic stewardship program as well as the QMS. See IC.2, IC.3 and QM.7 (SR.4h(2)).

Surveyor Guidance:

Review organization policy and procedure to verify that elements of the antimicrobial stewardship program are included.

Review meeting minutes from the antimicrobial stewardship team to determine the antibiotic use measures, how prescribing is monitored, outcomes measurement.

Review interventions made by the pharmacy related to automatic changes from intravenous to oral antibiotic therapy, dose adjustments, dose optimization, automatic alerts in situations where therapy might be unnecessarily duplicative, time-sensitive automatic stop orders, detection and prevention of antibiotic-related drug – drug interactions as the hospital deems necessary.

MM.9 SELF-ADMINISTERED MEDICATIONS

SR.1 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 shall have policies and procedures in place to:

SR.1a Ensure that a practitioner responsible for the care of the patient has issued an order, consistent with hospital policy, permitting self-administration;

SR.1b Assess the capacity of the patient (or the patient's caregiver/support person where appropriate) to self-administer the specified medication(s);

SR.1c Instruct the patient (or the patient's caregiver/support person where appropriate)

in the safe and accurate administration of the specified medication(s);

SR.1d Address the security of the medication(s) for each patient;

SR.1e 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; and,

SR.2 If the hospital allows a patient to self-administer his or her own specific medications brought into the hospital, then the hospital shall have policies and procedures in place to:

SR.2a 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.2b 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.2c Identify the specified medication(s) and visually evaluate the medication(s) for integrity;

SR.2d Address the security of the medication(s) for each patient; and,

SR.2e 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.

Interpretive Guidelines:

Note that Patient-controlled Analgesia (PCA) pumps are a special variant of patient self-administration. Such pumps allow patients, within tightly controlled, pre-determined parameters with respect to dosage and minimum time intervals between doses, to release an intravenous dose of a controlled substance pain medication that has been pre-loaded into the PCA pump in a manner that prevents tampering by an unauthorized person. PCA pumps are considered secure despite their use of controlled substances.

PCA pumps allow for the self-administration of intravenous (IV) medications to patients. See the interpretive guidelines for §482.23(c)(4) concerning assessment and monitoring requirements for post-surgical patients receiving IV opioids, including via patient-controlled analgesia (PCA) pumps, in and out of the post-anesthesia care and intensive care units.

Hospitals are also free to exclude other medications besides controlled substances from their patient self-administered medication programs when the hospital has concerns over its capacity to address the safety and security of these other medications for patients.

A hospital may choose to have a policy where it maintains a list of medications that it excludes

from self-administration entirely, due to security concerns. It may choose to have a policy that addresses the security of a particular medication on a patient-by-patient basis. Or it may establish a policy that is a combination of both of these approaches to medication security.

Surveyor Guidance:

If the hospital permits patient self-administration of hospital-issued medications:

- *Ask the hospital to identify current inpatients for whom self-administration of hospital-issued medications is permitted.*

- *Interview several of these patients (or their caregivers/support persons when applicable) to verify that they received instruction on how to administer their medications.*

Interview nurses caring for the selected patients. Ask them:

- *What the applicable hospital policies and procedures are regarding supervision of self-medication.*

- *How they assess a patient's (or patient's caregiver/support person's) capacity to self-administer medication. If they have concerns, how do they communicate them to the responsible practitioner? Does the hospital permit nurses to return to nurse administration of medications in response to temporary reduction in patient capacity or absence of the patient's caregiver/support person? If so, how do the nurses make this assessment?*

- *How they instruct a patient (or patient's caregiver/support person's) in medication self-administration.*

- *How self-administered medications are secured.*

- *How they document self-administration of medications.*

Review the medical records for the selected patients. Is there documentation of:

- *An order for self-administration of specific medication(s).*

- *A nurse assessment of the patient's (or patient's caregiver/support person's) capacity to self-administer medication.*

- *Documentation of nurse instruction to the patient or (or patient's caregiver/support person) in safe and appropriate techniques for self-administration of medication.*

- *Documentation of self-administration times and doses, as reported by the patient or (or patient's caregiver/support person) or directly observed by a nurse.*

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 nationally recognized standards of practice and guidelines, including but not limited to AORN, CDC, APIC, ASA, AANA, AAMI, and other professional organizations are applicable to surgical services.

SR.2 If outpatient surgical services are offered, the services shall be consistent in quality with inpatient care in accordance with the complexity of services offered.

SR.3 Surgical care shall be designed to assure the achievement and maintenance of high standards of medical practice and patient care and shall be consistent with needs and resources.

SR.4 The organization shall develop and implement policies and procedures for providing surgical services that are in accordance with acceptable standards of medical practice and surgical patient care. Policies and procedures shall include at least the following:

SR.4a Aseptic surveillance and practice, including scrub techniques;

SR.4b Identification of infected and non-infected cases;

SR.4c Housekeeping requirements/procedures;

SR.4d Duties of scrub and circulating nurse. Duties may be defined within a job description, but may vary depending on the cases for which these staff members are involved (see also SM.5);

SR.4e Conducting surgical counts in accordance with accepted nationally recognized standards of practice and guidelines. The organization will have a process in place to ensure that no foreign bodies are retained in patients following surgical procedures;

SR.4f The scheduling of patients for surgery;

SR.4g Patient care requirements including:

SR.4g(1) Pre-operative testing;

SR.4g(2) Clinical procedures; and,

SR.4g(3) Patient identification procedure and site verification process;

SR.4h Resuscitative techniques;

SR.4i Patient consents and releases;

SR.4i(1) How the DNR status is addressed when indicated in the patient's records;

SR.4j Handling, care and labeling of surgical specimens;

SR.4k 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;

SR.4l Sterilization and high-level disinfection procedures (see also SS.10);

SR.4m Handling infectious and biomedical/medical waste;

SR.4n Malignant Hyperthermia (See SS.5 policy to include all areas in any surgical/procedural areas, or any area using volatile anesthetic agents with succinylcholine, or succinylcholine alone (e.g., RSI))

SR.4o Monitoring of temperature and humidity;

SR.4p Safety practices (e.g., fire safety, site marking, time-outs, etc.); and,

SR.4q Acceptable operating room attire.

SR.4r Outpatient surgery post-operative care planning and coordination, and provisions for follow-up care.

Interpretive Guidelines:

For the purposes of determining compliance with the hospital surgical services CoP, CMS relies, with minor modification, upon the definition of surgery developed by the American College of Surgeons. ***Accordingly, the following definition is used to determine whether or not a procedure constitutes surgery and is subject to this CoP:***

Surgery is performed for the purpose of structurally altering the human body by the incision or destruction of tissues and is part of the practice of medicine. Surgery also is the diagnostic or therapeutic treatment of conditions or disease processes by any instruments causing localized alteration or transposition of live human tissue which include lasers, ultrasound, ionizing radiation, scalpels, probes, and needles. The tissue can be cut, burned, vaporized, frozen, sutured, probed, or manipulated by closed reductions for major dislocations or fractures, or otherwise altered by mechanical, thermal, light-based, electromagnetic, or chemical means. Injection of diagnostic or therapeutic substances into body cavities, internal organs, joints, sensory organs, and the central nervous system also is considered to be surgery (this does not include the administration by nursing personnel of some injections, subcutaneous, intramuscular, and intravenous, when ordered by a physician). All of these surgical procedures are invasive, including those that are performed with lasers, and the risks of any surgical procedure are not eliminated by using a light knife or laser in place of a metal knife, or scalpel. Patient safety and quality of care are paramount and, therefore, patients should be assured that individuals who perform these types of surgery are licensed physicians (physicians as defined in

482.12(c)(1)) who are working within their scope of practice, hospital privileges, and who meet appropriate professional standards.

If the organization provides any surgical services (inpatient or outpatient), they shall be organized and staffed in such a manner to ensure the health and safety of patients and be in accordance with nationally recognized standards of practice and guidelines, including but not limited to the American College of Surgeons, Association of periOperative Registered 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.

The organization shall design the surgical services to ensure the standards of medical practice and patient care are implemented and maintained.

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

Surveyor Guidance:

Review and verify the extent of surgical services provided by the organization and verify that services are in accordance with nationally recognized standards of practice and guidelines. 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.

Verify that the hospital has assured that the medical staff has specified which procedures are considered surgery and, thus, are those that require a properly executed informed consent form.

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.

Malignant hyperthermia rescue capability should be thoroughly assessed in all surgical/procedural areas, or any area using volatile anesthetic agents with succinylcholine, or succinylcholine alone (e.g., RSI).

Verify that access to the operative and recovery area is limited to authorized personnel and that the traffic flow pattern adheres to accepted nationally recognized standards of practice and guidelines.

Verify that operating room attire is suitable for the kind of surgical case performed, that persons working in the operating suite shall wear only clean surgical costumes, and that surgical costumes are designed for maximum skin and hair coverage.

Verify that the organization 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 organization's biomedical equipment/clinical engineering program. See also PE.7.

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 nationally recognized standards of practice and guidelines.)

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

The organization shall provide the appropriate equipment and the types and numbers of qualified personnel necessary to furnish the surgical services offered by the organization in accordance with acceptable nationally recognized standards of practice and guidelines.

Qualified registered nurses shall 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, LPNs/LVNS, 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 organization's organization 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 organization 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 The organization shall have delineated surgical privileges established by the organization's department of surgery and medical staff and approved by the governing body for each practitioner that performs surgical tasks (see MS.6). This includes practitioners such as MD/DO, dentists, oral surgeons, podiatrists, RN first assistants, nurse practitioners, surgical physician assistants, surgical technicians, etc.

SR.1a The organization shall establish criteria, qualifications and a credentialing process to grant specific privileges to individual practitioners based on each individual practitioner's compliance with the privileging/credentialing criteria and in accordance with Federal and State laws and regulations.

SR.1a(1) This would include surgical services tasks conducted by these practitioners while under the supervision of an MD/DO.

SR.2 A current roster of practitioners and their privileges shall be maintained by the department of surgery and made available in the area/location(s) where surgical procedures occur. A current list of surgeons suspended from surgical privileges or whose surgical privileges have been restricted shall also be maintained in these areas/location(s).

Interpretive Guidelines:

A current roster listing each practitioner's specific surgical privileges shall be available in the surgical suite and area/location where the scheduling of surgical procedures is done. A current list of surgeons suspended from surgical privileges or whose surgical privileges have been restricted shall also be retained in these areas/locations.

The hospital shall delineate the surgical privileges of all practitioners performing surgery and surgical procedures. (This would include practitioners such as MD/DO, dentists, oral surgeons, podiatrists, RN first assistants, nurse practitioners, surgical physician assistants, surgical technicians, etc. (see SS.8)) The medical staff is accountable to the governing body for the quality of care provided to patients. The medical staff bylaws shall include criteria for determining the privileges to be granted to an individual practitioner and a procedure for

applying the criteria to individuals requesting privileges. Surgical privileges are granted in accordance with the competencies of each practitioner. The medical staff appraisal procedures shall evaluate each individual practitioner's training, education, experience, and demonstrated competence as established by the hospital's QAPI program, credentialing process, the practitioner's adherence to hospital policies and procedures, and in accordance with scope of practice and other State laws and regulations.

If the hospital utilizes RN First Assistants, surgical PA, or other non-MD/DO surgical assistants, the hospital shall establish criteria, qualifications and a credentialing process to grant specific privileges to individual practitioners based on each individual practitioner's compliance with the privileging/credentialing criteria and in accordance with Federal and State laws and regulations. This would include surgical services tasks conducted by these practitioners while under the supervision of an MD/DO.

When a practitioner may perform certain surgical procedures under supervision, the specific tasks/procedures and the degree of supervision (to include whether or not the supervising practitioner is physically present in the same OR, in line of sight of the practitioner being supervised) shall be delineated in that practitioner's surgical privileges and included on the surgical roster.

When practitioners whose scope of practice for conducting surgical procedures requires the direct supervision of an MD/DO surgeon, the term "supervision" would mean the supervising MD/DO surgeon is present in the same room, working with the same patient.

Surveyor Guidance:

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

Confirm that the organization 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 also retained in these areas/locations.

SS.4 HISTORY AND PHYSICAL OR OUTPATIENT ASSESSMENT

SR.1 Except in emergencies, there shall be a complete H&P in the medical record of every patient prior to surgery or procedure requiring anesthesia services.

SR.2 The medical staff bylaws shall include a requirement that a medical history and physical examination (H&P) for each patient shall be completed and documented in the medical record no more than 30 days before or 24 hours after an admission or registration, and prior to surgery, or procedures requiring anesthesia services, and placed in the patient's medical record within 24 hours after admission. The H&P shall be in the medical record prior to surgery or other procedure requiring anesthesia services.

SR.2a An H&P completed within 30 days prior to admission or registration shall include an update 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, oral and maxillofacial surgeon or other LP who has been granted these privileges by the medical staff in accordance with state law.

SR.2b Any H&P or outpatient assessment update of the patient's current medical condition shall document:

SR.2b(1) That the patient has been examined;

SR.2b(2) That the H&P has been reviewed;

SR.2b(3) Any changes in the patient's condition, or that ''no change'' has occurred in the patient's condition since the H&P or outpatient assessment was completed.

SR.2c 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, and prior to surgery or other procedure requiring anesthesia services.

SR.3 A Doctor of Medicine or Osteopathy, or oral and maxillofacial surgeon shall perform the H&P described above. Alternatively, a LP may perform an H&P if permitted by State law and scope of practice.

SR.4 The content of the HP examination and applicability shall be determined by the medical staff and may be done by the individuals described in SS.4 (SR.3) (see also MS.13 (SR.2)). The content of the H&P examination or outpatient assessment 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 shall be in the medical record prior to any surgery, or other procedure requiring anesthesia services and within 24 hours of admission or registration as stated in SS.4 (SR.2) (see also MS.13 (SR.1)).

SR.5 Outpatient assessment: The medical staff may elect to permit an outpatient assessment rather than an H&P for patients receiving specific outpatient surgical or procedural services and when the medical staff has chosen to develop and maintain a policy that identifies specific patients as not requiring a comprehensive medical history and physical, in accordance with the requirements at MS.13 (SR.4).

SR.5a Medical staff shall develop and maintain a policy that identifies specific patients as not requiring a comprehensive medical history and physical examination, or any update to it, prior to specific outpatient surgical or procedural services as per 42 CFR § 482.22(c)(5)(v), and 42 CFR § 482.51(b)(1)(iii) (see also MS.13 (SR.4));

SR.5b If an outpatient assessment is determined to be appropriate as per the requirements of MS.13 (SR.4) the outpatient assessment shall be:

SR.5b(1) Completed and documented by a Doctor of Medicine or Osteopathy (as defined in section 1861(r) of the Act), an oral and maxillofacial surgeon, or other LP in accordance with state law and organization policy;

SR.5b(2) Completed and documented after registration, but prior to the outpatient surgery or procedure requiring anesthesia services.

SR.6 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.

Interpretive Guidelines:

There shall 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 shall contain an H&P (as required for all inpatient and appropriate outpatient settings) and shall 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 shall 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 organization shall ensure that this H & P is updated to document any changes in the patient's condition.

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.

SS.5 AVAILABLE EQUIPMENT

SR.1 The following equipment shall be present and in operating condition and immediately available to each surgical suite:

SR.1a Call-in system;

SR.1b Cardiac monitor;

SR.1c Resuscitator;

SR.1d Defibrillator;

SR.1e Suction equipment;

SR.1f Provisions for emergency airway intervention; including a tracheotomy set; and,

SR.2 Hyperthermia (MH) rescue materials;

SR.2a Dantrolene and all components to administer and sufficiently treat an MH episode shall be available in any surgical/procedural area, or any area using volatile anesthetic agents with succinylcholine, or succinylcholine alone (e.g., RSI) within 10 minutes of the decision to treat for MH.

Interpretive Guidelines:

All facilities, including ambulatory surgery centers and offices, where MH triggering anesthetics (isoflurane, desflurane, sevoflurane, enflurane, halothane, and succinylcholine) are administered, should stock the minimum amount of dantrolene necessary to treat an MH episode along with the other drugs and devices necessary to treat an MH episode. If none of these agents are ever in use in the facility, then dantrolene need not be kept at hand.

Two formulations of dantrolene are available. Per the recommendations of the Malignant Hyperthermia Association of the United States (MHAUS):

"To treat an MH episode, an initial dose of dantrolene at 2.5 mg/kg is recommended, with a suggested upper limit of 10 mg/kg. If a patient of average weight (approximately 70 kg) were to require dantrolene at the upper dosing limit, then at least 700 mg of dantrolene would be needed.

•DANTRIUM®/REVONTO® – stock a minimum of 36 - 20 mg vials

•RYANODEX®– stock a minimum of 3 - 250 mg vials"

Surveyor Guidance:

Review and verify that the hospital has required equipment immediately available to each surgical suite to include at least those items in SS.5.

Validate that all equipment is working as intended and is maintained, inspected, and tested by the organization'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

SR.1 The operating room register shall be complete and current. The operating room register will include at least the following information:

SR.1a Patient's name;

SR.1b Patient's hospital identification number;

SR.1c Date of the operation/procedure;

SR.1d Inclusive or total time of the operation/procedure;

SR.1e Name of the surgeon and any assistant(s);

SR.1f Name of nursing personnel (scrub and circulating);

SR.1g Type of anesthesia used and name of the administering practitioner;

SR.1h Operation/procedure performed;

SR.1i Pre-and post-operative diagnosis; and,

SR.1j 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 requirements for SS.6.

SS.7 POST-OPERATIVE CARE

SR.1 There shall be adequate provisions 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.

SR.3 Policies and procedures shall specify assessments, reassessments, and transfer requirements to and from the PACU. Depending on the type of anesthesia and length of surgery, the post-operative check before transferring the patient from the PACU includes, but is not limited to*:*

SR.3a Level of activity;

SR.3b Respirations;

SR.3c Blood pressure;

SR.3d Level of consciousness;

SR.3e Level of pain;

SR.3f Patient color; and

SR.3g Consistent with accepted standards of practice.

SR.4 If a patient is not transferred to the PACU, provisions are made for close observation until the patient has regained consciousness; e.g., direct observation by a qualified RN.

Interpretive Guidelines:

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

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

If patients are not transferred to the post-operative care area, there shall 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.

Patients receiving post-operative intravenous (IV) opioid medications are of particular concern, due to the higher risk for oversedation and respiratory depression. Once out of the PACU, patients receiving IV opioid medication may be placed on units where vital signs and other monitoring traditionally has not been done as frequently as in the PACU or intensive care units, increasing the risk that patients may develop respiratory compromise that is not immediately recognized and treated.

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

Prior to discharge, the organization shall 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.

Surveyor Guidance:

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

Review and verify that the organization 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. The operative report will contain at least the following:

SR.1a Name and hospital identification number of the patient;

SR.1b Date and times of the surgery;

SR.1c Name(s) of the surgeon(s) and assistants or other practitioners who performed surgical tasks (even when performing those tasks under supervision);

SR.1d Pre-operative and post-operative diagnosis;

SR.1e Name of the specific surgical procedure(s) performed;

SR.1f Type of anesthesia administered;

SR.1g Complications, if any;

SR.1h A description of techniques, findings, and tissues removed or altered;

SR.1i Estimated blood loss (specify N/A if no blood loss);

SR.1j 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 tasks include: opening and closing, harvesting grafts, dissecting tissue, removing tissue, implanting devices, altering tissues); and,

SR.1k Prosthetic devices, grafts, tissues, transplants, or devices implanted (if any).

SR.2 All surgeries or invasive procedures require an operative report, or a postoperative/post-procedure note if the operative report is not immediately available. (See CMS Definition of surgery in the Interpretive Guidelines for SS.1.)

SR.3 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.4 In the event that an operative report cannot be dictated before transfer to the next level of care in an inpatient setting, an immediate postoperative/post procedure note is required to be documented. The note shall include identification or description of:

SR.4a The surgeon and assistants;

SR.4b Pre-operative and post-operative diagnosis;

SR.4c Procedures performed;

SR.4d Specimens removed;

SR.4e Estimated blood loss (specify N/A if no blood loss);

SR.4f Complications (if any encountered);

SR.4g Type of anesthesia administered; and,

SR.4h Grafts or implants (may indicate where in chart for detail, if any).

SR.5 If information identified in the immediate post-operative/post procedure note is available elsewhere in the medical record; it is acceptable if referred to and authenticated as accurate by the attending surgeon.

Interpretive Guidelines:

The definition of surgery is found in the IG under SS.1.

The intent of the immediate operative report or post-operative/post-procedure note is to ensure that the next provider of care has the information necessary to make further appropriate care decisions.

The organization may, in some circumstances, choose to require a postoperative/post procedure note in other settings or for specific high-risk procedures.

For example, at the discretion of the Medical Staff, a hospital may, following a risk-based assessment, choose to require a postoperative/post procedure note for:

- *Any procedure requiring moderate sedation outside of the surgical setting (e.g., Endoscopy)*
- *Other identified high-risk procedures*

If such determinations were made, the expectation is that the requirements would be delineated in the Medical Staff Rules and Regulations and applied accordingly.

A post-operative/post-procedure note would not generally be expected for bedside procedures or in other settings (e.g., Emergency Department) where a patient would be transferred home.

If information identified in the immediate post-operative/post procedure note is available elsewhere in the medical record, it is acceptable if referred to and authenticated as accurate by the attending surgeon.

Surveyor Guidance:

In a sampling of surgical patients' medical records, validate that the records contain an operative report that includes the information specified in SR.1a-SR.1k.

In a sampling of medical records of surgical patients and a delay in dictation has been identified,

validate that the medical record contains an immediate postoperative note that includes the information specified in SR.4a-SR.4h (above).

In the event that there is no delay in dictation during the time the surveyor is on-site, validate that the organization has a process in place for the immediate postoperative note to be written and that this is enforced by the organization.

With the advent of the electronic medical record (EMR), instances might exist where a surgeon's operative report or immediate postoperative/post procedure note is completed prior to the close of the surgical case rather than immediately following surgery (e.g., multidisciplinary operations that require the involvement of two or more surgeons of different specialties; overlapping surgeries where the surgeon proceeds to a subsequent surgical procedure once the critical portions of the first procedure are completed). In such cases, it is acceptable if the operative report is dated and timed prior to the end of the surgical procedure.

SS.9 SURGICAL INFORMED CONSENT

SR.1 A properly executed informed consent form for the surgery and/or procedure shall be in the patient's medical record before surgery except in a medical emergency as defined by the organization's policy. A properly executed informed consent form shall contain at least the following (See also PR.5):

SR.1a Name of the patient, and when appropriate, the patient's legal representative;

SR.1b Name of hospital/organization where the procedure is being performed;

SR.1c Name of the surgical procedure(s), including if anesthesia is to be used (when a separate anesthesia consent is not obtained);

SR.1d Name of the responsible practitioner(s) performing the procedure(s);

SR.1e Statement that procedure or treatment, including the anticipated benefits, material risks, and alternative therapies, was explained to the patient or the patient's legal representative; (Material risks could include risks with a high degree of likelihood but a low degree of severity, as well as those with a very low degree of likelihood but high degree of severity. Hospitals are free to delegate to the responsible practitioner, who uses the available clinical evidence as informed by the practitioner's professional judgment, the determination of which material risks, benefits and alternatives will be discussed with the patient.)

SR.1f Signature of patient or his/her legal representative;

SR.1g Date and time written informed consent is signed by the patient or patient's legal representative.

SR.2 The organization's surgical informed consent policy shall describe the following (see PR.5):

SR.2a Who may obtain the patient's informed consent;

SR.2b Which procedures require informed consent;

SR.2c The circumstances under which surgery is considered an emergency and may be undertaken without an informed consent;

SR.2d The circumstances when a patient's representative, rather than the patient, may give informed consent for surgery;

SR.2e The content of the informed consent form and instructions for completion;

SR.2f The process used to obtain informed consent, including how the informed consent is to be documented in the medical record;

SR.2g 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); and

SR.2h If the informed consent process and informed consent form are obtained outside the organization, how the properly executed informed consent form is incorporated into the patient's medical record prior to surgery.

Interpretive Guidelines:

Hospitals shall assure that the practitioner(s) responsible for the surgery obtain informed consent from patients in a manner consistent with the hospital's policies governing the informed consent process. The organization 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 emergency, as defined by the medical staff.

A written consent form is required for all procedures which are considered surgery, as defined by the medical staff and the organization's policies, for patients undergoing procedures using sedation or anesthesia, and any other procedures as required by the organization's policy. The organization's policy and process shall comply with any applicable state and federal laws and regulations.

In the event that the organization's policy does not require a written informed consent form for a procedure not requiring the use of sedation or anesthesia, these patients with the ability to verbally affirm consent for procedures that do not require sedation or anesthesia shall minimally have their medical record reflect that consent was given.

In either instance (regardless of whether sedation or anesthesia is used), there shall be a written consent form for any training- and education-related sensitive examinations or invasive procedures that may be performed. Examinations or invasive procedures conducted for educational and training purposes include, but are not limited to, breast, pelvic, prostate, and rectal examinations, as well as others specified under state law.

It should be noted that there is no specific requirement for informed consent within the

regulation at §482.52 governing anesthesia services. However, given that surgical procedures generally entail use of anesthesia, hospitals may wish to consider specifically extending their informed consent policies to include obtaining informed consent for the anesthesia component of the surgical procedure.

If there are additional requirements under State law for informed consent, the hospital shall comply with those requirements.

Example of a Well-Designed Informed Consent Process

A well-designed informed consent process would include discussion of the following elements:

- *A description of the proposed surgery, including the anesthesia to be used;*
- *The indications for the proposed surgery;*
- *Material risks and benefits for the patient related to the surgery and anesthesia, including the likelihood of each, based on the available clinical evidence, as informed by the responsible practitioner's clinical judgment. Material risks could include risks with a high degree of likelihood but a low degree of severity, as well as those with a very low degree of likelihood but high degree of severity;*
- *Treatment alternatives, including the attendant material risks and benefits;*
- *The probable consequences of declining recommended or alternative therapies;*
- *Who will conduct the surgical intervention and administer the anesthesia;*
- *Whether practitioners other than the operating practitioner, including but not limited to other physicians, residents, advance practice providers, and medical and other applicable students (such as nurse practitioner and physician assistant), will be performing important tasks related to the surgery, or sensitive examinations or invasive procedures for educational and training purposes. Important surgical tasks include opening and closing, dissecting tissue, removing tissue, harvesting grafts, transplanting tissue, administering anesthesia, implanting devices and placing invasive lines. Examinations or invasive procedures conducted for educational and training purposes include, but are not limited to, breast, pelvic, prostate, and rectal examinations, as well as others specified under state law.*

  For surgeries in which residents will perform important parts of the surgery, discussion is encouraged 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 on their availability and level of competence;*
  - *That it will be decided at the time of the surgery which residents will participate and their manner or participation, and that this will depend on the availability of residents with the necessary competence; the knowledge 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; and*

NOTE: A "moonlighting" resident or fellow is a postgraduate medical trainee who is practicing independently, outside the scope of his/her residency training program and would be treated as a physician within the scope of the privileges granted by the hospital.

- *Whether, as permitted by State law, qualified medical practitioners who are not physicians will perform important parts of the surgery or administer the anesthesia, and if so, the types of tasks each type of practitioner will carry out; and that such practitioners will be performing only tasks within their scope of practice for which they have been granted privileges by the hospital.*

Surveyor Guidance:

- *Verify that the medical staff has specified which procedures require a written informed consent (in addition to standard requirements at SS.9 and as specified at PR.5). Verify that medical records contain consent forms for all procedures as required by standard, hospital policy, state and federal laws and regulations.*

- *Compare the organization's standard informed consent form to its policies on informed consent to verify that the form is consistent with the policies, and if applicable, to requirements of state and federal laws and regulations.*

- *Verify that the organization'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.*

- *In a sampling of a minimum of six patient records who had surgery, review and first verify that the patients did not require emergency surgery. Validate that informed consent forms were executed prior to the surgery as required. When possible, review medical records of patients who are about to undergo surgery, or who are located in a surgical recovery area.*

- *When possible, interview at least two to three patients who are undergoing, or have undergone surgery, as appropriate based on their ability to provide a cogent response, or the patients' representatives, and have them tell you about the informed consent process and their understanding of the procedure they are having (or have had) performed.*

SS.10 REPROCESSING OF SURGICAL INSTRUMENTS, IMPLANTS AND MEDICAL EQUIPMENT

SR.1 The organization shall reprocess all surgical instrumentation and medical devices according to the manufacturer's instructions for use (IFU) and ensure access to the IFUs are readily available to all staff reprocessing these items; including all but not limited to:

SR.1a Device manufacturer;

SR.1b Chemicals utilized for disinfection, sterilization, and high-level disinfection;

SR.1c Sterilizer manufacturer;

SR.1d Containment device manufacturer (rigid and soft containment).

SR.1e

SR.2 The organization shall have a process in place for the resolution of conflicting manufacturer IFU referenced in SS.10 (SR.1).

SR.3 The organization shall maintain and retain documentation of reprocessing activities according to professionally recognized standards of practice and organizational policies.

SR.4 The organization shall allow adequate time for reprocessing to ensure adherence to all steps recommended by device manufacturer, including drying and proper storage:

SR.4a The organization shall have defined processes for limited and/or eliminating immediate-use steam sterilization (IUSS) for instrumentation:

SR.4a(1) IUSS shall be limited to urgent or emergent situations;

SR.4a(2) The IUSS of implantable devices shall be limited to emergent situations; and

SR.4a(3) All occurrences of IUSS shall be traceable to the patient.

SR.5 The organization shall have a process in place for all surgical instruments, implants, medical equipment, and devices not solely owned by the organization, including:

SR.5a Acceptance of items;

SR.5b Inventory of items;

SR.5c Manufacturer's IFU on all items; and

SR.5d Documented training for use and reprocessing of items.

SR.6 The organization policy ensures a reliable, high-quality process for gastrointestinal endoscope reprocessing which minimizes infection risks.

SR.6a The organization shall have a process in place to identify which gastrointestinal endoscope was used on a patient for each procedure (traceability).

Interpretive Guidelines:

IUSS is a sterilization method used to sterilize medical instruments in urgent or emergency situations. All decontamination processes must be followed during IUSS. IUSS deviates from the standard time required for the sterilization of instrumentation as outlined by manufacturer's IFU. IUSS should be utilized only in emergency or urgent cases where there is a sudden need for a sterilized instrument but no other sterilization options (e.g., standard cycle) are available within the necessary timeframe. This includes situations where an unexpected complication or emergency arises during a surgical procedure, requiring immediate access to sterile instruments. Excessive use of IUSS for schedule management, insufficient inventory, or vendor management in elective cases could constitute a condition-level nonconformity.

Processes referenced in the standards shall be documented as policies or procedures (See IC.1(SR.1) and IC.1 (SR.5).

Surveyor Guidance:

Surveyors should assess the following:

- *Verify that IUSS is only used in urgent or emergent situations, as outlined in the organization's policies and procedures. Confirm that the request meets the emergent/urgent use criteria defined by the organization.*
- *Check if the urgent or emergent use of IUSS is clearly documented, including the justification, the nature of the procedure, and review how the urgency/emergency is validated (e.g., surgeon's notes, OR documentation).*
- *Surveyors should note that unless the IFU specifically prohibits the use of IUSS on the device it may be appropriate to utilize IUSS in urgent or emergent situations.*

Surgeons may request IUSS when instruments are needed urgently (patient has arrived and started the pre-operative process) but were not sterilized ahead of time, or when a procedure suddenly requires additional sterile equipment. Surveyors should review for excessive late requests or patterns that may indicate a more significant problem.

If surveyors identify recurring late requests for IUSS, it may indicate a process failure and a patient safety issue. Potential causes could include inefficiencies in scheduling, inadequate preparation, or a lack of communication between surgical teams and sterile processing.

- *Review the history of IUSS requests and identify trends in late or last-minute requests. Are there specific surgeons, departments, or times of day where these requests are more frequent?*

- *Review late requests by interviewing staff members, including surgeons. Common causes may include last-minute changes in surgical procedures, failure to account for instrument needs during preoperative planning, or insufficient instrument inventory.*

- *If no excessive patterns are established the surveyor should consider the appropriate level of nonconformity.*

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 organization (including all departments in all campuses and off-site locations).

SR.1a The hospital's medical staff shall establish criteria for the qualifications for the director of the hospital's anesthesia services in accordance with federal and state law and acceptable standards of practice.

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

Interpretive Guidelines:

The organization may or may not offer anesthesia/sedation services. If an organization 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 or medicine or osteopathy. This individual will be responsible for all anesthesia/sedation administered throughout the organization.

"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 exists along a continuum. For some medications there is no bright line that distinguishes when their pharmacological properties bring about the physiologic transition from the analgesic to the anesthetic effects. Furthermore, each individual patient may respond differently to different types of medications.

"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 (e.g., 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 organization shall 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 organization (including all departments in all campuses and off-site locations where anesthesia services are provided) shall be organized into one anesthesia service, under the direction of a qualified MD/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 anesthesia services shall be under the direction of one individual who is a qualified Doctor of Medicine (MD) or Doctor of Osteopathy (DO). Consistent with the requirement at §482.12(a)(4) for it to approve medical staff bylaws, rules and regulations, the hospital's governing body approves, after considering the medical staff's recommendations, medical staff rules and regulations establishing criteria for the qualifications for the director of the anesthesia services. Such criteria shall be consistent with State laws and acceptable standards of practice.

The anesthesia services CoP establishes certain requirements that apply only when anesthesia is administered. Consequently, each hospital that provides anesthesia services shall establish policies and procedures, based on nationally recognized guidelines, that address whether specific clinical situations involve anesthesia versus analgesia. (It is important to note that anesthesia services are usually an integral part of "surgery," as we have defined that term in our guidance. Because the surgical services CoP at §482.51 requires provision of surgical services in accordance with acceptable standards of practice, this provides additional support for the expectation that anesthesia services policies and procedures concerning anesthesia are based on nationally recognized guidelines.) Hospitals shall address whether the sedation typically provided in the emergency department or procedure rooms involves anesthesia or analgesia. In establishing such policies, the hospital is expected to take into account the characteristics of the patients served, the skill set of the clinical staff in providing the services, as well as the characteristics of the sedation medications used in the various clinical settings.

Surveyor Guidance:

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 a qualified physician (MD or DO) is responsible for the direction of all anesthesia/sedation services offered hospital wide. 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.

Review the defined scope of responsibilities or similar documentation that describes this role within the organization. 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).

Verify that anesthesia services are integrated into the organization's QMS oversight.

AS.2 ADMINISTRATION

Anesthesia shall only be administered by the following, in accordance with the organization's approved policies and procedures and with State scope of practice laws:

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 Section 410.69(b), unless exempted in accordance with AS.2 (SR.5) (42 CFR §482.52(c)), who is under the supervision of the operating practitioner or of an anesthesiologist who is immediately available;

SR.4 An anesthesiologist's assistant as defined in 42 CFR Section 410.69(b), if approved by State law, who is under the supervision of an anesthesiologist who is immediately available.

SR.5 The hospital may be exempted from the requirement for physician supervision or CRNAs as described in AS.2 (SR.3), if the State in which the hospital is located submits a letter to CMS signed by the Governor, following consultation with the State's Boards of Medicine and Nursing, requesting exemption from physician supervision of CRNAs. The letter from the Governor shall attest that he or she has consulted with the State Boards of Medicine and Nursing about issues related to access to and the quality of anesthesia services in the State and has concluded that it is in the best interests of the State's citizens to opt-out of the current physician supervision requirement, and that the opt-out is consistent with State law. The request for exemption and recognition of State laws, and the withdrawal of the request may be submitted at any time and are effective upon submission.

SR.5a The request for exemption and the withdrawal of the request may be submitted at any time and is effective upon submission.

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.

SR.8 The organization's governing body (or persons legally responsible) shall specify and approve the anesthesia privileges for each practitioner who furnishes anesthesia services, addressing the type of supervision, if any, required, and for each practitioner who supervises the administration of anesthesia by another practitioner.

SR.8a The organization's medical staff shall define the criteria and qualifications for determining the anesthesia privileges to be granted to each individual practitioner and a procedure for applying the criteria to individuals requesting privileges (see MS.6).

SR.8b The type and complexity of procedures for which the practitioner may administer anesthesia shall be specified in the privileges granted to the individual practitioner.

SR.8c Privileges are granted in accordance with the practitioner's scope of practice, state law, the individual competencies of the practitioner, organization policy, and credentialing and privileging criteria.

SR.9 The medical staff bylaws or rules and regulations shall specify for each category of operating practitioner, the type and complexity of procedures that category of practitioner may supervise.

SR.9a The organization's medical staff establishes criteria for the qualifications for supervision in accordance with the physician's scope of practice and state law. Criteria and qualifications shall include competencies, training, education and (if required) experience regarding the administration of anesthesia/sedation.

Interpretive Guidelines:

The organization'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 nationally recognized standards of practice and guidelines.

AS.2 (SR.1 – SR.4) defines those physicians and other practitioners who can administer anesthesia/sedation.

Anesthesia Services Policies

The medical staff bylaws or rules and regulations shall 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. The organization's governing body (or persons legally responsible) shall specify and approve the specific anesthesia privileges for each practitioner who furnishes anesthesia services, addressing the type of supervision, if any, required. The privileges granted shall be in accordance with the practitioner's scope of practice, state law, the individual competencies of the practitioner, organization policy, and credentialing and privileging criteria. The type and complexity of procedures for which the practitioner may administer anesthesia shall be specified in the privileges granted to the individual practitioner.

Guidelines for Developing Policy Regarding Immediate Availability:

Per the ASA position statement, "Definition of "Immediately Available" When Medically Directing" (https://www.asahq.org/quality-and-practice-management/standards-and-guidelines):

"An anesthesiologist who is personally performing an anesthetic is exclusively and completely dedicated to that case. A medically directing anesthesiologist is immediately available if s/he is in physical proximity that allows the anesthesiologist to re-establish direct contact with the patient to meet medical needs and any urgent or emergent clinical problems. These responsibilities may also be met through coordination among anesthesiologists of the same group or department.

Differences in the design and size of various facilities make it impossible to define a universally applicable specific time or distance for physical proximity. The physical layout of the operating room and other anesthetizing locations are important in determining how medically directing anesthesiologists can fulfill the requirement to be immediately available."

The organization shall establish objective and specific written policies regarding immediate availability that consider objective elements such as distance, a map or time that recognizes the specific local environment, and factors that should be taken into account so that a medically directing anesthesiologist is available to immediately conduct hands- on intervention for each patient. The demands of particular surgical and other diagnostic or therapeutic procedures and the clinical needs of patients may further restrict what constitutes immediate availability under specific circumstances.

When an organization permits operating practitioners to supervise a CRNA administering anesthesia, the medical staff bylaws or rules and regulations shall 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.

Guidelines for Developing Policy Regarding Supervision by the Operating Practitioner or by an Anesthesiologist:

The organization's medical staff establishes criteria for the qualifications for supervision in accordance with the physician's scope of practice and state law. Criteria and qualifications shall include competencies, training, education and (if required) experience regarding the administration of anesthesia/sedation.

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 organization shall have policies and procedures, consistent with State scope of practice law, governing the provision of these types of anesthesia services. Further, the organization shall 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 shall 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 organization's anesthesia services policies shall 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 shall be permissible under State law and comply with all State requirements concerning qualifications. The organization 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 shall be supervised either by the operating practitioner who is performing the procedure, or by an anesthesiologist who is immediately available.

The organization 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 an organization may permit a CRNA to administer anesthesia without operating practitioner or anesthesiologist supervision.

A CRNA is defined in 42 CFR Section 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 shall be immediately available. 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 Section 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:

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 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).

As of May 1, 2024, there are a total of twenty-four states and Guam that have chosen to opt-out (note partial vs. full opt-out detail below):

- *Alaska, Arizona, Arkansas, California, Colorado, Delaware, Idaho, Iowa, Kansas, Kentucky, Michigan, Minnesota, Montana, Nebraska, New Hampshire, New Mexico, North Dakota, Oklahoma, Oregon, South Dakota, Washington, Wisconsin*

Partial opt-out

- *Utah (February 2022: partial opt-out limited to Critical Access Hospitals and specified rural hospitals)*
- *Wyoming (May 2023: partial opt-out limited to Critical Access Hospitals and hospitals with 25 licensed beds or less)*

Review the organization'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 organization's anesthesia service policies.

AS.3 POLICIES AND PROCEDURES

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

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

SR.2a A pre-anesthesia evaluation shall be performed for each patient who will receive general, regional or monitored anesthesia.

SR.2a(1) Performed and documented by an individual, qualified as specified by AS.2 (§482.52(a)), 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.2b Patients who will be receiving moderate sedation shall 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.2c A pre-anesthesia evaluation shall include;

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

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

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

SR.2c(4) An anesthesia risk assessment,

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

SR.3 An intra-operative anesthesia record shall be present for each patient who will receive general, regional or monitored anesthesia. Patients who will be receiving moderate sedation shall 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.4 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.4a The elements of an adequate post-anesthesia evaluation should be clearly documented in accordance with State law and with hospital policies and procedures that have been approved by the medical staff and that reflect current standards of anesthesia care, and conform to current standards of anesthesia care, including:

SR.4a(1) Respiratory function, including respiratory rate, airway patency, and oxygen saturation;

SR.4a(2) Cardiovascular function, including pulse rate and blood pressure;

SR.4a(3) Mental status;

SR.4a(4) Temperature;

SR.4a(5) Pain;

SR.4a(6) Nausea and vomiting; and,

SR.4a(7) Postoperative hydration.

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

SR.5 A post-anesthesia evaluation for anesthesia recovery is required for each patient who will receive general, regional or monitored anesthesia.

SR.5a If the required elements of the post-anesthesia evaluation are available elsewhere in the medical record, it is acceptable if referred to and authenticated as accurate by the individual qualified to administer anesthesia.

SR.5b While the evaluation shall 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 organization 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 shall be addressed by organization policies and procedures.

SR.6 All anesthesia patients shall be discharged from the hospital in the company of a responsible adult unless exempted by the practitioner who performed the surgical procedure.

Interpretive Guidelines:

The organization shall 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 shall

address the following:

Pre-anesthesia/sedation responsibilities:

- *Physical examination of the airway (by those qualified and privileged to administer sedation) shall 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 organization'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.*

Intra-operative 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.*

If the required elements of the post-anesthesia evaluation are available elsewhere in the medical record, it is acceptable if referred to and authenticated as accurate by the individual qualified to administer anesthesia. For example, the provider's post-anesthesia evaluation documentation might include an attestation that the provider reviewed the required evaluation elements as part of the post-operative assessment and evaluation.

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

All anesthesia patients shall be discharged from the hospital in the company of a responsible adult unless exempted by the practitioner who performed the surgical procedure.

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 organization 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 organization

policies and procedures approved by the medical staff.

OBSTETRICAL CARE SERVICES (OB)

OB.1 ORGANIZATION

SR.1 If the hospital offers obstetrical care services, the services shall be well organized and provided for the health care (including physical and behavioral health) of pregnant, birthing, and postpartum patients in accordance with nationally recognized acceptable standards of practice, including but not limited to ACOG, AWHONN, WHO, and other professional organizations applicable to obstetrical services.

SR.2 If outpatient obstetrical care services are offered, the services shall be consistent in quality with inpatient care in accordance with the complexity of services offered.

SR.3 The scope of obstetrical care services provided by the hospital shall be defined in writing and approved by the medical staff.

SR.4 Obstetrical care services shall be organized and integrated with other departments of the hospital.

SR.5 Obstetrical services leadership must engage in QAPI as specified in QM.1 and QM.7 for obstetrical services, including but not limited to participating in data collection and monitoring as specified in QM.1.

SR.5a If a maternal mortality review committee (MMRC) is available at the State, Tribal, or local jurisdiction in which the hospital is located, the facility leadership, obstetrical services leadership, or their designate(s) must further have a process for incorporating publicly available MMRC(s) data and recommendations into the hospital QAPI program as specified in QM.1.

Interpretive Guidelines:

If the organization provides any inpatient or outpatient obstetrical care services, they shall be organized and staffed in such a manner to ensure the health and safety of patients and be in accordance with nationally recognized standards of practice and guidelines, including but not limited to the ACOG, AWHONN, WHO, and other professional organizations that are applicable to the scope and complexity of obstetrical care services provided.

The organization shall design obstetrical care services to ensure the standards of medical practice and patient care are implemented and maintained.

The organization shall develop and implement policies and procedures for providing obstetrical care services that are in accordance with acceptable standards of medical practice and obstetrical patient care. (See OB.4)

Surveyor Guidance:

Review and verify the extent of surgical services provided by the organization and verify that services are in accordance with nationally recognized standards of practice and guidelines.

OB.2 SUPERVISION, STAFFING, AND STAFF EDUCATION

SR.1 Labor and delivery rooms/suites (including labor rooms, delivery rooms (including rooms for operative delivery), and post-partum/recovery rooms whether combined or separate) shall be supervised by a registered nurse with appropriate experience, certified nurse midwife, nurse practitioner, physician assistant, or a Doctor of Medicine or Osteopathy.

SR.2 The hospital shall develop policies, procedures, and protocols to ensure that relevant staff are trained on select topics for improving the delivery of maternal care.

SR.2a Training concepts shall reflect the scope and complexity of services offered within the facility, including but not limited to:

SR.2a(1) Facility-identified evidence-based best practices and protocols to improve the delivery of maternal care within the facility; and

SR.2a(2) The hospital shall use findings from its QAPI program, as required at QM.1 (§ 482.21), to inform staff training needs and any additions, revisions, or updates to training topics on an ongoing basis.

SR.2b The governing body shall identify and document which staff shall complete initial training and subsequent biennial training on the topics identified in OB.2 and OB.4.

SR.2c The hospital shall provide relevant new staff with initial training.

SR.2d The hospital shall document in the staff personnel records that the training was successfully completed.

SR.2e The hospital shall be able to demonstrate staff knowledge on the topics identified in OB.2 and OB.4.

Interpretive Guidelines:

The organization's obstetrical care services (including both inpatient and outpatient) shall be supervised by an experienced RN, certified nurse midwife, nurse practitioner, physician assistant, or a Doctor of Medicine or Osteopathy. The individual supervising the department shall possess appropriate education, experience working in obstetrical care services, and specialized training in the provision of obstetrical care services/management.

Surveyor Guidance:

Review the organization's organization chart regarding obstetrical care services to confirm that there are lines of authority and delegation of responsibility indicated within obstetrical care services.

Verify that an RN, certified nurse midwife, nurse practitioner, physician assistant or a Doctor of Medicine or Osteopathy is assigned responsibility for supervision of obstetrical care services.

Request a copy of the supervisor's position description to determine that it specifies qualifications, duties, and responsibilities of the position.

Review and verify the governing body has identified which staff shall complete initial and ongoing training. Verify training was completed in accordance with organization policies.

Review scope of service and verify it matches the services provided and has been approved by the medical staff.

Interview staff to determine knowledge of requirements as defined in OB.2 and OB.4.

OB.3 PRACTITIONER PRIVILEGES

SR.1 The hospital shall have delineated obstetrical care privileges established by the organization's department of obstetrics and medical staff and approved by the governing body for each practitioner (see MS.6).

SR.1a The hospital shall establish criteria, qualifications and a credentialing process to grant specific privileges to individual practitioners based on each individual practitioner's compliance with the privileging/credentialing criteria and in accordance with Federal and State laws and regulations.

Interpretive Guidelines:

The hospital shall delineate the obstetrical care privileges of all practitioners performing obstetrical care and obstetric procedures. The medical staff is accountable to the governing body for the quality of care provided to patients. The medical staff bylaws shall include criteria for determining the privileges to be granted to an individual practitioner and a procedure for applying the criteria to individuals requesting privileges. Obstetrical care privileges are granted in accordance with the competencies of each practitioner. The medical staff appraisal procedures shall evaluate each individual practitioner's training, education, experience, and demonstrated competence as established by the hospital's QAPI program, credentialing process, the practitioner's adherence to hospital policies and procedures, and in accordance with scope of practice and other State laws and regulations.

Surveyor Guidance:

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

OB.4 POLICIES, PROTOCOLS, AND PROVISIONS

SR.1 Obstetrical care services shall be designed to ensure the achievement and maintenance of high standards of medical practice and patient care and shall be consistent with the needs and resources of the facility.

SR.2 The hospital shall develop and implement policies and procedures for providing obstetrical care that are in accordance with acceptable standards of medical practice and obstetrical patient care.

SR.3 The following equipment shall be kept at the hospital and be readily available for treating obstetrical cases to meet the needs of patients in accordance with the scope, volume, and complexity of services offered:

SR.3a Call-in-system,

SR.3b Cardiac monitor, and

SR.3c Fetal doppler or monitor.

SR.4 The hospital shall develop protocols consistent with nationally recognized and evidence-based guidelines for the care of patients with obstetrical emergencies, complications, immediate post-delivery care, and other patient health and safety events as identified as part of the QAPI program in QM.1 (§ 482.21).

SR.4a The protocols shall be developed and approved by the medical staff.

SR.4b The hospital shall be able to demonstrate their protocols are based on nationally recognized and evidence-based guidelines.

SR.5 Provisions include equipment (in addition to the equipment required in OB.4 (SR.3), supplies, and medication used in treating emergency cases.

SR.5a Such provisions shall be kept in the hospital and be readily available for treating emergency cases.

Interpretive Guidelines:

The organization shall have policies, procedures, and protocols for the delivery of obstetrical care services that have been developed and approved by the medical staff. Policies and procedures developed by the hospital shall take into consideration obstetrical emergencies, complications, immediate post-delivery care, and other patient health and safety events.

Surveyor Guidance:

Validate the organization has approved policies, procedures, and protocols applicable to the obstetrical care scope of services provided by the organization and approved by the medical staff.

Determine what nationally evidence-based guidelines the organization uses as points of reference. Interview staff to determine staff knowledge of procedures and protocols in place.

Verify the organization has the required equipment available for use.

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.

SR.7 The performance of Laboratory services shall require a provider order (Doctor of Medicine or Osteopathy, or LP).

SR.7a Alternatively, laboratory services shall be performed when required as part of an approved order set or standing order.

Interpretive Guidelines:

The organization shall maintain, or have available, adequate laboratory services whenever its patients need those services. The organization 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 organization 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 shall 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 organization'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 human immunodeficiency virus (HIV) infectious blood and blood components can come from a donor who: tested negative at the time of donation but tests reactive for evidence of HIV infection on a later donation; tests positive on the supplemental (additional, more specific) test or other follow-up testing required by FDA; and for whom the timing of seroconversion cannot be precisely estimated. Potentially hepatitis C virus (HCV) infectious blood and blood components are the blood and blood components identified in 21 CFR 610.47.

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.

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 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 shall destroy or label prior collections of blood and blood products held in quarantine (as set forth at 21 CFR 610.46(b)(2) and 610.47(b)(2)).

SR.6 The organization shall 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, retested 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 organization 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 organizations 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 organization and blood bank shall 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(d)).

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 organization'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 shall 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 through an approved accreditation

organization under the Clinical Laboratory Improvement Amendments (CLIA). If the hospital laboratory does not maintain accreditation, then the following shall 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 organization'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 organization 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 shall 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.

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 For a possible HIV infectious transfusion patient that 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 shall notify the patient's parents or legal guardian.

Interpretive Guidelines:

The organization shall 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 organization 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 shall 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 shall 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 shall 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 shall 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. CDCs 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 shall notify the patient's representative or relative. Upon learning of the death of the patient transfused with HIV infectious blood, the hospital shall 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 through an approved accreditation organization under the Clinical Laboratory Improvement Amendments (CLIA). If the hospital laboratory does not maintain accreditation, then the following shall 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 24, 2007, the organization shall 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*

- *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*

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 through an approved accreditation organization under the Clinical Laboratory Improvement Amendments (CLIA). If the hospital laboratory does not maintain accreditation, then the following shall 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 organization 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. The organization shall meet the needs of the patients in accordance with acceptable standards of practice.

SR.2 The scope of diagnostic and/or therapeutic respiratory services offered by the hospital shall be defined in writing and approved by the medical staff.

SR.3 Respiratory care services provided at the organization shall be delivered in accordance with medical staff directives.

SR.4 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. The director may serve on either a full-time or part-time basis.

SR.4a The medical director shall be appointed by the medical staff and governing body.

SR.4b The hospital's medical staff shall establish criteria for the qualifications for the director of the hospital's respiratory care services in accordance with federal and state law and acceptable standards of practice.

SR.5 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 organization 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 nationally recognized standards of practice and guidelines.

Nationally recognized standards of practice and guidelines 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 medical director shall be appointed by the medical staff and governing body.

The organization shall provide the appropriate equipment and types and numbers of qualified personnel necessary to furnish the services offered by the organization in accordance with

acceptable nationally recognized standards of practice and guidelines.

The scope of diagnostic and/or therapeutic respiratory services offered by the organization shall 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 nationally recognized standards of practice and guidelines.

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

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 organization's policies and procedures and State laws.

SR.2 All orders for all respiratory treatment and interventions shall be documented in the patient's medical record in accordance with the requirements defined under the Medical Records (MR) chapter 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 organization'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 be developed and approved by the medical staff, be consistent with applicable state law, nationally recognized standards of practice and guidelines

and specify:

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

SR.1a The qualifications, education, training and experience needed for each type of respiratory care service;

SR.1b Whether personnel can perform it without supervision; and

SR.1c The type of personnel qualified to provide the direct supervision.

Interpretive Guidelines:

The organization shall 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) shall 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) shall address, as applicable to the scope of respiratory services provided by the organization, 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;*
- *Procedures to follow in the advent of adverse reactions to treatments or interventions;*
- *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; and*

- *Procedures for obtaining and analyzing blood samples (e.g., arterial blood gases).*

Surveyor Guidance:

Validate that the above minimum list of policies and procedures have been developed and approved by the medical staff, as applicable for the scope of respiratory services provided by the organization.

Review treatment logs, job descriptions of respiratory care staff, and policies and procedures to determine the following:

- *Duties and responsibilities of staff;*
- *Qualifications and education required, including licensure, consistent with State law;*
- *Specialized training or experience needed to perform specific duties.*

RC.4 TESTS OUTSIDE THE LABORATORY

SR.1 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 Section 482.27 and LS.1.

Interpretive Guidelines

Refer to the guidelines under 42 C.F.R. Section 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:

All radiological services provided by the hospital, whether provided by hospital staff or under arrangement, including diagnostic, therapeutic, and nuclear medicine, shall be provided in accordance with nationally recognized standards of practice and guidelines and shall meet professionally approved standards for safety.

Nationally recognized standards of practice and guidelines 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 (American Medical Association, American College of Radiology, Radiological Society of North America, Alliance for Radiation Safety in Pediatric Imaging, American Society of Radiologic Technologists, American College of Cardiology, American College of Neurology, American College of Physicians, etc.).

The hospital shall maintain, and have available, diagnostic radiological services according to the needs of the patients the hospital serves, with the ability to provide the services promptly when needed. 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.

"Maintain" in this context means furnishing radiologic services on-site, while having them available means providing access to radiologic services even when they are not furnished on-site.

The scope and complexity of radiological services offered shall be specified in writing and approved by the governing body (or responsible individual) in order to demonstrate how the hospital has planned to meet the needs of its patients. The hospital has the flexibility to choose the types and complexity of radiologic services offered. They may offer only a minimal set of services or a more complex range of services (including nuclear medicine).

In determining the scope and complexity, this also includes considerations for determining which modalities are required to operate 24/7 in order to meet the needs of the hospital's patient population, including emergency services, and ensuring patient access to other modalities when they are not furnished on site. A hospital with a busy emergency department that handles

trauma, stroke, and other complex medical and surgical cases would be expected to maintain on-site a wider range of diagnostic radiologic services that are ready to be furnished when needed. Necessary radiological services shall be available to meet patients' needs in a clinically appropriate timeframe.

Surveyor Guidance:

Verify that the organization 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 nationally recognized standards of practice and guidelines and are maintained or available at all times to meet 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 labeling, storage, use, transport, 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 LPs who may be exposed to ionizing radiation during procedures.

SR.2a The radiologic services, particularly ionizing radiology procedures, shall be free from hazards for patients and personnel.

SR.3 Any high radiation readings shall be investigated and reported to Quality Management Oversight.

Interpretive Guidelines:

The organization shall develop and implement policies and procedures to provide a safe environment for patients and staff.

The organization policies and procedures shall address the safety standards for the following:

- *Adequate shielding for patients, personnel and facilities;*
- *Proper labeling, storage, use, transport, and disposal of radioactive materials and waste;*
- *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;*
- *Methods of identifying patients who may be pregnant;*
- *The organization shall implement and ensure compliance with its established safety standards;*
- *The organization shall require any staff member who may be regularly 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. The types or locations of employees requiring monitoring for radiation exposure shall be identified in policy and procedure and approved by the supervising radiologist and qualified radiation safety personnel.*

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 organization and review the records for the most recent inspection of the aprons;*
- *Verify that hazardous materials are stored properly in a safe manner with appropriate labeling of radioactive materials, waste, and hazardous areas;*
- *Review the process for hazardous material exposure incidents and the protocol followed when this occurs;*
- *Verify that the organization requires periodic checks on all radiology personnel and any other organization 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 organization) – review the records related to these checks;*
- *Verify that appropriate staff have a device to detect radiation and that it is worn appropriately without interference to detect radiation, and stored appropriately when not in use; and*
- *Review the organization and functioning of the radiation safety program including policies and systems used to identify and resolve safety issues.*

MI.3 EQUIPMENT

SR.1 Periodic inspection of equipment shall be performed, at least minimally according to manufacturer's recommendations (see PE.7). Hazards shall be identified and promptly corrected (See PE.1).

SR.2 Documentation of preventative maintenance and repairs of radiology equipment shall be maintained (See PE.7).

Interpretive Guidelines:

The organization shall have policies and procedures in place to ensure that periodic inspections of radiology equipment are conducted. Equipment includes not only devices used to deliver radiologic services, but also exposure meters, badges, or personal radiation monitoring devices used by staff, as well as equipment used to inspect or calibrate devices used to deliver diagnostic or therapeutic radiologic services. 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 organization shall maintain repair documentation and records for periodic maintenance.

Either the organization's staff or a qualified contract entity shall ensure that equipment is inspected in accordance with manufacturer's instructions, federal and state laws, regulations, guidelines, and organization 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 organization 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

SR.1 Medical imaging services shall 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 shall have these clinical privileges. This also applies to practitioners outside the organization 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 shall approve the qualifications necessary for radiologist appointment to the medical staff.

The organization shall develop and implement policies that have been approved by the medical staff to designate which radiology tests require interpretation by a radiologist, as opposed to another type of practitioner holding privileges.

In the event that the organization contracts for telemedicine to be used, the governing body of the hospital whose patients are receiving the telemedicine services may choose, in lieu of the requirements in MS.6, 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 radiologist(s) providing such services.

Otherwise, the radiologists are subjected to the complete credentialing and privileging process through the medical staff to be approved for providing this service for the organization. Regardless of whether the option of delegated credentialing is utilized, the governing body is still legally responsible for all privileging decisions and shall formally approve the privileges for the practitioners. See MS.15 and MS.6.

A radiologist who is a member of the medical staff who supervises radiology services, to include the following:

- *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);*
- *Assuring the enforcement of infection control practices within the radiology setting;*
- *Ensuring that a process is in place to provide emergency care to patients who experience an adverse reaction to diagnostic agents in the radiology setting;*
- *Ensuring the security of files, scans, and other image records and are readily retrievable when needed; and,*
- *Providing 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 organization 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 organization. See MS.15 and MS.6.

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

SR.1 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 organization 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 INTERPRETATION AND RECORDS

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

SR.2 Records of medical imaging services shall be maintained, in accordance with Nuclear Regulatory Commission requirements and any other applicable federal and state law.

SR.2a At a minimum, the organization shall maintain the following for at least 5 years:

SR.2a(1) Copies of reports and print outs; and,

SR.2a(2) Films, scans, and other image records.

Interpretive Guidelines:

The organization shall 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 organization 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 shall 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 organization'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 organization 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 shall meet the needs of the patients in accordance with nationally recognized standards of practice and guidelines as defined by the medical staff.

SR.1a 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.3a The hospital's medical staff shall establish criteria for the qualifications for the director of the hospital's nuclear medicine services in accordance with federal and state law and acceptable standards of practice.

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 organization 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 shall be in accordance with nationally recognized standards of practice and guidelines 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 shall be under the direction of a Doctor of Medicine or Osteopathy who shall be qualified in nuclear medicine.

The medical staff and physician responsible for nuclear medicine services shall 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.

Ask if the organization has had any medical event since the last survey that has been reported to the Nuclear Regulatory Commission. (NRC requires notification of such an event within one calendar day; the patient and ordering physician shall also be notified).

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 (See PE.5).

SR.2 The organization shall maintain records of the receipt and disposition of radiopharmaceuticals; and,

SR.2a Have a stated timeframe for retention of these records in accordance with federal and state law.

SR.3 In-house preparation of radiopharmaceuticals shall be by or under the supervision of an appropriately trained registered pharmacist or Doctor of Medicine or Osteopathy (See MM.1).

SR.4 If laboratory tests are performed in the nuclear medicine service, the service shall meet the applicable requirements for laboratory services as specified in 42 CFR 482.27.

Interpretive Guidelines:

The organization 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 organization 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 organization;*
- *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 shall 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 shall oversee the preparation of radiopharmaceuticals.

If laboratory tests are performed in the nuclear medicine service, the service shall 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 shall be appropriate for the types of nuclear medicine services offered and shall be maintained for safe and efficient performance (See PE.7).

SR.2 The equipment shall be maintained in safe operating condition and inspected, tested, and calibrated at least annually by qualified personnel (See PE.7).

SR.3 Documentation of equipment testing, and preventative maintenance shall be maintained (See PE.7).

Interpretive Guidelines:

The organization shall 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 shall 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 shall be appropriate for the types of nuclear medicine services offered and shall 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 shall sign and date the interpretation of these tests.

SR.2 The organization shall maintain signed and dated reports of nuclear medicine interpretations, consultations, and procedures.

SR.3 The organization shall 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 organization shall 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 shall comply with Medical Records Services standards as stated under MR.1 – MR.7. Such records will be retained according to 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.

SR.2 The scope of rehabilitation services offered by the organization shall be defined in writing and approved by the medical staff.

Interpretive Guidelines:

Rehabilitative services (including contractual services) may include physical therapy, occupational therapy, audiology and speech pathology services. The scope of rehabilitation services offered by the organization shall be defined in writing and approved by the medical staff.

The organization will adhere to acceptable nationally recognized standards of practice and guidelines, including 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 organization or through a contractual arrangement. Review the organization's policies and procedures to verify that the scope of rehabilitation services offered is defined in writing and approved by the medical staff.

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 organization's QMS 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 delivered 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 (See SM.1 and SM.2); and

SR.1c Adequate numbers of staff (physical therapists, physical therapist assistants, occupational therapists, occupational therapist assistants, speech-language

pathologists, or audiologists) to perform evaluations and treatments who meet the qualifications in 42 CFR 484.115 and as defined by the medical staff, organization, and consistent with State law. (See SM.1, SM.2).

Interpretive Guidelines:

The organization shall manage and support the service(s) as necessary to maintain the level of necessary services. In order to support these services, the appropriate equipment and qualified personnel shall be in place and follow nationally recognized standards of practice and guidelines.

The rehabilitation services offered shall 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 and consistent with state law, to provide these services.

Surveyor Guidance:

Verify that rehabilitation services under the direction of a qualified individual. Review the personnel file and job description to verify that that he/she has the necessary education, experience and specialized training, as defined by the organization, to properly supervise and administer the service.

Sample personnel files to verify that staff performing rehabilitative services (physical therapists, physical therapist assistants, occupational therapists, occupational therapist assistants, speech-language pathologists, or audiologists) meet the qualifications in 42 CFR 484.115 and as defined by the medical staff and the organization. Verify current licensure, certifications and ongoing training, consistent with applicable State laws.

Review medical records to verify that a qualified professional evaluates the patient and initiates each treatment episode.

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.

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 organization's medical staff to order these services in accordance with the organization's policies and procedures and State laws.

SR.2 All orders for rehabilitative services, treatment plan, results, and notes shall 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 shall be in accordance with national acceptable standards of practice and shall also meet the requirements of 42 CFR 409.17.

SR.3a The plan shall be established before treatment begins by one of the following:

SR.3a(1) A physician.

SR.3a(2) A nurse practitioner, a clinical nurse specialist or a physician assistant.

SR.3a(3) The physical therapist furnishing the physical therapy services.

SR.3a(4) A speech-language pathologist furnishing the speech-language pathology services.

SR.3a(5) An occupational therapist furnishing the occupational therapy services.

SR.3b The plan shall include:

SR.3b(1) The type, amount, frequency, and duration of the physical therapy, occupational therapy, or speech-language pathology services; and

SR.3b(2) The diagnosis and anticipated goals, results and notes.

SR.3c Any changes in the plan are implemented as necessary and in accordance with organization policy and procedure to account for changes in the patient's condition and response to therapeutic intervention.

Interpretive Guidelines:

The organization 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.

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 that meets the requirements of SR.3.

Verify that changes in the treatment plan are documented in the patient's medical record to include the evaluation, test results, orders, and practitioner approvals of changes as defined in organization policy and procedure.

EMERGENCY SERVICES (ES)

The organization shall meet the emergency needs of its patients in accordance with acceptable standards of practice and the requirements of this chapter.

ES.1 ORGANIZATION

SR.1 Emergency Services shall be organized and integrated with other departments under the direction of a qualified member of the medical staff.

SR.1a The hospital's medical staff shall establish criteria for the qualifications for the director of the hospital's emergency services in accordance with federal and state law and acceptable standards of practice.

SR.2 The medical staff shall be responsible for developing and maintaining policies and procedures governing the medical care delivered in the emergency department including, but not limited to, triage of the patient.

Interpretive Guidelines:

The organization's emergency services shall 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.

Emergency Services integration would include at a minimum:

- *Coordination and communication between the Emergency Department and other hospital services/departments;*
- *Physical access for emergency department patients to the services, equipment, personnel, and resources of other hospital departments/services;*
- *The immediate availability of services, equipment, personnel, and resources of other hospital departments/services to emergency patients; and*
- *That the provision of services, equipment, personnel and resources of other hospital departments/services to emergency department patients is within timeframes that protect the health and safety of patients and is within acceptable standards of practice, including:*
    - *The length of time it takes to transport the emergency patient from the ED to another hospital department where needed interventions or diagnostic services will be rendered.*
    - *The length of time it takes to deliver equipment or supplies, or for the staff from other departments to travel from their location to the emergency department in order to provide needed interventions, tests, care, or services.*

Time is critical in the provision of emergency care. The hospital must be able to demonstrate how the hospital's other departments provide emergency patients the care and services needed

within safe and appropriate times.

In emergency care situations, the time needed to provide the patient with appropriate diagnostic and care interventions can have a significant effect on the patient. Delays in diagnosis and the provision of needed interventions is likely to adversely affect the health and safety of patients who require emergency care. Therefore, a hospital that cannot demonstrate integration of its emergency services with its other departments (including radiological services, OR, intensive care, laboratory, etc.) would not be in compliance with the Emergency Services (ES) Chapter.

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 and acceptable standards of practice.

The medical staff will ensure that policies and procedures are developed and implemented to govern the emergency services provided.

The use of standing orders (see MR.7) in the Emergency Department, unless otherwise prohibited by Federal or State Law, does not relieve a hospital of its obligations under the Emergency Medical Treatment and Labor Act (EMTALA) to have qualified medical personnel complete required screening and, when applicable, stabilizing treatment in a timely manner.

Hospitals have the responsibility and shall 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. Potential EMTALA violations are to be referred by the Team Lead to the DNV Healthcare central office.

ES.2 STAFFING

SR.1 The organization shall staff the emergency department with the appropriate numbers and types of professionals and other staff who possess the skills, education, certifications, specialized training and experience in emergency care to meet the written emergency procedures and needs determined by the organization. See SM.3 and SM.4.

SR.1a The organization shall determine the categories and numbers of MD/DOs, specialists, RNs, EMTs, mid-level practitioners and emergency department support staff required to meet anticipated emergency needs.

SR.1a(1) The organization shall conduct periodic assessments of its emergency needs in order to anticipate the policies, procedures, staffing, training, and other resources that may be needed to address likely demands.

SR.1b The medical staff must establish criteria, in accordance with State law and regulations and acceptable standards of practice delineating the qualifications required for each category of emergency services staff (e.g., MD/DOs, specialists, RNs, EMTs, mid-level practitioners, etc.).

SR.2 A qualified registered nurse or paramedic, as allowable by state law, shall perform patient triage upon presentation to the emergency department.

SR.3 The organization shall ensure that a qualified member of the medical staff is on premises and available to supervise the provision of emergency services at all times.

SR.4 The organization shall work cooperatively with Federal, State and local emergency preparedness agencies and officials in order to identify likely risks to the community (e.g., natural disasters, mass casualties, terrorist acts, etc.), to anticipate demands and resources needed by the hospital emergency services, and to develop plans, methods and coordinating networks to address those anticipated needs (See PE.6).

Interpretive Guidelines:

The organization 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 organization shall 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.

A qualified clinician, as allowable by state law shall perform triage (e.g. RN, Paramedic).

The organization shall 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.

The hospital shall determine the categories and numbers of MD/DOs, specialists, RNs, EMTs, and emergency department support staff the hospital needs to meet its anticipated emergency needs.

The medical staff shall establish criteria, in accordance with State law and regulations and acceptable standards of practice, delineating the qualifications required for each category of emergency services staff (e.g., emergency physicians, specialist MD/DO, RNs, EMTs, mid-level practitioners, etc.).

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.

Interview staff to determine that they are knowledgeable, within their own level of participation in emergency care including:

- *Parenteral administration of electrolytes, fluids, blood and blood components;*
- *Care and management of injuries to extremities and central nervous system; and*
- *Prevention of contamination and cross infection.*

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.

ES.3 PROTOCOLS AND PROVISIONS

Note: The requirements of ES.3 *shall be implemented by July 1, 2025.*

In accordance with the complexity and scope of services offered, there shall be adequate provisions and protocols to meet the emergency needs of patients.

SR.1 The hospital shall develop protocols consistent with nationally recognized and evidence-based guidelines for the care of patients with emergency conditions.

SR.1a The protocols shall be developed and approved by the medical staff.

SR.1b The protocols shall include care of patients with obstetrical emergencies, complications, and immediate post-delivery care, regardless of whether the organization offers obstetrical care services.

SR.1b(1) If the hospital offers obstetrical care services, the protocols for obstetrical emergencies, complications, and immediate post-delivery care shall be developed and approved with input from provider(s) with privileges in obstetrical care.

SR.1c The hospital shall be able to demonstrate their protocols are based on nationally recognized and evidence-based guidelines.

SR.2 The hospital shall have provisions including equipment, supplies, and medication used in treating emergency cases. Such provisions shall be kept at the hospital and be readily available for treating emergency cases to meet the needs of patients. The available provisions shall include the following:

SR.2a Drugs and biologicals commonly used in life-saving procedures shall be provided at a minimum to include:

SR.2a(1) Analgesics;

SR.2a(2) Local Anesthetics;

SR.2a(3) Antibiotics;

SR.2a(4) Anticonvulsants;

SR.2a(5) Antidotes and emetics;

SR.2a(6) Serums and toxoids;

SR.2a(7) Antiarrhythmics;

SR.2a(8) Cardiac glycosides;

SR.2a(9) Antihypertensives;

SR.2a(10) Diuretics; and,

SR.2a(11) Electrolytes and replacement solutions.

SR.2b Equipment and supplies (adult and pediatric sizes) shall be provided at a minimum to include:

SR.2b(1) Airways, endotracheal and nasogastric tubes;

SR.2b(2) Ambu bag, valve and masks;

SR.2b(3) Oxygen;

SR.2b(4) Immobilization devices and splints;

SR.2b(5) Tourniquets;

SR.2b(6) Suction machine and related supplies;

SR.2b(7) IV therapy supplies;

SR.2b(8) Defibrillator and cardiac monitor; and,

SR.2b(9) Chest tubes and indwelling catheters.

SR.2c Each emergency services treatment area shall have a call-in system for each patient.

SR.2d Blood and blood products commonly used in life-saving procedures.

SR.3 Applicable staff, as identified by the hospital, shall be trained annually on the protocols and provisions implemented according to ED.3.

SR.3a The governing body shall identify and document which staff shall complete such training;

SR.3b The hospital shall document in the staff personnel records that the training was successfully completed;

SR.3c The hospital shall be able to demonstrate staff knowledge on the topics implemented pursuant to this section; and

SR.3d The hospital shall use findings from its QAPI program, as required at QM.1 (§ 482.21), to inform staff training needs and any additions, revisions, or updates to training topics on an ongoing basis.

Interpretive Guidelines:

The organization shall provide the appropriate equipment and qualified personnel necessary to furnish all services offered in a safe manner in accordance with nationally recognized standards of practice and guidelines.

There shall be written policies, procedures, and/or protocols for the delivery of any services provided. The policies, procedures, and/or protocols shall be developed and approved by the medical staff.

Surveyor Guidance:

Validate the organization has utilized nationally recognized guidelines and evidence-based practices in the creation of their protocols.

Review appropriate staff files to validate required training was completed.

How does the organization ensure that the required equipment, supplies and medications are always readily available in the organization?

How does the organization ensure that staff knows where drugs and biologicals are stored? How does the organization ensure that staff know where emergency equipment and supplies are stored?

Determine when the last time emergency supplies were used and who is responsible for monitoring supplies?

ES.4 EMERGENCY SERVICES NOT PROVIDED

SR.1 If emergency services are not provided at the organization, the governing body shall assure that the medical staff has written policies and procedures for appraisal of emergencies, initial treatment, and referral when appropriate.

SR.2 The organization shall have policies and procedures addressing individuals' emergency care needs 24 hours per day and 7 days per week. These policies include, at a minimum:

SR.2a Appraisal of persons with emergencies: The organization shall have medical staff policies and procedures for conducting appraisals of persons with emergencies. The policies and procedures shall ensure that:

SR.2a(1) The MD/DO (on-site or on-call) directly provides appraisals of emergencies or provides medical direction of on-site staff conducting appraisals;

SR.2a(2) An RN is immediately available, as needed, to provide bedside care to any patient and that,

SR.2a(3) Among such RN(s) who are immediately available at all times, there shall be an RN(s) who is/are qualified, through a combination of education, licensure, and training, to conduct an assessment that enables them to recognize the fact that a person has a need for emergency care.

SR.2b Initial treatment: Medical staff policies and procedures are developed and implemented for providing the initial treatment needed by persons with emergency conditions.

SR.2b(1) Among the RN(s) who must be available at all times in the hospital (see NS.1), there shall be RN(s) who are qualified, through a combination of education, licensure, and training, to provide initial treatment to a person experiencing a medical emergency.

SR.2c Referral when appropriate: The organization shall have medical staff policies and procedures to address situations in which a person's emergency needs may exceed the hospital's capabilities. The policies and procedures shall be designed to enable staff members who respond to emergencies to:

SR.2c(1) Recognize when a person requires a referral or transfer, and

SR.2c(2) Assure appropriate handling of the transfer (see also DC.3 (SR.3)). This includes arrangement for appropriate transport of the patient.

SR.2c(2)(i) The hospital shall transfer patients to appropriate facilities, i.e., those with the appropriate capabilities to handle the patient's condition.

SR.2c(2)(ii) All necessary medical information shall be sent along with the patient being transferred.

SR.2d Patient transportation and emergency transport.

Interpretive Guidelines:

This requirement applies hospital-wide (on-campus and off-campus locations) that do not provide emergency services.

The governing body shall assure that the medical staff has written policies and procedures for appraisal of emergencies, initial treatment, and referral when appropriate.

The organization shall 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.

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

The organization may arrange transportation of the referred patient by several methods, including using their own ambulance service, the receiving hospital's ambulance service, a contracted ambulance service, or, in extraordinary circumstances, alerting EMS via calling 9-1-1.

There is no specific Medicare prohibition on a hospital with or without an emergency department

calling 9-1-1 in order to obtain transport of a patient to another hospital. Use of 9-1-1 to obtain transport does not, however, relieve the hospital of its obligation to arrange for the patient's transfer to an appropriate facility and to provide the necessary medical information along with the patient.

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

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.

ES.5 OFF-CAMPUS DEPARTMENTS

SR.1 The governing body shall assure that the medical staff has written policies and procedures for appraising and referring emergencies that occur in off-campus departments where emergency services are not provided. These policies include, at a minimum:

SR.1a Appraisals of persons with emergencies: The off-campus locations shall have staff available during all hours of operation who are qualified through education, licensure, training, to assess and recognize the need for emergency care.

SR.1b Provision of initial treatment and stabilization consistent with the services provided at the location and the qualifications of staff.

SR.1c Referral when appropriate. Policies shall identify the clinical situations that would exceed the capabilities of the off-campus department that is not a dedicated emergency department.

Interpretive Guidelines:

This requirement applies to off-campus departments that do not provide emergency services.

The organization shall 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 shall be provided within the capabilities and complexities of services provided and the staff on-site at these off-campus departments.

A hospital policy or practice that relies on calling 9-1-1 in order for EMS to substitute its emergency response capabilities for those the hospital is required to maintain at its off-campus departments/locations, as described above, is not consistent with the requirements.

Given the limited capabilities of off-campus (off-site) locations calling 911 to respond to an emergency might be appropriate.

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

SR.1 If the organization provides outpatient services, the services shall be appropriately organized, integrated with inpatient services, and meet the needs of patients in accordance with acceptable standards of practice.

Interpretive Guidelines

If the organization 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 shall be appropriate to the scope and complexity of services offered.

All outpatient services provided by the organization shall meet the needs of the patients, in accordance with acceptable standards of practice. The organization shall 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 shall be integrated into the organization's QMS 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 organization's QMS 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

SR.1 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 organization shall designate one or more individuals responsible for the overall operation of the hospital's entire outpatient services (all outpatient services). The organization should define in writing the qualifications and competencies necessary to direct the outpatient services.

Adequate types and numbers of qualified professional and nonprofessional personnel shall be available to provide patients with the appropriate level of care and services.

Surveyor Guidance:

Verify that the organization 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.

OS.4 ORDERS

Orders for outpatient services shall be ordered by a practitioner who meets the following conditions:

SR.1 Is responsible for the care of the patient.

SR.2 Is licensed in the State where he or she provides care to the patient.

SR.3 Is acting within his or her scope of practice under State law.

SR.4 Is authorized in accordance with State law and policies adopted by the medical staff, and approved by the governing body, to order the applicable outpatient services. This applies to the following:

SR.4a All practitioners who are appointed to the organization's medical staff and who have been granted privileges to order the applicable outpatient services.

SR.4b All practitioners not appointed to the medical staff, but who satisfy the above criteria for authorization by the medical staff and the organization for ordering the applicable outpatient services for their patients.

Interpretive Guidelines:

Orders for outpatient services may be made by any practitioner who is:

- *Responsible for the care of the patient;*
- *Licensed in, or holds a license recognized in, the jurisdiction where he/she provides care to the patient;*
- *Acting within his/her scope of practice under State law; and,*

- *Authorized by the medical staff to order the applicable outpatient services under a written organization policy that is approved by the governing body. This includes both practitioners who are on the hospital medical staff and who hold medical staff privileges that include ordering the services, as well as other practitioners who are not on the hospital medical staff, but who satisfy the organization's policies for ordering applicable outpatient services.*

This regulation allows organizations to accept orders for outpatient services both from practitioners who hold hospital privileges as well as practitioners who do not, including those who are not located in the hospital's close geographic area.

It is not uncommon for individuals to obtain health care services in a variety of locations from a variety of practitioners. Sometimes an individual elects to seek services from a specialist in a tertiary setting removed from the area where the individual lives, but prefers to get follow-up care, such as physical therapy after a surgery, closer to home.

Sometimes an individual may have multiple residences in different areas and may need to continue care locally when moving between residences. Sometimes individuals receive urgent or even emergent care while traveling. Accepting orders and referrals for outpatient services from practitioners not on the medical staff or not holding privileges enables an organization to promote ready access to care for patients in the area it serves.

Finally, sometimes a practitioner who does not practice in a local hospital may nevertheless refer patients to that hospital for outpatient services, such as diagnostic imaging, physical and occupational therapy, etc.

The authority to write orders for outpatient services is covered under the organization's medical staff privileging process for members of the hospital's medical staff and for practitioners who have been granted privileges by the organization without being appointment to the medical staff.

For practitioners who do not hold hospital privileges the organization's medical staff policy may permit them to refer patients to the hospital with orders for specific outpatient services so long as all of the above criteria are met. The policy shall address how the hospital verifies the referring/ordering practitioner is appropriately licensed and acting within his/her scope of practice. The regulation does not prescribe the details of the licensure and scope of practice verification process but instead provides a hospital the flexibility to accomplish this in the manner it finds efficient and effective. The organization is expected to ensure the verification process is followed for all outpatient services in all hospital locations.

The policy shall also make clear whether the policy applies to all hospital outpatient services, or whether there are specific services for which orders may only be accepted from practitioners with medical staff privileges. For example, a hospital may prefer not to accept orders for a regimen of outpatient chemotherapy or outpatient therapeutic nuclear medicine services from a referring physician who does not hold medical staff privileges. In such cases, the organization's policy shall make these exceptions clear to the general authorization for accepting orders from referring practitioners.

Surveyor Guidance:

Survey a variety of settings that offer outpatient services. Ask department staff whether orders or referrals for that type of outpatient service are accepted from practitioners who do not hold

hospital privileges. If yes:

- *Ask for evidence that the medical staff has adopted the policy.*
- *Ask how the hospital verifies that the order or referral comes from a referring practitioner who is appropriately licensed in the jurisdiction where he/she provides care to the patient and is practicing within his/her scope of practice under State law to prescribe such orders. Ask for documentation of such verification efforts.*
- *Ensure the same verification process is followed consistently in all outpatient settings.*

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 dietary 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 dietary 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.

SR.5 The organization shall have written policies and procedures that address at least the following:

SR.5a Orientation, work assignments, supervision of work and personnel performance;

SR.5a(1) Dietary services staff shall also have specific training regarding fire safety and their role in the activation of kitchen hood fire suppression systems.

SR.5b Safety practices for food handling;

SR.5c Provision for emergency food supplies;

SR.5d Supervision of the menu planning function, purchasing of foods and supplies, and retention of required records (e.g., cost, menus, personnel, training records, QAPI reports, etc.);

SR.5e Availability of a diet manual and therapeutic diet menus to meet patients' nutritional needs;

SR.5f Frequency of meals served;

SR.5g Process for ordering and delivery of food to respective patient areas;

SR.5h Accommodation of non-routine occurrences (e.g., enteral nutrition (tube feeding), total parenteral nutrition, peripheral parenteral nutrition, change in diet orders, early/late trays, nutritional supplements, etc.);

SR.5i Guidelines for acceptable hygiene practices of dietary personnel and the sanitation protocols for the preparation and cleaning areas; and,

SR.5j Integration of the dietary service into the organization-wide Quality Management Oversight and Infection Control programs.

Interpretive Guidelines:

The nutritional needs of the patients are met in accordance with practitioners' orders, acceptable standards of practice (e.g., Academy of Nutrition and Dietetics, American Society for Parenteral and Enteral Nutrition), and the organization being in compliance with federal and state licensure requirements for food and dietary personnel as well as food service standards (e.g., FDA food code), 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 dietary services will be authorized and have the delegated responsibility for these services from the organization'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.

The full-time individual responsible for dietary services shall 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 dietary operations.

The organization shall 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 organization and medical staff, and, where applicable, State licensure or registration when applicable.

The qualified dietitian will be responsible for:

- *Approving menus and nutritional supplements provided to patients;*
- *Providing 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 shall make adequate provisions for dietary consultation that meets the needs of the patients.

Surveyor Guidance:

Verify that the director of dietary 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 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.

Review personnel files for administrative and technical staff to determine they have appropriate credentials as required and have received adequate training and are competent in their respective duties.

DS.2 SERVICES AND DIETS

Dietary Services shall be provided, and menus/diets offered that meet the needs of the patients in accordance with recognized dietary practices. The following criteria shall be applied:

SR.1 All patients shall be screened for risk for nutritional deficiencies, need for therapeutic diets and/or other nutritional supplementation, and if indicated, a detailed nutritional assessment performed by a dietitian per hospital policy and procedure.

SR.2 All menus/diets offered shall meet the needs of the patients.

SR.3 All patient diets, including therapeutic diets shall be prescribed by a practitioner or practitioners responsible for the care of the patient; OR by a qualified dietitian or qualified nutritional professional when permitted under State law and when granted such privileges by the medical staff.

SR.4 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 responsible for the care of the patients.

Interpretive Guidelines:

Affected patients include all inpatients and those patients in outpatient status, including the provision of observation services, whose stay is sufficiently long that they shall be fed. These patients shall be screened for risk for nutritional deficiencies, need for therapeutic diets and/or other nutritional supplementation. Based on positive screening results and as defined by hospital policy and procedure, a detailed nutritional assessment shall then be performed by a dietitian.

Menus provided by the hospital shall 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.

The following represent examples of patients who require a detailed nutritional assessment. The organization may define additional criteria for the provision of nutritional assessments:

- *All patients requiring artificial nutrition by any means (e.g., enteral 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, renal diseases, etc.).*

Meeting individual patient nutritional needs may include the use of therapeutic diets. Therapeutic diets refer to a diet ordered as part of the patient's treatment for a disease or clinical condition, to eliminate, decrease, or increase certain substances in the diet (e.g., sodium or potassium), or to provide mechanically altered food when indicated.

All patient diets, including therapeutic diets provided to patients as a result of a detailed nutritional assessment, shall be:

- *Prescribed in writing by a qualified practitioner responsible for the care of the patient, a qualified dietitian, or qualified nutritional professional as authorized by the medical staff and in accordance with State law governing dietitians and nutrition professionals;*
    - *It is the responsibility of the hospital to ensure that individuals are qualified under State law before appointing them to the medical staff or granting them privileges to order diets.*
    - *If the hospital chooses not to grant diet-ordering privileges to dietitians or other nutrition professionals, even when permitted under State law, the patient's diet shall be prescribed by a practitioner responsible for the patient's care. In this situation, a dietitian or nutrition professional who does not have privileges to order diets may nevertheless assess a patient's nutritional needs and provide recommendations or consultations for patients to a practitioner responsible for the care of the patient.*

- *Documented in the patient's medical record (include the patient's tolerance to the diet); and,*

- *Evaluated for nutritional adequacy to meet the patient's needs.*

    - *The care plan for patients identified as having specialized nutritional needs shall address those needs as well as monitoring of their dietary intake and nutritional status. The methods and frequency of monitoring could include one or more of the following, as well as other methods:*

        - *Patient weight (BMI, unintended weight loss or gain)*

        - *Intake and output*

        - *Lab values*

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 (e.g., 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 the screening criteria used to identify patients at nutritional risk who require a detailed nutritional assessment performed by a dietitian. Verify through medical record review that the process for assessment and re-assessment is occurring consistently with hospital policy and procedure.

Review medical records to verify that all diet orders are prescribed and authenticated by the practitioner(s) responsible for the care of the patient, or by a qualified dietitian or qualified nutrition professional who is permitted to order diets under State law and has been granted privileges by the medical staff. 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.*

- *If diets are being prescribed/ordered by a qualified dietitian or qualified nutritional professional, verify that such person has been granted that authority by the medical staff and state law permits this practice. Review staff records to verify that dietitians/nutrition professionals demonstrate the required qualifications.*

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 shall 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 shall 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 shall include the diets currently available to patients and meet current national standards, such as RDA or DRI. The therapeutic diet manual shall 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 and is in accordance with the current national standards, such as RDA or DRI; includes the different types of therapeutic diets routinely ordered at the hospital; and is consistently used as guidance for ordering and preparing patient diets.

PATIENT RIGHTS (PR)

The organization shall protect and promote each patient's rights.

PR.1 NONDISCRIMINATION

SR.1 The organization will comply with the nondiscrimination provisions of Section 1557 of the Affordable Care Act (ACA) and will not deny access to health care because of race, color, national origin, sex, age, or disability.

SR.2 The organization will recognize all state-sanctioned marriages and spouses for purposes of compliance with the Conditions of Participation, regardless of any laws to the contrary of the state or locality where the organization is located.

Interpretive Guidelines:

In compliance with Section 1557 of the Affordable Care Act:

The organization will post information notifying patients about their rights.

The organization will post information notifying patients with limited English proficiency (LEP) about the right to receive communication assistance.

The organization is required to provide information in a language and format that the patient understands, including provision of interpreters or communication aids for those who are deaf, blind, have LEP, or are otherwise impaired. When necessary, hospitals should continue to provide taglines in top languages whenever they are necessary to ensure meaningful access by LEP individuals to covered services and programs.

Except where CMS regulations explicitly require an interpretation in accordance with State law, wherever the text of a regulation or associated guidance uses the terms "marriage" or "spouse" or includes a reference to a patient's "representative," "surrogate," "support person," "next-of-kin," or similar term in such a manner as would normally implicitly or explicitly include a spouse, the terms are to be interpreted consistent with the guidance noted below:

"spouse" means an individual who is married to another individual as a result of marriage lawful where it was entered into, including a lawful same-sex marriage, regardless of whether the jurisdiction where the hospital is located, or in which the spouse lives, permits such marriages to occur or recognizes such marriages.

"marriage" means a marriage lawful where entered into, including a lawful same-sex marriage, regardless of whether the jurisdiction where the hospital is located, or in which the spouse lives, permits such marriages to occur or recognizes such marriages;

"family" includes, but is not limited to, an individual's "spouse" (see above); and,

"relative" when used as a noun, includes, but is not limited to, an individual's "spouse" (see above).

PR.2 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 Notices:

SR.1a Of non-coverage and right to appeal premature discharge; and,

SR.1b Medicare Outpatient Observation Notice (MOON).

SR.2 Patient participation and means for making informed decisions regarding his/her plan of care (See also NS.3 (SR.1 and SR.5));

SR.3 The patient or his or her representative (as allowed under State law) has the right to make informed decisions regarding his or her care. The patient's rights include being informed of his or her health status, being involved in care planning and treatment, and being able to request or refuse treatment. This right shall not be construed as a mechanism to demand the provision of treatment or services deemed medically unnecessary or inappropriate;

SR.4 The patient's right to have a family member or representative of their choice and to have their own physician notified promptly of their admission;

SR.5 Personal privacy;

SR.6 Provision of care in a safe setting (see also PR.10);

SR.7 Freedom from all forms of abuse or harassment;

SR.8 Confidentiality of clinical records;

SR.9 The patient's right to access their medical records, including current medical records, upon an oral or written request, in the form and format requested by the individual, if it is readily producible in such form and format (including in an electronic form or format when such medical records are maintained electronically); or, if not, in a readable hard copy form or such other form and format as agreed to by the facility and the individual, and within a reasonable time frame.

SR.9a The organization shall not impede the legitimate efforts of individuals to gain access to their own clinical records and shall 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.6, Grievance Procedure);

SR.11 Pain management plan;

SR.12 Patient visitation rights – the organization shall:

SR.12a 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 organization may need to place on such rights and the reasons for the clinical restriction or limitation;

SR.12b 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 Section 482.13(a);

SR.12c 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.12d Not restrict, limit, or otherwise deny visitation privileges on the basis of race, color, national origin, religion, sex, sexual orientation, gender identity, or disability; and,

SR.12e Ensure that all visitors enjoy full and equal visitation privileges consistent with patient preferences.

SR.13 Other rights defined within the Patient Rights requirements (PR.1 – PR.10).

Interpretive Guidelines:

Hospitals are expected to stay current with and abide by all revisions to the Medicare Claims Processing Manual, CoP's, and the forms listed in these IG's which are current as of the publication date of this revision.

This standard requires that whenever possible, the organization informs each patient and/or legal representative of the patient's rights in advance of providing or discontinuing care. The organization will inform both inpatients and outpatients of their rights to include the elements as described in PR.1 (SR.1 – SR.12).

The MOON is a standardized notice to inform beneficiaries (including Medicare health plan enrollees) that they are an outpatient receiving observation services and are not an inpatient of the hospital.

The MOON is mandated by the Federal Notice of Observation Treatment and Implication for Care Eligibility Act (NOTICE Act), passed on August 6, 2015. The NOTICE Act requires all hospitals to provide written and oral notification under specified guidelines.

All organizations are required to provide the MOON beginning no later than March 8, 2017.

The MOON shall be delivered to a beneficiary who receives observation services as an outpatient for more than 24 hours and shall be delivered not later than 36 hours after

observation services begin. The MOON shall be delivered before 36 hours following initiation of observation services if the beneficiary is transferred, discharged, or admitted. The MOON may be delivered before a beneficiary receives 24 hours of observation services as an outpatient.

The start time of observation services, for purposes of determining when more than 24 hours of observation services have been received, is the clock time observation services are initiated (furnished to the patient), as documented in the patient's medical record, in accordance with a physician's order. This follows the elapsed clock time, rather than the billed time, associated with the observation services.

The hospital shall ensure that the beneficiary or representative signs and dates the MOON to demonstrate that the beneficiary or representative received the notice and understands its contents. Use of assistive devices may be used to obtain a signature.

If the beneficiary refuses to sign the MOON, and there is no representative to sign on behalf of the beneficiary, the notice shall be signed by the staff member of the hospital who presented the written notification. The staff member's signature shall include the name and title of the staff member, a certification that the notification was presented, and the date and time the notification was presented. The staff member annotates the "Additional Information" section of the MOON to include the staff member's signature and certification of delivery. The date and time of refusal is considered to be the date of notice receipt.

Determinations of Inpatient Hospital Discharges

Medicare beneficiaries who are hospital inpatients have a statutory right to appeal to a BFCC-QIO for an expedited review when a hospital, with physician concurrence, determines that inpatient care is no longer necessary.

The expedited determination process is available to beneficiaries in Original Medicare who are being discharged from a Medicare covered inpatient hospital stay. ***All beneficiaries receiving covered inpatient hospital care shall receive an Important Message from Medicare (IM).*** *This includes, but is not limited to, beneficiaries in the following circumstances:*

- *Beneficiaries for whom Medicare is either the primary or secondary payer.*
- *Beneficiaries with brief inpatient hospital stays.*
- *Beneficiaries physically discharged from the hospital or discharged to a lower level of care (such as a Swing Bed) in the same hospital.*

The following situations are not eligible for an expedited determination. Hospitals should not deliver an IM in these instances.

- *When a beneficiary transfers to another hospital at the same level of care (e.g., a beneficiary transfers from one hospital to another while remaining a hospital inpatient).*
- *When beneficiaries exhaust their benefits (e.g., a beneficiary reaches the number of lifetime reserve days of the Medicare inpatient hospital benefit.)*
- *When beneficiaries end care on their own initiative (e.g., a beneficiary elects the*

hospice benefit).

- *Condition Code 44 (CC44) (See Section 50.3 of Chapter 1 of the Medicare Claims Processing Manual)*

- *Physician does not concur with discharge. (See Section 220 of this chapter.)*

NOTE:

The IM should only be given when an inpatient admission is pending or has occurred. It should not be given 'just in case', such as a hospital delivering to all Medicare patients being treated in a hospital emergency room.

The IM is subject to the Paperwork Reduction Act (PRA) process and approval by the Office of Management and Budget (OMB). The IM may only be modified as per the accompanying instructions, as well as per guidance in this section. Unapproved modifications cannot be made to the OMB-approved, standardized IM. The notice and accompanying instructions may be found online at Hospital Discharge Appeal Notices.

Completing the IM

Hospitals shall use the OMB-approved IM (CMS-10065). Hospitals shall add the following information in the corresponding blanks of the IM: 1. Patient name 2. Patient number 3. BFCC-QIO contact information.

NOTE: The Patient number may be a unique medical record or other provider-issued identification number. It may not be the Social Security Number, HICN or any other Medicare number issued to the beneficiary such as the MBI (Medicare Beneficiary Identifier).

Hospital Delivery of the IM

Hospitals shall deliver the IM to all beneficiaries eligible for the expedited determination process per §200.2. An IM shall be delivered even if the beneficiary agrees with the discharge.

- *The hospital shall ensure that the beneficiary or representative signs and dates the IM to demonstrate that the beneficiary or representative received the notice and understands its contents. See 200.3.7 'Ensuring Beneficiary Comprehension'.*

- *Use of assistive devices may be used to obtain a signature.*

- *Electronic issuance of the IM is permitted.*

If a hospital elects to issue an IM viewed on an electronic screen before signing, the beneficiary shall be given the option of requesting paper issuance over electronic issuance if that is what the beneficiary prefers. Regardless of whether a paper or electronic version is issued and regardless of whether the signature is digitally captured or manually penned, the beneficiary shall be given a paper copy of the IM, as specified in 200.3.9, and the required beneficiary specific information shall be inserted, at the time of notice delivery.

200.3.4- Required Delivery Timeframes
First IM

Hospitals shall deliver the first copy of the IM at or near admission, but no later than 2 calendar days following the date of the beneficiary's admission to the hospital.

Hospitals may deliver the first copy of the notice if the beneficiary is seen during a preadmission visit, but not more than 7 calendar days in advance of admission.

A hospital shall deliver the IM to all inpatients, including those in the hospital for a short stay.

Once the discharge date is planned, a hospital does not need discharge orders in advance of delivering the IM.

Timing of First IM Delivery

- *Pre-Admission – Up to 7 days before admission*
- *At Admission – At admission*
- *After Admission – Up to 2 days following admission*

200.3.4.2 - Follow-Up Copy of the IM

Hospitals shall deliver the follow up copy of the IM within 2 days of discharge. It may be given as late as four hours prior to discharge.

However, if delivery of the first IM is within 2 calendar days of the date of discharge, no follow-up notice is required. For example, if a beneficiary is admitted on Monday, the IM is delivered on Wednesday and the beneficiary is discharged on Friday, no follow-up notice is required.

- *A hospital may deliver a new copy of the IM (not a copy of the signed IM) during the required timeframes; however, the hospital shall obtain the beneficiary's or representative's signature and date on the notice again at that time, or*
- *A hospital may deliver a copy of the signed, first IM with the date of delivery of the follow up copy indicated on the IM.*

Timing of Follow-Up IM Delivery

- *No sooner than two days before discharge.*
- *No later than four hours prior to discharge.*

Each Medicare beneficiary who is an inpatient is provided with a standardized notice, the "Important Message from Medicare" Form CMS-10065 within two days of their admission and prior to discharge. 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 organization 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

organization may decide it is most effective to bundle the patients' rights and advance directives notice with these existing notices.

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 organization shall respect the patient's wishes and follow these accordingly. If the patient is unconscious or otherwise incapacitated and unable to make a decision, the organization shall 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 organization 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 organization 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 shall 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 organization staff shall follow nationally recognized standards of practice and guidelines for patient environmental safety, infection control, and security. The organization shall protect vulnerable patients, including newborns and children.

The organization shall ensure that patients are free from all forms of abuse, neglect, or harassment. The organization shall have mechanisms/methods in place that ensure patients are free of all forms of abuse, neglect, or harassment.

The organization shall 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 organization shall 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 organization shall 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 organization may need to place on such rights and the reasons for the clinical restriction or limitation.

A hospital shall (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 organization'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 organization has alternative means, such as written materials, signs, or interpreters, to communicate patients' rights, when necessary.

Validate that the organization 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 organization 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 organization 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 organization 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 (e.g., 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 organization has a written procedure for investigating allegations of abuse and neglect including methods to protect patients from abuse,

Verify that the organization 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 (e.g., 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 organization 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 organization policies on visitation and validate that the policies delineate any reasonable clinical restrictions or limitations, if needed.

Verify that the organization 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.3 ADVANCE DIRECTIVE

The organization shall 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 shall maintain written policies in accordance with 42 CFR Section 489.102 requirements for providers and 42 CFR Section 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 42 CR Section 482.13(a)(1), 42 CFR Section 489.102(b)(1) requires that notice of the hospital's advance directive policy be provided at the time an individual is admitted as an inpatient. However, in view of the broader notice requirements at §482.13(a)(1), the hospital shall also provide the advance directive notice to outpatients (or their representatives) who are in the emergency department, who are in an observation status, or who are undergoing same-day surgery. The notice shall be presented at the time of registration. Notice is not required for other outpatients, given that they are unlikely to become incapacitated.

42 CFR Section 489.102 also requires that the hospital provide community education regarding advance directives and that the organization shall document its efforts.

The organization shall 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 organization shall document in a prominent part of the patient's medical record whether or not the patient has executed an advance directive.

The organization shall 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 organization shall 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 shall be in place to address the follow-up and compliance. When necessary, the organization 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 organization has complied with the patient's advance directive notice requirements.

Review and verify the organization has a procedure in place to allow patients to formulate an advance directive or to update their current advance directive.

Verify that the organization educates its staff regarding advance directives, including psychiatric advance directives, as indicated by organization policy and state law.

Verify that the organization provides community education regarding advance directives and documents its efforts.

Determine how the organization 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.4 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 organization 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 organization's obligation to communicate with patients requires that the organization 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 organization has alternative means, such as written materials, signs, or interpreters, to communicate patients' rights, when necessary.

Verify how the organization meets the needs of these diverse patients.

PR.5 INFORMED CONSENT

SR.1 The organization shall obtain an informed written consent from each patient or authorized representative for surgeries, procedures and treatments for medical and/or surgical care, in accordance with any applicable state and federal laws and regulations, except in a medical emergency as specified by the hospital's medical staff. See also SS.9 and MR.6 (SR.1b).

SR.2 The medical staff shall specify which procedures are considered surgery, and thus require a properly executed written informed consent, as well as any other procedures or treatments that require a properly executed written informed consent.

SR.2a At minimum, a properly executed written consent is required for:

SR.2a(1) High-risk procedures (including blood transfusions);

SR.2a(2) Participation in research projects;

SR.2a(3) Filming or videotaping;

SR.2a(4) Procedures with the use of sedation or anesthesia;

SR.2a(5) Training- and education- related sensitive examinations or invasive procedures (see Interpretive Guidelines), when sedation or anesthesia is used;

SR.3 For patients with the ability to verbally affirm consent for procedures that do not require sedation or anesthesia, and where state or federal laws or regulations and the organization's policy do not otherwise require written informed consent, the patient's medical record shall minimally reflect that consent was given.

SR.4 The medical staff shall define in policy, the circumstances when a procedure/surgery is considered an emergency that does not require a written informed consent.

SR.5 The consent discussion shall include an explanation of risks, benefits, and alternatives for high-risk procedures, sedation, and other procedures or services, as defined by the medical staff and state law.

Interpretive Guidelines:

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, intervention, or treatment that requires consent. Informed consent would include that the patient is informed as to who will actually perform planned surgical interventions.

All patients receiving either inpatient and outpatient care shall complete an informed written

consent form for all procedures and treatments as outlined in the standard requirements, as specified by the hospital's medical staff, state and federal laws and regulations. In the event of a medical emergency (emergencies shall be defined by the medical staff in policies), 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.

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 or other type of medical treatment);*
- *Name of the responsible practitioner who is performing the procedure(s) or administering the medical treatment;*
- *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.)*
- *Signature of patient or legal representative;*
- *Date and time consent form is signed by the patient or the patient's legal representative;*

It should be noted that there is no specific requirement for informed consent within the regulation at §482.52 governing anesthesia services. However, given that surgical procedures generally entail use of anesthesia, hospitals may wish to consider specifically extending their informed consent policies to include obtaining informed consent for the anesthesia component of the surgical procedure (See SS.9).

If there is applicable State law governing the content of the informed consent form, then the hospital's form shall comply with those requirements. The informed consent form contained in the medical record shall provide evidence that it was properly executed.

*A **well-designed** informed consent form **might** also include the following additional information:*

- *Name of the practitioner who conducted the informed consent discussion with the patient or the patient's representative.*
- *Date, time, and signature of the person witnessing the patient or the patient's legal representative signing the consent form.*
- *Indication or listing of the material risks of the procedure or treatment that were discussed with the patient or the patient's representative;*

- *Whether practitioners other than the operating practitioner, including but not limited to other physicians, residents, advance practice providers, and medical and other applicable students (such as nurse practitioner and physician assistant), will be performing important tasks related to the surgery, or sensitive examinations or invasive procedures for educational and training purposes. Important surgical tasks include opening and closing, dissecting tissue, removing tissue, harvesting grafts, transplanting tissue, administering anesthesia, implanting devices and placing invasive lines. Examinations or invasive procedures conducted for educational and training purposes include, but are not limited to, breast, pelvic, prostate, and rectal examinations, as well as others specified under state law.*

- *Statement, if applicable, that qualified medical practitioners who are not physicians who will perform important parts of the surgery or administration of anesthesia will be performing only tasks that are within their scope of practice, as determined under State law and regulation, and for which they have been granted privileges by the hospital.*

The responsible practitioner shall disclose to the patient any information necessary to enable the patient to evaluate a proposed medical or surgical procedure before submitting to it. Informed consent requires that a patient have a full understanding of that to which he or she has consented. An authorization from a patient who does not understand what he/she is consenting to is not informed consent. 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.

Patients shall be given sufficient information to allow them to make intelligent choices from among the alternative courses of available treatment for their specific ailments.

Informed consent shall be given despite a patient's anxiety or indecisiveness.

The responsible practitioner shall provide as much information about treatment options as is necessary based on a patient's personal understanding of the practitioner's explanation of the risks of treatment and the probable consequences of the treatment.

Surveyor Guidance:

Verify that the medical staff has specified which procedures or treatments require a written informed consent (in addition to standard requirements and as specified at SS.9). Verify that medical records contain consent forms for all procedures or treatments as required by standard, organization policy, and state and federal laws and regulations.

Compare the organization's standard informed consent form to its policies on informed consent to verify that the form is consistent with the policies, and if applicable, to requirements of state and federal laws and regulations.

In a sampling of a minimum of six medical records of patients who had procedures or treatments requiring an informed consent, review and validate that consent forms are properly executed and contain at least the elements identified above (standard, hospital policy, and state and federal laws and regulations).

Verify that the organization'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.

In a sampling of a minimum of six patient records, review and first verify that the patients did not require emergency surgery. Verify that informed consent forms were executed prior to the surgery as required and contain at least the elements identified above (standard, hospital policy, and state and federal laws and regulations). When possible, review medical records of patients who are about to undergo surgery, or who are located in a surgical recovery area.

When possible, interview at least two to three patients who are undergoing, or have undergone surgery as appropriate based on their ability to provide a cogent response, or the patients' representatives, and have them tell you about the informed consent process and their understanding of the procedure they are having (or have had) performed.

PR.6 GRIEVANCE PROCEDURE

The organization shall develop and implement a formal, written grievance process, approved by the governing body, that provides for prompt resolution of patient grievances. The written and implemented process shall provide for the following:

SR.1 Provide each patient with whom to contact to file a grievance;

SR.2 Review and resolution. The governing body shall be responsible for the effective operation of the grievance process, and shall review and resolve grievances, unless it delegates the responsibility in writing to a grievance committee.

SR.3 A referral process for quality-of-care issues to the Utilization Review, Quality Management or Peer Review functions, as appropriate.

SR.3a The referral process shall also include a mechanism for timely referral, at a Medicare beneficiary's request, of concerns related to quality of care or premature discharge to the appropriate Utilization and Quality Control Quality Improvement Organization (QIO). (See PR.2 (SR.1), (SR.1a))

SR.4 Specification of reasonable timeframes for review and prompt response and resolution to patient grievances.

SR.5 In the resolution of the grievance, the organization shall provide the patient (and/or the patient's representative, as indicated) with written notice of its decision that contains the following:

SR.5a Name of organization contact person;

SR.5b Steps taken to investigate all grievances made by the patient;

SR.5c Results of the grievance process; and,

SR.5d Date of completion.

Interpretive Guideline:

The organization shall 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 and/or the patient's representative.

The organization's grievance procedure shall be approved by the governing body. The hospital's governing body is responsible for the effective operation of the grievance process. This includes the hospital's compliance with all of the CMS grievance process requirements. The hospital's governing body shall review and resolve grievances, unless it delegates this responsibility in writing to a grievance committee. A committee is more than one person. The committee membership should have adequate numbers of qualified members to review and resolve the grievances the hospital receives (this includes providing written responses) in a manner that complies with the CMS grievance process requirements.

The patient should have reasonable expectations of care and services, and the organization should address those expectations in a timely, reasonable, and consistent manner. Although 482.13(a)(2)(ii) and (iii) address documentation of facility time frames for a response to a grievance, the expectation is that the facility will have a process to comply with a relatively minor request in a timelier manner than a written response. For example, a change in bedding, housekeeping of a room, and serving preferred food and beverage may be made relatively quickly and would not usually be considered a "grievance" and therefore would not require a written response.

The hospital shall inform the patient and/or the patient's 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 shall provide the patient or the patient's representative a phone number and address for lodging a grievance with the State agency. The hospital shall inform the patient that he/she may lodge a grievance with the State agency (the State agency that has licensure survey responsibility for the hospital) directly, regardless of whether he/she has first used the hospital's grievance process.

Definition elements: A "patient grievance" is a formal or informal written or verbal complaint that is made to the organization by a patient, or the patient's representative, regarding the patient's care (when the complaint is not resolved at the time of the complaint by staff present), abuse or neglect, issues related to the hospital's compliance with the CMS Hospital Conditions of Participation (CoPs), or a Medicare beneficiary billing complaint related to rights and limitations provided by 42 CFR 489.

A complaint from someone other than a patient or a patient's representative or surrogate, in the absence of express permission from the patient, is not a grievance. The hospital's policy/procedure shall include a process for verifying that the individual submitting the complaint on behalf of the patient is authorized to do so prior to sharing the patient's information with that individual. Verification means that the hospital has confirmed that the individual is the patient's authorized representative or surrogate, or the hospital has obtained permission from the patient to discuss the patient's care with the individual submitting the complaint. When a complaint is submitted by the patient's authorized representative or surrogate and/or the patient's permission has been obtained and the patient wants to proceed with filing of a formal complaint, this meets the definition of a grievance.

- *"Staff present" includes any hospital staff present at the time of the complaint or who can quickly be at the patient's location (i.e., nursing, administration, nursing supervisors, patient advocates, etc.) to resolve the patient's complaint.*

- *If a patient care complaint cannot be resolved at the time of the complaint by staff present, is postponed for later resolution, is referred to other staff for later resolution, requires investigation, and/or requires further actions for resolution, then the complaint is a grievance for the purposes of these requirements. A complaint is considered resolved when the patient is satisfied with the actions taken on their behalf.*

- *Billing issues are not usually considered grievances for the purposes of these requirements. However, a Medicare beneficiary billing complaint related to rights and limitations provided by 42 CFR 489 is considered a grievance.*

- *A written complaint is always considered a grievance. This includes written complaints from an inpatient, an outpatient, a released/discharged patient, or a patient's representative regarding the patient care provided, abuse or neglect, or the hospital's compliance with CoPs. For the purposes of this requirement, an email or fax is considered "written."*

- *Information obtained from patient satisfaction surveys usually does not meet the definition of a grievance. If an identified patient writes or attaches a written complaint on the survey and requests resolution, then the complaint meets the definition of a grievance. If an identified patient writes or attaches a complaint to the survey but has not requested resolution, the hospital shall treat this as a grievance if the hospital would usually treat such a complaint as a grievance.*

- *Patient complaints that are considered grievances also include situations where a patient or a patient's representative telephones the hospital with a complaint regarding the patient's care or with an allegation of abuse or neglect, or failure of the hospital to comply with one or more CoPs, or other CMS requirements. Those post-hospital verbal communications regarding patient care that would routinely have been handled by staff present if the communication had occurred during the stay/visit are not required to be defined as a grievance.*

- *All verbal or written complaints regarding abuse, neglect, patient harm, or hospital compliance with CMS requirements are considered grievances for the purposes of these requirements.*

- *Whenever the patient or the patient's representative requests that his or her complaint be handled as a formal complaint or grievance or when the patient requests a response from the hospital, the complaint is considered a grievance, and all the requirements apply.*

- *Data collected regarding patient grievances, as well as other complaints that are not defined as grievances (as determined by the hospital), shall be incorporated in the hospital's Quality Assessment and Performance Improvement (QAPI) Program. Regardless of the nature of the grievance, the organization shall ensure it is responding to the substance of each grievance while identifying, investigating, and resolving any deeper, systemic problems indicated by the grievance that require resolution (see QM.5).*

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 calendar days. If the grievance is

not resolved, the investigation is not complete, or if the corrective action is still being evaluated, the organization's response should address that the organization is still working to resolve the complaint and states that the organization will follow-up with another written response within a specified timeframe (depending on what actions the organization may have to take). The organization shall attempt to resolve all grievances as soon as possible.

The written notice of the hospital's determination regarding the grievance shall be communicated to the patient or the patient's representative in a language and manner the patient or the patient's legal representative understands. The hospital may use additional tools to resolve a grievance, such as meeting with the patient and his family. The regulatory requirements for the grievance process are minimum standards, and do not inhibit the use of additional effective approaches in handling patient grievances. However, in all cases the hospital shall provide a written notice (response) to each patient's grievance(s). The written response shall contain the elements listed in this requirement. When a patient communicates a grievance to the hospital via email the hospital may provide its response via email pursuant to hospital policy. (Some hospitals have policies against communicating to patients over email.) If the patient requests a response via email, the hospital may respond via email. When the email response contains the information stated in this requirement, the email meets the requirement for a written response. The hospital shall maintain evidence of its compliance with these requirements.

Quality Improvement Organizations (QIOs) are CMS contractors charged with reviewing the appropriateness and quality of care rendered to Medicare beneficiaries in the hospital setting. The QIOs are also tasked with reviewing utilization decisions. Part of this duty includes reviewing discontinuation of stay determinations based upon a beneficiary's request. The regulations state the functions of the QIOs in order to make Medicare beneficiaries aware of the fact that if they have a complaint regarding quality of care, disagree with a coverage decision, or they wish to appeal a premature discharge, they may contact the QIO to lodge a complaint. The hospital is required to have procedures for referring Medicare beneficiary concerns to the QIOs; additionally, CMS expects coordination between the grievance process and existing grievance referral procedures so that beneficiary complaints are handled timely and referred to the QIO at the beneficiary's request.

This regulation requires coordination between the hospital's existing mechanisms for utilization review notice and referral to QIOs for Medicare beneficiary concerns (See 42 CFR Part 489.27). This requirement does not mandate that the hospital automatically refer each Medicare beneficiary's grievance to the QIO; however, the hospital shall inform all beneficiaries of this right and comply with his or her request if the beneficiary asks for QIO review.

A grievance is considered resolved when the patient is satisfied with the actions taken on their behalf. There may be situations where the hospital has taken appropriate and reasonable actions on the patient's behalf in order to resolve the patient's grievance and the patient or the patient's representative remains unsatisfied with the hospital's actions. In these situations, the hospital may consider the grievance closed for the purposes of these requirements. The hospital shall maintain documentation of its efforts and demonstrate compliance with the requirements.

In its written response, the hospital is not required to include statements that could be used in a legal action against the hospital, but the hospital shall provide adequate information to address each item stated in this requirement. The hospital is not required to provide an exhaustive explanation of every action the hospital has taken to investigate the grievance, resolve the

grievance, or other actions taken by the hospital; however, a form letter with generic statements about grievance process steps and results is not acceptable.

Surveyor Guidance:

Review and verify the organization's policies and procedures to assure that its grievance process encourages all personnel to alert appropriate staff concerning any patient grievance and that the organization's governing body has approved the grievance process.

Verify that the organization's process assures 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 organization's grievance procedures. Verify that time frames are established to review and respond to patient grievances.

Verify that the organization 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 organization's grievance process.

PR.7 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.

Note: 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.

SR.1d 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 organization 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 organization 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) shall 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 organization's policies or procedures.*

*Many types of **hand mitts** would not be considered restraint. However, pinning or otherwise attaching those same mitts to bedding or using a wrist restraint in conjunction with the hand mitts would meet the definition of restraint and the requirements would apply. In addition, if the mitts are applied so tightly that the patient's hand or fingers are immobilized, this would be considered restraint and the requirements would apply. Likewise, if the mitts are so bulky that the patient's ability to use their hands is significantly reduced, this would be considered restraint and the requirements would apply.*

- ***NOTE**: Because this definition of physical restraint does not name each device and situation that can be used to immobilize or reduce the ability of the patient to move his or her arms, legs, body or head freely, it promotes looking at each patient situation on a case-by-case basis.*

***In addition**, if a patient can easily remove a device, the device would not be considered a restraint. In this context, **"easily remove"** means that the manual method, device, material, or equipment can be removed intentionally by the patient in the same manner as it was applied by the staff (e.g., side rails are put down, not climbed over; buckles are intentionally unbuckled; ties or knots are intentionally untied; etc.) considering the patient's physical condition and ability to accomplish the objective (e.g., transfer to a chair, get to the bathroom in time).*

***CMS does not consider the use of weapons in the application of restraint or seclusion as a safe, appropriate health care intervention.** For the purposes of this regulation, the term "weapon" includes, but is not limited to, pepper spray, mace, nightsticks, tasers, cattle prods, stun guns, and pistols. Security staff may carry weapons as allowed by hospital policy, and State and Federal law. However, the use of weapons by security staff is considered a law enforcement action, not a health care intervention. CMS does not support the use of weapons by any hospital staff as a means of subduing a patient in order to place that patient in restraint or seclusion. If a weapon is used by security or law enforcement personnel on a person in a hospital (patient, staff, or visitor) to protect people or hospital property from harm, we would expect the situation to be handled as a criminal activity and the perpetrator be placed in the custody of local law enforcement.*

*The use of handcuffs, manacles, shackles, other chain-type restraint devices, or other restrictive devices applied by non-hospital employed or contracted law enforcement officials for custody, detention, and public safety reasons are not governed by this rule. **The use of such devices is considered law enforcement restraint devices and would not be considered safe, appropriate health care restraint interventions for use by hospital staff to restrain patients.** The law enforcement officers who maintain custody and direct supervision of their prisoner (the hospital's patient) are responsible for the use, application, and monitoring of these restrictive devices in accordance with Federal and State law. However, the hospital is still responsible for an appropriate patient assessment and the provision of safe, appropriate care to its patient (the law enforcement officer's prisoner).*

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 LP's knowledge of that patients 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 organization will keep the patient safe and protect their rights when restraints or seclusion are applied.

SR.2a The organization 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 shall 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 shall 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 shall 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 organization 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 shall 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 shall 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 organization 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 shall 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.

Organization 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).

Organization 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 organization 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 organization 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 shall be considered within the context of an ongoing process of assessment, intervention, evaluation, and re-evaluation.

The use of restraint or seclusion interventions shall 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 organization 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 are permitted to order restraints.*

- *Verify that the organization has defined who has the authority to discontinue restraints (based on State law and organization 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 organization 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 organization 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 shall be in accordance with the order of a physician or other LP who is responsible for the care of the patient and is authorized to order restraint or seclusion by organization policy in accordance with state law.

SR.3b An order for restraint or seclusion shall be obtained prior to the application of restraints, except in emergency situations when the need for intervention may occur quickly;

SR.3b(1) In these emergency application situations, the order shall be obtained either during the emergency application of the restraint or seclusion, or immediately (within a few minutes) after the restraint or seclusion has been applied.

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 shall be consulted as soon as possible if restraint or seclusion is not ordered by the patient's attending physician.

SR.3e Unless superseded by State law that is more restrictive, 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 the limits in PR.7 (SR.3e(1)) for up to a total of 24 hours.

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 LP who is responsible for the care of the patient and authorized to order restraint or seclusion by organization policy in accordance with state law shall 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 shall be obtained prior to re-initiation of the restraint or seclusion.

SR.3e(5) Hospital restraint and seclusion policies shall address at a minimum:

SR.3e(5)(i) Who has the authority to discontinue the use of restraint or seclusion (based on State law and hospital policies); and

SR.3e(5)(ii) Circumstances under which restraint or seclusion should be discontinued.

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 organization policy.

Interpretive Guidelines:

An LP is any individual permitted by State law and organization 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 organization policy.

The standard requires that a physician or other LP responsible for the care of the patient order restraint or seclusion prior to the application of restraint or seclusion. In some situations, however, the need for a restraint or seclusion intervention may occur so quickly that an order cannot be obtained prior to the application of restraint or seclusion. In these emergency application situations, the order shall be obtained either during the emergency application of the restraint or seclusion, or immediately (within a few minutes) after the restraint or seclusion has been applied. The failure to immediately obtain an order is viewed as the application of restraint or seclusion without an order. The organization should address this process in its restraint and seclusion policies and procedures. The policies and procedures should specify who can initiate the emergency application of restraint or seclusion prior to obtaining an order from a physician or other LP.

When the restraint or seclusion is not ordered by the patients attending physician, the order shall 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. The intent

of this standard is to ensure that the physician who has overall responsibility and authority for the management and care of the patient is aware of the patient's condition and is aware of the restraint or seclusion intervention. It is important to consult with the attending physician to promote continuity of care, to ensure patient safety, and to elicit information that might be relevant in choosing the most appropriate intervention for the patient. The attending physician may have information regarding the patient's history that may have a significant impact on the selection of a restraint or seclusion intervention or an alternative intervention, and the subsequent course of treatment. Therefore, consultation should occur as soon as possible. Organization policies and procedures should address the definition of "as soon as possible" based on the needs of their particular patient population. However, any established time frames shall be consistent with "as soon as possible," but ought not exceed 24 hours after restraint application, in the absence of a shorter state timeframe requirement. A consultation that is not conducted prior to a renewal of the order would not be consistent with the requirement, "as soon as possible."

When the attending physician is unavailable, responsibility for the patient shall be delegated to another physician, who would then be considered the attending physician.

The attending practitioner shall be able to conduct both a physical and psychological assessment of the patient in accordance with State law, their scope of practice, and organization policy.

When implementing a protocol that includes the use of an intervention that meets the definition of a restraint, a separate order shall be obtained for the restraint.

The patient's medical record shall 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.

Organizations 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 shall be obtained either during the emergency application of the restraint or seclusion, or immediately after the restraint has been applied. The organization should address this process in its restraint policies and procedures.*

- *Organization 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 LP.*

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 LP 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 LP 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 LP shall occur before a new order for the continued use of restraint or seclusion is written.*

The regulation does not require the ordering LP to be physically present to re-evaluate the need for continuing restraint for non-violent and non-self-destructive behaviors. Organizations 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. However, the requirement that restraint use be ended at the earliest possible time applies to all uses of restraint. Restraint or seclusion may only be imposed to ensure the immediate physical safety of the patient, staff, or others and shall be discontinued at the earliest possible time (see PR.7 (SR.2b)).

Surveyor Guidance:

Review a sample of medical records of patients for whom restraints were used to manage non-violent, non-self-destructive behavior, as well as a sample of medical records of patients for whom restraint or seclusion was used to manage violent or self-destructive behavior.

Include in the review patients who are currently in restraint or seclusion, as well as those who have been in restraint or seclusion during their hospital stay (include both violent or self-destructive patients as well as non-violent, non-self-destructive patients).

What evidence is there that hospital staff identified the reason for the restraint or seclusion, and determined that other less restrictive measures would not be effective before applying the restraint?

Interview staff who work directly with patients to determine their understanding of the restraint and seclusion policies. If any patients are currently in restraint or seclusion, ascertain the rationale for use and when the patient was last monitored and assessed.

Is the actual use of restraints or seclusion consistent with hospital restraint and seclusion policies and procedures, as well as CMS requirements?

Review incident and accident reports to determine whether patient injuries occurred proximal to or during a restraint or seclusion intervention. Are incidents and accidents occurring more frequently with restrained or secluded patients?

If record review indicates that restrained or secluded patients sustained injuries, determine what the hospital did to prevent additional injury. Determine if the hospital investigated possible changes to its restraint or seclusion policies.

Obtain data on the use of restraint and seclusion for a specified time period (e.g., 3 months) to determine any patterns in their use for specific units, shifts, days of the week, etc.

Does the number of patients who are restrained or secluded increase on weekends, on

holidays, at night, on certain shifts; where contract nurses are used; in one unit more than other units? Such patterns of restraint or seclusion use may suggest that the intervention is not based on the patient's need, but on issues such as convenience, inadequate staffing or lack of staff training. Obtain nursing staffing schedules during time periods in question to determine if staffing levels impact the use of restraint or seclusion.

Interview a random sample of patients who were restrained to manage non-violent, non-self-destructive behavior. Were the reasons for the use of a restraint to manage non-violent, non-self-destructive behavior explained to the patient in understandable terms? Could the patient articulate his/her understanding?

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 organization 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 shall 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 LP, or a RN trained in accordance with the requirements specified under PR.7 shall see the patient face-to-face within 1- hour after the initiation of the intervention to evaluate and document the following:

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, the attending physician or other LP responsible for the care of the patient shall be consulted as soon as possible (as defined by the organization) 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 shall 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 organization 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 conducts the 1-hour evaluation, the physician or LP 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 or LP 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 patients' 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 shall 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 shall 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 organization 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 organization 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 LP or trained staff at an interval determined by organization policy, at least every 24 hours.

SR.5a(1) Organization 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) Organization 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 shall 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 shall 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 shall 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 shall 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 organization 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 LP shall occur before a new order is written for restraints or seclusion for the violent or self-destructive patient.

Restraint or seclusion shall 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 shall 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 organization policy.*
- *The patient was reassessed according to criteria established by organization policy.*

SR.6 Documentation in the Medical Record

SR.6a When restraint or seclusion is used, there shall 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 organization 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 organization policy.

SR.6b In addition, staff shall 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 shall be able to demonstrate that the restraint or seclusion intervention is the least restrictive intervention that protects the patient's safety. Patient care staff shall 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 shall 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 QMS (see also QM.7 (SR.4f)). The following shall be recorded within a log or other data collection mechanism for monitoring:

SR.7a(1) Shift;

SR.7a(2) Date, time of order;

SR.7a(3) Staff who initiated the process;

SR.7a(4) The length of each episode;

SR.7a(5) Date and time each episode was initiated;

SR.7a(6) Day of the week each episode was initiated;

SR.7a(7) Type of restraint or seclusion used (including physical restraint or drug used as restraint);

SR.7a(8) Compliance with requirements defined in the standards;

SR.7a(9) Whether injuries were sustained by the individual or staff; and

SR.7a(10) Age of individual.

SR.7b Evidence of prolonged restraint, as defined by the organization, and, if possible, actions taken to reduce or eliminate the use of restraints shall be analyzed by the treatment team.

SR.7c Aggregate data regarding the use of restraint shall be collected and analyzed for the identification of patterns and trends. Using data from SR.7a analyze the following:

SR.7c(1) Patterns of excessive use of all types of restraints;

SR.7c(2) 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 the night, which may be indicative of unmet patient care needs;

SR.7c(3) Opportunities for improving compliance with the requirements of the standards.

SR.7c(4) Prolonged restraint use

SR.7c(4)(i) Analysis of data for trends including patterns of prolonged restraint that coincide with use of devices- device days;

SR.7c(4)(ii) Analysis of trends associated with prolonged use of restraints that are not related to devices (e.g., intubation, lines, tubes, etc.); and

SR.7c(4)(iii) Effectiveness of actions taken to reduce prolonged restraint.

SR.7c(5) Causal analysis shall occur in the event a patient and/or staff 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.

Surveyor Guidance:

Review the aggregate data regarding the use of restraints and seclusion to see if the organization 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 organization has conducted a causal 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.8 RESTRAINT OR SECLUSION: STAFF TRAINING REQUIREMENTS

The patient has the right to safe implementation of restraint or seclusion by trained staff.

SR.1 Staff shall 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 shall occur before performing any of these actions, as part of orientation, and subsequently on a periodic basis consistent with organization policy.

SR.1b Training will occur subsequently on a periodic basis consistent with organization policy.

SR.2 The organization shall 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 based on the specific needs of the patient population;

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 organization 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 LPs authorized to order restraint or seclusion by organization policy in accordance with State law shall have a working knowledge of the organization policy regarding the use of restraint or seclusion.

SR.3a Physician and other LP training requirements shall be specified in organization policy.

SR.4 Individuals providing staff training shall be qualified as evidenced by education, training, and experience in techniques used to address patients' behaviors.

SR.5 The organization shall 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 shall 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 shall be trained in the application, monitoring, patient care, and discontinuation of restraint or seclusion.*
- *Non-nursing staff shall 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.*

Organizations are required to provide a safe environment for the patients in their care. When restraint or seclusion techniques are used, patients are placed at a higher risk for injuries or even death. Organizations shall require appropriate staff (all staff who apply restraint or seclusion, monitor, access or provide care for a patient in restraint or seclusion) to receive education and training in the use of first aid techniques as well as training and certification in the use of cardiopulmonary resuscitation.

Training shall be comprehensive and shall involve demonstration and return demonstration.

The written training curriculum reflects the defined competency skill sets defined for each level of clinical personnel:

- *The organization 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.*

- *Organization 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.*

Training for an RN or PA to conduct the 1-hour face-to-face evaluation would include all of the training requirements at §482.13(f) as well as content to evaluate the patient's immediate situation, the patient's reaction to the intervention, the patient's medical and behavioral condition, and the need to continue or terminate the restraint or seclusion. 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, medications, most recent lab results, etc. The purpose of the 1-hour face-to-face evaluation is to complete a comprehensive review of the patient's condition and determine if other factors, such as drug or medication interactions, electrolyte imbalances, hypoxia, sepsis, etc., are contributing to the patient's violent or self-destructive behavior.

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 shall 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 shall be covered.

Surveyor Guidance:

Review organization 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, LP's and hospital staff as defined.*
- *Training has been provided for all new employees and contract staff during orientation and before participating in the application of restraints.*
- *Does the training include demonstration of required competencies?*
- *Does the hospital educational program address choosing the least restrictive intervention based on an individualized assessment of the patient's medical or behavioral status or condition?*
- *Does the hospital educational program address how to conduct an assessment of a patient's medical and behavioral conditions?*
- *Does the hospital educational program address types of interventions appropriate to the specific needs of the patient population(s) served and ranging from less to more restrictive?*

Review and validate that the organization has documented instructional training for the use of all restraint techniques used and the alternatives to the use of restraint and seclusion.

Interview staff to assess their non-physical intervention skills.

PR.9 REPORTING DEATHS ASSOCIATED WITH RESTRAINT USAGE

SR.1 Organizations shall report deaths associated with the use of restraint or seclusion. With the exception of deaths described under (SR.2) of this section, the hospital shall report the following information to CMS by telephone, facsimile, or electronically, as determined by CMS, no later than the close of business on the next business day following knowledge of the patient's death.

SR.1a Each death that has occurred while a patient is in restraint or seclusion.

SR.1b Each death that has occurred within 24 hours after the patient has been removed from restraint or seclusion.

SR.1c Each death known to the organization that occurs within 1 week after restraint or seclusion where it is reasonable to assume that use of restraint or placement in seclusion contributed directly or indirectly to the patient's death, regardless of the type 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.

SR.2 When no seclusion has been used and when 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 organization staff shall record in an internal log or other system, the following information:

SR.2a Any death that occurs while a patient is in these restraints.

SR.2b Any death that occurs within 24 hours after a patient has been removed from such restraints.

SR.3 Staff shall document in the patient's medical record the date and time the death was:

SR.3a Reported to CMS for deaths described in SR.1 (SR.1a-c); or

SR.3b Recorded in the internal log or other system for deaths described in SR.2 (SR.2a-b).

SR.4 For deaths described in SR.2 (SR.2a-b), entries into the internal log or other system shall be documented as follows:

SR.4a Each entry shall be made not later than seven days after the date of death of the patient.

SR.4b Each entry shall document the patient's name, date of birth, date of death, name of attending physician or other licensed practitioner who is responsible for the care of the patient, medical record number, and primary diagnosis(es).

SR.4c The information shall be made available in either written or electronic form to CMS immediately upon request.

Interpretive Guidelines:

Access the electronic Form CMS-10455 at the following for reporting deaths to CMS.

https://restraintdeathreport.gov1.qualtrics.com/jfe/form/SV_5pXmjIw2WAzto8J

The hospital shall complete sections A-D of the electronic Form CMS-10455. CMS-10455 will automatically send to the respective CMS Location for view. The CMS Location will determine if an investigation is warranted.

The CMS Location shall be informed no later than the close of business on the next business day following knowledge of the patient's death of each reportable death.

Surveyor Guidance:

Review the organization 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.

PR.10 CARE IN A SAFE SETTING: PATIENTS AT RISK OF HARM TO SELF OR OTHERS

Organizations shall identify patients at risk for intentional harm to self or others, identify environmental safety risks for such patients, implement the appropriate monitoring and observation, and provide education and training for staff and volunteers.

SR.1 Patient risk screening and assessment. The organization shall utilize a screening and assessment process that is developed with consideration of a nationally recognized tool(s) for assessing and evaluating patient risk for suicidal behavior, other forms of self-harm, or homicidal ideation. Policies and procedures specify:

SR.1a The patient population requiring screening or assessment (such as all emergency department patients, all inpatient admissions, etc.); and

SR.1b Frequency of screening and reassessment, to include minimum, regular defined intervals based on the initial results (i.e., high, moderate, low, or no risk) and with consideration to changes in patient factors.

SR.2 Safety precautions. Patients at risk of suicide, other forms of self-harm, or homicidal ideation or behaviors shall be cared for in an environment with appropriate monitoring, reflective of their specific medical and behavioral health needs. Organization policy/procedure defines, at minimum:

SR.2a Required safety precautions (i.e., level of observation/monitoring) to be implemented based on the identified patient risk in SR.1;

SR.2b Required documentation for safety precautions, including but not limited to the frequency with which documentation must occur; and

SR.2c Staff authorized to order and/or implement and discontinue safety precautions.

SR.3 Education and Training. Appropriate staff shall be trained and able to demonstrate competency to the organization's policies and procedures related to patients at risk of harm to self or others.

SR.3a Training shall occur before performing any of these actions, as part of orientation, and subsequently on a periodic basis consistent with organization policy, not to exceed two years, and whenever policies and procedures change.

SR.3a(1) Minimum training includes at least the following:

SR.3a(1)(i) Identification of patients at risk of harm to self or others and use of the screening and assessment process and tool;

SR.3a(1)(ii) Identification of environmental patient safety risk factors and ensuring the safety of the patient's environment; and

SR.3a(1)(iii) Mitigation, observation and monitoring requirements.

SR.4 Environmental ligature and safety risk assessment. The organization shall perform and document an environmental ligature and safety risk assessment in psychiatric hospitals, dedicated behavioral health units and/or dedicated behavioral health care spaces.

SR.4a The environmental ligature and safety risk assessment shall be reviewed at least annually and updated whenever conditions or processes change.

SR.4b The environmental ligature and safety risk assessment addresses, at minimum, the following:

SR.4b(1) Ligature risks, including but not limited to hand or shower rails, door handles/knobs, door hinges, shower curtains, exposed plumbing/pipes, water fountains, soap and paper towel dispensers on walls, power cords on medical equipment or call bell cords, oxygen tubing, and light fixtures or projections from ceilings, toilets or toilet seats, etc.;

SR.4b(2) Unattended items such as utility or housekeeping carts that contain hazardous items (mops, brooms, cleaning agents, hand sanitizer, etc.);

SR.4b(3) Sharp objects, harmful substances, access to medications, plastic bags (for suffocation), non-tamper proof screws, and others;

SR.4b(4) Furniture that can be easily moved or be thrown;

SR.4b(5) Windows that can be opened or broken;

SR.4b(6) Unprotected lighting fixtures;

SR.4b(7) Inadequate staffing levels to provide appropriate patient observation and monitoring; and

SR.4b(8) Unsafe items brought to patients by visitors.

SR.4c A level of risk shall be assigned for each required element of the environmental ligature and safety risk assessment.

SR.4c(1) For each risk identified, the organization shall document:

SR.4c(1)(i) Action that will be taken:

(a) Correction/elimination of the identified risk with the use of interim safety measures, such as increased monitoring or observation of patients until the risk can be completely eliminated; or

(b) For risks that are unable to be permanently eliminated due to unreasonable hardship on the part of the hospital, but are mitigated through the use of safety measures and

therefore do not adversely affect the health and safety of the patients:

(i) The organization shall document the rationale for why it is not reasonable to permanently eliminate the risk.

(ii) These risks shall be mitigated through the use of safety measures defined by the hospital.

SR.4c(1)(ii) Responsible party(ies); and

SR.4c(1)(iii) Due date for completion.

SR.5 The organization shall have policies and documented processes and/or procedures providing for a safe environment, such as an environmental ligature and safety risk assessment strategy, that is implemented when non-dedicated spaces are used to care for patients at risk of harm to self or others.

Interpretive Guidelines:

In order to provide care in a safe setting, organizations shall identify patients at risk for intentional harm to self or others, identify environmental safety risks for such patients, and provide education and training for staff and volunteers. The intention of this requirement is to specify that each patient receives care in an environment that a reasonable person similarly situated as the patient would consider to be safe. Additionally, this standard is intended to provide protection for the patient's emotional health and safety as well as his/her physical safety. Respect, dignity, and comfort would also be components of an emotionally safe environment.

The hospital Patient's Rights Condition of Participation (CoP) at 482.13(c)(2) and NIAHO® requirements provide all patients with the right to care in a safe setting. Behavioral health patients receiving care and treatment in a hospital setting are particularly vulnerable. Left unmitigated, the presence of ligature and safety risks in the behavioral health patient's physical environment compromises their right to receive care in a safe setting. A ligature risk (point) is defined as anything which could be used to attach a cord, rope, or other material for the purpose of hanging or strangulation. Potential safety risks include, but are not limited to, those that are required to be addressed in the organization's environmental ligature and safety risk assessment.

The focus of ligature risk management should be to place patients in an environment, with the appropriate monitoring, reflective of their specific medical and behavioral health needs. Based on their clinical evaluation, some patients may require both a more restrictive environment and an increased level of monitoring than other patients. Therefore, it is not expected that hospitals have the same ligature risk configuration throughout their facility but rather focus on the specific needs and risks of individual patients, based on their clinical or behavioral health assessment.

Patients at risk of suicide (or other forms of self-harm) or who exhibit violent behaviors toward others receive healthcare services in both inpatient and outpatient locations of hospitals. Therefore, behavioral health patients requiring medical care in a non-dedicated behavioral

health setting (medical inpatient units, ED, ICU, etc.) must also be evaluated, monitored, and cared for appropriately when demonstrating suicidal ideation or potential harm to others.

The organization shall ensure that its behavioral health care environments are included in the QMS (see QM.6) and engaged in continuous measurement, monitoring and analysis (see QM.6/QM.7) to evaluate the effectiveness of processes for care delivery and prevention of medical errors and adverse events to ensure patient safety (see QM.8). Behavioral health care environments are high-risk, problem-prone areas. Areas which do not routinely care for behavioral health patients (such as Med/Surg, ICU, or other medical units) may present even greater risk.

Patient Screening and Assessment

There are numerous models and versions of patient risk assessment tools available to identify patients at risk for harm to self or others. No one size fits all tool is available. Therefore, the type of patient risk assessment tool used should be appropriate to the patient population, care setting and staff competency. All hospitals are expected to implement a documented patient risk assessment strategy, but it is up to the organization to implement the appropriate strategies. For example, a patient risk assessment strategy in a post-partum unit would most likely not be the same risk assessment strategy utilized in the emergency department.

Safety Precautions

Patients shall be screened and assessed, per hospital policy and according to nationally accepted standards of practice, to ensure they do not harm themselves in a non-ligature resistant environment. Mitigation of safety and ligature risks present includes the use of safety measures based on the level of identified risk such as 1:1 continuous observation for high-risk suicidal patients or video monitoring, if appropriate, in which staff are available to intervene when necessary, observation and/or rounding processes for low-risk suicidal patients, removal of sharp objects from the room/area, removal of equipment that can be used as a weapon or for self-harm, securing personal belongings, and removal of any other item(s) that may contribute to harmful behavior. Staff shall mitigate the risk for medical supplies and equipment required for the provision of patient care that are introduced into the patient's room on a case-by-case basis due to patient need and assessment and unable to be removed from the patient care setting. This includes, but is not limited to, items such as a standard medical bed required for a patient, infusion pump, etc. In common areas of a dedicated unit, such as corridors, day rooms, activity rooms, cafeterias, etc., safety measures may include but are not limited to patients being accompanied by staff, continuous rounding, continuous observation by staff via camera monitoring, and locking rooms in which ligature risks have been identified to prevent patient access.

Education and Training

Organizations shall provide the appropriate level of education and training to staff regarding the identification of patients at risk of harm to self or others and the use of the screening and assessment process and tool, the identification of environmental patient safety risk factors, and mitigation, observation and monitoring strategies. Staff includes direct employees, volunteers, contractors, per diem staff and any other individuals providing clinical care under arrangement. Organizations have the flexibility to tailor the training to the particular services staff provide and the patient populations they serve. Organizations shall provide education and training to all new staff initially upon orientation, at least every two years, and whenever policies and procedures

change.

Environmental Ligature and Safety Risks

An environmental ligature and safety risk assessment is required to be performed and documented for dedicated behavioral health spaces. The risk assessment process is not a static activity, and organizations are expected to determine the appropriate frequency based on patient population and the scope of services provided. Hospitals shall maintain documentation of their environmental ligature and safety risk assessments and mitigation plans and provide these for review at the time of survey. Documented actions to be taken as a result of the environmental ligature and safety risk assessment in (SR.4) may be located in documents outside of the risk assessment (policies, procedures, other written communication).

The organization shall document the environmental ligature and safety risk assessment strategy to be used for other locations that may care for patients at risk for harm to self or others. Environmental ligature and safety risk assessment strategies may not be the same in all hospitals or hospital units. The organization shall implement environmental risk assessment strategies appropriate to the specific care environment and patient population (see also PE.1). The risk assessment strategy shall be appropriate to the unit and should consider the possibility that the unit may sometimes care for patients at risk for harm to self or others.

Although all risks cannot be eliminated, hospitals shall be able to demonstrate how they identify patients at risk of self-harm or harm to others and steps they are taking to minimize and mitigate those risks in accordance with nationally recognized standards and guidelines. The presence of unmitigated ligature or safety risks in a dedicated psychiatric hospital, behavioral health unit in an acute care or critical access hospital or dedicated behavioral health space is an immediate jeopardy situation. Additionally, this also includes any location where patients at risk of harm to self or others are identified.

Outpatient behavioral health areas (e.g. clinics, etc.) are to be designed for a safe environment based upon the results of Safety Risk Assessment required by the FGI Guidelines for Design and Construction of Outpatient Facilities (see also PE.1 (SR.10a).

Patient Safety System

Corrective actions implemented in response to deficiencies or adverse events (see QM.5/QM.8) should focus on appropriately addressing the findings or failures and their causes, rather than universal remedies. The incident is 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. For example, the attempted use of a door as a ligature point does not mean all patient doors in the hospital need to be replaced. Instead, the failure should be further investigated to determine whether it could have been the result of something more basic to safe patient care, such as insufficient monitoring and/or patient assessment and evaluation. All contributing factors should be considered before corrective action is initiated.

Corrective actions may include, but are not limited to, changes in policies and procedures, repairing or replacing equipment, staff education and training, etc. Where appropriate, the hospital should make all affected staff aware of the strategies and related actions it has implemented to correct and prevent specific errors and adverse events and also provide applicable training. Hospitals shall provide evidence of the implemented changes, such as documented staff education and training, documentation of new or revised policies, evidence

that equipment has been repaired or replaced, etc. The means by which these incidents are prevented or occur shall be identified, implemented and regularly assessed.

In accordance with QM.5, the organization shall ensure that high-risk nonconformities and corrective actions are included in Quality Management Oversight. When corrective actions are implemented, the organization shall evaluate the effectiveness of the actions in reducing and eliminating the risk (see QM.5). Consistent with the requirements under QM.1, the hospital's governing body (GB.2), medical leadership and administrative leadership are responsible and accountable for setting and communicating clear expectations for safety and ensuring that all identified problems are addressed, with further ongoing reassessment to achieve improvement.

INFECTION PREVENTION AND CONTROL PROGRAM (IC)

IC.1 INFECTION PREVENTION AND CONTROL PROGRAM

The organization shall have an active, facility-wide Infection Prevention and Control Program (IPCP) in place, incorporating the requirements and/or recommendations of the CDC, CMS, OSHA, and related professional organizations (e.g., APIC). This program shall be inclusive of documented policies, procedures, and processes, ensures the safety of patients, healthcare workers, volunteers, contract workers, and visitors.

SR.1 The IPCP shall provide the means for the surveillance, prevention, and control of Healthcare-Associated Infections (HAIs) and other infectious diseases, and for the optimization of antibiotic use through stewardship.

SR.1a The programs shall demonstrate adherence to nationally recognized infection prevention and control guidelines, as well as to best practices for improving antibiotic use where applicable, and for reducing the development and transmission of HAIs and antibiotic- resistant organisms. Infection prevention and control problems and antibiotic use issues identified in the programs shall be addressed in collaboration with the organization wide QAPI program.

SR.2 The organization shall demonstrate that:

SR.2a An individual (or individuals), who is qualified through education, training, experience, or certification in infection prevention and control, is appointed by the governing body as the infection preventionist(s)/ infection control professional(s) responsible for the IPCP;

SR.2a(1) The appointment is based on the recommendations of medical staff leadership and nursing leadership;

SR.2a(2) Minimum qualification requirements shall be defined by the organization.

SR.2b The IPCP, as documented in its policies and procedures, employs methods for preventing and controlling the transmission of infections within the organization and between the organization and other institutions and settings;

SR.2c The IPCP includes surveillance, prevention, and control of HAIs, including maintaining a clean and sanitary environment to avoid sources and transmission of infection, addresses any infection control issues identified by public health authorities; and,

SR.2d The IPCP reflects the scope and complexity of the organization services provided.

SR.3 The organization's IPCP shall have documented processes, policies and procedures to define how infections and communicable diseases are prevented, controlled and investigated throughout the organization including, but not limited to:

SR.3a Designation of individual(s) responsible for infection prevention and control activities;

SR.3b Processes for ongoing monitoring for infections among patients and personnel and subsequent documentation of infections that occur;

SR.3c Preparations for possible bioterrorism or pandemic events;

SR.3d Prevention, monitoring, and control of the transmission of healthcare associated infections and infectious/communicable diseases;

SR.3e Risk Assessments, including but not limited to;

SR.3e(1) Infection Control Risk Assessments (ICRA) for areas undergoing repair, renovation, or construction; and,

SR.3e(2) The overall infection prevention and control risk assessment.

SR.3f Hand hygiene compliance & monitoring;

SR.3g Guidelines for the implementation of isolation precautions;

SR.3h Maintenance of a sanitary environment for personnel, patients, visitors, contracted personnel, volunteers and students;

SR.3h(1) 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 shall be part of the Infection Prevention and Control Plan. No patient care items are permitted to be stored under sinks in any policy.

SR.3i Contributions to the reduction of mortality and morbidity.

SR.4 The organization shall have a process in place to address potential exposure incidents:

SR.4a The organization shall be in compliance with the OSHA Bloodborne Pathogens regulation at 29 CFR 1910.1030 to include:

SR.4a(1) The Infection Prevention and Control System shall have a written Exposure Control Plan that is reviewed annually.

SR.4a(2) Training and education are provided as required by the regulation and organization policy.

SR.4a(2)(i) All staff, regardless of employment status, shall receive initial and annual education on the *Methods of compliance (1910.1030(d))* sections of the organization's written Exposure Control Plan.

SR.4b The Infection Prevention and Control System shall have a tuberculosis (TB) screening program that ensures:

SR.4b(1) All organization staff are screened for TB upon hire with ongoing TB screening criteria for staff who test negative based upon facility/unit risk classification;

SR.4b(2) Personnel with TB test conversions are provided with appropriate follow-up (e.g., evaluation and treatment, as needed); and,

SR.4c All organization staff likely to be exposed to TB and other aerosol-transmissible diseases and illnesses who are required to wear respirators shall be fit tested in accordance with the Respiratory Protection Program requirements of PE.3 (SR.9).

SR.4d All organization staff are offered annual influenza vaccination and those that work directly with patients or handle material that could spread infection are offered vaccinations recommended as appropriate in keeping with CDC (ACIP) recommendations and applicable state law.

SR.4e RESERVED

SR.4f RESERVED

SR.5 Sterilization and High-Level Disinfection of Reusable Instruments and Devices is accomplished in a manner consistent with organization policies and procedures to maximize the prevention of infection and communicable disease and in accordance with manufacturer, state and federal requirements, CDC recommendations, and the recommendations of related professional organizations (e.g., AORN, SGNA, etc. (See SS.10)).

SR.6 The IPCP shall be evaluated at least annually by the Infection Prevention and Control oversight group and that evaluation forwarded to the QMS oversight group for review. Surveillance methodology shall be appropriate for the population(s) served and approved by the Infection Prevention and Control oversight group.

SR.6a The inpatient and outpatient population data shall be reported to the Infection Prevention and Control oversight group as an annual summary of reported illnesses.

SR.6b Significant infection control data/information shall be disseminated no less than quarterly to the Infection Prevention and Control oversight group.

SR.6b(1) Incidences of infections and communicable diseases shall be measured and analyzed to identify any patterns or trends that require the organization to take corrective or preventive actions.

Interpretive Guidelines:

The organization shall maintain an Infection Prevention and Control Program for the prevention, control, and surveillance of infections (which includes, but is not limited to healthcare associated 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, helminths, 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.

Healthcare-associated infection - one that develops in a patient who is cared for in any setting where healthcare is delivered (e.g., acute care hospital, chronic care facility, ambulatory clinic, dialysis center, surgical center, home) and is related to receiving health care (e.g., was not incubating or present at the time healthcare was provided).

Healthcare facility – buildings or portions of buildings in which medical, dental, psychiatric, nursing, obstetrical, or surgical care are provided.

Staff - Organization employees, licensed practitioners, students, trainees, and volunteers, and individuals who provide care, treatment, or other services for the organization and/or its patients, under contract or by other arrangement.

The Infection Prevention and Control System 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 Prevention and Control System program shall be continually evaluated for effectiveness and when necessary, corrective and/or preventive action shall be taken to reduce risks of infections. The Infection Prevention and Control System should be conducted in accordance with nationally recognized infection control practices or guidelines, as well as applicable regulations of other federal or state agencies. Examples of organizations that promulgate nationally recognized infection and communicable disease control guidelines, and/or recommendations include: the CDC (including ACIP and HICPAC), APIC, SHEA, SGNA, and AORN. OSHA also issues federal regulations applicable to infection control practice. Adoption or integration of the specific recommendations by these nationally recognized organizations is determined by the organization. The organization shall document and provide the source

practices, guidelines, recommendations, and/or standards that form the basis for its infection prevention and control policies and procedures.

The organization shall provide for and maintain a sanitary environment to avoid the sources and transmission of infections and communicable diseases. All areas shall be regularly cleaned and sanitary including all patient care units, campuses and off-site locations (as applicable). The Infection Prevention and Control surveillance program will include monitoring of housekeeping and maintenance (including when applicable areas of the organization are under repair, renovation, or construction) as well as any other activities to ensure the organization maintains a sanitary environment. Examples of areas to monitor would include the organization's: onsite laundry facilities, food storage, preparation, serving and dish rooms, refrigerators, ice machines, air handlers, autoclave rooms, venting systems, inpatient rooms, treatment areas, labs, waste handling, surgical areas, supply storage, equipment cleaning, etc.

The organization shall provide adequate resources to accomplish the activities of the Infection Prevention and Control System. 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, to include not only the organization but between the organization and other institutions or settings. 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 medical waste and non-regulated waste*
    - *Pest control*
- *Measures related to organization 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 (e.g., 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 Multidrug-resistant organisms (MDRO). This applies to, but is not limited to, organisms such as methicillin-resistant staphylococcus aureus (MRSA), clostridium difficile (C. diff), 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 organization 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 Prevention and Control preventionist/professional and the scope of responsibilities*
- *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.*
  - *Policies and procedures address:*
    - *Appropriate steps to diagnose and manage cases, implement appropriate precautions, and prevent further transmission of the disease as well as documentation of follow-up activity.*
- *Roles and responsibilities for infection control within the organization and how various committees and departments interface with the infection control program*
- *The organization 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 organization staff.*

- *Records are maintained and controlled to account for incidents related to infections and communicable diseases.*
    - *Although not required, the organization 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 organization;*
        - *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 organization or local, state or federal health agencies.*
- *A procedure for meeting the reporting requirements of the local health authority as required.*
- *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 (e.g., Infection Control Committee)*
- *How education of patients, family members and caregivers about infections and communicable diseases is conducted.*
- *Orientation of all new organization personnel, including contract staff, students and volunteers, to infections, communicable diseases, and to the infection control program.*

Surveyor Guidance:

Interview the infection control preventionist/professional to verify the scope and activities of the organization's infection control program and organization issues regarding infection control.

Review the personnel file of the infection preventionist(s)/infection control professional(s) to verify that he or she was appointed by the governing body based on recommendations of medical staff leadership and nursing leadership and is qualified through education, training, experience, and certification or licensure to oversee the infection control program. The organization determines the process for such an appointment, and it may be included in minutes

of the governing body or other executive level meeting minutes, or within the job description. The organization shall define the qualifications for the infection preventionist(s)/infection control professional(s).

Review and validate that appropriate policies and procedures included under the Interpretive Guidelines above have been developed and implemented, based on national standards of practice and best practices, to identify, prevent, control, monitor, report, investigate and measure the control of infections and communicable diseases.

Determine whether the infection control program is organization-wide and identifies all organization locations and take these various locations into account under the program and there is active surveillance in place.

Review how areas of the organization are monitored to include: onsite laundry facilities, areas where food is stored, prepared and served, refrigerators, ice machines, air handlers, autoclave rooms/areas, ventilation systems, inpatient rooms, patient care areas, laboratory, waste handling, 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, medication preparation, etc.

Review the Infection Prevention and Control Oversight Group's meeting minutes to evaluate compliance with requirements and follow-up on corrective and preventive actions taken.

Review a sampling of records for incidents related to infections and communicable diseases, including those identified through employee/occupational health services and reported to or by local health authorities 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 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 organization's QMS 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. Verify that data/information is reported at least quarterly to the organization oversight group responsible for the infection control function.

Verify compliance with the OSHA Bloodborne Pathogens regulation at 29 CFR 1910.1030 to include:

- *The organization has a written Exposure Control Plan that has been reviewed annually.*
- *Training is provided as required by the regulation and organization policy.*

- *All staff, regardless of employment status, have received education on the organization's written Exposure Control Plan.*

Validate through record review that:

- *All organization personnel are screened for TB upon hire with ongoing TB screening criteria for staff who test negative based upon facility/unit risk classification and organization policy. Personnel with TB test conversions are provided with appropriate follow-up (e.g., evaluation and treatment, as needed).*

- *Respiratory fit testing is provided in accordance with PE.3 (SR.9).*

- *All personnel are offered annual influenza vaccination and those personnel that work directly with patients or handle material that could spread infection are offered vaccinations recommended as appropriate in keeping with CDC (ACIP) recommendations and applicable state law, as well as organization policy.*

Review the organization's policy/procedure for performing sterilization and high-level disinfection of reusable instruments and devices as directed by the manufacturer and consistent with state and federal requirements, CDC recommendations, and the recommendations of related professional organizations (e.g., AORN, SGNA, AAMI, etc.). Adoption or integration of the specific recommendations by these nationally recognized organizations is determined by the organization. The organization documents and provides the source practices, guidelines, recommendations, and/or standards that form the basis for its infection prevention and control policies and procedures.

Validate that all areas of the organization that perform sterilization or high-level disinfection, to include off-site locations as applicable, demonstrate compliance with the organization's policies and procedures and manufacturer's recommendations.

Verify that there is a policy and process for endoscope reprocessing, to include identification of which endoscope was used on a patient for each procedure (traceability). Review documentation of a sample of endoscopy cases to validate that the policy/procedure are followed.

IC.2 ANTIBIOTIC STEWARDSHIP PROGRAM

SR.1 The organization shall demonstrate that:

SR.1a An individual (or individuals), who is qualified through education, training, or experience in infectious diseases and/or antibiotic stewardship, is appointed by the governing body as the leader(s) of the antibiotic stewardship program.

SR.1a(1) The appointment is based on the recommendations of medical staff leadership and pharmacy leadership.

SR.2 The organization-wide antibiotic stewardship program:

SR.2a Demonstrates coordination among all components of the organization responsible for antibiotic use and resistance, including, but not limited to:

SR.2a(1) The IPCP;

SR.2a(2) The QAPI program;

SR.2a(3) The medical staff;

SR.2a(4) Laboratory services;

SR.2a(5) Nursing services; and,

SR.2a(6) Pharmacy services.

SR.2b Documents the evidence-based use of antibiotics in all departments and services of the organization; and,

SR.2c Documents any improvements, including sustained improvements, in proper antibiotic use.

SR.3 The antibiotic stewardship program adheres to nationally recognized guidelines, as well as best practices, for improving antibiotic use; and,

SR.3a The antibiotic stewardship program reflects the scope and complexity of the organization services provided.

Interpretive Guidelines:

The organization shall designate an individual or group of individuals as its antibiotic stewardship program leaders. Ideally, an antibiotic stewardship program is jointly led by a physician and pharmacist. The individual(s) shall be appointed by the organization's governing body based on the recommendations of the medical staff leadership and pharmacy leadership.

In designating its antibiotic stewardship leader(s), the organization shall assure that the individual(s) are qualified through education, training, experience, or certification in antibiotic stewardship. The organization shall define the qualifications. Training and/or certification may be obtained through organizations such as the specialty boards in adult or pediatric infectious diseases offered for physicians by the American Board of Internal Medicine (for internists), the American Board of Pediatrics (for pediatricians), and the Society for Infectious Disease Pharmacists (for pharmacists).

Antibiotic stewardship staff should maintain their qualifications through ongoing education and training, which can be demonstrated by participation in antibiotic stewardship courses, or in local and national meetings organized by recognized professional societies. Organizations that provide ongoing training and education include the Society for Healthcare Epidemiology of America (SHEA), and the Infectious Diseases Society of America (IDSA) and the Society for Infectious Disease Pharmacists (SIDP).

The antibiotic stewardship staff shall develop and implement policies governing the optimal use of antibiotics. Antibiotic stewardship policies shall address:

- *Roles and responsibilities for antibiotic stewardship and use within the organization;*

- *How the various organization committees and departments interface with the antibiotic stewardship program; and*

- *How to optimize antibiotic use.*

Organizations shall develop and implement appropriate antibiotic stewardship interventions to address issues identified through its assessment activities and then monitor the effectiveness of interventions through further data collection and analysis. Organizations should improve their internal coordination among all components responsible for antibiotic use and reducing the development of resistance, including, but not limited to, the antibiotic stewardship programs, the infection prevention and control program, the QAPI program, the medical staff, nursing services, laboratory services, and pharmacy services.

Organizations shall promote evidence-based use of antibiotics, to reduce the incidence of adverse consequences of inappropriate antibiotic use including, but not limited to, treatment failures, C. difficile infections (CDIs), and growth of antibiotic resistance in the organization overall.

The organization shall implement and maintain an active and organization-wide antibiotic stewardship program as an effective means to improve organization antibiotic-prescribing practices and thereby curb patient risks for adverse drug events, treatment failures and for potentially life-threatening, antibiotic-resistant infections, including CDIs. A robust antibiotic stewardship program shall be coordinated with the organization overall infection prevention and control program to address healthcare acquired infections and antibiotic resistance.

The organization shall provide documentation of improvements and the sustained improvement toward the proper use of antibiotics through the implementation of the organization wide antibiotic stewardship program. It is expected that the organization will reduce patient risk for adverse drug events and potentially life-threatening, antibiotic-resistant infections, including CDIs. The antibiotic stewardship program should be updated with any advancing evidence-based improvements in antibiotic-prescribing practices.

Organizations shall implement and maintain an active and organization-wide antibiotic stewardship program consistent with nationally recognized standards for improving antibiotic use. Optimizing the use of antibiotics is critical to effectively treat infections, protect patients from harms caused by unnecessary antibiotic use, and combat antibiotic resistance. For example, the Centers for Disease Control and Prevention (CDC) provides "Core Elements of Antibiotic Stewardship" at Core Elements of Antibiotic Stewardship | Antibiotic Prescribing and Use | CDC.

CDC's Core Elements of Antibiotic Stewardship offer providers and facilities a set of key principles to guide efforts to improve antibiotic use and, therefore, advance patient safety and improve outcomes. There is no "one size fits all" approach to optimize antibiotic use for all settings. The complexity of medical decision-making surrounding antibiotic use and the variability in hospital size and types of care in U.S. healthcare settings require flexible programs and activities.

Examples of other organizations that promulgate nationally recognized antibiotic stewardship guidelines and/or recommendations include and are not limited to the Society for Healthcare Epidemiology of America (SHEA), and the Infectious Diseases Society of America (IDSA), the American Society for Health System Pharmacists (ASHP) and the Society for Infectious Disease

Pharmacists (SIDP).

Surveyor Guidance:

Review the antibiotic stewardship program for evidence that the organization has an active organization-wide program for the optimization of antibiotic use through stewardship based on national standards of practice and best practices.

Review the antibiotic stewardship program for evidence that the organization is working collaboratively between antibiotic stewardship and the organization's QAPI program when antibiotic use issues are identified.

Review the file(s) of the antibiotic stewardship leader(s) to verify that the individuals were appointed by the governing body based on recommendations of medical staff leadership and pharmacy leadership and are qualified through education, training, experience, or certification in antibiotic stewardship. The organization defines the qualifications for the antibiotic stewardship leaders.

Determine whether the antibiotic stewardship staff have developed and implemented organization antibiotic stewardship policies and that there is a process in place for coordination among all components of the organization responsible for antibiotic use and resistance, including, but not limited to, the antibiotic stewardship program, the infection prevention and control program, the QAPI program, the medical staff, nursing services, laboratory services, and pharmacy services.

Verify that the organization's antibiotic use is consistent with their documented evidence-based organization-wide antibiotic stewardship program recommendations and policies/procedures.

Review documentation of improvements and/or sustainment of improvements through the use of the evidence-based organization-wide antibiotic stewardship program recommendations.

Verify evidence that nationally recognized standards have been implemented for their evidence-based organization-wide antibiotic stewardship program.

Verify that core elements of best practices have been included within the organization-wide antibiotic stewardship program that may include: organization leadership commitment, accountability, pharmacy expertise, tracking, reporting, education, and appropriate interventions or actions being taken to improve antibiotic use to reduce adverse events, prevent emergence of resistance, and ensure better outcomes for patients in this setting.

IC.3 LEADERSHIP RESPONSIBILITIES

SR.1 The governing body shall ensure all of the following:

SR.1a Systems are in place and operational for the tracking of all infection surveillance, prevention, and control, and antibiotic use activities, in order to demonstrate the implementation, success, and sustainability of such activities; and,

SR.1b All HAIs and other infectious diseases identified by the IPCP as well as antibiotic use issues identified by the antibiotic stewardship program are addressed in collaboration with organization QAPI leadership.

SR.2 The infection preventionist(s)/infection control professional(s) is responsible for:

SR.2a The development and implementation of organization-wide infection surveillance, prevention, and control policies and procedures that adhere to nationally recognized guidelines;

SR.2b All documentation, written or electronic, of the IPCP and its surveillance, prevention, and control activities;

SR.2c Communication and collaboration with the organization's QAPI program on infection prevention and control issues;

SR.2d Competency-based training and education of organization staff, including medical staff, and, as applicable, personnel providing contracted services, on the practical applications of infection prevention and control guidelines, policies, and procedures;

SR.2e The prevention and control of HAIs, including auditing of adherence to infection prevention and control policies and procedures by organization personnel; and,

SR.2f Communication and collaboration with the antibiotic stewardship program.

SR.3 The leader(s) of the antibiotic stewardship program is responsible for:

SR.3a The development and implementation of an organization-wide antibiotic stewardship program, based on nationally recognized guidelines, to monitor and improve the use of antibiotics, including but not limited to:

SR.3a(1) Development of actions to minimize the risk of development, and transmission of, multidrug resistant organisms (MDROs) within the organization (See MM.8).

SR.3b All documentation, written or electronic, of antibiotic stewardship program activities;

SR.3c Communication and collaboration with medical staff, laboratory, nursing, and pharmacy leadership, as well as with the organization's IPCP and the QAPI program, on antibiotic use issues; and,

SR.3d Competency-based training and education of organization personnel and staff, including medical staff, and, as applicable, personnel providing contracted services, on the practical applications of antibiotic stewardship guidelines, policies, and procedures.

Interpretive Guidelines:

The organization's governing body shall ensure that an infection prevention and control program is in place and operational for the monitoring and prevention of healthcare associated infections and the transmission of pathogens and an antibiotic stewardship program is in place and operational for the monitoring and improvement of antibiotic use. The development and implementation of both the infection control and antibiotic stewardship programs should include leadership support and accountability via the participation of the medical director, pharmacy director, nursing and administrative leadership, and individuals with designated responsibility for the infection control program and the antibiotic stewardship program; however the governing body or responsible individual is responsible to demonstrate the implementation, success, and sustainability of such activities.

CMS does not specify either the number of infection preventionist(s)/infection control professional(s) to be designated or the number of infection preventionist(s)/infection control professional(s) hours that shall be devoted to the infection prevention and control programs. However, resources shall be adequate to accomplish the tasks required for the infection prevention and control program. In organizations with more than one infection preventionist(s)/infection control professional(s), the staff members should work as an integrated team to ensure the functions of an infection prevention and control program are covered. A prudent organization would consider patient census, characteristics of the patient population, and complexity of the healthcare services it offers in determining the size and scope of the resources it commits to infection prevention and control.

CMS does not specify either the number of antibiotic stewardship staff to be designated or the number of antibiotic stewardship hours that shall be devoted to the antibiotic stewardship programs. However, resources shall be adequate to accomplish the tasks required for the antibiotic stewardship program. In organizations with more than one antibiotic stewardship staff member, the staff members should work as an integrated team to ensure the functions of an antibiotic stewardship program are covered. A prudent organization would consider patient census, characteristics of the patient population, and complexity of the healthcare services it offers in determining the size and scope of the resources it commits to antibiotic stewardship. SHEA has studies and recommendations on resource allocation that organizations may find useful.

The organization is required to coordinate internally among all components responsible for infection control and antibiotic stewardship including, but not limited to, the infection prevention and control program, the antibiotic stewardship program, the QAPI program, the medical staff, nursing services, laboratory services, and pharmacy services.

The organization's governing body, the medical staff, and the director of nursing shall ensure that the organization-wide Quality Assessment and Performance Improvement (QAPI) program and staff in-service training programs address problems identified through the infection prevention and control program and the antibiotic stewardship program. To reflect the importance of infection control and antibiotic stewardship, the regulations specifically require that the organization's QAPI and training programs shall be involved in addressing problems identified by the infection control program and antibiotic stewardship program and hold the leadership jointly responsible for linking the infection control program and antibiotic stewardship program with the QAPI and training programs. These organizational leaders are also held explicitly responsible for implementing successful corrective action plans. In order to accomplish this, organization leaders shall monitor adherence to corrective action plans, as well as assess the effectiveness of actions taken, with implementation of revised corrective actions as needed.

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

The organization shall implement and maintain an active and organization-wide infection control program consistent with nationally recognized standards for preventing infections and the transmission of pathogens. The infection preventionist(s) and/or infection control professional(s) is responsible for the development and implementation of organization-wide infection surveillance, prevention, and control policies and procedures that adhere to nationally recognized guidelines.

The organization's infection preventionist(s) and/or infection control professional(s) is responsible for all documentation, written or electronic, of the prevention and control program, and its surveillance, prevention, and control activities. "Documentation" encompasses both collecting and maintaining pertinent information in a systematic fashion.

When considering priority activities, the infection preventionist(s) and/or infection control professional(s) can review the HHS HAI National Action Plan | HHS.gov.

The organization's infection preventionist(s) and/or infection control professional(s) shall communicate and collaborate with the organization's QAPI program on all infection prevention and control issues. Such issues include all concerns, including ones which are emerging and ones which are already problematic. This communication and collaboration are intended to foster and enhance a proactive culture around an organization's infection prevention and control programs.

The organization's infection preventionist(s) and/or infection control professional(s) shall take an active role in the competency-based training and education of personnel and staff, including medical staff, and, as applicable, personnel providing contracted services in the hospital. This training and education shall include the practical applications of infection prevention and control guidelines, policies, and procedures.

The organization's infection preventionist(s) and/or infection control professional(s) are responsible for preventing and controlling healthcare acquired infections, and transmission of pathogens, including auditing of adherence to infection prevention and control policies and procedures by organization personnel.

The organization's infection preventionist(s) and/or infection control professional(s) is responsible for communication and collaboration with the antibiotic stewardship program. Collaboration between the organization's infection prevention and control and antibiotic stewardship programs provides the optimal approach to reducing healthcare acquired infections and antibiotic resistance.

The organization's designated antibiotic stewardship program leader, similar to the responsibilities of the organization's designated infection preventionist(s) and/or infection control professional(s) ensures the appropriate antibiotic use for reducing adverse drug events, treatment failures and antibiotic resistance, including deadly C. difficile infections. The antibiotic

stewardship program shall have dedicated and expert leadership responsible and accountable for its success, whose responsibilities include the development and implementation of an organization-wide antibiotic stewardship program, based on nationally recognized guidelines, to monitor and improve the use of antibiotics.

The organization's designated antibiotic stewardship program leader is responsible for documentation, written or electronic, of antibiotic stewardship program activities and antibiotic-use issues.

The organization's designated antibiotic stewardship program leader is responsible for communication and collaboration with medical staff, nursing, laboratory services, and pharmacy leadership, as well as the organization's infection prevention and control and QAPI programs on antibiotic use issues.

The organization's designated antibiotic stewardship program leader is responsible for competency-based training and education of organization personnel and staff, including medical staff, and, as applicable, personnel providing contracted services in the organization on the practical applications of antibiotic stewardship guidelines, policies, and procedures.

Surveyor Guidance:

Review the criteria the organization used to determine the resources necessary to operate effectively and ensure the resource allocation matches the determined needs.

Confirm that the organization's infection control program and antibiotic stewardship program are being coordinated with their QAPI leadership, medical staff, nursing services, laboratory services, and pharmacy services.

Determine whether the organization's QAPI program and staff in-service training programs address problems identified by the infection control officer(s) and antibiotic stewardship staff.

Determine whether infection control and antibiotic use problems identified are reported to the organization's leadership. Verify that organization leadership takes steps to assure that corrective actions are implemented and successful.

Verify that the organization's infection preventionist(s) and/or infection control professional(s) is documenting, in written or electronic form, the prevention and control program, and its surveillance, prevention, and control activities.

Verify that the organization's infection preventionist(s) and/or infection control professional(s) is communicating and collaborating with the organization's QAPI program on all infection prevention and control issues.

Review the organization's policies and procedures on training and educating staff.

Confirm that the organization's infection preventionist(s) and/or infection control professional(s) training and education of organization personnel and staff is competency based.

Verify that training on the practical applications of infection prevention and control guidelines is occurring by reviewing the staff records on completed competencies.

Verify that the organization's infection preventionist(s) and/or infection control professional(s) has an active role in auditing the adherence to infection prevention and control policies and procedures by organization personnel.

Verify that the organization's infection preventionist(s) and/or infection control professional(s) is communicating and collaborating with the antibiotic stewardship program.

Verify that the organization's designated antibiotic stewardship program leader develops and implements the organization-wide antibiotic stewardship program, based on nationally recognized guidelines, to monitor and improve the use of antibiotics.

Verify that the organization's designated antibiotic stewardship program leader documents the organization's antibiotic stewardship program activities and antibiotic use issues.

Verify that the organization's designated antibiotic stewardship program leader communicates and collaborates with medical staff, nursing, and pharmacy leadership, as well as the organization's infection prevention and control and QAPI programs.

Verify that the organization's designated antibiotic stewardship program leader provides competency-based training and education of organization personnel and staff, including medical staff, and, as applicable, personnel providing contracted services in the organization on the practical applications of antibiotic stewardship guidelines, policies, and procedures.

IC.4 UNIFIED AND INTEGRATED INFECTION PREVENTION AND CONTROL AND ANTIBIOTIC STEWARDSHIP PROGRAMS FOR MULTI-HOSPITAL SYSTEMS

If the organization is part of a hospital system consisting of multiple separately certified/accredited organizations using a system governing body that is legally responsible for the conduct of two or more hospitals, the system governing body can elect to have unified and integrated infection prevention and control and antibiotic stewardship programs for all of its member organizations after determining that such a decision is in accordance with all applicable state and local laws.

SR.1 The system governing body is responsible and accountable for ensuring that each of its separately certified/accredited hospitals meets all of the requirements of IC.4.

SR.2 Each separately certified/accredited organization subject to the system governing body shall demonstrate that:

SR.2a The unified and integrated infection prevention and control and antibiotic stewardship programs are established in a manner that takes into account each member organization's unique circumstances and any significant differences in patient populations and services offered in each organization;

SR.2b The unified and integrated infection prevention and control and antibiotic stewardship programs establish and implement policies and procedures to ensure that the needs and concerns of each of its separately certified/accredited organizations, regardless of practice or location, are given due consideration;

SR.2c The unified and integrated infection prevention and control and antibiotic stewardship programs have mechanisms in place to ensure that issues localized to particular organizations are duly considered and addressed; and,

SR.2d A qualified individual (or individuals) with expertise in infection prevention and control and in antibiotic stewardship has been designated at the organization as responsible for:

SR.2d(1) Communicating with the unified infection prevention and control and antibiotic stewardship programs;

SR.2d(2) Implementing and maintaining the policies and procedures governing infection prevention and control and antibiotic stewardship as directed by the unified infection prevention and control and antibiotic stewardship programs: and,

SR.2d(3) Providing education and training on the practical applications of infection prevention and control and antibiotic stewardship to organization staff.

Interpretive Guidelines:

The hospital shall have an infection prevention and control program and antibiotic stewardship program for the entire hospital (including all campuses, provider-based locations, satellites, remote locations, etc.). In the case of a hospital system, it is permissible for the system to have unified and integrated infection prevention and control and antibiotic stewardship programs (hereafter referred to as a "unified infection prevention and control and antibiotic stewardship") for multiple, separately certified hospitals.

If the hospital uses a unified and integrated program that it shares with other hospitals that are part of a multi-hospital system, this does not change the requirement that each separately certified hospital is held responsible and accountable to the system's governing body for meeting all of the requirements of an infection prevention and control program and antibiotic stewardship program as outlined in the regulations at §482.42.

Although a hospital system has the flexibility to develop a unified and integrated infection prevention and control program and antibiotic stewardship program for all of the separately certified hospitals within its system, there shall be evidence that the system wide programs have taken in to account the significant differences in patient populations and services offered that provide unique circumstances for each member hospital.

The unified infection prevention and control and antibiotic stewardship programs shall develop and implement policies and procedures for each certified hospital to address the needs and concerns of each hospital separately. The practice and location of the hospital shall be given consideration when developing these policies and procedures.

Each hospital shall also demonstrate that the unified and integrated programs have mechanisms in place to ensure that issues localized to particular hospitals in the system are also considered and addressed. Therefore, each hospital should be able to identify and address QAPI issues particularly specific to their hospital in addition to any of the issues being

addressed in the unified and integrated programs.

The hospital shall designate an individual or group of individuals with expertise in infection prevention and control and antibiotic stewardship. This individual or group of individuals are responsible for communicating, implementing, and maintaining the policies and procedures governing infection prevention and control and antibiotic stewardship. They are directed by the unified infection prevention and control and antibiotic stewardship programs. Additionally, they are responsible for providing education and training on the practical applications of infection prevention and antibiotic stewardship to hospital staff.

Surveyor Guidance:

Review the infection prevention and control program and antibiotic stewardship program and identify unified infection prevention and control and antibiotic stewardship policies and activities and how these take into account the hospitals population and services offered.

Identify the process for which the hospitals' population and services are integrated into the infection prevention and control and antibiotic stewardship programs.

Review the infection prevention and control and antibiotic stewardship programs and identify unified infection prevention and control and antibiotic stewardship policies and procedures and identify how each separately certified hospital's unique needs and areas of concern have been considered in the development of those policies and procedures.

Review the QAPI program and identify unified QAPI elements and identify QAPI elements that are unique to the particular hospital.

Identify the process for which these unique elements are integrated into the QAPI program.

Review governing body policies for evidence that a qualified individual(s) has/have been designated as responsible for communicating with the unified infection prevention program and antibiotic stewardship program, for implementing and maintaining policies and procedures governing the infection prevention and control and antibiotic stewardship programs, and training of hospital staff.

Review documentation that the designated individual(s) communicate(s) with the unified program leadership related to issues with infection prevention and antibiotic stewardship.

Review hospital training documents related to education in infection prevention and antibiotic stewardship as evidence of training of hospital staff.

MEDICAL RECORDS SERVICE (MR)

The organization shall have a medical record service that has administrative responsibility for medical records. A medical record shall be maintained for every individual evaluated or treated in the organization.

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 written policies and procedures, the scope and complexities of services offered, and allocate the appropriate resources to ensure efficient functioning.

Interpretive Guidelines:

The organization shall have administrative responsibility for all medical records- both inpatient and outpatient. The medical record service shall be organized, equipped, and staffed in accordance with the scope and complexities of services offered.

There shall be an established medical record system that is organized and employs adequate personnel to ensure prompt:

- *Completion of medical records;*
- *Filing of medical records; and*
- *Retrieval of medical records.*

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:

Interview staff, if needed, review written job descriptions and staffing schedules to determine if staff is carrying out all designated responsibilities.

Verify that the organization employs adequate medical record personnel as previously described.

MR.2 COMPLETE MEDICAL RECORD

SR.1 The organization shall maintain an accurately written, promptly completed, properly filed and retained, accessible 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 shall address timeframes (see also MR.3).

SR.2a The organization shall have policies and procedures that define how any patient care information that is considered part of the patient's legal health record is entered (transcribed, scanned, or otherwise made available) in the medical record at organization designated timeframes.

SR.3 The organization shall use a system of author identification and record maintenance that ensures the integrity of the authentication and protects the security of all record entries (see MR.5).

Interpretive Guidelines:

The organization shall maintain a medical record for each inpatient and outpatient evaluated or treated in any part or location of the organization.

Medical information such as consultations, orders, practitioner notes, x-ray interpretations, lab test results, diagnostic test results, patient assessments and other patient information shall be accurately written, promptly completed and properly filed in the patients' medical record, and accessible to the physicians or other care providers when needed for use in making assessments of the patient's condition, decisions on the provision of care to the patient, and in planning the patient's care. This requirement applies to the medical records of current inpatients and outpatients of the organization.

*All medical records shall be **accurately written**. The organization shall 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.*

*All medical records shall be **promptly completed**. Every medical record shall be complete with all documentation of orders, diagnosis, evaluations, treatments, test results, care plans, discharge plans, consents, interventions, discharge summary, and care provided along with the patient's response to those treatments, interventions, and care. The record shall be completed promptly after discharge in accordance with State law and organization policy but no later than 30 days after discharge.*

A medical record is considered complete if it contains sufficient information to identify the patient; support the diagnosis/condition; justify the care, treatment, and services; document the course and results of care, treatment, and services; and promote continuity of care among providers. With these criteria in mind, an individual entry into the medical record shall contain sufficient information on the matter that is the subject of the entry to permit the medical record to satisfy the completeness standard (see MR.6).

*The medical record shall be **properly filed and retained**. The organization shall have a medical record system that ensures the prompt retrieval of any medical record, of any patient evaluated or treated at any location of the organization within the past 5 years. [§482.24(b)(1) addresses the 5 year medical record retention requirement].*

*The medical record shall be **accessible**. The organization shall have a medical record system that allows the medical record of any patient, inpatient or outpatient, evaluated and/or treated at any location of the organization within the past 5 years to be accessible by appropriate staff, 24 hours a day, 7 days a week, whenever that medical record may be needed.*

Medical records shall be properly stored in secure locations where they are protected from fire, water damage and other threats.

*The organization shall have a system of author identification and record maintenance that ensures the integrity of the authentication and protects the security of **all** record entries. The medical record system shall correctly identify the author of every medical record entry and must protect the security of all medical record entries. The medical record system shall ensure that medical record entries are not lost, stolen, destroyed, altered, or reproduced in an unauthorized manner. Locations where medical records are stored or maintained shall ensure the integrity, security and protection of the records. These requirements apply to both manual and electronic medical record systems.*

The organization 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 organization shall ensure there is a process in place to protect and retrieve these records in a timely manner.

Surveyor Guidance:

Review the area(s) where medical records are maintained by the organization.

Verify that a medical record is maintained for each person treated or receiving care and documents all orders, test results, evaluations, care plans, treatments, interventions, and care provided. Details of treatments, interventions, etc., including the patient's response to them, may be located in various locations in the medical record (unless dictated otherwise by organization policy), including but not limited to notes and flow sheets. These may also be located as an overall summary of the effectiveness of treatments and interventions in notes, discharge summaries, consult notes, nursing care plans, etc.

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 organization 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.

Verify that there is an established system that addresses at least the following activities of the medical records services:

- *Timely processing of records;*
- *Coding/indexing of records;*
- *Retrieval of records;*
- *Compiling and retrieval of data of quality assurance activities.*

Verify that the system is reviewed and revised as needed.

Are medical records promptly completed in accordance with State law and organization policy?

Select a sample of past patients of the organization (inpatient and/or outpatient). Request those patients' medical records. Can the organization promptly retrieve those records?

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 federal, state or local laws and regulations or it the records may be required for any pending proceeding.

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 federal, state or local laws and regulations. These records may be in the form of a hard copy, microfilm, computer memory, or other electronic storage media. The organization shall have a process to promptly retrieve the complete medical record of every individual evaluated or treated in accordance with federal and state or local laws 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 records is in place and these records are retained for at least 5 years, or more if required by federal, state or local laws and regulations.

Verify that the organization uses a coding and indexing system that allows for timely retrieval of patient records by diagnosis and procedures.

Ask for the records of patients undergoing any procedures, including but not limited to endoscopy, bronchoscopy, or by specific diagnosis (alcohol withdrawal syndrome, altered mental status, etc.) to evaluate the effectiveness of the organization's coding and indexing systems.

MR.4 CONFIDENTIALITY

Written policies and procedures govern the use and removal of records from the organization and the conditions for the release of information.

SR.1 Confidentiality of patient records shall be assured to provide safeguards against loss, destruction, or unauthorized use.

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.2a The patient's written consent is required for release of information not required by law.

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.

SR.4a The organization shall have policies and procedures that address how it assures that its "original" medical records are retained, unless their release is mandated by law/court order/subpoena.

Interpretive Guidelines:

The organization shall have a means of ensuring that access to all information regarding patients' records is limited to those individuals designated by law, regulation, and policy or duly authorized as having a need to know. The process shall 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 organization will maintain a compliance program as required under the Health Insurance Portability and Accountability Act (HIPAA).

The organization is permitted to disclose medical record information, without a patient's authorization, in order to provide patient care and perform related administrative functions, such as payment and other organizational operations.

- *Payment operations include activities to obtain payment or be reimbursed for the provision of health care to an individual.*

- *Health care operations are administrative, financial, legal, and quality improvement activities of an organization that are necessary to conduct business and to support the core functions of treatment and payment. These activities include, but are not limited to: quality assessment and improvement activities, case management and care coordination; competency assurance activities, conducting or arranging for medical reviews, audits, or legal services, including fraud and abuse detection and compliance programs; business planning, development, management, and administration and certain organization-specific fundraising activities.*

The organization shall develop policies and procedures that reasonably limit disclosures of information contained in the patient's medical record to the minimum disclosure necessary, except when the disclosure is for treatment or payment purposes, or as otherwise required by State or Federal law.

When the minimum necessary standard is applied, an organization may not disclose the entire medical record for a particular purpose, unless it can specifically justify that the whole record is the disclosure amount reasonably required for the purpose.

An organization may disclose information from the medical record electronically and may also share an electronic medical record system with other health care facilities, physicians and

practitioners, so long as the system is designed and operated with safeguards that ensure that only authorized disclosures are made.

The organization shall obtain written authorization from the patient or the patient's representative for any other disclosure of medical record information.

Preventing Unauthorized Access

The organization shall ensure that unauthorized individuals cannot gain access to patient records. This applies to records in electronic as well as hard copy formats. Patient records shall be secure at all times and in all locations. This includes open patient records for patients who are currently inpatients in the hospital and outpatients in outpatient clinics. For hard copy records, techniques such as locked cabinets or file rooms and limiting access to keys or pass codes may be employed. For electronic records technical safeguards, such as business rules that limit access based on need to know, passwords, or other control mechanisms shall be in place. When disposing of copies of medical records, physical safeguards might include first shredding documents containing confidential information, taking appropriate steps to erase information from media used to store electronic records, etc.

Release of Original Records

The organization shall not release the original of a medical record that exists in a hard copy, paper version only, unless it is required to do so in response to a court order, a subpoena, or Federal or State laws. For electronic records, the organization shall ensure that the media or other mechanism by which the records are stored electronically is not removed in such a way that all or part of the record is deleted from the medical record system. The organization shall have policies and procedures that address how it assures that retains its "original" medical records, unless their release is mandated by law/court order/subpoena.

Surveyor Guidance:

Verify that the organization 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. Conduct observations and interview staff to verify the methods in place to prevent unauthorized persons from gaining physical access or electronic access to information in patient records.

If the organization uses electronic patient records, is access to patient records controlled through standard measures, such as business rules defining permitted access, passwords, etc.?

Ask the organization to demonstrate what precautions are taken to prevent physical or electronic altering of content previously entered into a patient record, or to prevent unauthorized disposal of patient records.

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 organization 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.

Do the organization's policies and procedures provide that "original" medical records are retained, unless their release is mandated under federal or state law, court order or subpoena? Interview staff responsible for medical records to determine if they are aware of the limitations on release of "original" medical records.

Validate the organization's current practices in place for protecting and securing the confidentiality of patient records. Verify the elements of the organization compliance program as required under (HIPAA).

MR.5 MEDICAL RECORD ENTRIES

SR.1 The organization shall have a system to identify the author of each entry into the medical record.

SR.2 The organization shall have procedures and features that maintain the integrity of entries and verification of electronic signatures and authorizations.

SR.3 All entries shall be:

SR.3a Legible, complete, dated and timed; and,

SR.3b Authenticated by the person responsible for providing or evaluating the services provided consistent with organization policy.

SR.3b(1) Authentication may include written signatures or initials. Electronic authentication is permissible.

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 organization and medical staff policies. This includes verifying signatures or initials that are written, electronic, codes, or stamps.

If the organization, through the approval of the medical staff and leadership, allows rubber stamps, the individual whose signature the stamp represents shall place in the administrative offices of the organization 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.

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

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. shall be promptly filed in the patient's medical record in order to be available to the physician and other care providers.

These entries shall 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.

All entries in the medical record shall 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 organization 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.6 REQUIRED RECORD CONTENT

SR.1 The medical record shall contain:

SR.1a Accurate identification of the patient and social data;

SR.1b Properly executed informed written consent forms for procedures and treatments specified by the medical staff, or by federal or state law if applicable, and consistent with organization policy. See also SS.9 and PR.5.

SR.1c Admitting diagnosis and information to support the diagnosis;

SR.1d Pertinent medical history (see MS.13, SS.4);

SR.1d(1) A medical history and physical examination or outpatient assessment (see MS.13 (SR.4)) completed and documented no more than 30 days before or 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia services.

SR.1d(1)(i) The medical history and physical examination or outpatient assessment shall be placed in the patient's medical record within 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia services.

SR.1d(1)(ii) When the history and physical or outpatient assessment (see MS.13 (SR.4)) 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 shall be completed and documented in the patient's medical record within

24 hours after admission or registration, and prior to surgery, or a procedure requiring anesthesia services;

SR.1d(2) When the patient is receiving specific outpatient surgical or procedural services and when the medical staff has chosen to develop and maintain a policy that identifies specific patients as not requiring a comprehensive medical history and physical examination, or any update to it, prior to specific outpatient surgical or procedural services, the requirement for an update does not apply (see MS.13 (SR.4)).

SR.1e Assessment of the health status and healthcare needs of the patient;

SR.1f Brief summary of the episode;

SR.1g 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.1h Results of all physical examinations, consultative evaluations of the patient and appropriate findings by clinical and other staff involved in the care of the patient;

SR.1i Description of the patient's progress through nursing documentation and progress notes (including vital signs, response to medications and treatment, complications, HAIs, unfavorable reactions to drugs and anesthesia, and other pertinent information necessary to monitor the patient's progress);

SR.1j Justification for admission and continued hospitalization;

SR.1k Discharge summary with outcome of hospitalization, disposition of case, and provisions for follow up care;

SR.1l Final diagnosis with completion of medical records within thirty (30) days following discharge.

Interpretive Guidelines:

The medical record shall 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 shall be performed by an authorized practitioner no more than 30 days prior to admission or within 24 hours after admission.

The H&P shall 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 organization shall ensure that the H&P is updated to document any changes in the patient's condition.

The patient's medical record shall document the following:

- *Admitting diagnosis;*

- *Results of all consultative evaluations of the patient and appropriate findings by clinical and other staff involved in the care of the patient; and*

- *Documentation of complications, hospital-acquired infections, and unfavorable reactions to drugs and anesthesia.*

The requirement means that the stated information is necessary to monitor the patient's condition and that this and other necessary information shall be in the patient's medical record. In order for necessary information to be used it shall be promptly filed in the medical record so that health care staff involved in the patient's care can access/retrieve this information in order to monitor the patient's condition and provide appropriate care.

The medical record shall contain:

- *All practitioner's orders (properly authenticated);*
- *All nursing notes (including nursing care plans);*
- *All reports of treatment (including complications and hospital-acquired infections);*
- *All medication records (including unfavorable reactions to drugs);*
- *All radiology reports;*
- *All laboratory reports;*
- *All vital signs; and*
- *All other information necessary to monitor the patient's condition.*

All patient medical records shall contain a discharge summary. A discharge summary discusses the outcome of the hospitalization, the disposition of the patient, and provisions for follow-up care. Follow-up care provisions include any post hospital appointments, how post hospital patient care needs are to be met, and any plans for post-hospital care by providers such as home health, hospice, nursing homes, or assisted living.

The MD/DO or other qualified practitioner with admitting privileges in accordance with State law and organization policy, who admitted the patient is responsible for the patient during the patient's stay in the hospital. This responsibility would include developing and entering the discharge summary.

Other MD/DOs who work with the patient's MD/DO and who are covering for the patient's MD/DO and who are knowledgeable about the patient's condition, the patient's care during the hospitalization, and the patient's discharge plans may write the discharge summary at the responsible MD/DO's request.

In accordance with organization policy, and 42 CFR Part 482.12(c)(1)(i) the MD/DO may delegate writing the discharge summary to other qualified health care personnel such as nurse practitioners and MD/DO assistants to the extent recognized under State law or a State's regulatory mechanism.

Whether delegated or non-delegated, it is expected that the person who writes the discharge summary will authenticate, date, and time their entry and additionally for delegated discharge summaries, the MD/DO responsible for the patient during his/her hospital stay will co-authenticate and date the discharge summary to verify its content.

The discharge summary requirement would include outpatient records. For example:

- *The outcome of the treatment, procedures, or surgery;*
- *The disposition of the case;*
- *Provisions for follow-up care for an outpatient surgery patient or an emergency department patient who was not admitted or transferred to another hospital.*

All medical records must contain a final diagnosis. All medical records must be complete within 30 days of discharge or outpatient care.

Surveyor Guidance:

Review a sample of medical records during the survey. Validate that that MR.6 is consistently applied throughout the organization.

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.

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 organization shall 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 standard and Interpretive Guidelines for MR.6.

Select a sample of patients who have been discharged for more than 30 days. Request their medical records. Are those records complete?

Verify that a discharge summary is included to assure that proper continuity of care is required.

Verify that a final diagnosis is included in the discharge summary.

MR.7 ORDERS

SR.1 All orders, including verbal orders, shall 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, organization policies, and medical staff bylaws, rules, and regulations.

SR.1a The practitioner shall 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.1b If a preprinted order set is used, the ordering practitioner shall 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.1b(1) Changes, such as additions, deletions, or strikeouts 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.2 If the organization uses a HIPAA compliant secure platform for the texting of patient orders, there shall be a medical staff approved policy that designates the process for entry into the medical record and the timeframes for those orders to be entered into the medical record.

SR.3 Verbal orders are issued in accordance with organization policy and federal and state law. Policies shall, at a minimum, address the following.

SR.3a Situations in which verbal orders may be used, as well as limitations or prohibitions on their use. Telephone or verbal orders are to be used infrequently and when used shall be accepted only by personnel authorized by the medical staff and in accordance with federal and state law.

SR.3b Elements required for inclusion in the verbal order process;

SR.3c A read-back and verification process;

SR.3d Identification of the categories of clinical staff who are authorized to receive and act upon a verbal order; and,

SR.3e Verbal orders shall be promptly documented and 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 shall be authenticated within the timeframe defined in the organization's policy.

SR.4 Hospitals may use preprinted and electronic standing orders, order sets, and protocols (hereafter referred to interchangeably as "standing orders") for patient orders only if the following requirements are met:

SR.4a The organization defines the specific clinical scenarios where standing orders are used to expedite the delivery of patient care

SR.4a(1) Standing orders may be initiated as part of an emergency response or as part of an evidence-based treatment regimen where it is not practicable for a nurse or other non-practitioner to obtain a verbal or authenticated written order from a physician or other practitioner responsible for the care of the patient prior to the provision of care.

SR.4b Each standing order and protocol shall be reviewed and approved by the medical staff and nursing and pharmacy leadership before it may be used in the clinical setting.

SR.4b(1) The review ensures that such orders and protocols are consistent with nationally recognized standards of practice and guidelines; and,

SR.4b(2) 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.

SR.4c The organization's policies and procedures for standing orders shall address the process by which a standing order is developed; approved; monitored; initiated by authorized staff; and subsequently authenticated by physicians or other practitioners responsible for the care of the patient.

SR.4d For each approved standing order, there shall be specific criteria clearly identified in the protocol for the order for a nurse or other authorized personnel to initiate the execution of a particular standing order, for example, the specific clinical situations, patient conditions, or diagnoses by which initiation of the order would be justified.

SR.4e Policies and procedures shall also address the instructions that the medical, nursing, and other applicable professional staff receive on the conditions and criteria for using standing orders as well as any individual staff responsibilities associated with the initiation and execution of standing orders.

SR.4f An order that has been initiated for a specific patient shall be added to the patient's medical record at the time of initiation, or as soon as possible thereafter.

SR.4g The 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:

Orders

Computerized Provider Order Entry (CPOE) continues to be the preferred method of order entry by a provider.

All orders transmitted via secure text shall be transcribed into the medical record using the medical staff approved policy and specific timeframes.

The prescribing practitioner shall verify, sign, date and time the order as soon as possible after issuing the order, in accordance with policy, and state and federal requirements.

Authentication of a verbal order may be written, electronic, or faxed. The organization shall have a method for establishing the identity of the practitioner who has given a verbal order, including verification of the author of faxed verbal orders or computer entries.

In some instances, the ordering practitioner may not be able to authenticate his or her order, including a verbal order (e.g., the ordering practitioner gives a verbal order which is written and transcribed, and then is "off duty" for the weekend or an extended period of time). In such cases it is acceptable for another practitioner who is responsible for the patient's care to authenticate the order, including a verbal order, of the ordering practitioner as long as it is permitted under state law, organization policies and medical staff bylaws, rules, and regulations. Organizations may choose in their policies to restrict which practitioners it would authorize to authenticate another practitioner's orders. For example, choosing to restrict authentication of orders for pediatric patients to practitioners who are privileged to provide pediatric care. (77 FR 29053, May 16, 2012)

- *All practitioners responsible for the patient's care are expected to have knowledge of the patient's hospital course, medical plan of care, condition, and current status.*
- *When a practitioner other than the ordering practitioner authenticates an order, that practitioner assumes responsibility for the order as being complete, accurate and final.*
- *A qualified non-physician practitioner, such as a physician assistant (PA) or nurse practitioner (NP), who is responsible for the care of the patient may authenticate a*

physician's or other qualified non-physician practitioner's order only if the order is within his/her scope of practice.

If state law requires that the ordering practitioner authenticate his/her own orders, or his/her own verbal orders, then a practitioner other than the prescribing practitioner would not be permitted to authenticate the verbal order in that state.

(71 FR 68682 and 77 FR 29053, May 16, 2012)

Although verbal and telephone orders shall be minimized, when possible, for such orders, these shall be in accordance with federal and state law, standard requirements, organization policy, and authenticated as required by state law. If there is not state law that designates a specific timeframe for the authentication of verbal orders, the orders shall be authenticated in accordance with policy.

NOTE CONCERNING VERBAL ORDERS FOR LABORATORY TESTS:

The requirement to promptly authenticate a verbal order applies to verbal orders associated with both inpatients and outpatients. It is possible that a hospital verbal order for a laboratory test could be authenticated in compliance with the Clinical Laboratory Improvement Amendment (CLIA) regulatory standard of authentication, i.e., within 30 days, but nonetheless be out of compliance with the hospital Medical Records Services requirement for prompt authentication of all orders, including verbal orders. Because CLIA laboratories – even if physically situated in a hospital – are surveyed for compliance only with CLIA regulations, the laboratory would not be cited for a deficiency by a CLIA survey team. However, hospital surveyors conducting a survey would cite the hospital's inpatient or outpatient recordkeeping for deficiencies under the standards for Medical Record Services if the lab order originated for a patient during a hospital inpatient stay or hospital outpatient clinic visit, and the order was not authenticated promptly.

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

Order Sets:

There is no standard definition of a "standing order" in the hospital community at large (77 FR 29055, May 16, 2012), but the terms "pre-printed standing orders," "electronic standing orders," "order sets," and "protocols for patient orders" are various ways in which the term "standing orders" has been applied. See also MM.1 and MM.4 specific to medications.

For purposes of brevity, CMS guidance generally uses the term "standing order(s)" to refer interchangeably to pre-printed and electronic standing orders, order sets, and protocols. However, CMS also notes that the lack of a standard definition for these terms and their interchangeable and indistinct use by hospitals and health care professionals may result in confusion regarding what is or is not subject to the requirements of 42 CFR Section 482.24(c)(3), particularly with respect to "order sets."

- *Not all pre-printed and electronic order sets are considered a type of "standing order" covered by 42 CFR Section 482.24(c)(3).* ***Where the order sets consist solely of***

menus of treatment or care options designed to facilitate the creation of a patient-specific set of orders by a physician or other qualified practitioner authorized to write orders, and none of the treatment choices and actions can be initiated by non-practitioner clinical staff before the physician or other qualified practitioner actually creates the patient-specific order(s), such menus would not be considered "standing orders" *subject to the requirements of 42 CFR Section 482.24(c)(3). In such cases the menus provide a convenient and efficient method for the physician/practitioner to create an order, but the availability of such menu options does not create an "order set" that is a "standing order" subject to the requirements of 42 CFR Section 482.24(c)(3). The physician/practitioner may, based on his/her professional judgment, choose to: use the available menu options to create an order; not use the menu options and instead create an order from scratch; or modify the available menu options to create the order. In each case the physician/practitioner exercises his privileges to prescribe specific diagnosis and/or treatment activities that are to be implemented for a patient.*

- *On the other hand, in cases where organization policy permits treatment to be initiated, by a nurse, for example, without a prior specific order from the treating physician/practitioner, this policy and practice shall meet the requirements of this regulation for review of standing orders, regardless of whether it is called a standing order, a protocol, an order set, or something else. Such treatment is typically initiated when a patient's condition meets certain pre-defined clinical criteria. For example, standing orders may be initiated as part of an emergency response or as part of an evidence-based treatment regimen where it is not practical for a nurse to obtain either a written, authenticated order or a verbal order from a physician or other qualified practitioner prior to the provision of care.*

- *Hybrids, where a component for non-practitioner-initiated treatment is embedded within a menu of options for the physician or other qualified practitioner, still require compliance with the requirements for a standing order for that component. For example, if an order set includes a protocol for nurse-initiated potassium replacement, that protocol shall be reviewed under the requirements of this regulation before it may become part of a menu of treatment options from which a physician or other qualified practitioner would select treatments for a particular patient.*

Requirements for "Standing Orders"

Organizations have the flexibility to use standing orders to expedite the delivery of patient care in well-defined clinical scenarios for which there is evidence supporting the application of standardized treatments or interventions.

Appropriate use of standing orders can contribute to patient safety and quality of care by promoting consistency of care, based on objective evidence, when orders may be initiated as part of an emergency response or as part of an evidence-based treatment regimen where it is not practicable for a nurse or other non-practitioner to obtain a verbal or authenticated written order from a physician or other practitioner responsible for the care of the patient prior to the provision of care.

In all cases, implementation of a standing order shall be medically appropriate for the patient to whom the order is applied.

Much of the evidence on the effectiveness of standing orders in hospitals has been narrowly focused on aspects of their use by Rapid Response Teams addressing inpatient emergencies. However, standing orders may also be appropriate in other clinical circumstances, including, but not limited to:

- *Protocols for triaging and initiating required screening examinations and stabilizing treatment for emergency department patients presenting with symptoms suggestive of acute asthma, myocardial infarction, stroke, etc. (This does not relieve a hospital of its obligations under the Emergency Medical Treatment and Labor Act (EMTALA) to have qualified medical personnel complete required screening and, when applicable, stabilizing treatment in a timely manner.)*

- *Post-operative recovery areas.*

- *Timely provision of immunizations, such as certain immunizations for newborns, for which there are clearly established and nationally recognized guidelines.*

Standing orders may not be used in clinical situations where they are specifically prohibited under Federal or State law. For example, the hospital patient's rights regulation at §482.13(e)(6) specifically prohibits the use of standing orders for restraint or seclusion of hospital patients.

When deciding whether to use standing orders, hospitals should also be aware that, although use of standing orders is permitted under the hospital Conditions of Participation, some insurers, including Medicare, may not pay for the services provided because of the use of standing orders. (77 FR 29056)

Minimum requirements for standing orders

Organizations may employ standing orders only if the following requirements are met for each standing order for a particular well-defined clinical scenario:

- *Each standing order shall be reviewed and approved by the organization's medical staff and nursing and pharmacy leadership before it may be used in the clinical setting. The standard requires a multi-disciplinary collaborative effort in establishing the protocols associated with each standing order.*

- *The organization's policies and procedures for standing orders shall address the process by which a standing order is developed; approved; monitored; initiated by authorized staff; and subsequently authenticated by physicians or other practitioners responsible for the care of the patient.*

- *For each approved standing order, there shall be specific criteria clearly identified in the protocol for the order for a nurse or other authorized personnel to initiate execution of a particular standing order, for example the specific clinical situations patient conditions or diagnosis by which initiation of the order would be justified. Under no circumstances may an organization use standing orders in a manner that requires any staff not authorized to write patient orders to make clinical decisions outside of their scope of practice in order to initiate such orders.*

  Since residents are physicians, this standard does not require specific criteria for a

resident to initiate the execution of a particular standing order. However, there may be state laws governing the practice of residents in hospitals that are more restrictive; if so, the hospital is expected to comply with the State law. Likewise, the organization may choose through its policies and medical staff bylaws, rules and regulations to restrict the role of residents with respect to standing orders.

- *Policies and procedures shall also address the instructions that the medical, nursing, and other applicable professional staff receive on the conditions and criteria for using standing orders as well as any individual staff responsibilities associated with the initiation and execution of standing orders. An order that has been initiated for a specific patient shall 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 shall specify the process whereby the physician or other practitioner responsible for the care of the patient acknowledges and authenticates the initiation of all standing orders after the fact, with the exception of influenza and pneumococcal vaccines, which do not require such authentication in accordance with § 482.23(c)(2).*

  (76 FR 65896, October 24, 2011 & 77 FR 29056, May 16, 2012)

- *The organization shall be able to document that the standing order is consistent with nationally recognized and evidence-based guidelines. This does not mean that there must be a template standing order available in national guidelines which the organization copies, but rather that the content of each standing order in the organization shall be consistent with nationally recognized, evidence-based guidelines for providing care. The burden of proof is on the organization to show that there is a sound basis for the standing order.*

- *Each standing order shall be subject to periodic and regular review by the medical staff and nursing and pharmacy leadership, to determine the continuing usefulness and safety of the orders and protocols. At a minimum, an annual review of each standing order would satisfy this requirement. However, the organization's policies and procedures shall also address a process for the identification and timely completion of any requisite updates, corrections, modifications, or revisions based on changes in nationally recognized, evidence-based guidelines. The review may be prepared by the organization's QAPI program, so long as the medical staff and nursing and pharmacy leadership read, review, and, as applicable, act upon the final report. Among other things, reviews are expected to consider:*

  - *Whether the standing order's protocol continues to be consistent with the latest standards of practice reflected in nationally recognized, evidence-based guidelines;*

  - *Whether there have been any preventable adverse patient events resulting from the use of the standing order, and if so, whether changes in the order would reduce the likelihood of future similar adverse events. Note that the review would not be expected to address adverse events that are a likely outcome of the course of patient's disease or injury, even if the order was applied to that patient, unless there is concern that use of the standing order exacerbated the patient's condition; and*

- *Whether a standing order has been initiated and executed in a manner consistent with the order's protocol, and if not, whether the protocol needs revision and/or staff need more training in the correct procedures.*

- *An order that has been initiated for a specific patient shall be added to the patient's medical record at the time of initiation, or as soon as possible thereafter. The organization shall ensure each standing order that has been executed is dated, timed, and authenticated promptly in the patient's medical record by the ordering practitioner or another practitioner responsible for the care of the patient. Another practitioner who is responsible for the care of the patient may date, time and authenticate the standing order instead of the ordering practitioner, but only if the other practitioner is acting in accordance with State law, including scope of practice laws, organization policies, and medical staff bylaws, rules and regulations.*

  The organization's standing orders policies and procedures shall specify the process whereby the responsible practitioner, or another authorized practitioner, acknowledges and authenticates the initiation of each standing order after the fact, with the exception of standing orders for influenza and pneumococcal vaccines, which do not require such authentication. Further, the responsible practitioner shall be able to modify, cancel, void or decline to authenticate orders that were not medically necessary in a particular situation. The medical record shall reflect the physician's actions to modify, cancel, void or refusal to authenticate a standing order that the physician determined was not medically necessary. (76 FR 65896, October 24, 2011)

When a practitioner is using a written 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 strikeouts 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.

Surveyor Guidance:

Does the organization have policies and procedures requiring prompt authentication of all

orders, including verbal orders, by the ordering practitioner or, if permitted under State law, organization policy and medical staff bylaws, rules and regulations, another practitioner responsible for the care of the patient?

Review orders, including verbal orders, in a sample of medical records. Have orders been dated, timed, and authenticated promptly by the ordering practitioner or, if permitted under State law, organization policy and medical staff bylaws, rules and regulations, another practitioner who is responsible for the care of the patient?

Verify that the organization 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.

Has the receiver of a verbal order dated, timed, and signed the order according to organization policy?

Ask the medical staff and nursing and pharmacy leadership whether standing orders are used. If yes, ask them to describe how a standing order is developed and monitored, and their role in the process.

Ask to see an example of one or more standing orders, including documentation on the development of the order, including:

- *Reference to the evidence-based national guidelines that support it;*
- *Participation of medical staff and nursing and pharmacy leadership in the review and approval of the standing order;*
- *Description of the protocol to be followed when initiating the execution of the order, including description of the roles and responsibilities of various types of staff;*
- *Description of the process for authenticating the order's initiation by the practitioner responsible for the care of the patient, or another authorized practitioner;*
- *Evidence of training of personnel on the order's protocol; and*
- *Evidence of periodic evaluation and, if needed, modification of the standing order, including whether the order remains consistent with current evidence-based national guidelines, staff adherence to the protocol for initiation and execution, and whether there have been any preventable adverse events associated with the order.*

Ask staff providing clinical services in areas of the organization where standing orders might be typically used, including but not limited to, the emergency department, labor and delivery units, and inpatient units, whether standing orders are used. If they say yes, ask them:

- *To describe a typical scenario where a standing order would be used, and what they would do in that case.*

- *For a copy of the protocol for that standing order. Does their description conform to the protocol?*

Review a sample of medical records of patients where a nurse-initiated standing order was used and verify that the order was documented and authenticated by a practitioner responsible for the care of the patient.

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 strikeouts of components that do not apply, have been made.

MR.8 ELECTRONIC NOTIFICATION

SR.1 If the organization utilizes an electronic medical records system or other electronic administrative system, which is conformant with the content exchange standards at 45 CFR 170.205(d)(2), then the organization shall demonstrate the following:

SR.1a The system's notification capacity is fully operational, and the hospital uses it in accordance with all State and Federal statutes and regulations applicable to the hospital's exchange of patient health information.

SR.1b The system sends notifications that shall include at least patient name, treating practitioner's name, and sending institution's name.

SR.1c To the extent permissible under applicable federal and state law and regulations, and not inconsistent with the patient's expressed privacy preferences, the system sends notifications directly, or through an intermediary that facilitates exchange of health information, at the time of:

SR.1c(1) The patient's registration in the hospital's emergency department (if applicable).

SR.1c(2) The patient's admission to the hospital's inpatient services (if applicable).

SR.1d To the extent permissible under applicable federal and state law and regulations and not inconsistent with the patient's expressed privacy preferences, the system sends notifications directly, or through an intermediary that facilitates exchange of health information, either immediately prior to, or at the time of:

SR.1d(1) The patient's discharge or transfer from the hospital's emergency department (if applicable).

SR.1d(2) The patient's discharge or transfer from the hospital's inpatient services (if applicable).

SR.1e The hospital has made a reasonable effort to ensure that the system sends the notifications to all applicable post-acute care services providers and suppliers, as well as to any of the following practitioners and entities, which need to receive notification of the patient's status for treatment, care coordination, or quality improvement purposes:

SR.1e(1) The patient's established primary care practitioner;

SR.1e(2) The patient's established primary care practice group or entity; or

SR.1e(3) Other practitioner, or other practice group or entity, identified by the patient as the practitioner, or practice group or entity, primarily responsible for his or her care.

Interpretive Guidelines:

A hospital with an electronic health records system or electronic patient registration systems, which is conformant with the content exchange standard HL7 2.5.1 at 45 CFR 170.205(d)(2), is required to use system's notification capacity to facilitate the notification of patient admission, discharge, and transfer information in accordance with state and federal law. Upon the consent of patient or the patient representative, at a minimum, the information exchange shall include the name of the patient, the practitioner responsible for the treatment of the patient, and the name of the institution providing care to the patient. A patient or patient representative have the right to privacy and not permit the hospital to share this information through this exchange. A patient's refusal should be documented.

These requirements are applicable to all patients who are registered in the emergency department (ED) or who are receiving inpatient services. There may be instances of multiple admission notifications for one patient. For example, a patient that enters through the ED is not admitted receiving inpatient services, but the hospital would be responsible for sending a notification of the patient's ED visit; and once the patient is admitted and is receiving inpatient services, another notification would be sent as the patient's admission status has changed.

Transfer notifications would be applicable for any patients who may be transferring to another facility for additional needs or changes in level of care.

Discharge notifications would be applicable for all patient discharges from either inpatient or outpatient admissions.

For hospitals that do not have such electronic medical records system or other electronic administrative system, which are conformant with the content exchange standard HL7 2.5.1 at 45 CFR 170.205(d)(2), they are not required to be in compliance with this standard.

DISCHARGE PLANNING (DC)

DC.1 WRITTEN POLICIES

SR.1 The organization shall have an effective discharge planning process that focuses on the patient's goals and treatment preferences and includes the patient and his or her caregivers/support person(s) as active partners in the discharge planning for post-discharge care.

SR.4h The discharge planning process and the discharge plan shall be:

SR.4h(1) Consistent with the patient's goals for care and his or her treatment preferences;

SR.4h(2) Ensure an effective transition of the patient from hospital to post-discharge care; and,

SR.4h(3) Reduce the factors leading to preventable hospital readmissions.

SR.2 The discharge planning process shall identify at an early stage of hospitalization, those patients who are likely to suffer adverse health consequences upon discharge in the absence of adequate discharge planning; and,

SR.4i Shall provide a discharge planning evaluation for those patients so identified as well as for other patients upon the request of the patient, patient's representative, or patient's physician.

SR.3 Any discharge planning evaluation or discharge plan required under DC shall be developed by, or under the supervision of, registered nurse, social worker, or other appropriately qualified personnel.

Interpretive Guidelines:

For every inpatient identified under DC.1 (SR.2) as at potential risk of adverse health consequences without a discharge plan, a discharge planning evaluation shall be completed by the hospital. An evaluation shall also be completed if the patient, or the patient's representative, or the patient's attending physician requests one. Unless the hospital has adopted a voluntary policy of developing an evaluation for every inpatient, the hospital shall also have a process for making patients, including the patient's representative, and attending physicians aware that they may request a discharge planning evaluation, and that the hospital will perform an evaluation upon request. Hospitals shall perform the evaluation upon request, regardless of whether the patient meets the hospital's screening criteria for an evaluation.

The hospital's written discharge planning policies and procedures shall specify the qualifications for personnel other than registered nurses or social workers who develop or supervise the development of the plan. The qualifications should include such factors as previous experience in discharge planning, knowledge of clinical and social factors that affect the patient's functional status at discharge, knowledge of community resources to meet post-discharge clinical and social needs, and assessment skills. All personnel performing or

supervising development of discharge plans, including registered nurses and social workers, shall have knowledge of clinical, social, insurance/financial and physical factors that shall be considered when evaluating how a patient's expected post-discharge care needs can be met.

Surveyor Guidance:

Review the hospital's discharge planning policies and procedures to determine whether it requires the development of a discharge plan for all inpatients, or only for those identified as needing a plan through a risk-based identification and evaluation process. Validate that discharge planning evaluation activities are occurring in every unit with inpatient beds.

If the hospital does not require a discharge planning evaluation for all inpatients, validate that the hospital has standard process to notify patients, their representative, and physicians that they may request a discharge planning evaluation, and that the hospital will conduct an evaluation. Validate that staff that can describe the process for a patient or the patient's representative to request a discharge planning evaluation.

The surveyor may interview patients and their family members who are expecting discharge with approval from the organization. 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?*

Review a sample of cases to determine if the discharge plan was developed by an RN, Social Worker, or other qualified personnel, as defined in the hospital discharge planning policies and procedures.

If the policy permits someone other than a RN or social worker to be responsible for developing or supervising the development of the plan, validate that the policy specifies the qualifications of the personnel to perform this function and that their discharge plans are reviewed by an RN or social worker before being finalized.

Review personnel files to determine if the RN, Social Worker, or other qualified personnel meet the qualifications defined in the hospital's policies and procedures and job description.

DC.2 TRANSFER PROTOCOLS

SR.1 The organization shall have written policies and procedures for transferring patients under its care (inclusive of inpatient services) to the appropriate level of care (including to another hospital) as needed to meet the needs of the patient. These policies and procedures shall be approved by the medical staff and address the following:

SR.1a Outpatient to inpatient transfers (e.g. ED to inpatient);

SR.1b Internal transfers (e.g. inpatient transfer between hospital units); and

SR.1c Transfers to external organizations (e.g. inpatient to outside hospital for inpatient care)

SR.2 The organization shall provide training to relevant staff regarding the hospital policies and procedures for transferring patients under its care.

SR.2a The hospital shall provide relevant new staff with initial training;

SR.2b Training shall occur at least annually thereafter; and

SR.2c The hospital shall document in the staff personnel records that the training was successfully completed.

Interpretive Guidelines:

Implementing policies and procedures will assist organizations in improving transitions of care and increase an organization's ability to transfer patients promptly.

These requirements apply to all organizations, including those which may not have an emergency department or are otherwise not covered by EMTALA.

Each organization will establish and/or tailor its policies and procedures according to its specific patient population, organization needs and resources, and medical staff recommendations.

The organization will determine which staff are relevant to receiving the initial and annual training.

Surveyor Guidance:

Validate the required protocols have been developed and approved by the medical staff.

Review records of patients transferred to evaluate if protocols were followed appropriately.

Review employee records to ensure relevant staff have completed training as required.

DC.3 DISCHARGE PLANNING EVALUATION

SR.1 Any discharge planning evaluation shall be made on a timely basis to ensure that appropriate arrangements for post-hospital care will be made before discharge and to avoid unnecessary delays in discharge.

SR.2 A discharge planning evaluation shall include an evaluation of:

SR.4j The likelihood of a patient's capacity for self-care of the possibility of the patient being cared for in the environment from which he or she entered the hospital, to

include the availability of family or friends able to assist in providing required care;

SR.4k Care needs upon discharge, including, but not limited to:

SR.4k(1) Specialized medical equipment and related supplies;

SR.4k(2) Pharmaceuticals and related supplies; and,

SR.4k(3) Appropriate post-hospital services, including but not limited to:

SR.4k(3)(i) Ambulatory health care (e.g., referrals and/or follow-up appointments with primary and/or specialty care);

SR.4k(3)(ii) Rehabilitation services (PT, OT, Speech, etc.);

SR.4k(3)(iii) Hospice care services;

SR.4k(3)(iv) Post-hospital extended care services;

SR.4k(3)(v) Home health services;

SR.4k(3)(vi) Non-health care services; and

SR.4k(3)(vii) Community based care providers.

SR.4l A determination of the availability, capability and capacity of the appropriate services to meet the patient's care needs, as well as the patient's access to those services.

SR.5 The discharge planning evaluation shall be included in the patient's medical record for use in establishing an appropriate discharge plan; and,

SR.5a The results of the evaluation shall be discussed with the patient (or the patient's representative).

Interpretive Guidelines:

In contrast to the screening process at DC.1 (SR.2), the evaluation entails a more detailed review of the individual patient's post-discharge needs, in order to identify the specific areas that shall be addressed in the discharge plan. The purpose is to determine continuing care needs after the patient leaves the hospital setting. The organization 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 addresses the changes in the patient condition and other circumstances of the patient.

The discharge planning evaluation shall include an assessment of the patient's capacity for self-care or, alternatively, to be cared for by others in the environment, i.e., the setting, from which the patient was admitted to the hospital. In general, the goal upon discharge is for a patient to be able to return to the setting in which they were living prior to admission. The evaluation shall

consider what the patient's care needs will be immediately upon discharge, and whether those needs are expected to remain constant or lessen over time.

The evaluation shall consider the patient's likelihood of needing post-hospital services and the availability of such services. Services may also include those that are not traditional health care services, but which may be essential to a patient's ongoing ability to live in the community, including, but not limited to, home and physical environment modifications, transportation services, meal services, and/or household services, such as housekeeping, shopping, etc. Some of the information related to needed services will emerge from the required evaluation of the patient's ability to receive care in the home, either as self-care or provided by someone else. Some patients might have more complex care needs which nevertheless may still be met in the home setting, depending on the specific clinical needs and the services available in the patient's community.

If the result of the evaluation is that the patient cannot receive required care if he/she returns to home, then an assessment shall be made of options for transfer to another inpatient or residential health care facility that can address the patient's needs, including other types of hospitals, such as rehabilitation hospitals, skilled nursing facilities, assisted living facilities, nursing homes, or inpatient hospice facilities.

Hospitals are expected to have knowledge of the capabilities and capacities of not only post-acute care facilities, but also of the various types of service providers in the area where most of the patients it serves receive post-hospital care, in order to develop a discharge plan that not only meets the patient's needs in theory, but also can be implemented. This includes knowledge of community services, as well as familiarity with available Medicaid home and community-based services (HCBS), since the State's Medicaid program plays a major role in supporting post-hospital care for many patients. If the hospital is one with specialized services that attract a significant number of patients who will receive their post-hospital care in distant communities, the hospital is expected to take reasonable steps to identify the services that will be available to the patient.

Once the determination has been made that services will be necessary post-discharge, the organization shall then determine availability of those services or identify comparable substitutions. Included in the evaluation is coordination with insurers and other payors, including the State Medicaid agency, as necessary to ensure resources prescribed are approved and available.

The ability to pay out of pocket for services shall also be discussed with the family or other support persons. Although hospitals are not expected to have definitive knowledge of the terms of any given patient's insurance coverage or eligibility for community-based services, or for Medicaid coverage, they are expected to have a general awareness of these matters and their impact on the patient's post-discharge needs and prospects for recovery. If the patient is a Medicare beneficiary, the hospital is expected to be aware of Medicare coverage requirements for home health care or admission to a rehabilitation hospital, a skilled nursing facility, or a long-term care hospital, etc. and to make the beneficiary aware that they may have to pay out of pocket for services not meeting the coverage requirements.

Surveyor Guidance:

Validate, through a sample of discharge planning evaluations, that staff responsible for the evaluation are performing it in a timely manner, generally within 24 hours of the request or

identification of the need for an evaluation, and in accordance with the hospital's policies and procedures. Confirm timely placement of the evaluation in the medical record.

Validate that evaluations include an assessment of:

- *The likelihood of a patient's capacity for self-care or the possibility of the patient being cared for in the environment from which he or she entered the hospital, to include the availability of family or friends able to assist in providing required care and*

- *Care needs upon discharge.*

DC.4 PLAN IMPLEMENTATION

SR.1 Upon the request of a patient's physician, the organization shall arrange for the development and initial implementation of a discharge plan for the patient.

SR.2 The organization's discharge planning process shall require regular re-evaluation of the patient's condition to identify changes that require modification of the discharge plan.

SR.2a The organization shall define in policy or procedure either a routine reassessment of all plans or a process for triggering a reassessment of the patient's post-discharge needs, capabilities and discharge plan when significant changes in the patient's condition or available supports occur.

SR.2b The discharge plan shall be updated, as needed, to reflect these changes.

SR.3 The organization shall discharge the patient, and also transfer or refer the patient where applicable, to the appropriate post-acute care service providers and suppliers, facilities, agencies, and other outpatient service providers and practitioners responsible for the patient's follow-up or ancillary care:

SR.3a At the time of discharge, transfer, or referral, the organization shall transmit to the receiving provider(s) all necessary medical information pertaining to the patient's:

SR.3a(1) Current course of illness and treatment; and,

SR.3a(2) Post-discharge goals of care, and treatment preferences.

Interpretive Guidelines:

Changes in a patient's condition may warrant adjustments to the discharge plan. Hospitals shall define in policy or procedure either a routine reassessment of all plans or a process for triggering a reassessment of the patient's post-discharge needs, capabilities and discharge plan when significant changes in the patient's condition or available supports occur.

The hospital shall take steps to ensure that patients receive appropriate post-hospital care by arranging, as applicable, transfer to appropriate facilities or referrals to follow-up ambulatory care services.

SR.3 refers to entities such as skilled nursing facilities, nursing facilities, home health agencies, hospice agencies, mental health agencies, dialysis centers, suppliers of durable medical equipment, suppliers of physical and occupational therapy, physician offices, etc., which offer post-acute care services that address the patient's post-hospital needs identified in the patient's discharge planning evaluation. This may also include other hospitals to which a patient is transferred for follow-up care, such as rehabilitation hospitals, long term care hospitals, or even other short-term acute care hospitals. The term does not refer to non-healthcare entities, but hospitals also are encouraged to make appropriate referrals to community-based resources that offer transportation, meal preparation, and other services that can play an essential role in the patient's successful recovery.

Necessary medical information shall be provided not only for patients being transferred, but also for those being discharged home, to make the patient's physician aware of the outcome of hospital treatment or follow-up care needs. When the hospital provides the patient's physician with necessary medical information promptly, among other things, this provides an opportunity for the patient's physician to discuss with the hospital care team changes to the patient's preadmission medication regimen or other elements of the post-discharge care plan about which the physician may have questions. Facilitating opportunities for such communication and dialogue enhances the likelihood of better patient outcomes after discharge.

Medical information considered necessary for transfer or referral includes, but is not limited to:

- *Brief reason for hospitalization (or, if hospital policy also requires a discharge summary for certain types of outpatient services, the reason for the encounter) and principal diagnosis;*
- *Brief description of hospital course of treatment;*
- *Patient's condition at discharge, including cognitive and functional status and social supports needed;*
- *Medication list (reconciled to identify changes made during the patient's hospitalization) including prescription and over-the-counter medications and herbal. (Note, an actual list of medications needs to be included in the discharge information, not just a referral to an electronic list available somewhere else in the medical record.);*
- *List of allergies (including food as well as drug allergies) and drug interactions;*
- *Pending laboratory work and test results, if applicable, including information on how the results will be furnished;*
- *For transfer to other facilities, a copy of the patient's advance directive, if the patient has one; and*
- *For patients discharged home:*
    - *Brief description of care instructions reflecting training provided to patient and/or family or other informal caregiver(s);*
    - *If applicable, list of all follow-up appointments with practitioners with which the patient has an established relationship and which were scheduled prior to*

discharge, including who the appointment is with, date and time.

- *If applicable, referrals to potential primary care providers, such as health clinics, if available, for patients with no established relationship with a practitioner.*

Surveyor Guidance:

Verify that the hospital has defined the process for reassessment of the discharge plan in its policy or procedure.

Interview staff responsible for discharge planning when and how they reassess a patient's discharge plan.

Review a sample of cases to confirm that discharge plan reassessments were performed according to policy or procedure. Determine if any significant changes in the patient's condition were noted in the medical record that changed post-discharge needs, and if the discharge plan was updated accordingly. If none of the records being used for the tracers suggest a need to revise the discharge plan, ask staff to present one or more clinical records that document reassessment.

DC.5 EVALUATION

SR.1 The organization shall assess its discharge planning process on a regular basis. The assessment shall include ongoing, periodic review of a representative sample of discharge plans, including those patients who were readmitted within 30 days of a previous admission, to ensure that the plans are responsive to patient post-discharge needs.

Interpretive Guidelines:

The organization shall have a mechanism in place for ongoing reassessment of its discharge planning process. The organization 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;*
- *Discharge personnel to maintain complete and accurate information to advise patients and their representatives of appropriate options; and*
- *The organization 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.*

Once the hospital has identified potentially preventable readmissions, it is expected to conduct an in-depth review of the discharge planning process for a sample of such readmissions (at least 10% of potentially preventable readmissions, or 15 cases/quarter, whichever is larger is suggested but not required) in order to determine whether there was an appropriate discharge

planning evaluation, discharge plan, and implementation of the discharge plan.

Hospitals are also expected to follow up on trends identified through analysis of their readmissions, such as a concentration of readmissions related to post-surgical infections, discharges from a particular service or unit, discharges to a particular extended care facility or home health agency, discharges with the same primary diagnosis on the first admission, etc. Such clustering or concentration may identify areas requiring more follow-up analysis and potential remedial actions. Having identified factors that contribute to preventable readmissions, hospitals are expected to revise their discharge planning and related processes to address these factors. Consistent with the requirements under QM.1, the hospital's governing body, medical leadership and administrative leadership are all expected to ensure that identified problems are addressed, with further ongoing reassessment to achieve improvement.

Surveyor Guidance:

Verify that the organization includes the discharge planning process within the QMS, and this process is effective.

Confirm that the hospital's discharge planning reassessment process includes tracking and analysis of readmissions. Review policies and procedures and discuss with staff to determine the extent and frequency with which the discharge planning process is reassessed and how this process is evaluated for effectiveness.

DC.6 POST ACUTE CARE SERVICES

For those patients discharged home and referred for HHA services, or for those patients transferred to a SNF for post-hospital extended care services or transferred to an IRF or LTCH for specialized hospital services, the following requirements apply, in addition to the requirements of DC.1-DC.5.

SR.1 The organization shall include in the discharge plan a list of HHAs, SNFs, IRFs, or LTCHs that are available to the patient, that are participating in the Medicare program, and that serve the geographic area (as defined by the HHA) in which the patient resides, or in the case of a SNF, IRF, or LTCH, in the geographic area requested by the patient. HHAs shall request to be listed by the organization as available.

SR.2 The list in DC.6 (SR.1) shall only be presented to patients for whom home health care post-hospital extended care services, SNF, IRF, or LTCH services are indicated and appropriate as determined by the discharge planning evaluation.

SR.3 For patients enrolled in managed care organizations, the organization shall make the patient aware of the need to verify with their managed care organization which practitioners, providers or certified suppliers are in the managed care organization's network. If the organization has information on which practitioners, providers or certified supplies are in the network of the patient's managed care organization, it shall share this with the patient or the patient's representative.

SR.4 The organization shall document in the patient's medical record that the list was presented to the patient or to the patient's representative.

SR.5 The organization, as part of the discharge planning process, shall inform the patient or the patient's representative of their freedom to choose among participating Medicare providers and suppliers of post- discharge services and shall, when possible, respect the patient's or the patient's representative's goals of care and treatment preferences, as well as other preferences they express. The organization shall not specify or otherwise limit the qualified providers or suppliers that are available to the patient.

SR.6 The organization shall assist patients, their families, or the patient's representative in selecting a post-acute care provider by using and sharing data that includes, but is not limited to, HHA, SNF, IRF, or LTCH data on quality measures and data on resource use measures. The organization shall ensure that the post-acute care data on quality measures and data on resource use measures is relevant and applicable to the patient's goals of care and treatment preferences.

SR.7 The list in DC.6 (SR.1) shall identify any HHA or SNF to which the patient is referred in which the organization has a disclosable financial interest, as specified by the Secretary, and any HHA or SNF that has a disclosable financial interest in a hospital under Medicare. Financial interests that are disclosable under Medicare are determined in accordance with the provisions of Title 42, Chapter IV, part 420, subpart C-Disclosure of Ownership and Control Information.

Interpretive Guidelines:

The hospital shall include a list of Medicare-participating home health agencies (HHAs) and skilled nursing facilities (SNFs) in the discharge plan for those patients for whom the plan indicates home health or post-hospital extended care services are required. Hospitals have the flexibility either to develop their own lists or to print a list of skilled nursing facilities and home health agencies in the applicable geographic areas from the CMS websites, Nursing Home Compare (www.medicare.gov/NHcompare) and Home Health Compare (www.medicare.gov/homehealthcompare). If hospitals develop their own lists, they are expected to update them at least annually.

If the hospital has a disclosable financial interest in a HHA or SNF on a patient's list, or an HHA or SNF on the list has a disclosable financial interest in the hospital, this shall be included on the list provided to the patient.

During the discharge planning process, the hospital shall inform the patient of his/her freedom to choose among Medicare-participating post-hospital providers and shall not direct the patient to specific provider(s) or otherwise limit which qualified providers the patient may choose among.

In its process to use and share quality and resource use measure data (SR.6), hospitals may also refer patients and their families to the Nursing Home Compare and Home Health Compare websites for additional information regarding Medicare-certified skilled nursing facilities and home health agencies, as well as Medicaid-participating nursing facilities. The data on the Nursing Home Compare website includes an overall performance rating, nursing home characteristics, performance on quality measures, inspection results, and nursing staff information. Home Health Compare provides details about every Medicare-certified home health agency in the country. Included on the website are quality indicators such as managing daily activities, managing pain and treating symptoms, treating wounds and preventing pressure

sores, preventing harm, and preventing unplanned hospital care.

The hospital might also refer the patient and their representatives to individual State agency websites, Long-Term Care Ombudsmen Program, Protection and Advocacy Organizations, Citizen Advocacy Groups, Area Agencies on Aging, Centers for Independent Living, and Aging and Disability Resource Centers for additional information on long term care facilities and other types of providers of post-hospital care. Having access to the information found at these sources may assist in the decision-making process regarding post-hospital care options. Regardless of the method used, hospitals shall demonstrate that the data is provided to patients and their families.

Surveyor Guidance:

Review a sample of cases of patients who are being newly referred or transferring to a different HHA or SNF to determine if, when applicable, the hospital provided the patient with lists of Medicare-participating HHAs or SNFs.

Validate that the list provided to the patient included options for multiple HHAs or SNFs. If not, documentation shall support an acceptable rationale for providing only one option, e.g., the patient's home is included in the service area of only one Medicare-participating HHA that requested to be included on hospital lists, or there is only one Medicare-participating SNF in the area preferred by the patient.

If the hospital has a disclosable financial interest in a HHA or SNF on a patient's list, or an HHA or SNF on the list has a disclosable financial interest in the hospital, validate that this is included on the list provided to the patient.

UTILIZATION REVIEW (UR)

UR.1 DOCUMENTED PLAN

The organization shall have in effect and maintain a documented utilization review plan that provides for review of services provided to patients by the organization and medical staff, 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 shall carry out the UR function. At least two of the members of the committee shall be Doctor of Medicine or Osteopathy. The other members may be any of the other types of practitioners as defined in MS.11 (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 shall 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)(i) Has a direct financial interest (for example, an ownership interest) in the hospital; or

SR.1d(1)(ii) 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 the full Utilization Review Committee and 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 (see UR.2-UR.4) with respect to medical necessity of:

SR.4a Admissions;

SR.4b Length of stay (e.g., extended stays); and

SR.4c Professional services, including medications and biologicals.

Interpretive Guidelines:

The hospital UR plan shall 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 full Utilization Review Committee and the Quality Management Oversight body, and ensure that there is no conflict of interest (financial or otherwise) by those individuals participating in the review.

This utilization review process shall be documented and approved by the Governing Body.

Surveyor Guidance:

Verify that the organization 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 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 regulation at 42 CFR 489.20(e) requires a hospital to maintain an agreement with a QIO to review the admissions, quality, appropriateness, and diagnostic information related to inpatient services for Medicare patients, if there is a QIO with a contract with CMS in the area where the hospital is located. CMS anticipates that most hospitals comply with the UR CoP by means of the QIO exception. If the hospital has an agreement with a QIO, it is not necessary for surveyors to assess the remaining UR standards.*
- *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 the UR requirements for the Medicaid program at 42 CFR 456.50 through 456.245. 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.

- *CMS would have to determine that UR procedures established by a State under Medicaid are superior to the UR requirements for Medicare. Currently no UR plans established by a State under Medicaid have been approved as exceeding the requirements under Medicare and required for hospital compliance with the Medicare UR CoP within that State.*

UR.2 ADMISSION REVIEW

SR.1 Medical necessity of admissions to the institution shall be reviewed.

SR.2 The reviews may be done before, at, or after admission and may be conducted by sampling.

Interpretive Guidelines:

Admissions may be reviewed for medical necessity before, during, or after hospital admission as stated in the hospital's UR plan. Reviews may be conducted on a sample basis, but as specified in the hospital's UR plan.

A medical necessity review for admissions is performed to determine the appropriateness of the status of the patient's stay (inpatient vs. observation), as well as the appropriate level of care/setting (i.e., intensive or intermediate versus a medical-surgical floor) based on patient acuity, needs, and the hospital's scope of services).

UR.3 LENGTH OF STAY (EXTENDED STAY) REVIEW

SR.1 The utilization review plan shall include a process to perform medical necessity reviews for length of stay.

SR.2 In hospitals that are not paid under the prospective payment system, the UR Committee shall, at a minimum, periodically review all patients who receive services during a continuous period of extended duration.

SR.2a The scheduling of the periodic reviews may:

SR.2a(1) Be the same for all cases; or

SR.2a(2) Differ for different classes of cases.

SR.2b The periodic review shall be performed no later than seven (7) days after the extended stay period defined in the UR plan.

SR.3 For organizations paid under the prospective payment system, all patients whose length of stay is considered a reasonable outlier shall be reviewed.

SR.3a This includes, at a minimum, cases where the extended length of stay exceeds the threshold criteria for the diagnosis as described in 412.80(a)(1)(i). The

hospital is not required to review an extended stay that does not exceed the outlier threshold for the diagnosis.

SR.3b The review shall be performed on or before the expiration of the stated period above or no later than seven (7) days after the day required in the hospital's plan, if the review period defined by the hospital in the plan is more stringent than that required from the outlier threshold defined by CMS.

Interpretive Guidelines:

Hospitals shall document the processes in place to perform length of stay reviews in the UR plan. This shall include, at a minimum, the process to perform extended stay reviews. The plan shall address any differences between review of traditional Medicare and Medicaid patients, managed care patients, and commercial patients. Both traditional and managed care Medicare and Medicaid patients are required to be reviewed; commercial patients may be reviewed at the discretion of the hospital.

In addition to the extended stay reviews required by this standard, hospitals may also choose to perform continued stay reviews, which are performed daily or at another short-term, defined frequency to assess whether each day of the stay is justifiable, and the level of care and setting is appropriate. A continued stay review also monitors for any potentially avoidable delays in care. However, these reviews are not explicitly required by the CMS CoP nor this standard.

Prospective Payment System (PPS) Hospitals

Length of stay reviews for hospitals that are paid under the prospective payment system shall be performed, at a minimum, when the following occurs according to 412.80(a)(1)(i) (see also UR.4):

The beneficiary's length of stay (including days at the SNF level of care if a SNF bed is not available in the area) exceeds the mean length-of-stay for the applicable DRG by the lesser of the following:

- *A fixed number of days, as specified by CMS; or*
- *A fixed number of standard deviations, as specified by CMS.*

The PPS hospital shall document its process for performing medical necessity reviews for length of stay, including extended stay reviews. The organization shall demonstrate that review criteria are minimally consistent with the CMS criteria above or other recognized, evidence-based, objective guidelines that are comparable to or as stringent as that of CMS. The organization shall maintain its review criteria as documented information.

Prospective Payment System (PPS)-Excluded Hospitals and Units

PPS-excluded hospitals and units shall document their processes for performing medical necessity reviews for length of stay, including extended stay reviews. The organization shall demonstrate that review criteria are consistent with recognized, evidence-based, objective guidelines. The organization shall maintain its review criteria as documented information.

Surveyor Guidance:

Prospective Payment System (PPS)-Excluded Hospitals and Units

Review the facility's process for performing medical necessity reviews of length of stay, including extended stay, in the UR plan.

Verify that the hospital's UR plan requires, at a minimum, a periodic review of each inpatient receiving hospital services of extended duration and that the reviews are carried out no later than seven (7) days of the specified extended stay period stated in the facility's UR plan.

The review may be the same for all cases or be different for different classes of care. If the committee uses a different number of days for different diagnosis or functional categories for the period of extended stay, the surveyor shall verify that there is a written list with lengths of stay designated for each diagnosis of functional category.

Prospective Payment System (PPS) Hospitals

Hospitals under IPPS need only review cases reasonably assumed to be outlier cases, and extended stay that exceeds the outlier threshold for the diagnosis. Review the facility's documented criteria for extended stays in the UR plan. The criteria shall be consistent with the CMS criteria as defined in the standard or other recognized, evidence-based, objective guidelines that are comparable to or as stringent as that of CMS.

Determine that the extended stay reviews are carried out on or before the expiration of the stated outlier threshold period by CMS or no later than seven (7) days after the day required in the hospital's plan, if the review period defined by the hospital in the plan is more stringent than that required from the outlier threshold defined by CMS.

Review the facility's process for performing medical necessity reviews of length of stay outside of (in addition to) the extended stay review process, if applicable. Validate that the length of stay reviews are performed according to the hospital's UR plan.

UR.4 REVIEW OF PROFESSIONAL SERVICES

SR.1 The committee shall review professional services, including drugs and biologicals, to determine medical necessity and to promote the most efficient use of available health facilities and services.

SR.2 Hospitals that are paid for inpatient hospital services under the prospective payment system shall, at a minimum, conduct review of cases that they reasonably assume to be outlier cases based on extraordinarily high costs as described in 412.80(a)(1)(ii).

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

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

- *Therapeutic procedures*

Reviews of professional services furnished in the PPS hospital, including medications, shall be reviewed when (reference 412.80(a)(1)(ii)) the beneficiary's length of stay does not exceed the outlier threshold criteria for length of stay, but the hospital's charges for covered services, adjusted to operating costs and capital costs by applying cost-to-charge ratios, exceed the DRG payment for the case plus a fixed dollar amount (adjusted for geographic variation in costs) as specified by CMS.

UR.5 MEDICAL NECESSITY DETERMINATION

SR.1 Before making a determination that an admission or continued stay is not medically necessary, the UR Committee shall consult with the practitioner(s) responsible for the care of the patient as specified in MS.11(482.12(c)) and afford the practitioner(s) the opportunity to present their views.

SR.2 The determination that an admission or continued stay is not medically necessary:

SR.2a May be made by one member of the UR Committee if the practitioner(s) responsible for the care of the patient concurs with the determination or fail to present their views when afforded the opportunity.

SR.2b Shall be made by at least two members of the UR Committee in all other cases.

SR.3 If the committee decides that admission to or continued stay in the hospital is not medically necessary, the practitioner(s) as specified in MS.11(482.12(c)), the organization and the patient shall receive written notification of a decision that admission or continued stay is determined to be not medically necessary.

SR.3a The notification shall be given no later than two (2) days after such decision is made.

Interpretive Guidelines:

Both traditional and managed care Medicare and Medicaid patients are required to be reviewed; commercial patients may be reviewed at the discretion of the hospital.

In this context, a continued stay is used synonymously with "extended stay."

Cases that are determined to have not met medical necessity will be reviewed. When other than a Doctor of Medicine or Osteopathy makes an initial finding that the written criteria for an admission or extended stay are not met, the case shall be referred to the UR committee, or subgroup thereof, which contains at least one physician. If the committee or subgroup agrees after reviewing the case that admissions, or extended stay is not medically necessary or appropriate, the attending physician or practitioner is notified and allowed an opportunity to present his views and any additional information relating to the patient's needs for admissions or extended stay. When a physician member of the committee performs the initial review instead of a non-physician reviewer, and he finds that admissions or extended stay is not necessary no referral to the committee or subgroup is necessary and he may notify the attending practitioner directly.

If the attending 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 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 shall 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 shall be sent to the attending patient (or next of kin), the facility administrator, and the single State agency (in the case of Medicaid) within two days after such final decision and in no event later than three working days after the end of the assigned extended stay period.

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 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 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.

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.

Note:

The standards incorporated by reference in this section are approved for incorporation by reference by the Director of the Office of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may inspect a copy at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to:

http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

If any changes in this edition of the Code are incorporated by reference, CMS will publish a document in the FEDERAL REGISTER to announce the changes.

(1) National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02169, www.nfpa.org, 1.617.770.3000.

(i) NFPA 99, Health Care Facilities Code, 2012 edition, issued August 11, 2011.

(ii) Tentative interim amendment (TIA) 12-2 to NFPA 99, issued August 11, 2011.

(iii) TIA 12-3 to NFPA 99, issued August 9, 2012.

(iv) TIA 12-4 to NFPA 99, issued March 7, 2013.

(v) TIA 12-5 to NFPA 99, issued August 1, 2013.

(vi) TIA 12-6 to NFPA 99, issued March 3, 2014.

(vii) NFPA 101, Life Safety Code, 2012 edition, issued August 11, 2011.

(viii) TIA 12-1 to NFPA 101, issued August 11, 2011.

(ix) TIA 12-2 to NFPA 101, issued October 30, 2012.

(x) TIA 12-3 to NFPA 101, issued October 22, 2013.

(xi) TIA 12-4 to NFPA 101, issued October 22, 2013.

SR.1 The condition of the physical plant and the overall hospital environment shall be developed and maintained in such a manner that the safety and well-being of patients, visitors, and staff are assured.

SR.2 The organization shall maintain safe and adequate facilities for its services.

SR.5b Diagnostic and therapeutic facilities shall be located for the safety of patients.

SR.5c Facilities, supplies, and equipment shall be maintained to ensure an acceptable level of safety and quality.

SR.5d The extent and complexity of facilities shall be determined by the services offered.

SR.3 Except as otherwise provided in this section, the organization shall meet the applicable provisions and shall proceed in accordance with the 2012 Health Care Facilities Code (NFPA 99 and Tentative Interim Amendments TIA 12-2, TIA 12-3, TIA 12-4, TIA 12-5 and TIA 12-6), and Life Safety Code (NFPA 101 and Tentative Interim Amendments TIA 12-1, TIA 12-2, TIA 12-3, and TIA 12-4).

SR.3a Chapters 7, 8, and 12 of the adopted Health Care Facilities Code do not apply to a hospital.

SR.3b If application of the Health Care Facilities Code as required in PE.1 (SR.3) would result in unreasonable hardship for the organization, CMS may waive specific provisions of the Health Care Facilities Code, but only if the waiver does not adversely affect the health and safety of patients.

Note: The waiver allowance afforded by PE.1 (SR.3b) is not applicable to Chapter 13 of the adopted Health Care Facilities Code (HCFC). Compliance with Chapter 13 of the HCFC is a DNV specific requirement.

SR.4 The organization shall have policies, procedures and processes, and management plans 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.5 The organization shall have documented processes, management plans, 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.6 The organization shall evaluate the effectiveness of the facility's physical environment management systems at least annually. This evaluation shall be forwarded to QMS oversight.

SR.7 Occurrences, incidents, or impairments shall be measured and analyzed to identify any patterns or trends and used to evaluate the effectiveness of the organization's physical environment management systems.

SR.8 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.9 Significant physical environment data/information shall be disseminated regularly to Quality Management Oversight.

SR.10 Construction, Repair, and Improvement operations shall involve the following activities:

SR.10a During construction, repairs, or improvement operations, or activities otherwise affecting the space, the current edition of the Guidelines for Design and Construction of Hospitals or the Guidelines for Design and Construction of Outpatient Facilities (FGI), as appropriate, shall be consulted for design purposes.

NOTE: If a state has adopted a specific edition of the FGI or has promulgated its own hospital and outpatient facility design and construction standards, the state requirements shall prevail.

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 241-2009, 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 2012 National Fire Protection Association (NFPA) 101- Life Safety Code (LSC), the 2012 edition of the NFPA 99-Health Care Facilities Code (HCFC) and State and local building and fire codes. Should standards and codes conflict, the most stringent standard or code shall prevail.

SR.11 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. DNV Healthcare will permit temporary tobacco use in the areas of the hospital where patient visits may be abbreviated, in behavioral health units and other areas near the main campus that are not under hospital control. In order for this to be permissible the hospital shall obtain from the local and/or state fire prevention agencies (Authority Having Jurisdiction or AHJ) written documentation stating that these areas which are to be located outdoors, can be used

for smoking while the hospital continues to demonstrate progression toward a tobacco-free campus over time. (See the PE.1 Interpretive Guidelines for specific direction on this procedure).

Interpretive Guidelines:

Annual reviews of effectiveness of the physical environment management systems, as well as any resulting changes to the physical environment management systems, plans, etc. should be completed within 90-days of the ending of the annual cycle. For example, if the annual cycle ends on January 31, the resulting evaluations should be completed by May 1.

Tobacco-free Campus

To apply for areas in which smoking is acceptable,

1. *The documented AHJ permission shall list:*
    a. *Which specific patient populations are permitted to participate in smoking;*
    b. *What specific areas will be included in the policy;*
    c. *Any specific applicable controls (e.g., smokers could be under physician's orders and/or accompanied by a security guard in specific approved areas);*
    d. *All arrangements/precautions/restrictions that pertain to this special permission.*
2. *The organization shall also perform a documented risk assessment of the area in which tobacco use is proposed including:*
    a. *The specific areas where smoking will be allowed;*
    b. *The smoking areas are designed and built to resist fire, including but not limited to the landscaping in the immediate area;*
    c. *The smoking areas are located adequately from windows, air intakes and entrances to the facility;*
    d. *The hospital areas are compliant with NFPA 101, 2012 Chapter 18/19:18.7.4* or 19.7.4**

Once it is established that the arrangements described in the inquiry are endorsed/permitted by the local/state fire prevention agency or AHJ documentation, then the organization can continue demonstrate progression towards a tobacco-free campus while using the AHJ-approved specific areas for smoking described in the hospital tobacco-free policy and the AHJ documentation. The hospital policy shall also include plans and/or processes that will be developed and maintained to demonstrate continual progress in achieving a tobacco-free campus.

Ligature risk

The presence of unmitigated ligature risks in a psychiatric hospital or psychiatric unit of a

hospital is an immediate jeopardy situation. Additionally, this also includes any location where patients at risk of suicide are identified. Ligature risk findings shall be referred to the clinical surveyors for further evaluation and possible citation under Patients' Rights.

This standard shall apply to all locations of the organization, all campuses, and all off-site facilities.

The organization's department(s) that is responsible for the hospital's buildings and equipment (both facility equipment and patient care equipment) shall 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.

Facility Equipment

Facility equipment shall be maintained to ensure an acceptable level of safety and quality.

To ensure an acceptable level of safety and quality, the organization shall identify 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 organization shall make adequate provisions to ensure the availability and reliability of equipment needed for its operations and services. Equipment includes, but is not limited to, 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.)

All equipment shall be inspected and tested for performance and safety before initial use and after major repairs or upgrades.

All equipment shall 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 shall be qualified. The organization shall maintain records of hospital personnel qualifications and be 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 maintenance personnel who have been assigned responsibility for equipment maintenance by the organization's leadership.

Organizations comply with these requirements when they follow the manufacturer-recommended maintenance activities and schedule. Organizations may choose to perform maintenance more frequently than the manufacturer recommends but shall use the manufacturer-recommended maintenance activities in such cases. When equipment is maintained in accordance with the manufacturer's recommendations, the organization shall 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. Organizations that choose to employ alternate maintenance activities and/or schedules shall develop, implement, and maintain a documented AEM program to minimize risks to patients and others in the hospital associated with the use of facility equipment. The AEM program shall be based on nationally recognized standards of practice and guidelines for facility equipment maintenance.

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 equipment maintenance without following the equipment manufacturer recommendations shall be made by qualified personnel, regardless of whether they are hospital employees or contractors.

In the case of facility equipment, a Healthcare Facility Management professional (facility manager, director of facilities, vice president of facilities) 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.

The organization shall maintain records of the qualifications of hospital personnel who make decisions on placing equipment in an AEM program and shall 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 organization shall 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 setting within the hospital where it is used.

An organization is expected to identify any equipment in its AEM program which is "critical equipment," e.g., 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 shall focus their review of an organization's AEM program on critical equipment in that program and the organization's documentation of the factors and evidence it considered in developing an AEM strategy for that equipment.

Factors for an organization 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?*
- *How widespread is the harm likely to be? 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 facility 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 shall be considered, since different types of equipment present different combinations of severity of potential harm and likelihood of failure. The organization 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 into the AEM Program:

Some equipment may not be eligible for placement into 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 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 organization shall comply with these other federal or state requirements.

- *Other CoPs require adherence to manufacturer's recommendations and/or set specific standards. 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.*

- *New equipment for which sufficient maintenance history, either based on the organization's own or its contractor's records, or available publicly from nationally recognized sources, is not available to support a risk-based determination. New equipment shall 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 frequency would be safe. If a hospital later transitions the equipment to a risk-based maintenance regimen different than the manufacturers' recommendations, the organization shall 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. An organization 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 shall be explained and documented in the AEM program.

In developing AEM maintenance strategies organizations 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 organization 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 shall 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 shall 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 shall 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 organization 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 shall 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 organization has multiple identical equipment items, the documentation may be generic to that type of equipment, except that documentation of maintenance activities performed shall be specific to each item of equipment.

Evaluating Safety and Effectiveness of the AEM Program

The organization shall have policies and procedures which address the effectiveness of its AEM program. In evaluating the effectiveness of the AEM program the organization 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 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 organization is using an AEM program, the equipment managed through that program shall be readily separately identifiable as subject to AEM. Critical equipment, whether in an AEM program or not, shall 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.*

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 organization 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 organization's routine and preventive maintenance schedules to determine that ongoing maintenance inspections are performed and that necessary repairs are completed.

Verify that the organization 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.

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 101-2012 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 as made provisions for the respective elements as described in the Interpretive Guidelines (above).

If there is no renovation or construction taking place within the organization, verify that the organization has a process to follow the current edition of the Guidelines for Design and Construction of Hospitals or Outpatient Facilities, published by the Facility Guidelines Institute (FGI), 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.

PE.2 LIFE SAFETY MANAGEMENT SYSTEM

SR.1 Except as otherwise provided in NIAHO® Accreditation Requirements:

SR.1a The organization shall meet the applicable provisions and shall proceed in accordance with the 2012 Life Safety Code (NFPA 101 and Tentative Interim Amendments TIA 12-1, TIA 12-2, TIA 12-3, and TIA 12-4). Outpatient surgical departments shall meet the provisions applicable to Ambulatory Health Care Occupancies, regardless of the number of patients served.

SR.1b Corridor doors and doors to rooms containing flammable or combustible materials shall be provided with positive latching hardware. Roller latches are prohibited on such doors.

SR.1c In consideration of a recommendation by the state survey agency or Accrediting Organization or at the discretion of the Secretary, may waive, for periods deemed appropriate, specific provisions of the Life Safety Code, which would result in unreasonable hardship upon a hospital, but only if the waiver will not adversely affect the health and safety of the patients.

SR.1d The provisions of the Life Safety Code do not apply in a state where CMS finds that a fire and safety code imposed by state law adequately protects patients in hospitals.

SR.2 The organization shall maintain drawings depicting the current configuration of life safety features, including, but not necessarily limited to fire and smoke barriers, suite boundaries and smoke compartments.

SR.3 The organization shall maintain written evidence of regular inspection and approval by State or local fire control agencies.

SR.4 The organization shall 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 training of staff in the following areas (NFPA 101-2012, 18.7.2.2 & 19.7.2.2):

SR.4a Use of alarms;

SR.4b Transmission of alarm to fire department;

SR.4c Emergency phone call to fire department;

SR.4d Response to alarms;

SR.4e Isolation of fire;

SR.4f Evacuation of immediate area;

SR.4g Evacuation of smoke compartment;

SR.4h Preparation of floors and building for evacuation; and,

SR.4i Extinguishment of fire.

SR.5 The Life Safety Management System shall include in the elements of SR.4e a written barrier protection plan for the preservation of the integrity of hospital smoke and fire barriers. The plan shall include:

SR.5a Name(s) of responsible hospital staff for barrier protection program;

SR.5b Requirement for written permission for anyone (including all hospital staff, contractors, and vendors) to penetrate a smoke or fire barrier wall, ceiling or floor;

SR.5c Input from Infection Control and Prevention Practitioner on critical clinical areas prior to issuance of written permit for performing work on barriers; and

SR.5d Establishment of monitoring process to ensure all work is completed correctly.

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 (i.e., audible alarm) 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 101-2012, 18.7.1.7. & 19.7.1.7).

SR.6a Business occupancies shall conduct at least one unannounced fire drill annually per shift.

SR.6b Fire drills shall be thoroughly documented and evaluate the organization's knowledge to the items listed in PE.2 (SR.4).

SR.6c 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.6d Operating room fire exit drills and operating room fire safety training shall be conducted in accordance with the requirements of NFPA 99-2012.

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 safety measures shall be approved by the authority having local jurisdiction. Life safety measures for redundant and/or common minor renovations/repairs/testing may be preapproved for the specific task by the AHJ.

SR.8 When a sprinkler system is shut down for more than 10 hours, the hospital shall:

SR.8a Evacuate the building or portion of the building affected by the system outage until the system is back in service, or

SR.8b Establish a fire watch until the system is back in service.

SR.9 Buildings shall have an outside window or outside door in every patient sleeping room, and for any building constructed after July 5, 2016, the sill height shall not exceed 36 inches above the floor. Windows in atrium walls are considered outside windows for the purposes of this requirement.

SR.9a The sill height requirement does not apply to newborn nurseries and rooms intended for occupancy for less than 24 hours.

SR.9b The sill height in special nursing care areas of new occupancies shall not exceed 60 inches.

SR.10 The Life Safety Management System shall require that Life Safety systems (e.g., fire suppression, notification, and detection equipment) shall be tested, inspected, and maintained (including portable systems) in accordance with applicable requirements.

SR.10a Portable fire extinguishers shall be inspected at least once per calendar month at intervals not exceeding 31 days.

SR.11 The Life Safety Management System shall require a process for reviewing the acquisition of bedding, draperies, furnishings and decorations for fire safety.

SR.12 All non-patient sleeping rooms shall be equipped with an approved, single station smoke alarm.

Note: NFPA 101, 2012 9.6.2.10.1.4: System smoke detectors in accordance with NFPA 72, National Fire Alarm and Signaling Code, and arranged to function in the

same manner as single-station or multiple-station smoke alarms shall be permitted in lieu of smoke alarms.

Interpretive Guidelines:

The hospital, regardless of size or number of beds, and all locations under the hospital license, including inpatient care locations, emergency departments, and outpatient care locations, whether leased or owned, shall meet the applicable occupancy chapter provisions of the 2012 edition of the Life Safety Code® of the National Fire Protection Association.

Additionally, the hospital and all locations under the hospital license shall be in compliance with all applicable codes referenced in the Life Safety Code®, such as NFPA 99 Health Care Facilities Code.

Note: In order for PE.2 (SR.1d) to be applicable, the appropriate supporting documentation shall be in place.

The hospital will maintain and update, as necessary, a fire control plan that includes the elements of PE.2 (SR.4). The hospital will also have supporting documentation to verify the regular inspection and approval by State or local fire control agencies.

When construction, repairs, or improvement operations impacts occupied areas, the hospital shall also make provisions to include, as appropriate, infection control practices to be followed, utility requirements, and account for noise and vibration.

The surveyor should validate compliance with the inspection, testing, and maintenance of fire detection, notification, and suppression equipment and systems.

Acceptable frequencies for inspection, testing, and maintenance of life safety systems (unless more strictly specified in a code or standard) include the following:

- *Frequency. Minimum and maximum time between events.*
- *Weekly Frequency. Fifty-two times per year, once per calendar week.*
- *Monthly Frequency. Twelve times per year, once per calendar month.*
- *Quarterly Frequency. Four times per year with a minimum of 2 months, maximum of 4 months.*
- *Semiannual Frequency. Twice per year with a minimum of 4 months, maximum of 8 months.*
- *Annual Frequency. Once per year with a minimum of 9 months, maximum 15 months.*
- *Three Years Frequency. Occurring once every 36 months with a minimum if 30 months and a maximum of 40 months*
- *Five Years Frequency. Occurring once every 60 months with a minimum of 54 months and a maximum of 66 months.*

The drawings required by PE.2 (SR.2) shall depict life safety features so that compliance with NFPA 101 can be validated. These drawings are not required to be professionally produced.

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.

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 shall 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 including where equipment is in use (e.g., computers, sterilizing equipment, refrigerators).

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 facilities and grounds to observe and correct safety issues that may be identified.

SR.6 The Safety Management System shall address safety recalls and alerts.

SR.7 All eyewashes and emergency drench showers shall be tested and maintained according to the current ANSI Z358.1 Standard.

SR.8 The organization shall have procedures for the proper routine storage and prompt disposal of trash.

SR.9 An organization utilizing respirators for protection of staff shall have a documented Respiratory Protection Program (RPP).

SR.9a The RPP shall meet the requirements of OSHA 1910.134.

SR.9b If an organization is not subject to OSHA compliance, the organization shall establish and implement a written respiratory protection program at least as stringent as the OSHA requirements for respiratory protection.

SR.9c For non-employed and contract staff and providers, an organization may accept evidence of proper fit-testing from the non-employed and contract staff and providers to satisfy the requirements of PE.3 (SR.9).

Interpretive Guidelines:

The organization 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 nationally recognized standards of practice and guidelines.

Organizations, regardless of ownership, including government owned facilities, shall provide a safe workplace and have processes to prevent occupational illnesses and injuries by meeting at a minimum, OSHA requirements or their equivalent.

The term trash refers to common garbage as well as bio hazardous waste. The storage and disposal of trash shall be in accordance with federal, state and local laws and regulations (e.g., EPA, OSHA, CDC, State environmental, health and safety regulations). The Medical Imaging and Nuclear Medicine requirements address handling and storage of radioactive materials. (See also PE.5.)

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 organization shall meet the requirements set forth in NFPA 99, 2012 Chapter 13, Security Management.

SR.3 The Security Management System shall require that the organization conduct a security vulnerability assessment (SVA) and shall implement procedures and controls in accordance with the risks identified by the SVA.

SR.4 The Security Management System shall at a minimum:

SR.4a Provide for identification of patients, employees and others.

SR.4b Address issues related to abduction, elopement, visitors, workplace violence, cybersecurity, and investigation of property losses.

SR.4c Develop and implement a written, comprehensive workplace violence control and prevention program based on the current edition of OSHA Publication 3148 *Guidelines for Preventing Workplace Violence for Healthcare and Social Workers*.

SR.4d Establish emergency security procedures to include all hazard events identified in the SVA.

SR.4e Require vehicular access to emergency service areas.

SR.4f Require a process for reporting and investigating security related issues.

Interpretive Guidelines:

Security Vulnerability Assessment

There is no specific format required for the Security Vulnerability Assessment required by NFPA 99-2012 Chapter 13 and PE.4 (SR.3). The organization should utilize a format that meets its requirements/needs and that allows for the organization to meet the requirements of Chapter 13. Additional sources of information on conducting a Security Vulnerability Assessment can be found in the current edition of NFPA 730, Guide for Premises Security and IAHSS Healthcare Security Industry Guidelines.

Cybersecurity

Organizations are expected to address cybersecurity risks, including but not necessarily limited to, information technology systems, medical records, internet connected and networked medical and facility equipment as well as equipment that can be accessed via external devices, such as USB drives.

Organizations are advised to consult the following resources to assist in developing their cybersecurity processes:

- *HHS 405(d) Aligning Health Care Industry Security Approaches - https://405d.hhs.gov/*
- *NIST Cybersecurity Framework - https://www.nist.gov/cyberframework*

Workplace Violence Control and Prevention Program

The organization's workplace violence control and prevention program shall include as a minimum, the elements contained in OSHA Publication 3148 Guidelines for Preventing Workplace Violence for Healthcare and Social Workers, in addition to any state required elements.

PE.5 HAZARDOUS MATERIAL MANAGEMENT SYSTEM

SR.1 The organization shall provide a Hazardous Material (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 QMS.

SR.5 All compressed gas cylinders in service and in storage shall be secured and located to prevent abnormal mechanical shock or other damage to the cylinder valve or safety device.

SR.6 In anesthetizing locations, which use alcohol-based skin preparations, the organization shall implement effective fire risk reductions measures in accordance with NFPA 99, 15.13.3 which include but are not limited to:

SR.6a The use of unit dose skin prep solutions;

SR.6b Application of skin prep follows manufacturer/supplier instructions and warnings;

SR.6c Sterile towels are used to absorb drips and runs during the application and then removed from the anesthetizing location prior to draping; and,

SR.6d Verifying that all of the above has occurred prior to initiating the surgical procedure.

SR.7 An organization may install alcohol-based hand rub dispensers in its facility if the dispensers are installed in a manner that adequately protects against inappropriate access and in accordance with NFPA 101, Life Safety Code, 2012 edition.

Interpretive Guidelines:

The term waste refers to common garbage, hazardous material, pharmaceutical wastes, as well as biohazardous wastes. The handling, storage, transportation, using and disposal of hazardous materials, wastes, etc. shall be in accordance with federal, state and local laws and regulations (e.g., EPA, OSHA, CDC, US DOT, State environmental, health and safety regulations). The Conditions of Participation for Radiology and Nuclear Medicine Services address handling and

storage of radioactive materials.

There shall be proper ventilation in at least the following areas: Areas using formaldehyde, ethylene oxide, nitrous oxide, glutaraldehyde, xylene, pentamidine, or other potentially hazardous substances.

Surveyor Guidance:

Verify that the organization 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, US DOT, 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

The organization shall comply with all applicable Federal, State, and local emergency preparedness requirements. The organization shall develop and maintain a comprehensive emergency preparedness program utilizing an all-hazards approach. The emergency preparedness plan shall include, but not be limited to, the following elements:

SR.1 The organization shall develop and maintain an emergency preparedness plan that shall be reviewed and updated at least annually. The plan shall do all of the following:

SR.1a Be based on and include a documented, facility-based and community-based risk assessment, utilizing an all-hazards approach.

SR.1b Include strategies for addressing emergency events identified by the risk assessment.

SR.1c Address patient population, including, but not limited to, persons at-risk (including populations at risk); the type of services the organization has the ability to provide in an emergency; and continuity of operations, including delegations of authority and succession plans.

SR.1d Include a process for cooperation and collaboration with local, tribal, regional, State, and Federal emergency preparedness officials' efforts to maintain an integrated response during a disaster or emergency situation.

SR.2 The organization shall develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in PE.6 (SR.1), risk assessment at PE.6 (SR.1a), and the communication plan at PE.6 (SR.3). The policies and procedures shall be reviewed and updated at least annually. At a minimum, the policies and procedures shall address the following:

SR.2a The provision of subsistence needs for staff and patients, whether they evacuate or shelter in place, include, but are not limited to:

SR.2a(1) Food, water, medical, and pharmaceutical supplies;

SR.2a(2) Alternate sources of energy to maintain the following:

SR.2a(2)(i) Temperatures to protect patient health and safety and for the safe and sanitary storage of provisions;

SR.2a(2)(ii) Emergency lighting;

SR.2a(2)(iii) Fire detection, extinguishing, and alarm systems;

SR.2a(2)(iv) Sewage and waste disposal.

SR.2b A system to track the location of on-duty staff and sheltered patients in the organization's care during an emergency. If on-duty staff and sheltered patients are relocated during the emergency, the organization shall document the specific name and location of the receiving facility or other location.

SR.2c Safe evacuation from the organization, which includes consideration of care and treatment needs of evacuees; staff responsibilities; transportation; identification of evacuation location(s); and primary and alternate means of communication with external sources of assistance.

SR.2d A means to shelter in place for patients, staff, and volunteers who remain in the organization.

SR.2e A system of medical documentation that preserves patient information, protects confidentiality of patient information, and secures and maintains the availability of records.

SR.2f The use of volunteers in an emergency and other emergency staffing strategies, including the process and role for integration of State or Federally designated health care professionals to address surge needs during an emergency.

SR.2g The development of arrangements with other organizations and other providers to receive patients in the event of limitations or cessation of operations to maintain the continuity of services to organization patients.

SR.2h The role of the organization under a waiver declared by the Secretary, in accordance with section 1135 of the Social Security Act, in the provision of care and treatment at an alternate care site identified by emergency management officials.

SR.3 The organization shall develop and maintain an emergency preparedness communication plan that complies with Federal, State, and local laws and shall be

reviewed and updated at least annually. The communication plan shall include all of the following:

SR.3a Names and contact information for the following:

SR.3a(1) Staff.

SR.3a(2) Entities providing services under arrangement.

SR.3a(3) Patients' physicians.

SR.3a(4) Other hospitals and CAHs.

SR.3a(5) Volunteers.

SR.3b Contact information for the following:

SR.3b(1) Federal, State, tribal, regional, and local emergency preparedness staff.

SR.3b(2) Other sources of assistance.

SR.3c Primary and alternate means for communicating with the following:

SR.3c(1) Organization's staff.

SR.3c(2) Federal, State, tribal, regional, and local emergency management agencies.

SR.3d A method for sharing information and medical documentation for patients under the organization's care, as necessary, with other health care providers to maintain the continuity of care.

SR.3e A means, in the event of an evacuation, to release patient information as permitted under 45 CFR 164.510(b)(1)(ii).

SR.3f A means of providing information about the general condition and location of patients under the organization’s care as permitted under 45 CFR 164.510(b)(4).

SR.3g A means of providing information about the organization's occupancy, needs, and its ability to provide assistance, to the authority having jurisdiction, the Incident Command Center, or designee.

SR.4 The organization shall develop and maintain an emergency preparedness training and testing program that is based on the emergency plan set forth in PE.6 (SR.1), risk assessment at PE.6 (SR.1a), policies and procedures at PE.6 (SR.2), and the communication plan at PE.6 (SR.3). The training and testing program shall be reviewed and updated at least annually.

SR.4a The organization shall do all of the following:

SR.4a(1) Initial training in emergency preparedness policies and procedures to all new and existing staff, individuals providing services under arrangement, and volunteers, consistent with their expected role.

SR.4a(2) Provide emergency preparedness training at least annually.

SR.4a(3) Maintain documentation of the training.

SR.4a(4) Demonstrate staff knowledge of emergency procedures.

SR.4a(5) If the emergency preparedness policies and procedures are significantly updated, the organization shall conduct training on the updated policies and procedures.

SR.4b The organization shall conduct exercises to test the emergency plan at least twice per year. The organization shall do all of the following:

SR.4b(1) Participate in an annual full-scale exercise that is community-based; or

SR.4b(1)(i) When a community-based exercise is not accessible, conduct an annual individual, facility-based functional exercise; or

SR.4b(1)(ii) If the organization experiences an actual natural or man-made emergency that requires activation of the emergency plan, the organization is exempt from engaging in its next required full-scale community-based exercise or individual, facility-based functional exercise following the onset of the emergency event.

SR.4b(2) Conduct an annual additional exercise that may include, but is not limited to the following:

SR.4b(2)(i) A second full-scale exercise that is community-based or an individual, facility-based functional exercise; or

SR.4b(2)(ii) A mock disaster drill; or

SR.4b(2)(iii) A tabletop exercise or workshop that is led by a facilitator and includes a group discussion, using a narrated, clinically relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan.

SR.4c Analyze the organization's response to and maintain documentation of all drills, tabletop exercises, and emergency events, and revise the organization's emergency plan, as needed.

SR.5 The organization shall implement emergency and standby power systems based on the emergency plan set forth in PE.6 (SR.1) and in the policies and procedures set forth in PE.6 (SR.2a(1)) and PE.6 (SR.2a(2)).

SR.5a The generator shall be located in accordance with the location requirements found in the Health Care Facilities Code (NFPA 99 and Tentative Interim Amendments TIA 12-2, TIA 12-3, TIA 12-4, TIA 12-5, and TIA 12-6), Life Safety Code (NFPA 101 and Tentative Interim Amendments TIA 12-1, TIA 12-2, TIA 12-3, and TIA 12-4), and NFPA 110, when a new structure is built or when an existing structure or building is renovated.

SR.5b The organization shall implement the emergency power system inspection, testing, and maintenance requirements found in the Health Care Facilities Code, NFPA 110, and the Life Safety Code.

SR.5c Organizations that maintain an onsite fuel source to power emergency generators shall have a plan for how it will keep emergency power systems operational during the emergency, unless it evacuates.

SR.6 Integrated healthcare systems. If an organization is part of a healthcare system consisting of multiple separately certified healthcare facilities that elects to have a unified and integrated emergency preparedness program, the organization may choose to participate in the healthcare system's coordinated emergency preparedness program. If elected, the unified and integrated emergency preparedness program shall:

SR.6a Demonstrate that each separately certified facility within the system actively participated in the development of the unified and integrated emergency preparedness program.

SR.6b Be developed and maintained in a manner that takes into account each separately certified facility's unique circumstances, patient populations, and services offered.

SR.6c Demonstrate that each separately certified facility is capable of actively using the unified and integrated emergency preparedness program and is in compliance with the program.

SR.6d Include a unified and integrated emergency plan that meets the requirements of PE.6 (SR.1b), PE,6 (SR.1c), and PE.6 (SR.1d). The unified and integrated emergency plan shall also be based on and include the following:

SR.6d(1) A documented community-based risk assessment, utilizing an all-hazards approach.

SR.6d(2) A documented individual facility-based risk assessment for each separately certified facility within the health system, utilizing an all-hazards approach.

SR.6e Include integrated policies and procedures that meet the requirements set forth in PE.6 (SR.2), a coordinated communication plan and training and testing programs that meet the requirements of PE.6 (SR.3) and PE.6 (SR.4), respectively.

SR.7 If an organization has one or more transplant programs (as defined in 482.70):

SR.7a A representative from each transplant program shall be included in the development and maintenance of the organization's emergency preparedness program; and

SR.7b The organization shall develop and maintain mutually agreed upon protocols that address the duties and responsibilities of the organization, each transplant program, and the OPO for the DSA where the organization is situated, unless the hospital has been granted a waiver to work with an OPO, during an emergency.

SR.8 NFPA 110, Standard for Emergency and Standby Power Systems, 2010 edition, including TIAs to chapter 7, issued August 6, 2009, is incorporated for reference in this chapter in addition to the references incorporated by reference in PE.1.

Interpretive Guidelines:

The organization shall provide for an Emergency Management System that develops, implements, and maintains a comprehensive emergency preparedness program in accordance with the requirements of PE.6 and all applicable Federal, State, and local emergency preparedness requirements. The organization shall utilize an all-hazards approach in the development of its emergency preparedness plan.

An all-hazards approach is an integrated approach to emergency preparedness that focuses on identifying hazards and developing emergency preparedness capacities and capabilities that can address those as well as a wide spectrum of emergencies or disasters. This approach includes preparedness for natural, man-made, and or facility emergencies that may include but is not limited to: care-related emergencies; equipment and power failures; interruptions in communications, cyber-attacks; loss of a portion or all of a facility; and, interruptions in the normal supply of essentials, such as water, food, and pharmaceuticals. Planning for using an all-hazards approach shall also include pandemics and emerging infectious disease (EID) threats. Examples of EIDs include Influenza, Ebola, Zika Virus, COVID-19, and others.

Emergency Plan

The emergency plan shall be based on and include a documented facility based and community-based risk assessment, (Hazard Vulnerability Assessment – HVA) utilizing the all-hazards approach. The emergency plan shall:

- *Include strategies for addressing emergency events identified by the HVA.*
- *Address:*

- *Patient populations, including but not limited to persons and at-risk populations.*

At-risk populations include individuals who may need additional response assistance including those who have disabilities, live in institutionalized settings, are from diverse cultures and racial and ethnic backgrounds, have limited English proficiency or are non-English speaking, lack transportation, have chronic medical disorders, or have pharmacological dependency.

- *The type of services the organization has the ability to provide in an emergency.*
- *Continuity of business, including,*
  - *Delegation of authority.*
  - *Succession plans.*

Continuity of business incorporates all continuity operations and business continuity, which involves planning to ensure business operations will continue even during a disaster. The concept of continuity is the organization's ability to continue operations or services related to patient care and to ensure patient safety and quality of care is continued in an emergency event. The emergency plan provides the framework, which includes conducting facility-based and community-based risk assessments that will assist a organization in addressing the needs of their patient populations, along with identifying the continuity of business operations which will provide support to services that are necessary during an actual emergency.

- *Include a process for cooperation and collaboration with local, tribal, regional, State, and Federal emergency preparedness official's efforts to maintain an integrated response during a disaster or emergency situation.*

While the responsibility for ensuring a coordinated disaster preparedness response lies upon the state and local emergency planning authorities, the organization shall have a process to engage in collaborative planning for an integrated emergency response. The organization shall include this integrated response process in its emergency plan. organizations are encouraged to participate in a healthcare coalition as it may provide assistance in planning and addressing broader community needs that may also be supported by local health department and emergency management resources. While every detail of the cooperation and collaboration process is not required to be documented in writing, it is expected that the organization has documented sufficient details to support verification of the process.

Policies and Procedures

The organization shall develop policies and procedures based on its emergency plan, HVA, and communications plan. At a minimum, the policies and procedures shall address the following:

- *The provision of subsistence and resource needs for patients and staff, whether they evacuate of shelter in place, to include, but not be limited to:*
  - *Food, water, medical and pharmaceutical supplies.*

An organization shall conduct a sustainability assessment to determine resource capability for up to 96 hours and determine what mitigation efforts are needed. An organization is not required to have 96-hours worth of supplies on-hand. The 96-hour sustainability assessment is an assessment of the organization's ability to sustain its operations without support from the local community for at least 96 hours. The intent is for an organization to understand where it's shortfalls may be and to plan for contingencies to extend towards that 96 hour goal and to recognize when it may need to curtail operations if lack of assets and resources cannot be met through contingency planning. Sources of information for completing a 96-hour assessment include, but are not limited to, the American Society of Healthcare Engineers (ASHE) and the Iroquois Healthcare Association. Note that some States do set minimum requirements for some provisions such as food and water.

- *Alternate sources of energy to maintain:*
  - *Temperatures to protect patient health and safety and for the proper storage of provisions (food, medical supplies, pharmaceuticals)*
  - *Emergency lighting*
  - *Fire Protection, extinguishing, and alarm systems*
  - *Sewage and waste disposal*

Organizations shall establish policies and procedures that determine how required heating and cooling of their facility will be maintained during an emergency situation, as necessary, if there were a loss of the primary power source. Organizations are not required to heat and cool the entire building evenly, but shall ensure safe temperatures are maintained in those areas deemed necessary to protect patients, other people who are in the facility, and for provisions stored in the organization during the course of an emergency, as determined by the HVA. If unable to meet the temperature needs, an organization should have a relocation/evacuation plan (that may include internal relocation, relocation to other buildings on the campus or full evacuation). The relocation/evacuation should take place in a timely manner so as not to expose patients and residents to unsafe temperatures.

- *A system to track the location of on-duty staff and sheltered patients in the organization's care during an emergency. If on-duty staff and sheltered patients are relocated during an emergency, the organization shall document the specific name and location of the receiving facility or other location.*

  Organizations shall develop a means to track patients and on-duty staff in the organization's care during an emergency event. In the event staff and patients are relocated, the organization shall document the specific name and location of the receiving facility or other location for sheltered patients and on-duty staff who leave the facility during the emergency. An organization has the flexibility to determine how best to track patients and staff, whether it uses an electronic database, hard copy documentation, or some other method. However, it is important that the information be readily available, accurate, and shareable among officials within and across the emergency response systems as needed in the interest of the patient. It is

recommended that an organization that is using an electronic database consider backing up its computer system with a secondary source, such as hard copy documentation in the event of power outages. The tracking systems set up by organizations may want to consider who is responsible for compiling/securing patient records and what information is needed during tracking a patient throughout an evacuation.

- *Safe evacuation from the organization, which includes consideration of care and treatment needs of evacuees; staff responsibilities; transportation; identification of evacuation location(s); and primary and alternate means of communication with external sources of assistance.*

  Organizations shall have policies and procedures which address the needs of evacuees. The organization should also consider in development of the policies and procedures, the evacuation protocols for not only the evacuees, but also staff members and families/patient representatives or other personnel who sought potential refuge at the organization. Additionally, the policies and procedures shall address staff responsibilities during evacuations. organizations shall consider the patient population needs as well as their care and treatment. For example, if an evacuation is in progress leadership should consider the needs for critically ill patients to be evacuated and accompanied by staff who could provide care and treatment enroute to the designated relocation site, in the event trained medical professionals are unavailable by the transportation services.

  The organization's policies and procedures shall outline primary and alternate means for communication with external sources for assistance. For instance, primary methods may be via regular telephone services to contact transportation companies for evacuation or reporting evacuation needs to emergency officials; whereas alternate means account for loss of power or telephone services in the local area. In this event, alternate means may include satellite phones for contacting evacuation assistance.

- *A means to shelter in place for patients, staff, and volunteers who remain in the organization.*

  Emergency plans shall include a means for sheltering all patients, staff, and volunteers who remain in the organization in the event that an evacuation cannot be executed. In certain disaster situations (such as tornadoes), sheltering in place may be more appropriate as opposed to evacuation and would require an organization to have a means to shelter in place for such emergencies. Therefore, organizations are required to have policies and procedures for sheltering in place which align with the facility's risk assessment.

  Organizations are expected to include in their policies and procedures the criteria for determining which patients and staff would be sheltered in place. When developing policies and procedures for sheltering in place, organizations should consider the ability of their building(s) to survive a disaster and what proactive steps they could take prior to an emergency to facilitate sheltering in place or transferring of patients to alternate settings if their facilities were affected by the emergency. For example, if it is dangerous to evacuate or the emergency affects available sites for transfer or discharge, then the

patients would remain in the organization until it was safe to effectuate transfers or discharges. The plan should take into account the appropriate facilities in the community to which patients could be transferred in the event of an emergency. organizations shall determine their policies based on the type of emergency and the types of patients, staff, volunteers and visitors that may be present during an emergency. Based on its emergency plan, an organization could decide to have various approaches to sheltering some or all of its patients and staff.

- *A system of medical documentation that preserves patient information, protects confidentiality of patient information, and secures and maintains availability of records.*

  Organizations are required to ensure that patient records are secure and readily available to support continuity of care during emergency. This requirement does not supersede or take away any requirements found under the organization's medical records requirements, but rather, this standard adds to such policies and procedures. These policies and procedures shall also be in compliance with the Health Insurance Portability and Accountability Act (HIPAA), Privacy and Security Rules at 45 CFR parts 160 and 164, which protect the privacy and security of individual's personal health information.

- *The use of volunteers in an emergency or other emergency staffing strategies, including the process and role for integration of State and Federally designated health care professionals to address surge needs during an emergency.*

  Emergencies, whether natural disasters, man-made disasters or infectious disease outbreaks, stress healthcare systems through challenges with capacity and capability. While it is not possible to predict every scenario which could result in surge situations, healthcare facilities shall have policies and procedures which include emergency staffing strategies and plan for emergencies. These strategies encompass procedures to preserve the healthcare system while continuing to provide care for all patients, at the appropriate level. organizations shall have policies which address their ability to respond to a surge in patients; these policies and procedures shall be aligned with the organizations HVA and should include planning for EIDs.

  Surge Planning

  In most circumstances, staffing strategies and surge planning surrounding natural disasters, such as hurricanes, are generally event-specific and focus on evacuations, transfers, and staffing assistance from areas which are not impacted by the emergency.

  Infectious diseases may rise to the level of pandemic, causing severe impact on response and staffing strategies within the healthcare system. The primary goals in planning for infectious disease pandemics are to: reduce morbidity and mortality, minimize disease transmission, protect healthcare personnel, and preserve healthcare system functioning.

Organizations are encouraged to consider development of policies and procedures that could be implemented during an emergency to reduce non-essential healthcare visits and slow surge within the facility, such as:

- *Instructing patients to use available advice lines, patient portals, and/or on-line self-assessment tools;*
- *Call options to speak to an office/clinic staff and identification of staff to conduct telephonic interactions with patients;*
- *Development of protocols so that staff can triage and assess patients quickly;*
- *Determine algorithms to identify which patients can be managed by telephone and advised to stay home, and which patients will need to be sent for emergency care or come to your facility.*

Medical and Nonmedical Volunteers

If organizations use volunteers as part of their emergency staffing strategy, policies and procedures should clearly outline what type of volunteers would be accepted during an emergency and what role these volunteers might play. For example, an organization might decide to use Red Cross Volunteers to assist in directing incoming patients during a surge situation.

Emergency staffing strategy policies and procedures should outline how the organization would ensure healthcare professionals used for emergency staffing are credentialed, licensed (as applicable) or able to provide medical support within the facility in accordance with any state and federal laws.

Organizations have flexibility in determining how best to utilize volunteers during an emergency as long as such utilization is in accordance with state law, state scope of practice rules, and facility policy. These may also include federally designated health care professionals, such as Public Health Service (PHS) staff, National Disaster Medical System (NDMS) medical teams, Department of Defense (DOD) Nurse Corps, Medical Reserve Corps (MRC), or personnel such as those identified in federally designated Health Professional Shortage Areas (HPSAs) to include licensed primary care medical, dental, and mental/behavioral health professionals. Organizations are also encouraged to collaborate with State-established volunteer registries, and where possible, State-based Emergency System for Advanced Registration of Volunteer Health Professionals (ESAR-VHP).

Organizations are expected to include in its emergency plan a method for contacting off-duty staff during an emergency and procedures to address other contingencies in the event staff are not able to report to duty which may include, but are not limited to, utilizing staff from other facilities and state or federally-designated health professionals.

- *The development of arrangements with other organizations or other providers to receive patients in the event of limitations or cessation of operations to maintain the continuity of services to organization patients.*

  Organizations should consider all needed arrangements (written transfer agreements or contracted arrangements) for the transfer of patients during an evacuation. For example, if an organization is required to evacuate, policies and procedures should address what facilities are nearby and outside the area of disaster which could accept the organization's patients. Additionally, the policies and procedures and facility agreements should include pre-arranged agreements for transportation between the facilities. The arrangements should be in writing, such as Memorandums of Understanding (MOUs) and Transfer Agreements, in order to demonstrate compliance.

- *The role of the organization under a waiver declared by the Secretary, in accordance with section 1135 of the Social Security Act (the Act), in the provision of care and treatment at an alternate care site identified by emergency management officials.*

  The requirement under the emergency program is that facilities shall develop and implement policies and procedures which describe the organization's role in providing care at an Alternate Care Site (ACS) during emergencies. It is expected that state or local emergency management officials might designate such ACS's, and would plan jointly with local facilities on issues related to staffing, equipment and supplies at such alternate sites. This requirement encourages providers to collaborate with their local emergency officials in such proactive planning to allow an organized and systematic response to assure continuity of care even when services at their facilities have been severely disrupted.

  Policies and procedures shall specifically address the organization's role in emergencies where the Secretary waives or modifies certain statutory and regulatory requirements for healthcare facilities in response to emergencies under section 1135 of the Act related to the provision of care at an alternate care site identified by emergency officials.

  More guidance regarding 1135 waivers may be found in Appendix Z of the CMS State Operations Manual and at ASPR TRACIE Healthcare Emergency Preparedness Information Gateway.

Emergency Preparedness Communication Plan

The organization shall develop and maintain an emergency preparedness communication plan that complies with Federal, State, and local laws and shall be reviewed and updated at least annually. The communication plan shall include all of the following:

- *Names and contact information for:*
  - *Staff.*
  - *Entities providing services under arrangement.*

- *Patients' physicians.*
- *Other organizations and hospitals.*
- *Volunteers.*

Organizations have discretion in the formatting of this information, however it should be readily available and accessible to leadership, at a minimum, to the individual(s) designated as the emergency preparedness coordinator or person(s) responsible for the facility's emergency preparedness program and management during an emergency event. Organizations which utilize electronic data storage should be able to provide evidence of data back-up with hard copies or demonstrate capability to reproduce contact lists or access this data during emergencies. All contact information shall be reviewed and updated at least annually.

Contact information contained in the communication plan shall be accurate and current. Organizations shall update contact information for incoming new staff and departing staff throughout the year and any other changes to information for those individuals and entities on the contact list.

- *Contact information for the following:*
  - *Federal, State, tribal, regional, and local emergency preparedness staff.*
  - *Other sources of assistance.*

  Emergency management officials may include, but are not limited to, emergency management agencies which may be local to the community as well as local officials who support the Incident Command System depending on the nature of the disaster (e.g. fire, police, public health, etc.). Additionally, emergency management officials also include the state public health departments and State Survey Agencies as well as federal emergency preparedness officials (FEMA, ASPR, DHS, CMS, etc.) and tribal emergency officials, as applicable. The communications plan does not specifically require the organization to have an individual contact for emergency management staff/agencies. For instance, a state emergency management agency may have a specific phone line or contact method and not a specific individual person.

  Organizations have discretion in the formatting of this information, however it should be readily available and accessible to leadership during an emergency event. Organizations are encouraged but not required to maintain these contact lists both in electronic format and hard-copy format in the event that network systems to retrieve electronic files are not accessible. All contact information shall be reviewed and updated at least annually.

- *Primary and alternate means for communicating with the following:*
  - *Organization's staff.*
  - *Federal, State, tribal, regional, and local emergency management agencies.*

Facilities should identify their primary and alternate means of communication in their emergency preparedness communication plan. For instance, a primary means of communication may be hard wire lines, whereas the facilities alternate means (given interruption of primary means) may be cellular phones.

- *A method for sharing information and medical documentation for patients under the organization's care, as necessary, with other health care providers to maintain the continuity of care.*

- *A means, in the event of an evacuation, to release patient information as permitted under 45 CFR 164.510(b)(1)(ii).*

- *A means of providing information about the general condition and location of patients under the facility's care as permitted under 45 CFR 164.510(b)(4).*

Organizations are required to develop a method for sharing information and medical documentation for patients under the organization's care, as necessary, with other health care providers to maintain continuity of care. Such a system shall ensure that information necessary to provide patient care is sent with an evacuated patient to the next care provider and would also be readily available for patients being sheltered in place. While the regulation does not specify timelines for delivering patient care information, organizations are expected to provide patient care information to receiving facilities during an evacuation, within a timeframe that allows for effective patient treatment and continuity of care. Organizations should not delay patient transfers during an emergency to assemble all patient reports, tests, etc. to send with the patient. Organizations should send all necessary patient information that is readily available and should include at least, patient name, age, DOB, allergies, current medications, medical diagnoses, current reason for admission (if inpatient), blood type, advance directives and next of kin/emergency contacts. There is no specified means (such as paper or electronic) for how facilities are to share the required information.

Organizations are also required to have a means, in the event of an evacuation, to release patient information as permitted under 45 CFR 164.510 and a means of providing information about the general condition and location of patients under the organization's care as permitted under 45 CFR 164.510(b)(4). Thus, organizations shall have a communication system in place capable of generating timely, accurate information that could be disseminated, as permitted under 45 CFR 164.510(b)(4), to family members and others. Organizations have the flexibility to develop and maintain their own system in a manner that best meets its needs.

HIPAA requirements are not suspended during a national or public health emergency. However, the HIPAA Privacy Rule specifically permits certain uses and disclosures of protected health information in emergency circumstances and for disaster relief purposes.

- *A means of providing information about the organization's occupancy, needs, and its ability to provide assistance, to the authority having jurisdiction or the Incident Command Center, or designee.*

  Generally, in small community emergency disasters, reporting the organization's needs will be coordinated through established processes to report directly to local and state emergency officials. Reporting needs may include but are not limited to: shortages in PPE; need to evacuate or transfer patients; requests for assistance in transport; temporarily loss of part or all facility function; and, staffing shortages. In large scale emergency disasters or pandemics, reporting of needs specific to a organization may be altered by local, state and federal public health and emergency management officials due to the potential volume of requests. Some emergency management officials at all levels of governance may require facilities to report specific data or slow reporting to manage volume. It is recommended that organizations verify their reporting requirements with their local Incident Command Structures or State Agencies.

  During widespread disasters, reporting an organization's ability to provide assistance is critical within a community. Pre-planning and collaborating with emergency officials before an emergency to determine what assistance may be necessary directly supports surge planning within a community. For instance, in preparation for a natural disaster such as a hurricane, pre-planning reporting criteria such as the organization's response--e.g. closing the outpatient services in a forecasted natural disaster--may facilitate the Incident Command as they would be aware of the operating status of the organization. Reporting the ability to provide assistance would also include pre-planning with public health and emergency officials in the local community to make them aware of what capabilities are available within the specific facility, e.g. number of beds, critical care equipment, staffing, etc.

  Organizations shall also have a means for providing information about their occupancy. Occupancy reporting is considered, but not limited to, reporting the number of patients currently at the organization receiving treatment and care or the organization's occupancy percentage. The organization should consider how its occupancy affects its ability to provide assistance. The types of "needs" an organization may have during an emergency and should communicate to the appropriate authority would include but is not limited to, shortage of provisions such as food, water, medical supplies, assistance with evacuation and transfers, etc.

Emergency Preparedness Training and Testing Program

The organization shall develop and maintain an emergency preparedness training and testing program that is based on its emergency plan, HVA, and communications plan. The training and testing program shall be reviewed and updated at least annually.

- *Training Program – The organization shall do all of the following:*
  - *Initial training in emergency preparedness policies and procedures, to all new and existing staff, individuals providing services under arrangement, and volunteers, consistent with their expected roles.*

- *Provide emergency preparedness training at least every annually.*
- *Maintain documentation of the training.*
- *Demonstrate staff knowledge of emergency procedures.*
- *If the emergency preparedness policies and procedures are significantly updated, the organization shall conduct training on the updated policies and procedures.*

Organizations are required to provide initial training in emergency preparedness policies and procedures that are consistent with their roles in an emergency to all new and existing staff, individuals providing services under arrangement, and volunteers (staff includes licensed providers). This includes individuals who provide services on a per diem basis such as agency nursing staff and any other individuals who provide services on an intermittent basis and would be expected to assist during an emergency.

The training provided by the organization shall be based on the organization's HVA, policies and procedures, as well as the communication plan. The intent is that staff, volunteers and individuals providing services at the organization are familiar and trained on the organization's processes for responding to an emergency. Training should include individual-based response activities in the event of a natural disasters, such as what the process is for staff in the event of a forecasted hurricane. It should also include the policies and procedures on how to shelter-in-place or evacuate. Training should include how the organization manages the continuity of care to its patient population, such as triage processes and transfer/discharge during mass casualty or surge events. Training for staff should mirror the organization's emergency plan and should include training staff on procedures that are relevant to the hazards identified. For example, for EID's this may include proper use of PPE, assessing needs of patients and how to screen patients and provide care based on the facility's capacity and capabilities and communications regarding reporting and providing information on patient status with caregiver and family members. Facilities should provide initial emergency training during orientation (or shortly thereafter) to ensure initial training is not delayed.

Organizations shall provide training on their emergency plan at least annually. Initial and subsequent training should be modified as needed and if the organization updates the policies and procedures to include but not limited to incorporating any lessons learned from the most recent exercises and real-life emergencies that occurred in and during the review of the facility's emergency program, it would be expected the facility updated the training as well. For example, subsequent training could include training staff on new evacuation procedures that were identified as a best practice and documented in the facility "After Action Report" (AAR) during the last emergency drill and were incorporated into the emergency plan during the program's review.

It is up to the organization to decide what level of training each staff member will be required to complete based on an individual's involvement or expected role during an emergency. In addition, depending on specific staff duties during an emergency, an organization may determine that documented external training is sufficient to meet some or all of the organization's training requirements.

Organizations shall also be able to demonstrate additional training when the emergency plan is significantly updated. organizations which may have changed their emergency plan should plan to conduct initial training to all staff on the new or revised sections of the plan. If an organization determines the need to add additional policies and procedures based on a new risk identified in the organization's HVA, the organization shall train all staff on the new policies and procedures and the staff responsibilities.

Organizations shall maintain documentation of the initial and subsequent training for all staff. The documentation shall include the specific training completed as well as the methods used for demonstrating knowledge of the training program. Organizations have flexibility in ways to demonstrate staff knowledge of emergency procedures. The method chosen is likely based on the training delivery method. For example: computer-based or printed self-learning packets may contain a test to demonstrate knowledge. If organizations choose instructor-led training, a question-and-answer session could follow the training. Regardless of the method, organizations shall maintain documentation that training was completed, and that staff are knowledgeable of emergency procedures.

- *The organization shall conduct exercises to test the emergency plan at least twice per year. The organization shall do the following:*
    - *Participate in an annual full-scale exercise that is community-based; or*
        - *When a community-based exercise is not accessible, conduct an annual individual, facility-based functional exercise; or.*
        - *If the organization experiences an actual natural or man-made emergency that requires activation of the emergency plan, the organization is exempt from engaging in its next required full-scale community-based or individual, facility-based functional exercise following the onset of the emergency event.*
    - *Conduct an annual additional exercise, that may include, but is not limited to the following:*
        - *A second full-scale exercise that is community-based or an individual, facility-based functional exercise; or*
        - *A mock disaster drill; or*
        - *A tabletop exercise or workshop that is led by a facilitator and includes a group discussion, using a narrated, clinically relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan.*
    - *Analyze the organization's response to and maintain documentation of all drills, tabletop exercises, and emergency events, and revise the organization's emergency plan, as needed.*

An organization's testing exercises require they be based on the individual organization's HVA, policies and procedures, and communication plan and support the patient population it serves. Testing exercises should vary, based on the organization's requirements, by cycles and frequency of testing. The intent is that testing exercise provide a comprehensive testing and training for staff, volunteers, and individuals providing services under arrangement as well community partners. Testing exercises shall be based on the organization's identified hazards, to include natural or man-made disasters. This should include EID outbreaks. Organizations are expected to test their response to emergency events as outlined within their comprehensive emergency preparedness program. Testing exercises should not test the same scenario year after year or the same response processes. The intent is to identify gaps in the organization's emergency program as it relates to responding to various emergencies and ensure staff are knowledgeable on the organization's program. In the event gaps are identified, organizations should update their emergency programs as outlined within the requirements for After-Action Report (AAR).

For the purposes of this requirement, a full-scale exercise is defined and accepted as any operations-based exercise (drill, functional, or full-scale exercise) that assesses an organization's functional capabilities by simulating a response to an emergency that would impact the organization's operations and their given community. State and local agencies (emergency management agencies and health departments) and some regional entities, such as healthcare coalitions may conduct an annual full-scale, community-based exercise in an effort to more broadly assess community-wide emergency planning, potential gaps, and the integration of response capabilities in an emergency. Organizations are expected to contact their local and state agencies and healthcare coalitions, where appropriate, to determine if an opportunity exists and determine if their participation would fulfill this requirement.

Organizations which determine that a full-scale community-based exercise will be planned for the organization's exercise requirement shall also ensure that the exercise scenario developed is identified within the facility's risk assessment. Organizations shall ensure that participation in the exercise would adequately test the facility's emergency program (specifically its policies and procedures and communication plan). Organizations that are not able to identify a full-scale community-based exercise, can instead fulfill this part of their requirement by either conducting an individual facility-based exercise, documenting an emergency that required them to fully activate their emergency plan, or by conducting a smaller community-based exercise with other nearby facilities.

While the regulations do not specify a minimum number of staff, or the roles of staff in the exercises, it is strongly encouraged that organization leadership and department heads participate in exercises. If an exercise is conducted at the individual facility-based level and is testing a particular clinical area, staff who work in this clinical area should participate in the exercise for a clear understanding of their roles and responsibilities. Organizations that conduct an individual facility-based exercise will need to demonstrate how it addresses any risk(s) identified in its risk assessment.

Organizations are also required to conduct a second annual exercise of their choice, which can be a second full-scale exercise that is community based or an individual facility-based functional exercise, a mock disaster drill, or a tabletop exercise (TTX) or workshop. TTX's or workshops

are expected to be group discussions led by a facilitator. The intent behind TTX's or workshops is to test an exercise based on the facility's risk assessment.

After-Action Reviews

Organizations are responsible for documenting their compliance and ensuring that this information is available for review at any time for a period of no less than three (3) years. Organizations should also document the lessons learned following their tabletop and full-scale exercises and real-life emergencies and demonstrate that they have incorporated any necessary improvements in their emergency preparedness program. Organizations shall complete an after-action review process to help them develop an actionable after action report (AAR). The process includes a roundtable discussion that includes leadership, department leads and critical staff who can identify and document lessons learned and necessary improvements in an official AAR. The AAR, at a minimum, should determine 1) what was supposed to happen; 2) what occurred; 3) what went well; 4) what the organization can do differently or improve upon; and 5) a plan with timelines for incorporating necessary improvement. Lastly, organizations that are a part of a healthcare system, can elect to participate in their system's integrated and unified emergency preparedness program and exercises. However, those that do will still be responsible for documenting and demonstrating their individual organization's compliance with the exercise and training requirements.

Exemption Based on Actual Emergency

An actual emergency event or response of sufficient magnitude that requires activation of the relevant emergency plans meets the full-scale exercise requirement and exempts the organization from engaging in their next required community-based full-scale exercise or individual, facility-based exercise following the actual event; organizations shall be able to demonstrate this through written documentation. An actual event or response that requires activation of emergency plans does not exempt an organization from conducting its annual exercise of choice (another full-scale/individual facility based; mock disaster drill; or TTX/workshop).

For example, if an organization completed the full-scale exercise in January 2020 and is scheduled to conduct an exercise of choice in November 2020, but experiences an actual emergency in March 2020 which required activation of its emergency plan, the organization is exempt from the next required full-scale exercise in January 2021, but shall complete the exercise of choice. If the organization conducted an exercise of choice prior to the actual emergency and had a full-scale exercise scheduled for November 2020, then the organization would be exempt from that full-scale exercise as it would not be the exercise of choice.

Organizations shall document that they had activated their emergency program based on an actual emergency. Documentation may include but is not limited to: a section 1135 waiver issued to the organization (time limited and event-specific); documentation alerting staff of the emergency; documentation of facility closures; meeting minutes which addressed the time and event specific information. The organization shall also complete an after action review and integrated corrective actions into their emergency preparedness program.

Emergency and Standby Power Systems

The organization shall implement emergency and standby power systems based on the emergency plan set forth in PE.6 (SR.1).

- *The generator shall be located in accordance with the location requirements found in the Health Care Facilities Code (NFPA 99 and Tentative Interim Amendments TIA 12-2, TIA 12-3, TIA 12-4, TIA 12-5, and TIA 12-6), Life Safety Code (NFPA 101 and Tentative Interim Amendments TIA 12-1, TIA 12-2, TIA 12-3, and TIA 12-4), and NFPA 110, when a new structure is built or when an existing structure or building is renovated.*

- *The organization shall implement emergency power system inspection, testing, and maintenance requirements found in the Health Care Facilities Code, NFPA 110, and the Life Safety Code.*

- *Organizations that maintain an onsite fuel source to power emergency generators shall have a plan for how it will keep emergency power systems operational during the emergency, unless it evacuates.*

  This would include maintaining fuel onsite to maintain generator operation or it could include making arrangements for fuel delivery for an emergency event. If fuel is to be delivered during an emergency event, planning should consider limitations and delays that may impact fuel delivery during an event. In addition, planning should ensure that arranged fuel supply sources will not be limited by other community demands during the same emergency event. In instances when an organization maintains onsite fuel sources and plans to evacuate during an emergency, a sufficient amount of onsite fuel should be maintained to keep the EES operational until such time the building is evacuated.

Unified and Integrated Emergency Preparedness Program

If an organization is part of a healthcare system consisting of multiple separately certified healthcare facilities that elects to have a unified and integrated emergency preparedness program, the organization may choose to participate in the healthcare system's coordinated emergency preparedness program. If elected, the unified and integrated emergency preparedness program shall do all of the following:

- *Demonstrate that each separately certified facility within the system actively participated in the development of the unified and integrated emergency preparedness program.*

- *Be developed and maintained in a manner that takes into account each separately certified facility's unique circumstances, patient populations, and services offered.*

- *Demonstrate that each separately certified facility is capable of actively using the unified and integrated emergency preparedness program and is in compliance with the program.*

- *Include a unified and integrated emergency plan that meets the requirements of PE.6 (SR.1b), PE,6 (SR.1c), and PE.6 (SR.1d). The unified and integrated emergency plan shall also be based on and include:*

- *A documented community-based risk assessment, utilizing an all-hazards approach.*
- *A documented individual facility-based risk assessment for each separately certified facility within the health system, utilizing an all-hazards approach.*

- *Include integrated policies and procedures that meet the requirements set forth in PE.6 (SR.2), a coordinated communication plan and training and testing programs that meet the requirements of PE.6 (SR.3) and PE.6 (SR.4), respectively.*

If a healthcare system elects to have a unified emergency preparedness program, the integrated program shall demonstrate that each separately certified facility within the system that elected to participate in the system's integrated program actively participated in the development of the program. Therefore, each organization should designate personnel who will collaborate with the healthcare system to develop the plan. The unified and integrated plan should include documentation that verifies each facility participated in the development of the plan.

A unified program shall be developed and maintained in a manner that takes into account the unique circumstances, patient populations, and services offered at each facility participating in the integrated program.

Each separately certified facility shall be capable of demonstrating during a survey that it can effectively implement the emergency preparedness program and demonstrate compliance with all emergency preparedness requirements at the individual facility level. Compliance with the emergency preparedness requirements is the individual responsibility of each separately certified facility.

The unified emergency preparedness program shall include a documented community– based risk assessment and an individual facility-based risk assessment for each separately certified facility within the health system, utilizing an all-hazards approach. This is especially important if the facilities in a healthcare system are located across a large geographic area with differing weather conditions.

The unified program shall have a coordinated communication plan and training and testing program. For example, if the unified emergency program incorporates a central point of contact at the "system" level who assists in coordination and communication, such as during an evacuation, each facility shall have this information outlined within its individual plan. The training and testing program in a unified emergency preparedness program shall be developed considering all of the requirements of each facility type. For example, if a healthcare system includes, hospitals, LTC facilities, ESRD facilities and ASCs, then the unified training and testing programs shall meet all of the specific regulatory requirements for each of these facility types.

If the system decides to develop a unified and integrated training and testing program, the training and testing shall be developed based on the community and facility-based hazards assessments at each facility that is participating in the unified emergency preparedness program. Each facility shall maintain individual training records of staff and records of all required training exercises.

Portions of the above interpretive guidelines were derived from interpretive guidance provided by HHS ASPR TRACIE and Appendix Z of the CMS State Operations Manual. For more detailed guidance see https://files.asprtracie.hhs.gov/documents/aspr-tracie-cms-ep-rule-cah-requirements.pdf .

Transplant Programs

Transplant programs must be actively involved in their hospital's emergency planning and programming under PE.6 (SR.7). The transplant program's emergency preparedness plans must be included in the hospital's emergency plans. All of the Medicare-approved transplant programs are located within certified hospitals and, as part of the hospital, must be included in the hospital's emergency preparedness plans. The transplant program needs to be involved in the hospital's risk assessment because there may be risks to the transplant program that others in the hospital may not be aware of or appreciate. However, most of the risk assessment of the hospital and transplant program would be the same since the transplant program is located within the hospital. Therefore, a separate risk assessment would be unnecessary and overly burdensome.

Organizations which have transplant programs must include within their emergency planning and preparedness process one representative, at minimum, from the transplant program. If an organization has multiple transplant programs, each program must have at least one representative who is involved in the development and maintenance of the organization's emergency preparedness process. The organization must include the transplant program in its emergency preparedness plan policies and procedures, communication plans, as well is the training and testing programs.

NFPA 99

Organizations previously complying with Chapter 12 of NFPA 99, Health Care Facilities Code, 2012 edition may continue to utilize NFPA 99 Chapter 12 provided that compliance with the requirements of PE.6 are met. Chapter 12 can also be used as a resource in the development, implementation and maintenance of an organization's emergency preparedness plan.

Surveyor Guidance:

- *Interview organization leadership and ask them to describe the facility's emergency preparedness program. NOTE: In this guidance "leadership" can refer to the person responsible for emergency management.*
- *Ask to see the facility's written policy and documentation on the emergency preparedness program.*
- *Verify the organization's program was developed based on an all-hazards approach by asking their leadership to describe how the facility used an all-hazards approach when developing its program.*
- *Verify the organization has an emergency preparedness plan by asking to see a copy of the plan.*

- *Ask facility leadership to identify the hazards (e.g. natural, man-made, facility, geographic, etc.) that were identified in the facility's HVA and how the HVA was conducted.*

- *Review the plan to verify it contains all of the required elements.*

- *Verify that the plan is reviewed and updated annually by looking for documentation of the date of the review and updates that were made to the plan based on the review.*

- *Ask to see the written documentation of the facility's risk assessments and associated strategies.*

- *Interview the organization leadership and ask which hazards (e.g. natural, man-made, facility, geographic) were included in the facility's risk assessment, why they were included and how the risk assessment was conducted.*

- *Verify the HVA is facility-based and community-based and based on an all-hazards approach specific to the geographic location of the facility and encompasses potential hazards, such as EIDs.*

NOTE: Surveyors are not expected to analyze an organization's HVA to determine whether the identified risks are appropriate. Surveyors may take into consideration the geographic location and review the remaining standards to determine that the facility has addressed the hazards within their HVA through their policies and procedures. However, the intent is that surveyors review the HVA to determine if the facility has a HVA which is facility-based and also community-based. The organization's HVA should describe a process facilities use to assess and document potential hazards that are likely to impact their geographical region, community, facility and patient population. The ranking of priority of the hazards and the format of the HVA is at the discretion and expertise of the organization.

- *Interview leadership and ask them to describe the following:*

    - *The organization's patient populations that would be at risk during an emergency event;*

    - *Strategies the organization has put in place to address the needs of at-risk or vulnerable patient populations;*

    - *Services that the organization would be able to provide during an emergency and any plans to address services needed that cannot be provided by the facility during an emergency as part of continuity of operations and services.*

    - *How the organization plans to continue operations during an emergency;*

    - *Delegations of authority and succession plans.*

- *Verify that all of the above are included in the written emergency plan.*

- *If the organization has delegations and succession plans which identifies roles and responsibilities over individual organization staff names (e.g. Safety Officer = Emergency Department Charge Nurse or Pharmacy Department Lead), identify the individual who would be designated in one of the roles and interview the individual asking them to describe their role based on the organization's emergency program.*

- *Interview organization leadership and ask them to describe their process for ensuring cooperation and collaboration with local, tribal, regional, State, and Federal emergency preparedness officials' efforts to ensure an integrated response during a disaster or emergency situation.*

- *Review the written policies and procedures which address the organization's emergency plan and verify the following:*

  - *Policies and procedures were developed based on the facility-and community-based risk assessment and communication plan, utilizing an all-hazards approach.*

- *Ask to see documentation that verifies the policies and procedures have been reviewed and updated at least annually. Format is at the discretion of the organization.*

- *Verify the emergency plan includes policies and procedures for the provision of subsistence needs including, but not limited to, food, water and pharmaceutical supplies for patients and staff by reviewing the plan. This includes review of the organization's 96-hour sustainability assessment.*

- *Verify the emergency plan includes policies and procedures to ensure adequate alternate energy sources, including emergency power necessary to maintain:*

  - *Temperatures to protect patient health and safety and for the safe and sanitary storage of provisions;*

  - *Emergency lighting; and,*

  - *Fire detection, extinguishing, and alarm systems.*

- *Verify the emergency plan includes policies and procedures to provide for sewage and waste disposal.*

- *Ask staff to describe and/or demonstrate the tracking system used to document locations of patients and staff.*

  - *Verify that the tracking system is documented as part of the facilities' emergency plan policies and procedures.*

- *Review the emergency plan to verify it includes policies and procedures for safe evacuation from the organization and that it includes all of the required elements.*

- *Ask staff to describe how they would handle a situation in which a patient refused to evacuate.*

- *Verify the emergency plan includes policies and procedures for how it will provide a means to shelter in place for patients, staff and volunteers who remain in the organization.*

- *Review the policies and procedures for sheltering in place and evaluate if they aligned with the organization's emergency plan and HVA.*

- *Ask to see a copy of the policies and procedures that documents the medical record documentation system the organization has developed to preserve patient information, protects confidentiality of patient information, and secures and maintains availability of records.*

- *Ask organization leadership to explain their staffing strategies. Do they use volunteers? If, no volunteers are used, does the organization have other emergency staffing strategies?*

- *Verify the organization has included policies and procedures for the use of volunteers and other staffing strategies in its emergency plan.*

- *Verify that the organization's program includes a policy and procedure which addresses surge needs during an emergency.*

- *Ask to see copies of the arrangements and/or any agreements the organization has with other facilities to receive patients in the event the organization is not able to care for them during an emergency.*

- *Ask organization leadership to explain the arrangements in place for transportation in the event of an evacuation.*

- *Verify the organization has included policies and procedures in its emergency plan describing the facility's role in providing care and treatment at alternate care sites under an 1135 waiver.*

NOTE: This policy and procedure requirement does not require a facility to have an 1135 waiver on hand at the time of the survey as such waivers are established or granted by CMS only during a declared emergency period. Section 1135 waivers by nature are time limited.

- *Verify that the organization has a written communication plan by asking to see the plan. Ask to see evidence that the plan has been reviewed (and updated as necessary) at least annually.*

- *Ask organization leadership or the designee responsible for the emergency program to verbally explain how they are to collaborate with Federal, State and local officials to ensure their communication plan complies with the Federal, State and local requirements.*

- *Verify that all required contacts are included in the communication plan by asking to see a list of the contacts with their contact information. Verify that all contact information has been reviewed and updated at least annually by asking to see evidence of the review.*

- *Verify the communication plan includes primary and alternate means for communicating with facility staff, Federal, State, tribal, regional and local emergency management agencies.*

- *Ask to see the communications equipment or communication systems listed in the plan.*

- *Verify the communication plan includes a method for sharing information and documentation for patients under the organization's care, as necessary, with other healthcare providers to maintain the continuity of care by reviewing the communication plan.*

- *Verify the organization has developed policies and procedures that address the means the organization will use to release patient information to include the general condition and location of patients, by reviewing the communication plan.*

- *Verify the communication plan includes a means of providing information about the organization's needs, and its ability to provide assistance, to the authority having jurisdiction, the Incident Command Center, or designee by reviewing the communication plan. Also verify if the communication plan includes a means of providing information about their occupancy.*

- *Verify that the organization has a written training and testing program.*

- *Refer back to the facility's HVA to determine if the training and testing program is reflecting risks and hazards identified within the facility's program.*

- *Verify the program has been reviewed and updated at least annually.*

- *Ask for copies of the organization's initial and annual emergency preparedness trainings and training offerings.*

- *Verify the organization has a process to demonstrate staff knowledge of emergency procedures.*

- *Interview various staff and ask questions regarding the organization's initial and subsequent training to verify staff knowledge of emergency procedures.*

- *Review a sample of staff training files to verify staff have received initial and subsequent emergency preparedness training.*

- *Ask organization leadership to explain the participation of management and staff during scheduled exercises.*

- *Ask to see documentation of the annual exercises of choice and full-scale exercises (which may include, but is not limited to, the exercise plan, the AAR, and any additional*

documentation used by the facility to support the exercise). Documentation shall demonstrate the organization has conducted the exercises described in the requirements.

- *Ask to see the documentation of the organization's efforts to identify a full-scale community-based exercise if they did not participate in one (i.e. date and personnel and agencies contacted and the reasons for the inability to participate in a community-based exercise).*
- *Ask to see documentation of any real events, including AAR for the event(s).*
- *Request documentation of the organization's analysis and response and how the organization updated its emergency program based on this analysis.*
- *Verify that the organization has the required emergency and standby power systems to meet the requirements of the organization's emergency plan and corresponding policies and procedures.*
- *Review the emergency plan for "shelter in place" and evacuation plans.*
    - *Based on those plans, does the organization have emergency power systems or plans in place to maintain safe operations while sheltering in place?*
- *For organizations which are under construction or have existing buildings being renovated, verify the facility has a written plan to relocate the EPSS by the time construction is completed.*
- *For organizations with permanently attached generators:*
    - *For new construction that takes place between November 15, 2016, and is completed by November 15, 2017, verify the generator is located and installed in accordance with NFPA 110 and NFPA 99 when a new structure is built or when an existing structure or building is renovated. The applicability of both NFPA 110 and NFPA 99 addresses only new, altered, renovated or modified generator locations.*
- *Verify that organizations with an onsite fuel source maintains it in accordance with NFPA 110 for their generator and have a plan for how to keep the generator operational during an emergency, unless they plan to evacuate.*
- *Verify whether or not the organization has opted to be part of its healthcare system's unified and integrated emergency preparedness program. Verify that they are by asking to see documentation of its inclusion in the program.*
    - *Ask to see documentation that verifies the organization was actively involved in the development of the unified emergency preparedness program.*
    - *Ask to see documentation that verifies the organization was actively involved in the annual reviews of the program requirements and any program updates.*

- *Ask to see a copy of the entire integrated and unified emergency preparedness program and all required components (emergency plan, policies and procedures, communication plan, training and testing program).*

- *Ask organization leadership to describe how the unified and integrated emergency preparedness program is updated based on changes within the healthcare system such as when facilities enter or leave the system.*

Transplant Programs

- *If the organization has a transplant program, verify the transplant program has emergency preparedness policies and procedures*

  - *Verify that the transplant program's emergency preparedness policies and procedures are included in the hospital's emergency preparedness program.*

- *Verify the hospital has written documentation to demonstrate that a representative of each transplant program participated in the development of the emergency program.*

- *Ask to see documentation of emergency protocols that address transplant protocols that include the hospital, the transplant program, and the associated OPOs.*

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 organization owned, 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 shall be maintained to ensure an acceptable level of safety and quality. This shall include provisions for cybersecurity of medical equipment. For additional guidance on cybersecurity issues see:

- *HHS 405(d) Aligning Health Care Industry Security Approaches - https://405d.hhs.gov/*
- *NIST Cybersecurity Framework - https://www.nist.gov/cyberframework*

The Medical Equipment Management System shall apply to all medical equipment, regardless of ownership or hospital department responsible for the medical equipment.

In order to ensure an acceptable level of safety and quality, the organization shall 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 organization shall make adequate provisions to ensure the availability and reliability of equipment needed for its operations and services. Equipment includes 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 medical equipment shall be inspected and tested for performance and safety before initial use and after major repairs or upgrades.

All medical equipment shall be inspected, tested, and maintained to ensure their safety, availability, and reliability. Medical 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 medical equipment maintenance programs and activities shall be qualified. The organization shall maintain records of hospital personnel qualifications and is able to demonstrate how it assures all personnel, including contracted personnel, are qualified.

All medical equipment maintenance policies, procedures and programs, as well as specific medical 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 medical equipment maintenance by organization leadership.

Organizations comply with this regulation when they follow the manufacturer-recommended maintenance activities and schedule. Organizations may choose to perform maintenance more frequently than the manufacturer recommends but shall use the manufacturer-recommended maintenance activities in such cases. When medical equipment is maintained in accordance with the manufacturer's recommendations, the organization shall 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. Organizations that choose to employ alternate maintenance activities and/or schedules shall develop, implement, and maintain a documented AEM program to minimize risks to patients and others in the hospital associated

with the use of medical equipment. The AEM program shall be based on nationally recognized standards of practice and guidelines for 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. 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 medical equipment maintenance without following the equipment manufacturer recommendations shall 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.

The organization shall maintain records of the qualifications of hospital personnel who make decisions on placing equipment in an AEM program and shall 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 organization shall 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.

An organization is expected to identify any equipment in its AEM program which is "critical equipment," e.g., biomedical equipment for which there is a risk of serious injury or death to a patient or staff person should the equipment fail. Surveyors shall focus their review of an organization's AEM program on critical equipment in that program and the organization's documentation of the factors and evidence it considered in developing an AEM strategy for that equipment.

Factors for an organization 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 mis-calibrated scale in an adult internal medicine outpatient clinic might not present significant risk of harm. However, a mis-calibrated 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 shall be considered, since different types of equipment present different combinations of severity of potential harm and likelihood of failure. The organization 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 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 organization shall comply with these other federal or state requirements.*

- *Other CoP 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.*
    - *Imaging/radiologic equipment, whether used for diagnostic or therapeutic purposes, is governed by 42 CFR 482.26(b)(2) and shall 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 organization's own or its contractor's records, or available publicly from nationally recognized sources, is not available to support a risk-based determination shall not be immediately included in the AEM program. New equipment shall 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 manufacturer's recommendations, the organization shall 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. An organization 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 shall be explained and documented in the AEM program.

In developing AEM maintenance strategies organizations 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 organization 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 shall 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 shall 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 shall 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 organization 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 shall be documented in accordance with QM.8, as part of the organization's required tracking of patient safety-related incidents. However, there is no requirement to include operator failures in equipment maintenance documentation.)*

When the organization has multiple identical equipment items, the documentation may be generic to that type of equipment, except that documentation of maintenance activities performed shall be specific to each item of equipment.

Evaluating Safety and Effectiveness of the AEM Program

The organization shall have policies and procedures which address the effectiveness of its AEM program. In evaluating the effectiveness of the AEM program the organization 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 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 organization is using an AEM program, the equipment managed through that program shall be readily separately identifiable as subject to AEM. Critical equipment, whether in an AEM program or not, shall 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.*

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 organization 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 organization's routine and preventive medical equipment maintenance schedules to determine that ongoing maintenance inspections are performed and that necessary repairs are completed.

Verify that the organization has developed and implemented a comprehensive plan to ensure that the safety and wellbeing of patients are assured during emergency situations.

Interview personnel in charge of facility, supplies and equipment maintenance to verify:

- *The organization has identified supplies and equipment that are likely to be needed in emergency situation.*
- *The organization 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 organization 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 organization employs an AEM program, is equipment in this program readily identified?

- *Determine if the organization 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 organization 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 organization 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 organization 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 organization'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 organization has documented maintenance activities and frequencies for all equipment included in the AEM program.*

- *Verify the organization is evaluating the safety and effectiveness of the AEM program.*

- *If there is equipment on the inventory the organization 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 organization 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 shall 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 organization is evaluating the safety and effectiveness of the AEM maintenance activities for this equipment and taking corrective actions when needed.*

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.1a The Utility Management System shall have a water management program to reduce the risk of growth and spread of legionella and other opportunistic pathogens in building water systems.

SR.2 The Utility Management System shall provide for a process to evaluate critical operating components, to include, but not limited to cybersecurity issues.

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. The organization shall implement emergency power system inspection and testing requirements found in the Health Care Facilities Code, NFPA 110, and the Life Safety Code.

SR.7 The Utility Management System shall require proper ventilation, light and temperature controls in patient care areas, 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.

SR.8a Emergency lighting standards shall comply with Section 7.9 of the Life Safety Code, 101-2012, and applicable references, such as, NFPA-99, 2012: Health Care Facilities, for emergency lighting and emergency power.

SR.8b NFPA 99, 2012 6.3.2.2.11, Battery-Powered Lighting Units, shall apply to new and existing healthcare facilities and shall be installed in accordance with NFPA 70, National Electric Code, 2011 edition.

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 organization shall 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 organization 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.

The organization shall have processes in place to ensure the cybersecurity of utility and building systems. For additional guidance on cybersecurity issues see:

- *HHS 405(d) Aligning Health Care Industry Security Approaches - https://405d.hhs.gov/*
- *NIST Cybersecurity Framework - https://www.nist.gov/cyberframework*

Organizations shall have water management plans and documentation that, at a minimum, ensure that the organization:

- *Conducts a facility risk assessment to identify where Legionella and other opportunistic waterborne pathogens (e.g., Pseudomonas, Acinetobacter, Burkholderia, Stenotrophomonas, nontuberculous mycobacterial, and fungi) could grow and spread in the facility water system.*

- *Develops and implements a water management program that considers the recommendations of the current edition of ASHRAE 188, Legionellosis: Risk Management for Building Water Systems and the CDC Legionella Toolkit.*

- *Specifies testing protocols and acceptable ranges for control measures and document the results of testing and corrective actions taken when control limits are not maintained.*

- *Maintains compliance with other applicable Federal, State and local requirements.*

There shall be proper ventilation in at least the following areas:

- *Areas using formaldehyde, ethylene oxide, nitrous oxide, glutaraldehyde, 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 shall 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 (as defined in NFPA 99-2012).*

Temperature, humidity, and airflow in the anesthetizing locations shall be maintained within acceptable standards to inhibit microbial growth, reduce the risk of infection, control odor and promote patient comfort.

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 organization policy.

The organization shall 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 organization 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 organization 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 organization'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 organization's routine and preventive maintenance schedules to determine that ongoing maintenance inspections are performed, and that necessary corrective/preventive action(s) are taken.

The organization 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.*

- *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 organization 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 486. This 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 organization to initiate the request to the family shall be an organ procurement representative or a designated requestor. If a designated requestor is responsible for initiating this request, this individual shall 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 organization has a process in place for the procurement of organs, tissue, and eyes.

The organization shall have a written agreement with an Organ Procurement Organization (OPO), designated under 42 CFR Part 486. At a minimum, the written agreement shall 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 organization shall 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 shall notify the OPO of every death or imminent death in the hospital. When death is imminent, the hospital shall notify the OPO both before a potential donor is removed from a ventilator and while the potential donor's organs are still viable. The organization 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 shall 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 shall 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 shall call the OPO as soon as possible after the death of that individual has occurred.

The individual designated by the organization to initiate the request to a family shall be an organ procurement representative, an organization representative of a tissue or eye bank, or a designated requestor. Any individuals involved in a request for organ, tissue, and eye donation shall 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 shall 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 organization 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 organization has implemented its organ procurement policies. Verify that that all designated requestors have completed the required training.

Verify that the organization 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 organization 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 QMS 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 organization 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 organization has an alternative agreement with a different tissue and/or

eye bank.

TO.4 RESPECT FOR PATIENT RIGHTS

SR.1 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

SR.1 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. No hospital is considered to be out of compliance with section 1138(a)(1)(B) of the Act, or with the requirements of TO.6 (SR.1), unless the Secretary has given the OPTN formal notice that he or she approves the decision to exclude the hospital from the OPTN and has notified the hospital in writing.

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 organization shall ensure that appropriate candidates for receipt of transplanted organs have been screened, matched, and medically cleared prior to receipt of any organs. The organization 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 organization will accurately document the time of the organ transplantation. The organization will take such steps to ensure that there are no unnecessary delays when this process is initiated.

The organization 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 organization ensures that authority for transplantation is co-signed by the patient or designated representative of the patient and the practitioner(s) performing the transplantation.

APPENDIX A - SWING BEDS (SB)

A hospital that has a Medicare provider agreement shall meet the requirements of Appendix A of these NIAHO® Accreditation Requirements in order to be granted an approval from CMS to provide post-hospital extended care services, as specified in 42 CFR 409.30, and be reimbursed as a swing-bed hospital, as specified in 42 CFR 413.114.

SB.1 FACILTY ELIGIBILITY

SR.1 The hospital shall meet the following eligibility requirements of 42 CFR Section 482.58(a):

SR.1a The hospital has fewer than 100 hospital beds, excluding beds for newborns and beds in intensive care type inpatient units (for eligibility of hospitals with distinct parts electing the optional reimbursement method, see 42 CFR Section 413.24(d)(5).

SR.1b The hospital is located in a rural area. This includes all areas not delineated as "urbanized" areas by the Census Bureau, based on the most recent census.

SR.1c The hospital does not have in effect a 24-hour nursing waiver granted under 488.54(c).

SR.1d The hospital has not had a swing-bed approval terminated within the two years previous to application.

Interpretive Guidelines:

Hospitals seeking swing-bed approval are screened prior to survey for their eligibility for swing-beds. However, the CMS RO makes the determination whether the hospital has satisfied the eligibility criteria, regardless of whether the state agency or accrediting organization, as applicable, recommends approval of swing-bed status.

The swing-bed concept allows a hospital to use their beds interchangeably for either acute-care or post-acute care. A "swing-bed" is a change in reimbursement status. The patient swings from receiving acute-care services and reimbursement to receiving skilled nursing (SNF) services and reimbursement. It is not necessary for the patient to change location in the hospital when the reimbursement status changes but, moving to a different location is allowed.

Swing beds do not have to be located in a special section of the hospital. The patient does not have to change locations in the hospital merely because their status changes unless the hospital requires it. Beds in a hospital IPPS-excluded rehabilitation or psychiatric unit, or a separately certified co-located Medicare participating entity (e.g., a distinct part SNF/NF, another hospital, or an inpatient hospice) cannot be used by the hospital for providing swing-bed services.

A 3-day qualifying stay for the same spell of illness in any hospital is required prior to admission to swing-bed status for Medicare beneficiaries who seek Medicare coverage of their SNF services. The 3-day qualifying stay does not need to be from the same facility as the swing-bed

admission. Surveyors do not evaluate whether there is a qualifying stay, since this is a coverage requirement.

There shall be discharge orders changing status from acute care services, appropriate progress notes, discharge summary, and subsequent admission orders to swing-bed status regardless of whether the patient stays in the same hospital or transfers to another hospital with swing bed approval. If the patient remains within the hospital, the same chart can be utilized but the swing-bed section of the chart shall be separate and clearly delineated, with appropriate admission orders, progress notes, and supporting documents.

There is no length of stay restriction for any hospital swing-bed patient. There is no Medicare requirement to place a swing-bed patient in a nursing home and there are no requirements for transfer agreements between hospitals and nursing homes. While there is no length of stay limit for patients in swing-bed status, the intended use for swing beds is for a transitional time period to allow the patient to fully recover to return home or while awaiting placement into a nursing facility.

Swing-bed patients receive a SNF level of care, and the facility is reimbursed for providing a SNF level of care. However, swing-bed patients are not SNF patients. Swing-bed patients in facilities are considered to be patients of the facility.

ADMISSION, TRANSFER AND DISCHARGE (TD)

TD.1 TRANSFER AND DISCHARGE REQUIREMENTS

Transfer and discharge include movement of a resident to a bed outside of the certified facility whether that bed is in the same physical plant or not. Transfer and discharge do not refer to movement of a resident to a bed within the same certified facility.

The facility shall permit each resident to remain in the facility, and not transfer or discharge the resident from the facility unless:

SR.1 The transfer or discharge is necessary for the resident's welfare and the resident's needs cannot be met in the facility;

SR.2 The transfer or discharge is appropriate because the resident's health has improved sufficiently so the resident no longer needs the services provided by the facility;

SR.3 The safety of individuals in the facility is endangered due to the clinical or behavioral status of the resident;

SR.4 The health of individuals in the facility would otherwise be endangered; or

SR.5 The resident has failed, after reasonable and appropriate notice, to pay for (or to have paid under Medicare or Medicaid) a stay at the facility. Non-payment applies if the resident does not submit the necessary paperwork for third party payment or after the third party, including Medicare or Medicaid, denies the claim and the resident refuses to pay for his or her stay;

SR.5a For a resident who becomes eligible for Medicaid after admission to a facility, the hospital may charge a resident only allowable charges under Medicaid; or,

SR.6 The facility ceases operations.

SR.7 The facility may not transfer or discharge a resident while an appeal is pending, pursuant to § 431.230 when a resident exercises his or her right to appeal a transfer or discharge notice from the facility pursuant to § 431.220(a)(3), unless the failure to discharge or transfer would endanger the health or safety of the resident or other individuals in the facility. The facility shall document the danger that failure to transfer or discharge would pose.

Interpretive Guidelines:

Definition: Transfer and discharge includes movement of a resident to a bed outside of the certified facility whether that bed is in the same physical plant or not. Transfer and discharge do not refer to movement of a resident to a bed within the same certified facility. Specifically, transfer refers to the movement of a resident from a bed in one certified facility to a bed in another certified facility when the resident expects to return to the original facility. Discharge refers to the movement of a resident from a bed in one certified facility to a bed in another certified facility or other location in the community, when return to the original facility is not

expected.

The intent of the regulation on transfer and discharge provisions is to significantly restrict a facility's ability to transfer or discharge a resident once that resident has been admitted to the facility to prevent dumping of high care or difficult residents. This requirement applies to transfer or discharges that are initiated by the facility, not by the resident.

If transfer is due to a significant change in the resident's condition, the facility shall conduct the appropriate assessment, prior to any transfer or discharge to determine if a new care plan would allow the facility to meet the resident's needs. If the significant change in the resident's condition is an emergency, immediate transfer should be arranged. Residents who are sent emergently to an acute care setting, such as a hospital, shall be permitted to return to the facility. In a situation where the facility initiates discharge while the resident is in the hospital following emergency transfer, the facility shall have evidence that the resident's status at the time the resident seeks to return to the facility (not at the time the resident was transferred for acute care) meets one of the criteria at SR.1-SR.4. Additionally, the resident has the right to return to the facility pending an appeal of any facility-initiated discharge unless the return would endanger the health or safety of the resident or other individuals in the facility. The facility shall document the danger that the failure to transfer or discharge would pose.

The resident cannot be discharged for nonpayment while a determination on the resident's Medicaid eligibility is pending.

Residents who are sent to the acute care setting for routine treatment/planned procedures shall also be allowed to return to the facility.

A resident's declination of treatment does not constitute grounds for discharge, unless the facility is unable to meet the needs of the resident or protect the health and safety of others. The facility shall be able to demonstrate that the resident or, if applicable, resident representative, received information regarding the risks of refusal of treatment, and that staff conducted the appropriate assessment to determine if care plan revisions would allow the facility to meet the resident needs or protect the health and safety of others.

Surveyor Guidance:

During closed record review, determine the reasons for transfer/discharge.

- *Do records document accurate assessments and attempts through care planning to address the resident's needs through multidisciplinary interventions, accommodation of individual needs, and attention to the resident's customary routine?*

- *Did the resident's MD/DO document in the record if the resident was transferred/discharged for the sake of the resident's welfare and the resident's needs could not be met in the facility (e.g., a resident develops an acute condition requiring hospitalization) or the resident's health improved to the extent that the transferred/discharged resident no longer needed the services of the facility?*

- *Did a MD/DO document in the record if residents were transferred because the health of individuals in the facility is endangered?*

- *Do the records of residents who are transferred/discharged due to safety reasons*

reflect the process by which the facility concluded that in each instance transfer or discharge was necessary?

- *If the entity to which the resident was discharged is another long-term care facility, evaluate the extent to which the discharge summary and the resident's MD/DO justify why the facility could not meet the needs of this resident.*

TD.2 DOCUMENTATION

When the facility transfers or discharges a resident under any of the circumstances specified in TD.1, the facility shall ensure that the transfer or discharge is documented in the resident's medical record and appropriate information is communicated to the receiving health care institution or provider.

SR.1 Documentation in the resident's medical record shall include:

SR.1a The basis for the transfer per TD.1.

SR.1b In the case of paragraph TD.1 (SR.1), the specific resident need(s) that cannot be met, facility attempts to meet the resident needs, and the service available at the receiving facility to meet the need(s).

The documentation shall be made by:

SR.2 The resident's physician when transfer or discharge is necessary for the resident's welfare and the resident's needs cannot be met in the facility or the resident's health has improved sufficiently so the resident no longer needs the services provided by the facility.

SR.3 A physician (not necessarily the attending physician) when transfer or discharge is necessary as the health of individuals in the facility would otherwise be endangered or the safety of the individuals in the facility is endangered due to the clinical or behavioral status of the resident.

Interpretive Guidelines:

A physician extender may complete documentation of the transfer/discharge unless prohibited by State law or facility policy.

TD.3 NOTIFICATION

Notification shall be provided prior to transferring or discharging a resident.

The facility shall:

SR.1 Notify the resident and the resident's representative(s) of the transfer or discharge and the reasons for the move in writing and in a language and manner they understand. The facility shall send a copy of the notice to a representative of the Office of the State Long-Term Care Ombudsman.

SR.2 The written notice specified in TD.1 (SR.1) shall include the following:

SR.2a The reason for transfer or discharge;

SR.2b The effective date of transfer or discharge;

SR.2c The location to which the resident is transferred or discharged;

SR.2d A statement of the resident's appeal rights, including the name, address (mailing and email), and telephone number of the entity which receives such requests; and information on how to obtain an appeal form and assistance in completing the form and submitting the appeal hearing request;

SR.2e The name, address (mailing and email) and telephone number of the Office of the State Long-Term Care Ombudsman;

SR.2f For nursing facility residents with intellectual and developmental disabilities or related disabilities, the mailing and email address and telephone number of the agency responsible for the protection and advocacy of individuals with developmental disabilities established under Part C of the Developmental Disabilities Assistance and Bill of Rights Act of 2000 (Pub. L. 106-402, codified at 42 U.S.C. 15001 et seq.); and,

SR.2g For nursing facility residents with a mental disorder or related disabilities, the mailing and email address and telephone number of the agency responsible for the protection and advocacy of individuals with a mental disorder established under the Protection and Advocacy for Mentally Ill Individuals Act.

SR.3 Record the reasons for the transfer or discharge in the resident’s clinical record in accordance with TD.1.

SR.4 Timing of the written notice shall be made by the facility:

SR.4a As soon as practicable before transfer or discharge when:

SR.4a(1) The safety of individuals in the facility would be endangered (See TD.1 (SR.3));

SR.4a(2) The health of individuals in the facility would be endangered (See TD.1 (SR.4));

SR.4a(3) The resident’s health improves sufficiently to allow a more immediate transfer or discharge (See TD.1 (SR.2));

SR.4a(4) An immediate transfer or discharge is required by the resident’s urgent medical needs (See TD.1 (SR.1)); or,

SR.4a(5) A resident has not resided in the facility for 30 days.

SR.4b All other reasons require at least 30 days' notice before transfer or discharge.

Interpretive Guidelines:

Notice of Transfer or Discharge and Ombudsman Notification

For facility-initiated transfers or discharges of a resident, prior to the transfer or discharge, the facility shall notify the resident and the resident's representative(s) of the transfer or discharge and the reasons for the move in writing and in a language and manner they understand. Additionally, the facility shall send a copy of the notice of transfer or discharge to the representative of the Office of the State Long-Term Care (LTC) Ombudsman. The intent of sending copies of the notice to a representative of the Office of the State LTC Ombudsman is to provide added protection to residents from being inappropriately transferred or discharged, provide residents with access to an advocate who can inform them of their options and rights, and to ensure that the Office of the State LTC Ombudsman is aware of facility practices and activities related to transfers and discharges. The facility shall maintain evidence that the notice was sent to the Ombudsman. While Ombudsman Programs vary from state to state, facilities should know the process for ombudsman notification in their state.

Facility-Initiated Transfers and Discharges

In situations where the facility has decided to discharge the resident while the resident is still hospitalized, the facility shall send a notice of discharge to the resident and resident representative before the discharge and shall also send a copy of the discharge notice to a representative of the Office of the State LTC Ombudsman. Notice to the Office of the State LTC Ombudsman shall occur at the same time the notice of discharge is provided to the resident and resident representative, even though, at the time of initial emergency transfer, sending a copy of the transfer notice to the ombudsman only needed to occur as soon as practicable as described below. For any other types of facility-initiated discharges, the facility shall provide notice of discharge to the resident and resident representative along with a copy of the notice to the Office of the State LTC Ombudsman at least 30 days prior to the discharge or as soon as possible. The copy of the notice to the ombudsman shall be sent at the same time notice is provided to the resident and resident representative.

Emergency Transfers

When a resident is temporarily transferred on an emergency basis to an acute care facility, this type of transfer is considered to be a facility-initiated transfer and a notice of transfer shall be provided to the resident and resident representative as soon as practicable before the transfer. Copies of notices for emergency transfers shall also still be sent to the ombudsman, but they may be sent when practicable, such as in a list of residents on a monthly basis, as long as the list meets all requirements for content of such notices at SR.2a-SR.2g.

TD.4 ORIENTATION FOR TRANSFER OR DISCHARGE

SR.1 The facility shall provide and document sufficient preparation and orientation to residents to ensure safe and orderly transfer or discharge from the facility. This orientation shall be provided in a form and manner that the resident can understand.

Interpretive Guidelines:

This standard addresses the immediate orientation and preparation necessary for a facility-initiated transfer, such as to a hospital emergency room or therapeutic leave where discharge planning is not required because the resident will return, or for an emergent or immediate facility-initiated discharge where a complete discharge planning process is not practicable.

"Sufficient preparation and orientation" means the facility informs the resident where he or she is going, assures safe transportation, and takes steps under its control to minimize anxiety. Examples of preparation and orientation may include explaining to a resident why they are going to the emergency room or other location or leaving the facility; working with family or resident's representative to assure that the resident's possessions (as needed or requested by the resident) are not left behind or lost; and ensuring that staff handle transfers and discharges in a manner that minimizes anxiety.

When a complete discharge planning process is possible, the resident's health and safety needs, as well as preferences and goals should be considered. The facility should actively involve the resident and the resident's family in selecting the new residence. Some examples of orientation may include trial visits by the resident to a new location; working with family; and orienting staff in the receiving facility to the resident's daily patterns.

The facility shall orient and prepare the resident regarding his or her transfer or discharge in a form and manner that the resident can understand. The form and manner of this orientation and preparation shall take into consideration factors that may affect the resident's ability to understand, such as educational level, language and/or communication barriers, and physical and mental impairments. The facility shall also document this orientation in the medical record, including the resident's understanding of the transfer or discharge.

Surveyor Guidance:

Review nursing notes and any other relevant documentation to see if appropriate orientation and preparation of the resident prior to transfer and discharge has occurred.

Through record review and interviews, determine if the resident received sufficient preparation prior to transfer or discharge, and if they understood the information provided to them.

Were the resident's needed/requested possessions transferred with the resident to the new location?

Ask the resident or his or her representative if they understand why the transfer or discharge occurred.

TD.5 CHANGE OF ROOM IN COMPOSITE DISTINCT PART

SR.1 When a room change has been planned for the patient in the facility that is a composite distinct part (as defined in 483.5(c), will be limited to the patient being moved within the particular building in which the resident resides. If the resident is to be moved to another building of the distinct part location, the resident shall voluntarily agree to this move within the facility.

TD.6 DISCHARGE SUMMARY

When the facility anticipates discharge a resident shall have a discharge summary that includes, but is not limited to, the following:

SR.1 A recapitulation of the resident's stay that includes, but is not limited to;

SR.1a Diagnoses;

SR.1b Course of illness/treatment or therapy;

SR.1c Pertinent lab results;

SR.1d Pertinent radiology results; and,

SR.1e Consultation results.

SR.2 A final summary of the resident's status at the time of the discharge to include the items under PC.1 (SR.1), that is available for release to authorized individuals and agencies, with the consent of the resident or their legal representative;

SR.3 Reconciliation of all pre-discharge medications with the resident's post-discharge medications (both prescribed and over the counter); and,

SR.4 A post-discharge plan of care that is developed with the participation of the interdisciplinary team, the resident and, with the resident's consent, the resident's representative(s), which will assist the resident to adjust to his or her new living environment.

SR.4a The post-discharge plan of care shall indicate:

SR.4a(1) Where the individual plans to reside;

SR.4a(2) Any arrangements that have been made for the resident's follow-up care and that provider's contact information;

SR.4a(3) Any post-discharge medical and non-medical services;

SR.4a(4) Community care and support services, if needed; and

SR.4a(5) When and how to contact the continuing care provider.

Interpretive Guidelines:

"Anticipated Discharge" is a discharge that is planned and not due to the resident's death or an emergency (e.g., hospitalization for an acute condition or emergency evacuation).

"Post discharge plan of care" means the discharge planning process that includes assessing continuing care needs and developing a plan designed to ensure that the individual's needs will be met after discharge from the facility into the community.

"Adjust to his or her living environment" means that the post discharge plan should describe the resident's and family's preferences for care, how the resident and family will access these services, and how care should be coordinated if continuing treatment involves multiple care givers. It should identify specific resident needs after discharge such as personal care, sterile dressings, and physical therapy, as well as describe resident/caregiver education needs to ensure the resident/care giver is able to meet care needs after discharge.

In situations where there is no continuing care provider (e.g., resident has no primary care physician in the community), the facility is expected to document in the medical record efforts to assist the resident in locating a continuing care provider.

For residents discharged to their home, the medical record should contain documentation that written discharge instructions were given to the resident and if applicable, the resident representative. These instructions shall be discussed with the resident and resident representative and conveyed in a language and manner they will understand.

Surveyor Guidance:

In reviewing records of residents that have been transferred or discharged:

- *Is there evidence of discharge planning in the record for residents who had an anticipated discharge or those residents to be discharged shortly (e.g., in the next 7-14 days)?*
- *Do discharge plans address necessary post discharge care?*
- *Determine what types of pre-discharge preparation and education the facility provides for residents and their families.*
- *Review the discharge summaries. Is there information that addresses pertinent continuing care for the resident?*
- *Is there documentation that the facility aided the resident and his/her family in locating and coordinating post discharge services?*

PLAN OF CARE (PC)

PC.1 ASSESSMENT

The facility shall conduct initially and periodically a comprehensive, accurate, standardized, reproducible assessment of each resident's functional capacity.

SR.1 The assessment shall include at least the following:

SR.1a Identification and demographic information.

SR.1b Customary routine.

SR.1c Cognitive patterns.

SR.1d Communication.

SR.1e Vision.

SR.1f Mood and behavior patterns.

SR.1g Psychosocial well-being.

SR.1h Physical functioning and structural problems.

SR.1i Continence.

SR.1j Disease diagnoses and health conditions.

SR.1k Dental and nutritional status.

SR.1l Skin condition.

SR.1m Activity pursuit.

SR.1n Medications.

SR.1o Special treatments and procedures.

SR.1p Discharge planning.

SR.1q Documentation of summary information regarding the additional assessment performed through the resident assessment protocols.

SR.1r Documentation of participation in assessment.

SR.2 A comprehensive assessment shall be performed:

SR.2a Within 14 calendar days after admission, excluding readmissions in which there is no significant change in the resident's physical or mental condition, the facility shall make a comprehensive assessment of a resident's needs through a process of direct observation and communication with the resident, as well as communication with licensed and non-licensed direct care staff members on all shifts.

SR.2b Within 14 calendar days after the facility determines, or should have determined, that there has been a significant change in the resident's physical or mental condition.

SR.2c Not less often than once every 12 months.

Interpretive Guidelines:

The intent of this regulation is to provide the facility with ongoing assessment information necessary to develop a care plan, to provide the appropriate care and services for each resident, and to modify the care plan and care/services based on the resident's status. The facility is expected to use resident observation and communication as the primary source of information when completing the assessment. In addition to direct observation and communication with the resident, the facility should use a variety of other sources, including communication with licensed and non-licensed staff members on all shifts and may include discussions with the resident's MD/DO, family members, or outside consultants and review of the resident's record.

"Admission" to the facility is defined as an initial stay or a return stay (not a readmission) in the facility. A "return stay" applies to those residents who are discharged without expectation that they will return to the facility, but who do return to the facility.

A "readmission" is an expected return to the facility following a temporary absence for hospitalization, off-site visit or therapeutic leave.

A "significant change" means a major decline or improvement in the resident's status that will not normally resolve itself without further intervention by staff or by implementing standard disease-related clinical interventions, that has an impact on more than one area of the resident's health status and requires interdisciplinary review or revision of the care plan, or both.

Items in PC.1 (SR.1) would include comprehensive assessments of a resident which were done within 14 days of admission; within 14 days of a significant change in the resident's physical or mental condition; and annually (not less than once every 12 months means within 366 days). These assessments need to be in the final discharge summary.

Each resident is comprehensively assessed using the CMS-specified Resident Assessment Instrument (RAI) process. The RAI yields information about a resident's functional status, strengths, weaknesses, and preferences, as well as offering guidance on further assessment once problems have been identified.

The facility is expected to use resident observation and communication as the primary source of information when completing the RAI. In addition to record review, direct observation and communication with the resident, the facility shall use a variety of other sources, including

communication with licensed and non-licensed staff members on all shifts and may include discussions with the resident's physician, the resident's representative, family members, or outside consultants. The assessments are part of an ongoing process through which the facility identifies each resident's preferences and goals of care, functional and health status, strengths and needs, as well as offering guidance for further assessment once problems have been identified.

Documentation of participation in assessment refers to documentation of who participated in the assessment process. The assessment process shall include direct observation and communication with the resident, as well as communication with licensed and non-licensed direct care/direct access staff members on all shifts.

Surveyor Guidance:

Interview licensed and non-licensed direct-care staff about their participation in the resident assessment process.

In a sample of resident records, validate that the facility completes a comprehensive assessment, using the CMS-specified RAI process, within the required timeframes (i.e., within 14 days after admission and at least annually) for each resident in the sample.

Did the facility identify, in a timely manner, those residents who experienced a significant change in status? Is there documentation in the medical record when the determination was made that the resident met the criteria for an assessment as a result of the change in status?

Validate that the facility reassessed residents who had a significant change in status within 14 days after determining the change was significant.

Is there evidence of resident and/or resident representative participation in the assessment process? Examples include participating in the resident interviews, providing information about preferences or discharge goals.

PC.2 CARE PLAN

SR.1 The facility shall develop a comprehensive care plan for each resident that:

SR.1a Meets the resident's medical, nursing, mental and psychosocial needs identified in the comprehensive assessment;

SR.1b Includes measurable objectives/goals and timeframes;

SR.1c Is developed within 7 days after the completion of the comprehensive assessment;

SR.1d Is prepared by an interdisciplinary team, that includes:

SR.1d(1) The attending physician;

SR.1d(2) A registered nurse with responsibility for the resident;

SR.1d(3) A nurse aide with responsibility for the resident;

SR.1d(4) A member of food and nutrition services staff;

SR.1d(5) To the extent practicable, the participation of the resident, the resident's family or the resident's legal representative; and

SR.1d(5)(i) An explanation shall be included in a resident's medical record if the participation of the resident and their resident representative is determined not practicable for the development of the resident's care plan.

SR.1d(6) Other appropriate staff or professionals in disciplines as determined by the resident's needs or as requested by the resident.

SR.1e Is periodically reviewed and revised by a team of qualified persons after each assessment.

SR.2 The care plan shall describe the following;

SR.2a The services that are to be furnished to attain or maintain the resident's highest practicable physical, mental, and psychosocial well-being as required under 42 CFR Section 483.24, 483.25, or 483.40;

SR.2b Any services that would otherwise be required under 42 CFR Section 483.24, 483.25, or 483.40, but are not provided due to the resident's exercise of rights, including the right to refuse treatment under 42 CFR Section 483.10(c)(6); and,

SR.2c Documented consultation with the resident and the resident's legal representative(s) that specifies:

SR.2c(1) The resident's goals for admission and desired outcomes; and,

SR.2c(2) The resident's preference and potential for future discharge. The facility shall document whether the resident's desire to return to the community was assessed and any referrals to local contact agencies and/or other appropriate entities, for this purpose.

SR.2c(3) Discharge plans in the comprehensive care plan, as appropriate, in accordance with the requirements set forth in 42 CFR Section 483.21(c).

SR.3 The resident or his or her legal representative has the right to participate in the development and implementation of his or her person-centered plan of care, including but not limited to:

SR.3a The right to be informed, in advance, of changes to the plan of care.

SR.4 The services provided or arranged by the facility shall:

SR.4a Meet professional standards of quality;

SR.4b Be provided by qualified persons in accordance with each resident's written plan of care; and

SR.4c Be culturally competent and trauma-informed.

Interpretive Guidelines:

The requirements reflect the facility's responsibility to provide necessary care and services to attain or maintain the highest practicable physical, mental and psychosocial wellbeing, in accordance with the comprehensive assessment and plan of care.

"Interdisciplinary" means that professional disciplines, as appropriate, will work together to provide the greatest benefit to the resident. It does not mean that every goal shall have an interdisciplinary approach. The mechanics of how the interdisciplinary team meets its responsibilities in developing an interdisciplinary care plan (e.g., a face-to-face meeting, teleconference, written communication) are at the discretion of the facility.

An interdisciplinary team, in conjunction with the resident, resident's family, surrogate, or representative, as appropriate, should develop quantifiable objectives for the highest level of functioning the resident may be expected to attain, based on the comprehensive assessment. The care plan shall reflect intermediate steps for each outcome objective if identification of those steps will enhance the resident's ability to meet his/her objectives. Facility staff will use these objectives to follow resident progress. Facilities may, for some residents, need to prioritize needed care.

The MD/DO shall participate as part of the interdisciplinary team, and may arrange with the facility for alternative methods, other than attendance at care planning conferences, of providing his/her input, such as one-to-one discussions and conference calls. The resident has the right to refuse specific treatments and to select among treatment options before the care plan is instituted. The facility should encourage residents, surrogates, and representatives to participate in care planning, including encouraging attendance at care planning conferences if they so desire.

In some cases, a resident may wish to refuse certain services or treatments that professional staff believe may be indicated to assist the resident in reaching his or her highest practicable level of well-being. Desires of the resident should be documented in the clinical record.

"Professional standards of quality" means services that are provided according to accepted standards of clinical practice. Standards may apply to care provided by a particular clinical discipline or in a specific clinical situation or setting. Standards regarding quality care practices may be published by a professional facility, licensing board, accreditation body or other regulatory agency. Recommended practices to achieve desired resident outcomes might also be found in clinical literature.

"Cultural Competency" is a developmental process in which individuals or institutions achieve increasing levels of awareness, knowledge, and skills along a cultural competence continuum. Cultural competence involves valuing diversity, conducting self-assessments, avoiding stereotypes, managing the dynamics of difference, acquiring and institutionalizing cultural knowledge, and adapting to diversity and cultural contexts in communities. It refers to a person's ability to interact effectively with persons of cultures different from his/her own and means being respectful and responsive to the health beliefs, practices and cultural and linguistic needs of

diverse population groups, such as racial, ethnic, religious or social groups. The interventions in the resident's care plan shall reflect the individual resident's needs and preferences and align with the resident's cultural identity. See US Department of Health and Human Services publication: A Blueprint for Advancing and Sustaining CLAS Policy and Practice.

"Trauma-informed care" is an approach to delivering care that involves understanding, recognizing and responding to the effects of all types of trauma. A trauma-informed approach to care delivery recognizes the widespread impact, and signs and symptoms of trauma in residents, and incorporates knowledge about trauma into care plans, policies, procedures and practices to avoid re-traumatization. Facilities shall recognize the effects of past trauma on residents and collaborate with the resident, family and friends of the resident to identify and implement individualized interventions. Interventions for trauma survivors should recognize the interrelation between trauma and symptoms of trauma such as substance abuse, eating disorders, aggression, depression, anxiety, and withdrawal or isolation from others. Adapted from: SAMHSA's Concept of Trauma and Guidance for a Trauma-Informed Approach.

Surveyor Guidance:

In sampling of resident records, verify that:

- *The care plan addresses the needs, strengths and preferences identified in the comprehensive assessment;*
- *Objectives and interventions are person-centered, reflect the resident's cultural preferences, measurable, and include timeframes to achieve the desired outcomes;*
- *For residents with a history of trauma, the care plan describes corresponding interventions for care that are in accordance with professional standards of practice and accounts for residents' experiences and preferences in order to eliminate or mitigate triggers that may cause re-traumatization of the resident;*
- *Interdisciplinary expertise is utilized to develop a plan to improve the resident's functional abilities;*
- *The care plan is oriented toward preventing avoidable declines in functioning or functional levels;*
- *The care plan is evaluated and revised as the resident's status changes; and*
- *If a resident has refused treatment, the care plan reflects the facility's efforts to find alternative means to address the problem.*

Validate that care plan meetings are scheduled at the best time of the day for residents and their families.

Interview residents to determine if:

- *Facility staff attempt to make the process understandable to the resident/family.*
- *The resident had concerns or questions about their care and brought them to the*

attention of facility staff? If yes, "What happened as a result?"

- *The facility has provided adequate information to the resident so that the resident was able to make an informed choice regarding treatment.*

Review the care plan of new residents to determine if the assessment and care planning is sufficient to meet the needs of newly admitted residents.

Verify that staff can describe the care, services and expected outcomes of the care they provide.

RESIDENTS RIGHTS (RR)

The resident has a right to a dignified existence, self-determination, and communication with and access to persons and services inside and outside the facility. A facility shall protect and promote the rights of each resident.

RR.1 EXERCISE OF RIGHTS

SR.1 The resident has the right to exercise his or her rights as a resident of the facility and as a citizen or resident of the United States.

SR.2 The resident has the right to be free of interference, coercion, discrimination, and reprisal from the facility in exercising his or her rights.

SR.3 In the case of a resident adjudged incompetent under the laws of a State by a court of competent jurisdiction, the rights of the resident devolve to and are exercised by the resident representative appointed under State law to act on the resident's behalf. The court-appointed resident representative exercises the resident's rights to the extent judged necessary by a court of competent jurisdiction, in accordance with State law.

SR.3a In the case of a resident representative whose decision-making authority is limited by State law or court appointment, the resident retains the right to make those decisions outside the representative's authority.

SR.3b The resident's wishes and preferences shall be considered in the exercise of rights by the representative.

SR.3c To the extent practicable, the resident shall be provided with opportunities to participate in the care planning process.

SR.4 In the case of a resident who has not been adjudged incompetent by the State court, any legal surrogate designated in accordance with State law may exercise the resident's rights to the extent provided by State law.

RR.2 NOTICE OF RIGHTS AND SERVICES

SR.1 The facility shall inform the resident both orally and in writing in a language that the resident understands of his or her rights and all rules and regulations governing resident conduct and responsibilities during the stay in the facility.

SR.1a The facility shall also provide the resident with the notice (if any) of the State developed under section 1919(e)(6) of the Act. Such notification shall be made prior to or upon admission and during the resident's stay. Receipt of such information, and any amendments to it, shall be acknowledged in writing.

SR.2 The resident or his or her legal representative has the right:

SR.2a Upon an oral or written request, to access all records pertaining to himself or herself including current clinical records within 24 hours (excluding weekends and holidays); and

SR.2b After receipt of his or her records for inspection, to purchase at a cost not to exceed the community standard photocopies of the records or any portions of them upon request and 2 working days advance notice to the facility.

SR.3 The resident or his or her legal representative has the right to be informed of, and participate in his or her treatment, including but not limited to:

SR.3a The right to be fully informed in language that he or she can understand of his or her total health status, including but not limited to, his or her medical condition.

SR.4 The resident has the right to request, refuse, and/or discontinue treatment to participate in or refuse to participate in experimental research.

Interpretive Guidelines:

The intent of this requirement is to assure that each resident knows his or her rights and responsibilities and that the facility communicates this information prior to or upon admission, during the resident's stay, and when the facility's rules changes.

A facility shall promote the exercise of rights for all residents, including those who face barriers such as communication problems, hearing problems and cognition limits. These rights include the resident's right to:

- *Be informed about what rights and responsibilities the resident has*
- *Choose a MD/DO*
- *Participate in decisions about treatment and care planning*
- *Have privacy and confidentiality*
- *Work or not work*
- *Have privacy in sending and receiving mail*
- *Visit and be visited by others from outside the facility*
- *Retain and use personal possessions*
- *Share a room with a spouse*

"Total health status" includes functional status, medical care, nursing care, nutritional status, rehabilitation and restorative potential, activities potential, cognitive status, oral health status, psychosocial status, and sensory and physical impairments. Information on health status shall be presented in language that the resident can understand.

Communicating with the resident in language that the resident can understand includes minimizing the use of technical words, providing interpreters for non-English speaking residents, using sign language when needed, or other interventions, as appropriate.

"Treatment" is defined as care provided for purposes of maintaining/restoring health, improving functional level, or relieving symptoms.

"Experimental research" is defined as development and testing of clinical treatments, such as an investigational drug or therapy that involve treatment and/or control groups. The resident has the right to refuse to participate in experimental research. A resident being considered for participation in experimental research shall be fully informed of the nature of the experiment and understand the possible consequences of participating. The opportunity to refuse to participate in experimental research shall occur prior to the start of the research. Aggregated resident statistics that do not identify individual residents may be used for studies without obtaining resident permission.

"Advance directive" means a written instruction, such as living will or durable power of attorney for health care, recognized under state law, relating to the provisions of health care when the individual is incapacitated. A resident who has the capacity to make a health care decision and who withholds consent to treatment or makes an explicit refusal of treatment either directly or through an advance directive, may not be treated against his/her wishes.

Surveyor Guidance:

Validate that there are on-going efforts on the part of facility staff to keep residents informed.

Verify that information is communicated in a manner that is understandable to residents.

Verify that information available when it is most useful to the residents such as when they are expressing concerns, raising questions, and on an on-going basis.

Verify the medical record that the patient was informed of his rights, including the right to accept or refuse medical or surgical treatment.

Verify and validate that if the facility participates in any experimental research involving residents, it has an Institutional Review Board or other committee that reviews and approves research protocols.

RR.3 HEALTH CARE DECISIONS

SR.1 The resident has the right to choose his or her attending physician.

SR.1a The physician shall be licensed to practice, and

SR.1b If the physician chosen by the resident refuses to or does not meet requirements specified in this part, the facility may seek alternate physician participation as specified in RR.3 (SR.1d) and RR.3 (SR.1e) to assure provision or appropriate and adequate care and treatment.

SR.1c The facility shall ensure that each resident remains informed of the name, specialty, and way of contacting the physician and other primary care professionals responsible for his or her care.

SR.1d The facility shall inform the resident if the facility determines that the physician chosen by the resident is unable or unwilling to meet the requirements specified in this part and the facility seeks alternate physician participation to assure provision or appropriate and adequate care and treatment. The facility shall discuss the alternative physician participation with the resident and honor the resident's preferences, if any, among options.

SR.1e If the resident subsequently selects another attending physician who meets the requirements specified in this part, the facility shall honor that choice.

SR.2 Be fully informed in advance about care and treatment and of any changes in that care or treatment that may affect the resident's well-being.

SR.3 Participate in planning care and treatment or changes in care and treatment.

Interpretive Guidelines:

The right to choose a personal MD/DO does not mean that the MD/DO shall serve the resident. If the MD/DO of the resident's choosing fails to fulfill a given requirement, such as frequency of MD/DO visits, the facility will have the right, after informing the resident, to seek alternate MD/DO participation to assure provision of appropriate and adequate care and treatment.

A facility may not place barriers in the way of residents choosing their own MD/DO. If a resident does not have a MD/DO, or if the resident's MD/DO become unable or unwilling to continue providing care to the resident, the facility shall assist the resident in exercising his/her choice in finding another MD/DO. A resident can choose his/her own MD/DO but, cannot have a MD/DO who does not have swing-bed admitting privileges.

The requirement for free choice is met if a resident is allowed to choose a personal MD/DO from among those who have practice privileges.

"Informed in advance" means that the resident receives information necessary to make a health care decision. The information should include his/her medical condition, changes in his/her medical condition, the benefits and reasonable risks of the recommended treatment, and reasonable alternatives. If there are any financial costs to the resident in the treatment options, they should be disclosed in advance and in writing to the resident prior to his/her decision.

Unless adjudged incompetent or otherwise found to be incapacitated under the laws of the State, participates in planning care and treatment" means that the resident is afforded the opportunity to select from alternative treatments to the level of his ability to understand. This applies both to initial decisions about care and treatment and to decisions about changes in care and treatment. The resident has the right to participate in care planning and to refuse treatment.

Surveyor Guidance:

Validate that if there is a conflict between a resident's right and the resident's health or safety, how the facility attempted to accommodate both the exercise of the resident's rights and the resident's health, including exploration of care alternatives through a thorough care planning process in which the resident may participate.

Determine and validate if a resident whose ability to make decisions about care and treatment is impaired, how he was kept informed and what was consulted on personal preferences to the level of his ability to understand.

RR.4 ADVANCE DIRECTIVES

The facility shall allow the patient to formulate advance directives and to have facility staff and practitioners comply with the advance directives in accordance with Federal and State law, rules and regulations.

The facility is permitted to contract with other entities to furnish this information but are still legally responsible for ensuring that the requirements of RR.4 are met. If an adult individual is incapacitated at the time of admission and is unable to receive information (due to the incapacitating condition or a mental disorder) or articulate whether or not he or she has executed an advance directive, facility may give advance directive information to the individual's family or surrogate in the same manner that it issues other materials about policies and procedures to the family of the incapacitated individual or to a surrogate or other concerned persons in accordance with State law. The facility is not relieved of its obligation to provide this information to the individual once he or she is no longer incapacitated or unable to receive such information. Follow-up procedures shall be in place to provide the information to the individual directly at the appropriate time.

SR.1 The facility shall document in the patient's medical record whether or not the patient has executed an advance directive.

SR.2 The facility shall not condition the provision of care or otherwise discriminate based on the execution of the advance directive.

SR.3 The facility shall ensure compliance with State law regarding the provision of an advance directive.

SR.4 The facility shall provide education for staff regarding the advance directive.

SR.5 When the advance directive exists and is not in the patient's medical record, a written policy for follow-up and compliance shall exist.

Interpretive Guidelines:

ADVANCE DIRECTIVES: Refer to PATIENT RIGHTS – PR.3-ADVANCE DIRECTIVES

Surveyor Guidance:

Refer to PATIENT RIGHTS – PR.3-ADVANCE DIRECTIVES

RR.5 MEDICAID BENEFITS

Each resident who is entitled to Medicaid benefits, shall be informed in writing, at the time of admission to the facility or, when the resident becomes eligible for Medicaid of:

SR.1 The items and services that are included through facility services under the State plan and for which the resident may not be charged;

SR.2 Those other items and services that the facility offers and for which the resident may be charged, and the amount of charges for those services; and,

SR.2a Inform each Medicaid-eligible resident when changes are made to the items and services specified in RR.5 (SR.1 and SR.2) (483.10(g)(17)(i)(A) and (B)).

SR.3 The facility shall inform each resident before, or at the time of admission, and periodically during the resident's stay, of services available in the facility and of charges for those services, including any charges for services not covered under Medicare or by the facilities per diem rate.

Interpretive Guidelines:

If Medicare or Medicaid does not make payment for services, the provider shall fully inform the resident of any related charges both at the time of admission and prior to the time that changes will occur in their bills.

RR.6 PERSONAL PRIVACY AND CONFIDENTIALITY

Each resident has a right to be treated with respect and dignity. Each resident has a right to:

SR.1 Personal privacy and confidentiality of his or her personal and medical records.

SR.1a Personal privacy includes accommodations, medical treatment, written and telephone communications, personal care, visits, and meetings of family and resident groups, but this does not require the facility to provide a private room for each resident.

SR.2 The resident has the right to refuse the release of personal and medical records except as provided at 42 CFR Section 483.70(i)(2) or other applicable federal or state laws.

SR.2a The facility shall allow representatives of the Office of the State Long-Term Care Ombudsman to examine a resident's medical, social, and administrative records in accordance with State law.

SR.3 The facility shall respect the residents right to personal privacy, including the right to privacy in his or her oral (that is, spoken), written, and electronic communications, including the right to send and promptly receive unopened mail and other letters, packages and other materials delivered to the facility for the resident, including those delivered through a means other than a postal service. Further, the resident has the right to:

SR.3a Privacy of such communications; and,

SR.3b Access to stationery, postage, and writing implements at the resident's own expense.

SR.4 The facility shall provide immediate access to a resident by:

SR.4a Immediate family and other relatives of the resident, subject to the resident's right to deny or withdraw consent at any time; and,

SR.4b Others who are visiting with the consent of the resident, subject to reasonable clinical and safety restrictions and the resident's right to deny or withdraw consent at any time.

SR.5 Share a room with his or her spouse when married residents live in the same facility and both spouses consent to the arrangement.

SR.6 Retain and use personal possessions, including furnishings, and clothing, as space permits, unless to do so would infringe upon the rights or health and safety of other residents.

Interpretive Guidelines:

The resident has the right to refuse the release of personal and medical records except as provided at 483.70(i)(2):

The facility shall keep confidential all information contained in the resident's records, regardless of the form or storage method of the records, except when release is:

(i) To the individual, or their resident representative where permitted by applicable law;

(ii) Required by law;

(iii) For treatment, payment, or health care operations, as permitted by and in compliance with 45 CFR 164.506;

(iv) For public health activities, reporting of abuse, neglect, or domestic violence, health oversight activities, judicial and administrative proceedings, law enforcement purposes, organ donation purposes, research purposes, or to coroners, medical examiners, funeral directors, and to avert a serious threat to health or safety as permitted by and in compliance with 45 CFR 164.512.

"Right to personal privacy" means that the resident has the right to privacy with whomever the resident wishes to be private and that this privacy should include both visual and auditory privacy.

Private space may be created flexibly and need not be dedicated solely for visitation purposes. For example, privacy for visitation or meetings might be arranged by using a dining area between meals, a vacant chapel, office or room; or an activities area when activities are not in progress.

Facility staff shall examine and treat residents in a manner that maintains the privacy of their bodies. A resident shall be granted privacy when going to the bathroom and in other activities of personal hygiene. If an individual requires assistance, authorized staff should respect the individual's need for privacy. Only authorized staff directly involved in treatment should be present when treatments are given.

"Promptly" means delivery of mail or other materials to the resident within 24 hours of delivery by the postal service (including a post office box) and delivery of outgoing mail to the postal service within 24 hours of regularly scheduled postal delivery and pickup service.

The facility may set reasonable hours for visitation. If it would violate the rights of a roommate to have visitors in the resident's room, the facility shall establish alternate areas in the facility for visiting. These areas could include the chapel, a suitable office area, a dining room, or a porch or patio area.

When a room is available for a married couple to share, the facility shall permit them to share it if they choose.

All residents' possessions shall be treated with respect and safeguarded.

The facility has the right to limit personal property due to space limitations in the facility or for safety considerations.

Surveyor Guidance:

Document any instances where you observe a resident's privacy being violated. Completely document how the resident's privacy was violated.

> *Documentation Example: Resident #12 left without gown or bed covers and unattended on 2B Corridor at 3:30 p.m. February 25, 2001. Identify the responsible party, if possible.*

If residents' rooms have few personal possessions, ask residents and families if—

- *They are encouraged to have and to use personal items;*
- *Their personal property is safe in the facility.*

RR.7 RESTRAINTS

*Refer to **PATIENTS RIGHTS**;*

> *PR.7 – Restraint or Seclusion;*
>
> *PR.8 - Restraint or Seclusion: Staff Training Requirements and*
>
> *PR.9 - Reporting Deaths Associated with Restraint Usage*

RR.8 FREEDOM FROM ABUSE, NEGLECT, AND EXPLOITATION

SR.1 The resident has the right to be free from abuse, neglect, misappropriation of resident property, and exploitation as defined by CMS. This includes but is not limited to freedom from corporal punishment, involuntary seclusion and any physical or chemical restraint not required to treat the resident's medical symptoms. The facility shall:

SR.1a Not use verbal, mental, sexual, or physical abuse, corporal punishment, or involuntary seclusion, and

SR.1b Ensure that the resident is free from physical or chemical restraints imposed for purposes of discipline or convenience and that are not required to treat the resident's medical symptoms. When the use of restraints is indicated, the facility shall use the least restrictive alternative for the least amount of time and document ongoing re-evaluation of the need for restraints.

SR.2 The facility shall develop and implement written policies and procedures that:

SR.2a Prohibit and prevent abuse, neglect, and exploitation of residents and misappropriation of resident property, and,

SR.2b Investigate any such allegations.

SR.3 The facility shall not employ or otherwise engage individuals who:

SR.3a Have been found guilty of abuse, neglect, exploitation, misappropriation of property, or mistreatment by a court of law; or,

SR.3b Have had a finding entered into the State nurse aide registry concerning abuse, neglect, exploitation, mistreatment of residents or misappropriation of their property.

SR.4 The facility shall report to the State nurse aide registry or licensing authorities any knowledge it has of actions by a court of law against an employee, which would indicate unfitness for service as a nurse aide or other facility staff.

SR.5 In response to allegations of abuse, neglect, exploitation, or mistreatment, the facility shall:

SR.5a Ensure that all alleged violations involving abuse, neglect, exploitation or mistreatment, including injuries of unknown source, and misappropriation of resident property are reported immediately, but not later than 2 hours after the allegation is made, if the events that cause the allegation involve abuse or result in serious bodily injury, or not later than 24 hours if the events that cause the allegation do not involve abuse and do not result in serious bodily injury, to the administrator of the facility and to other officials (including to the State Survey Agency and adult protective services where state law provides for jurisdiction in

long-term care facilities) in accordance with State law through established procedures;

SR.5b Have evidence that all alleged violations are thoroughly investigated;

SR.5c Prevent further potential abuse, neglect, exploitation, or mistreatment while the investigation is in progress; and,

SR.5d Report the results of all investigations to the administrator or his or her designated representative and to other officials in accordance with State law, including to the State Survey Agency, within 5 working days of the incident, and if the alleged violation is verified appropriate corrective action shall be taken.

Interpretive Guidelines:

The facility shall assure that each resident is free from abuse, corporal punishment, and involuntary seclusion. The facility is responsible for preventing abuse, but also for those practices and omissions, neglect and misappropriation of property, which if left unchecked, lead to abuse. Residents shall not be subjected to abuse by anyone, including, but not limited to, facility staff, other residents, consultants or volunteers, staff of other agencies serving the individual, family members or legal guardians, friends, or other individuals.

Definitions:

- ***Abuse****: the willful infliction of injury, unreasonable confinement, intimidation, or punishment with resulting physical harm or pain or mental anguish, or deprivation by an individual, including a caretaker, of goods or services that are necessary to attain or maintain physical, mental, and psychosocial wellbeing. This presumes that instances of abuse of all residents, even those in a coma, cause physical harm, or pain or mental anguish. It includes verbal abuse, sexual abuse, physical abuse, and mental abuse including abuse facilitated or enabled through the use of technology.*

- ***Exploitation****: taking advantage of a resident for personal gain through the use of manipulation, intimidation, threats, or coercion.*

- ***Verbal abuse****: any use of oral, written or gestured language that willfully includes disparaging and derogatory terms to residents or their families, or within their hearing distance, regardless of their age, ability to comprehend, or disability. Examples of verbal abuse include but, are not limited to: threats of harm; and saying things to frighten a resident, such as telling a resident that they will never be able to see their family again.*

- ***Sexual abuse****: includes, but is not limited to, sexual harassment, sexual coercion, or sexual assault.*

- ***Physical abuse****: includes hitting, slapping, punching and kicking. It also includes controlling behavior through corporal punishment and restraints*

- ***Mental abuse****: includes, but is not limited to, humiliation, harassment, and threats of punishment or deprivation.*

- ***Neglect:*** *the failure of the facility, its employees or service providers to provide goods and services to a resident that are necessary to avoid physical harm, pain, mental anguish, or emotional distress.*

- ***Involuntary seclusion****: the separation of a resident from other residents or from his or her room or confinement to his or her room (with or without roommates) against the resident's will, or the will of the resident's legal representative. Emergency or short term monitored separation from other residents will not be considered involuntary seclusion and may be permitted if used for a limited period of time as a therapeutic intervention to reduce agitation until professional staff can develop a plan of care to meet the resident's needs.*

- ***Misappropriation of resident's property****: the patterned or deliberate misplacement, exploitation, or wrongful, temporary or permanent use of a resident's belongings or money without the resident's consent.*

In addition to inquiry of the State nurse aide registry or other licensing authorities, the facility should check all staff references and make reasonable efforts to uncover information about any past criminal prosecutions. "Found guilty by a court of law" applies to situations where the defendant pleads guilty, is found guilty, or pleads no contest to charges of abuse, neglect, exploitation, misappropriation of property, or mistreatment.

"Finding" is defined as a determination made by the State that validates allegations of abuse, neglect, mistreatment of residents or misappropriation of their property. Any facility staff found guilty of neglect, abuse, or mistreating residents or misappropriation of property by a court of law shall have his or her name entered into the nurse aide registry, or reported to the licensing authority, as appropriate.

Surveyor Guidance:

Request and review any resident complaints. Review of actual incidents and predisposing factors to abuse or neglect and misappropriation of property.

Determine if there are any residents being temporarily separated from other residents, for less than 24 hours, as an emergency short-term intervention. Validate the need for the separation to include:

- *What are the symptoms that led to the consideration of the separation?*

- *Are these symptoms caused by failure to:*

    - *Meet individual needs;*

    - *Provide meaningful activities;*

    - *Manipulate the resident's environment?*

- *Can the cause(s) be removed?*

- *If the cause(s) cannot be removed, has the facility attempted to use alternatives short of separation?*

- *Does the facility use the separation for the least amount of time?*

- *To what extent has the resident, surrogate or representative participated in care planning and made an informed choice about separation?*

- *Does the facility monitor and adjust care to reduce negative outcomes, while continually trying to find and use less restrictive alternatives?*

- *If residents are temporarily separated in secured units, staff should carry keys to these units at all times.*

- *If the purpose of the unit is to provide specialized care for residents who are cognitively impaired (through a program of therapeutic activities designed to enable residents to attain and maintain the highest practicable physical, mental or psychosocial well-being) then placement in the unit is not in violation of resident rights, as long as the resident's individual care plan indicates the need for the stated purpose and services provided in the unit and the resident, surrogate, or representative has participated in the placement decision.*

Report and record any instances where the survey team observes an abusive incident. Completely document who committed the abusive act, the nature of the abuse, and where and when it occurred. Ensure that the facility addresses that incident immediately.

If the survey team's observations and resident's responses signal the presence of abuse, determine how the facility prevents and reports abusive behavior.

Review the policies and procedures regarding abuse prevention: Note particularly the extent to which those policies concern the areas uncovered through complaints and/or previous survey.

Review a sampling of employment applications for questions about convictions or mistreatment, neglect or abuse of residents, or misappropriation of their property. Determine if applicants have answered these questions and if affirmative answers had resulted in rejections of employment candidates.

Review and verify the results of any in-house investigations of mistreatment, neglect, or abuse of residents, misappropriation of their property, or injuries of unknown sources. Determine if:

- *Was the administrator notified of the incident and when?*

- *Did investigations begin promptly after the report of the problem?*

- *Is there a record of statements or interviews of the resident, suspect (if one is identified), any eyewitnesses and any circumstantial witnesses?*

- *Was relevant documentation reviewed and preserved (e.g., dated dressing which was not changed when treatment recorded change)?*

- *Was the alleged victim examined promptly (if injury was suspected) and the finding documented in the report?*

- *What steps were taken to protect the alleged victim from further abuse (particularly*

where no suspect has been identified)?

- *What actions were taken as a result of the investigation?*

- *What corrective action was taken, including informing the nurse aide registry, State licensure authorities, and other agencies (e.g., long-term care ombudsman; adult protective services; Medicaid fraud and abuse unit)?*

FACILITY SERVICES (FS)

FS.1 PATIENT ACTIVITIES

SR.1 RESERVED

FS.2 SOCIAL SERVICES

SR.1 The facility shall provide medically related social services to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident.

Interpretive Guidelines:

This requirement specifies that facilities aggressively identify the need for medically related social services and pursue the provision of these services. A qualified social worker need not personally provide all of these services. It is the responsibility of the facility to identify the medically related social service needs of the resident and assure that the needs are met by the appropriate discipline.

"Medically-related social services" means services provided by the facility's staff to assist residents in maintaining or improving their ability to manage their everyday physical, mental, and psychosocial needs. These services could include:

- *Assisting residents in voicing and obtaining resolution to grievances about treatment, living conditions, visitation rights, and accommodation of needs;*
- *Assisting or arranging for a resident's communication of needs through the resident's primary method of communication or in a language that the resident understands;*
- *Making arrangements for obtaining needed adaptive equipment, clothing, and personal items;*
- *Maintaining contact with family (with resident's permission) to report on changes in health, current goals, discharge planning, and encouragement to participate in care planning;*
- *Assisting with informing residents and those they designate about the resident's health status and health care choices;*
- *Making referrals and obtaining services from outside entities (e.g., talking books, absentee ballots, community wheelchair transportation);*
- *Assisting residents with financial and legal matters (e.g., applying for pensions, referrals to lawyers, referrals to funeral homes for preplanning arrangements);*
- *Discharge planning services (e.g., helping to place a resident on a waiting list for community congregate living, arranging intake for home care services for residents returning home, assisting with transfer arrangements to other facilities);*
- *Providing or arranging provision of needed counseling services;*

- *Assisting residents to determine how they would like to make decisions about their health care, and whether or not they would like anyone else to be involved in those decisions;*

- *Identifying and promoting individualized, non-pharmacological approaches to care that meet the mental and psychosocial needs of each resident;*

- *Meeting the needs of residents who are grieving;*

- *Assisting residents with dental/denture care, podiatric care; eye care; hearing services, and obtaining equipment for mobility or assistive eating devices; and,*

- *Where the Medicaid State Plan does not cover needed services, facilities are still required to attempt to obtain these services.*

Situations in which the facility should provide social services or obtain needed services from outside entities include, but are not limited to the following:

- *Lack of an effective family or community support system or legal representative;*

- *Expressions or indications of distress that affect the resident's mental and psychosocial well-being, resulting from depression, chronic diseases (e.g., Alzheimer's disease and other dementia related diseases, schizophrenia, multiple sclerosis), difficulty with personal interaction and socialization skills, and resident to resident altercations;*

- *Abuse of any kind (e.g., alcohol or other drugs, physical, psychological, sexual, neglect, exploitation);*

- *Difficulty coping with change or loss (e.g., change in living arrangement, change in condition or functional ability, loss of meaningful employment or activities, loss of a loved one); and*

- *Need for emotional support.*

Surveyor Guidance:

In a sampling of medical records, validate that goal attainment been evaluated and the care plan changed accordingly and that there is evidence that social services interventions successfully address residents' needs and link social supports, physical care, and physical environment with residents' needs and individuality.

When interviewing staff who are responsible for social work, ascertain how they:

- *Monitor the resident's progress in improving physical, mental and psychosocial functioning;*

- *Establish and maintain relationships with the resident's family or legal representative;*

- *Implement social services interventions to assist the resident in meeting treatment goals; and,*

- *Access services for Medicaid recipients when a Medicaid State Plan does not cover those services.*

FS.3 DENTAL SERVICES

SR.9 The facility shall assist residents in obtaining routine and 24-hour emergency dental care.

SR.2 The facility shall have a policy identifying those circumstances when the loss or damage of dentures is the facility's responsibility and may not charge a resident for the loss or damage of dentures determined in accordance with facility policy to be the facility's responsibility;

SR.3 The facility shall promptly, within 3 days, refer residents with lost or damaged dentures for dental services. If a referral does not occur within 3 days, the facility shall provide documentation of what they did to ensure the resident could still eat and drink adequately while awaiting dental services and the extenuating circumstances that led to the delay.

SR.4 The facility shall assist the resident if necessary or if requested:

SR.4a In making appointments; and,

SR.4b By arranging for transportation to and from the dental services location.

SR.5 The facility may charge a Medicare resident an additional amount for routine and emergency dental services;

SR.6 The facility shall assist residents who are eligible and wish to participate to apply for reimbursement of dental services as an incurred medical expense under the State plan.

Interpretive Guidelines:

The facility shall ensure that a dentist is available for residents. It can satisfy this requirement by employing a staff dentist or having a contract/arrangement with a dentist to provide services.

For Medicare and private pay residents, facilities are responsible for having the services available, but they may impose an additional charge for the services. Medicaid residents may not be charged.

For all residents of the facility, if they are unable to pay for needed dental services, the facility should attempt to find alternative funding sources or alternative service delivery systems so that the resident is able to maintain his/her highest practicable level of wellbeing.

“Routine dental services” means an annual inspection of the oral cavity for signs of disease, diagnosis of dental disease, dental radiographs as needed, dental cleaning, fillings (new and repairs), minor dental plate adjustments, smoothing of broken teeth, and limited prosthodontic procedures (e.g., taking impressions for dentures and fitting dentures).

“Emergency dental services” includes services needed to treat an episode of acute pain in

teeth, gums, or palate; broken, or otherwise damaged teeth, or any other problem of the oral cavity that requires immediate attention.

"Prompt referral" means, within reason, as soon as the dentures are lost or damaged. Referral does not mean that the resident shall see the dentist at that time but, does mean that an appointment (referral) is made, or that the facility is aggressively working at replacing the dentures.

The facility shall have a policy identifying those instances when the loss or damage of partial or full dentures is the facility's responsibility, such as when facility staff discards dentures placed on a meal tray. A blanket policy of facility non-responsibility for the loss or damage of dentures or a policy stating the facility is only responsible when the dentures are in actual physical possession of facility staff would not meet the requirement. In addition, the facility is prohibited from requesting or requiring residents or potential residents to waive any potential facility liability for losses of personal property.

Surveyor Guidance:

When interviewing residents, determine if they have problems eating and maintaining nutritional status because of poor oral health or oral hygiene (missing teeth and may be in need of dentures).

Review the resident's records for identification of the resident's dental needs and the resident's responsiveness to dental services.

Determine if the facility provided the assistance to obtain dental services needed or requested by the resident or resident representative and whether the facility assisted the resident with arranging transportation to the dental appointment.

FS.4 SPECIALIZED REHABILITATIVE SERVICES

If specialized rehabilitative services such as, but not limited to, physical therapy, speech-language pathology, occupational therapy, respiratory therapy, and rehabilitative services for a mental disorder and intellectual disability or services of a lesser intensity as set forth at 42 CFR Section 483.120(c), are required in the resident's comprehensive plan of care, the facility shall:

SR.1 Provide the required services; or—

SR.2 In accordance with 42 CFR Section 483.70(g), obtain the required services from an outside resource that is a provider of specialized rehabilitative services and is not excluded from participating in any federal or state health care programs pursuant to section 1128 and 1156 of the Act.

SR.3 Specialized rehabilitative services shall be provided under the written order of a MD/DO by qualified personnel.

Interpretive Guidelines:

The intent of this regulation is to assure that residents receive necessary specialized rehabilitative services as determined by the comprehensive assessment and care plan, to

prevent avoidable physical and mental deterioration and to assist them in obtaining or maintaining their highest practicable level of functional and psychosocial wellbeing.

Specialized rehabilitative services are considered a facility service and are included within the scope of facility services. They shall be provided to residents who need them even when the services are not specifically enumerated in the State plan.

A facility is not obligated to provide specialized rehabilitative services if it does not have residents who require these services. If a resident develops a need for these services after admission, the facility shall either provide the services, or, where appropriate, obtain the service from an outside resource.

For a resident with mental illness (MI) or mental retardation (MR) to have his or her specialized needs met, the individual shall receive all services necessary to assist the individual in maintaining or achieving as much independence and self-determination as possible. Specialized services for mental illness or mental retardation refers to those services to be provided by the State which can only be delivered by personnel or programs other than those of the nursing facility (NF) because the overall level of NF services is not as intense as necessary to meet the individual's needs.

"Mental health rehabilitative services for MI and MR" refers to those services of lesser frequency or intensity to be implemented by all levels of nursing facility staff who come into contact with the resident who is mentally ill or who has mental retardation. These services are necessary regardless of whether or not they require additional services to be provided for or arranged by the State as specialized services.

Mental health rehabilitative services for MI and MR may include, but are not limited to:

- *Consistent implementation during the resident's daily routine and across settings, of systematic plans that are designed to change inappropriate behaviors;*

- *Drug therapy and monitoring of the effectiveness and side effects of medications which have been prescribed to change inappropriate behavior or to alter manifestations of psychiatric illness;*

- *Provision of a structured environment for those individuals who are determined to need such structure (e.g., structured socialization activities to diminish tendencies toward isolation and withdrawal);*

- *Development, maintenance and consistent implementation across settings of those programs designed to teach individuals the daily living skills they need to be more independent and self-determining including, but not limited to, grooming, personal hygiene, mobility, nutrition, vocational skills, health, drug therapy, mental health education, money management, and maintenance of the living environment;*

- *Crisis intervention services;*

- *Individual, group, and family psychotherapy;*

- *Development of appropriate personal support networks; and,*

- *Formal behavior modification progress.*

Determine the extent of follow through with the comprehensive care plan. Verify from the chart that the resident is receiving the frequency and type of therapy as outlined in the care plan.

1. Physical Therapy

- *What did the facility do to improve the resident's muscle strength? The resident's balance?*
- *What did the facility do to determine if an assistive device would enable the resident to reach or maintain his/her highest practicable level of physical function?*
- *If the resident has an assistive device, is he/she encouraged to use it on a regular basis?*
- *What did the facility do to increase the amount of physical activity the resident could do (for example, the number of repetitions of an exercise, the distance walked)?*
- *What did the facility do to prevent or minimize contractures, which could lead to decreased mobility and increased risk of pressure ulcer occurrence?*

2. Occupational Therapy

What did the facility do to:

- *Decrease the amount of assistance needed to perform a task?*
- *Decrease behavioral symptoms?*
- *Improve gross and fine motor coordination?*
- *Improve sensory awareness, visual-spatial awareness, and body integration?*
- *Improve memory, problem solving, attention span, and the ability to recognize safety hazards?*

3. Speech-Language Pathology

What did the facility do to:

- *Improve auditory comprehension?*
- *Improve speech production?*
- *Improve expressive behavior?*
- *Improve the functional abilities of residents with moderate to severe hearing loss who have received an audiology evaluation?*
- *For the resident who cannot speak, did the facility assess for a communication board*

or an alternate means of communication?

4. Rehabilitative Services for MI and MR

What did the facility do to:

- *Decrease incidents of inappropriate behaviors, for individuals with MR, or behavioral symptoms for persons with MI? To increase appropriate behavior?*
- *Identify and treat the underlying factors behind tendencies toward isolation and withdrawal?*
- *Develop and maintain necessary daily living skills?*
- *How has the facility modified the training strategies it uses with its residents to account for the special learning needs of its residents with MI or MR?*

A qualified professional provides specialized rehabilitative services for individuals under a MD/DO's order. Once the assessment for specialized rehabilitative services is completed, a care plan shall be developed, followed, and monitored by a licensed professional. Once a resident has met his or her care plan goals, a licensed professional can either discontinue treatment or initiate a maintenance program which either nursing or restorative aides will follow to maintain functional and physical status.

"Qualified personnel" means a physical therapist, occupational therapist, respiratory therapist, speech-language pathologist, physician, nurse practitioner, clinical nurse specialist, or physician's assistant, who is licensed or certified by the state to furnish therapy services. Qualified personnel may also include a physical therapist assistant (PTA), or an occupational therapy assistant (OTA) when furnishing services under the supervision of a qualified therapist. In addition to meeting the specific competency requirements as part of their license and certification requirements defined under State law or regulations, these personnel shall have the training, competencies and skill sets to care for residents as identified through resident assessments and described in the plan of care.

Health rehabilitative services for MI and MR shall be implemented consistently by all staff unless the nature of the services is such that they are designated or required to be implemented only be licensed or credentialed personnel.

Surveyor Guidance:

Verify that the facility employs professional staff who have experience working directly with or designing training or treatment programs to meet the needs of individuals with MI or MR.

Determine if there are any problems in quality of care related to maintaining or improving functional abilities. Determine if these problems are attributable in part to the qualifications of specialized rehabilitative services staff.

Review and verify that the care plan and record that qualified personnel provide rehabilitative services are under the written order of a MD/DO.

When interviewing a resident with MI or MR, determine

- *Who they talk to when they have a problem or need something?*
- *What they do when to feel happy? Sad? Can't sleep at night?*
- *In what activities are they involved, and how often?*

RESIDENT NUTRITION (RN)

RN.1 NUTRITIONAL STATUS

SR.1 Using the resident's comprehensive assessment, the facility shall ensure that a resident:

SR.1a Maintains acceptable parameters of nutritional status, such as usual body weight or desirable body weight range and electrolyte balance, unless the resident's clinical condition demonstrates that this is not possible or resident preferences indicate otherwise;

SR.1b Is offered sufficient fluid intake to maintain proper hydration and health; and,

SR.1c Is offered a therapeutic diet when there is a nutritional problem, and the health care provider orders a therapeutic diet.

SR.4 The facility shall have written policies and procedures in place that ensure that the nutritional needs of resident's are met in accordance with recognized dietary practices. All patient diets, including therapeutic diets, shall be ordered by the practitioner responsible for the care of the patients or by a qualified dietitian or qualified nutrition professional as authorized by the medical staff in accordance with State law governing dietitians and nutrition professionals and that the requirement of 42 CFR § 483.25 (Quality of care) is met with respect to inpatients receiving post hospital SNF care.

Interpretive Guidelines:

Refer to DIETARY SERVICES (DS)

"Acceptable parameters of nutritional status" refers to factors that reflect that an individual's nutritional status is adequate, relative to his/her overall condition and prognosis, such as weight, food/fluid intake, and pertinent laboratory values. "Nutritional status" includes both nutrition and hydration status.

Dietary requirements of 42 CFR §483.25 (g)- 483.25(h) (Quality of care) with respect to residents receiving post-hospital SNF care include:

- *Assisted nutrition and hydration. (Includes naso-gastric and gastrostomy tubes, both percutaneous endoscopic gastrostomy and percutaneous endoscopic jejunostomy, and enteral fluids). Based on a resident's comprehensive assessment, the facility shall ensure that a resident—*
    - *Maintains acceptable parameters of nutritional status, such as usual body weight or desirable body weight range and electrolyte balance, unless the resident's clinical condition demonstrates that this is not possible or resident preferences indicate otherwise;*
    - *Is offered sufficient fluid intake to maintain proper hydration and health; and*

- *Is offered a therapeutic diet when there is a nutritional problem, and the health care provider orders a therapeutic diet.*

- *A resident who has been able to eat enough alone or with assistance is not fed by enteral methods unless the resident's clinical condition demonstrates that enteral feeding was clinically indicated and consented to by the resident; and*

- *A resident who is fed by enteral means receives the appropriate treatment and services to restore, if possible, oral eating skills and to prevent complications of enteral feeding including but not limited to aspiration pneumonia, diarrhea, vomiting, dehydration, metabolic abnormalities, and nasal-pharyngeal ulcers.*

- *Parenteral fluids. Parenteral fluids shall be administered consistent with professional standards of practice and in accordance with physician orders, the comprehensive person-centered care plan, and the resident's goals and preferences.*

Failure to identify residents at risk for compromised nutrition and hydration may be associated with an increased risk of mortality and other negative outcomes, such as impairment of anticipated wound healing, decline in function, fluid and electrolyte imbalance/dehydration, and unplanned weight change. While food intake may be considered, ensuring a resident receives the fluids they require can more easily be overlooked. Individuals who do not receive adequate fluids are more susceptible to urinary tract infections, pneumonia, pressure injuries, skin infections, confusion, and disorientation.

Parameters of nutritional status that are unacceptable include unplanned weight loss as well as other indices such as peripheral edema, cachexia and laboratory tests indicating malnourishment (e.g., serum albumin levels).

Weight: Since ideal body weight charts have not yet been validated for the institutionalized elderly, weight loss (or gain) is a guide in determining nutritional status. An analysis of weight loss or gain should consider the loss or gain in light of the individual's former lifestyle as well as the current diagnosis.

Clinical Observations: Potential indicators of malnutrition are pale skin, dull eyes, swollen lips, swollen gums, and swollen and/or dry tongue with scarlet or magenta hue, poor skin turgor, cachexia, bilateral edema, and muscle wasting.

Risk factors for malnutrition are—

- *Drug therapy that may contribute to nutritional deficiencies such as—*

    - *Cardiac glycosides;*

    - *Diuretics;*

    - *Anti-inflammatory drugs;*

    - *Antacids (antacid overuse);*

    - *Laxatives (laxative overuse);*

- *Psychotropic drug overuse;*
- *Anticonvulsants;*
- *Antineoplastic drugs;*
- *Phenothiazines;*
- *Oral hypoglycemics;*

- *Poor oral health status or hygiene, eyesight, motor coordination, or taste alterations;*
- *Depression or dementia;*
- *Therapeutic or mechanically altered diet;*
- *Lack of access to culturally acceptable foods; and,*
- *Slow eating pace resulting in food becoming unpalatable, or in staff removing the tray before resident has finished eating.*

Clinical conditions demonstrating that the maintenance of acceptable nutritional status may not be possible include, but are not limited to:

- *Refusal to eat and refusal of other methods of nourishment;*
- *Advanced disease (e.g., cancer, malabsorption syndrome);*
- *Increased nutritional/caloric needs associated with pressure sores and wound healing (e.g., fractures, burns);*
- *Radiation or chemotherapy;*
- *Kidney disease, alcohol/drug abuse, chronic blood loss, hyperthyroidism;*
- *Gastrointestinal surgery; and,*
- *Prolonged nausea, vomiting, and diarrhea not relieved by treatment given according to nationally recognized standards of practice and guidelines.*

"Therapeutic diet" means a diet ordered by a MD/DO, physician assistant, nurse practitioner, clinical nurse specialist, or delegated registered or licensed dietitian (to the extent allowed by State law and clinical privileging) as part of treatment for a disease or clinical condition, to eliminate or decrease certain substances in the diet, (e.g., sodium) or to increase certain substances in the diet (e.g., potassium), or to provide food the resident is able to eat (e.g., a mechanically altered diet).

Surveyor Guidance:

Verify residents have maintained acceptable parameters of nutritional status. Where indicated by the resident's medical status, have clinically appropriate therapeutic diets been prescribed?

If a resident is receiving a therapeutic diet, is the diet prescribed by the attending physician or delegated registered or licensed dietitian?

If a registered or licensed dietitian has written the order, is this delegation by the physician allowed by State law?

Verify and determine, if residents did not maintain acceptable parameters of nutritional status:

- *Did the facility identify factors that put the resident at risk for malnutrition?*
- *What routine preventive measures and care did the resident receive to address unique risk factors for malnutrition?*
- *Were individual goals of the plan of care periodically evaluated and, if not met, were alternative approaches considered or attempted?*
- *Were staff responsibilities for maintaining nutritional status clear, including monitoring the amount of food the resident is eating at each meal and offering substitutes?*
- *Was this care provided consistently?*

APPENDIX B – PSYCHIATRIC SERVICES

NOTE: Appendix B is applicable to psychiatric hospitals.

GENERAL REQUIREMENTS (PH-GR)

SR.1 The psychiatric hospital shall:

SR.1a Be primarily engaged in providing, by or under the supervision of a Doctor of Medicine or Osteopathy, psychiatric services for the diagnosis and treatment of mentally ill persons;

SR.1b Meet the conditions of participation for hospitals specified in 42 CFR Sections 482.1 through 482.23 and Sections 482.25 through 482.57, and all NIAHO® Accreditation Requirements for hospitals;

SR.1c Maintain clinical records on all patients; including records sufficient to permit CMS to determine the degree and intensity of treatment furnished to Medicare beneficiaries, as specified in 42 CFR Section 482.61 (see SRs for PH-MR, PH-E, PH-TP, PH-PN, and PD-DP).; and,

SR.1d Meet the staffing requirements specified in CFR 42 Section 482.62 (See SRs for PH-PR, PH-MS, PH-NS, PH-PS, PH-SS, and PH-SS).

SR.2 The psychiatric hospital shall provide a comprehensive program structure that is delineated in a document that describes the scope of services that includes:

SR.2a Populations served;

SR.2b Various settings;

SR.2c Hours of service;

SR.2d Days of service;

SR.2e Frequency of service;

SR.2f Payer sources;

SR.2g Referral sources; and,

SR.2h Specific services offered, by contract or directly.

SR.3 The leadership reviews the scope of service annually and updates as indicated.

SR.4 The leadership provides the resources needed to support the scope of service of each program provided.

SR.4a Each program has the facilities, space, materials, and staffing to provide the care needed for the appropriate length of time for patients served, in all settings.

SR.4b Facilities will be clean, well maintained and designed for safety as well as personal dignity and optimizing positive self-regard.

SR.5 If a psychiatric hospital provides outpatient services (e.g., Intensive Outpatient Programs (IOP)), the leadership shall ensure that the services meet the requirements of PH-GR.1 (SR.1-4).

Interpretive Guidelines:

Maintain clinical records on all patients, including records sufficient to permit CMS to determine the degree and intensity of treatment furnished to Medicare beneficiaries as specified in 42 CFR Section 482.61; and 42 CRF Section 482.60(d) Meet the staffing requirements specified.

The scope of service is defined at the program level and shall provide all the interested parties such as people served, referral sources and other stakeholders as well as the staff of the psychiatric hospital, a description of each of the services provided and how it meets the needs of the patients served.

The /program leadership has an obligation to provide a safe, secure, clean and well-maintained physical environment that enhances personal dignity as well as much privacy as possible while still maintaining safety.

MEDICAL RECORDS SERVICE (PH-MR)

The medical records maintained by the psychiatric hospital shall permit determination of the degree and intensity of the treatment provided to individuals who are furnished services in the psychiatric hospital. Administrative responsibility for medical records shall rest with the medical record service of the psychiatric hospital.

SR.1 The psychiatric hospital shall provide these services in accordance with the scope and complexities of services offered and allocate the appropriate resources to ensure efficient functioning.

SR.2 The psychiatric hospital shall maintain an accurately written, promptly completed medical record for each inpatient and outpatient treatment.

SR.3 The psychiatric hospital shall comply with the requirements of MR.8 Electronic Notification.

Interpretive Guidelines:

The psychiatric hospital shall have administrative responsibility for all medical records- both inpatient and outpatient. The medical record service shall reflect the scope and complexities of services offered. The definition of a "medical record" refers to 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 psychiatric hospital, alternate outpatient settings and programs and the patients with respect to the scope and complexities of services. The psychiatric hospital shall maintain an accurately written, promptly completed medical record for each inpatient and outpatient episode of care.

SR.4 Medical records shall stress the psychiatric components of the record, including history of findings and treatment provided for the psychiatric condition for which the patient is hospitalized (or admitted into any alternative psychiatric services). In addition to the requirements of 42 CFR Section 482.24 (Condition of Participation: Medical record services) and the NIAHO® MR requirements, the psychiatric patient's medical record shall also include:

SR.4a Identification data including the patient's legal status;

SR.4b A provisional or admitting diagnosis at the time of admission, including the diagnosis of intercurrent diseases present as well as the psychiatric diagnosis;

SR.4c The reasons for admission shall be clearly documented as stated by the patient and/or others significantly involved;

SR.4d The social service records, including reports of interviews with patients, family members, and others, shall provide an assessment of home plans and family attitudes, and community resource contacts as well as a social history;

SR.4e When indicated, a complete neurological examination shall be recorded at the time of the admission physical examination;

SR.4f A psychiatric evaluation (See PH-E);

SR.4g A physical health screening (and as indicated for medically supervised outpatient services)

SR.4g(1) A health screening is completed for each person admitted to a medically supervised service that includes:

SR.4g(1)(i) The need for medical care;

SR.4g(1)(ii) The intensity of services needed; and,

SR.4g(1)(iii) Laboratory tests, when needed.

SR.4g(2) For patients admitted to an outpatient detoxification program, a full medical evaluation is obtained prior to or within 24 hours of admission and includes:

SR.4g(2)(i) A physical examination;

SR.4g(2)(ii) Orders for appropriate tests; and,

SR.4g(2)(iii) Face-to-face consultation with a physician.

Interpretive Guidelines:

Definitions:

- ***Legal Status*** *is defined in the State statutes and dictates the circumstances under which the patient was admitted and/or is being treated – e.g., voluntary, involuntary, committed by court, evaluation and recertification are in accordance with state requirements.*

- ***Admission or working psychiatric diagnosis*** *(including rule-out diagnoses) shall be written in keeping with the most current edition of the American Psychiatric Association's Diagnostic and Statistical Manual (DSM) or the approved International Classification of Diseases (ICD) nomenclature. This diagnosis shall be made and entered into the chart of each patient at the time of the admission examination. If a diagnosis is absent, there shall be justification for its absence.*

All current (other than psychiatric) physical illness diagnoses shall be documented when they are made. Attention shall be paid to physical examination notes, including known medical conditions.

Surveyor Guidance:

Determine through interview with staff the terminology they use in defining "legal status." If evaluation and recertification is required by the State, determine that legal documentation supporting this status is present. Changes in legal status shall also be recorded with the date of change.

Diagnoses may be found in a variety of locations in the medical record, e.g., the identification/face sheet, the finding of admission physical examination, the psychiatric evaluation the admission work up or the physician's progress notes.

NOTE: The final diagnosis may differ from the initial diagnosis if subsequent evaluation and observation support a change.

PSYCHIATRIC EVALUATION (PH-E)

The psychiatric evaluation is a total appraisal or assessment of the patient's illness. It is the physician's assessment of the contributing factors and forces in the evolution of the patient's illness including the patient's perception of his or her illness. The psychiatric evaluation is done for the purpose of determining the patient's diagnosis and treatment and, therefore, it shall contain the necessary information to justify the diagnosis and planned treatment.

SR.1 Each inpatient shall receive a psychiatric evaluation that is completed within a timeframe appropriate to the patient population served, but not to exceed 60 hours from admission.

SR.1a In any case where state regulations are more stringent, the organization shall follow state regulations.

SR.2 The psychiatric evaluation shall include:

SR.2a The patient's chief complaints and/or reaction to admission, recorded in patient's own words when possible;

SR.2b A medical history;

SR.2c Documentation of a mental status exam;

SR.2d Description of onset of illness and the circumstances leading to admission;

SR.2e Description of attitudes and behavior;

SR.2f Estimate of intellectual functioning, memory functioning and orientation; and,

SR.2g Inventory of patient assets in descriptive, not interpretive terms.

Interpretive Guidelines:

The expected length of time to complete a psychiatric evaluation varies with the psychiatric population served. For example, in psychiatric hospitals with a shorter length of stay (measured in days or weeks), the expectation is that the treatment plan be completed within a timeframe that allows for appropriate psychiatric/medical diagnosis of the patient (e.g., within 24 hours of a 7-day hospitalization). Similarly, in organizations that provide long-term or mandated care (e.g., civil, involuntary or other commitments measured in months or years), the expectation is that that the psychiatric evaluation be completed within a timeframe that allows for the collection of information necessary to meet the requirements of the commitment and provide for appropriate psychiatric/medical diagnosis of the patient (e.g., within 60 hours of admission).

The psychiatric evaluation shall include the non-psychiatric medical history including physical disabilities, intellectual disabilities, and treatment.

While performing the psychiatric evaluation, the physician reaches an understanding of the patient's basic personality structure, of the patient's developmental period, of his or her value systems, of his or her past medical history including surgical procedures and other treatments, his or her past psychological traumatic experiences, his or her defense mechanisms, his or her supporting systems, any precipitating factors and how all these may have impacted and interplayed with each other to result in the present illness. In the psychiatric evaluation, the patient should emerge as a dynamic human being with a past, a present and a potential future with a thread of logical continuity.

The psychiatric evaluation includes all the requirements described in this standard and the information necessary to justify the diagnosis and treatment. A physician's signature is necessary. In those cases, where the mental status portion of the psychiatric evaluation is performed by a non-physician, there shall be evidence that the person is credentialed by the psychiatric hospital, legally authorized by the State to perform that function, and a physician review and countersignature is present, where required by psychiatric hospital policy or State

law.

***Mental status** shall describe the appearance and behavior, emotional response, verbalization, thought content, and cognition of the patient as reported by the patient and observed by the examiner at the time of the examination. This description is appropriate to the patient's condition. From this information one can conclude that the patient is oriented, if his/ her memory is intact, if he/she has poor judgment and no insight. It is not acceptable just to write "oriented, memory intact, judgment poor, and insight nil," without any supportive information.*

***Identified problem** shall be related to the patient's need for admission. The psychiatric evaluation includes a history of present illness, including onset, precipitating factors and reason for the current admission, signs and symptoms, course, and the results of any treatment received.*

***Attitudes and behavior** Problem statement shall describe behavior(s) which require change in order for the patient to function in a less restrictive setting. The identified problems may also include behavioral or relationship difficulties with significant others which require active treatment in order to facilitate a successful discharge.*

***Inventory of the patient's assets** Although the term strength is often used interchangeably with assets, only the assets that describe personal factors on which to base the treatment plan or which are useful in therapy represent personal strengths. Strengths are personal attributes e.g., knowledge, interests, skills, aptitudes, personal experiences, education, talents and employment status, which may be useful in developing a meaningful treatment plan.*

Surveyor Guidance:

- *Review organization policy/procedure to determine organization requirements regarding timeframes for completion of psychiatric evaluation*
- *Determine if any state regulations regarding timeframes for the completion of psychiatric evaluations exist*
    - *Interview staff*
    - *Review regulations as appropriate*

Ensure the evaluation includes a description of any past relevant surgeries as well as past medical conditions and disabilities especially those of a chronic nature. There may be some determination if these contributed to the patient's psychiatric condition. It is essential to note if any of these conditions are still present to any significant degree and if they are likely to impact the patient's recovery/remission. If these physical issues need to be addressed immediately, the psychiatric hospital will need to determine if they have the capability to treat the patient's condition. Medication reconciliation is of vital importance for the patients and shall be well documented.

The psychiatric assessment shall detail why the patient is admitted, how the patient came to be admitted, voluntarily or not, and how the patient feels about the admission.

The assessment shall include any past history of psychiatric problems and treatment, including prior precipitating factors, diagnosis, course and treatment will give an indication of how long the

patient has been ill and how it has affected their life, either long or short term (school, relationships, employment, health etc.).

What medications or supports helped him/her improve in the past? Are the same resources available to impact on the patient's treatment during this episode?

Past family, educational, vocational, occupational and social history can determine if there is a presence or absence of familial predisposition to mental illness.

Within the psychiatric evaluation does one find the specific signs and symptoms, and other factors that justify the diagnosis?

NEUROLOGICAL EXAMINATION (PH-NE)

Upon admission, the patient shall receive a thorough history and physical examination with all indicated laboratory examinations. These investigations shall be sufficient to discover all structural, functional, systemic and metabolic disorders. As part of the physical examination, the physician will perform a "screening" neurological examination. In any case where a system review indicates positive neurological symptomatology, a more detailed examination would be necessary, with neurological work-up or consultation ordered as appropriate after the screening neurological examination was completed.

SR.1 When indicated, a complete neurological examination (including gross testing of Cranial Nerves II through XII) shall be recorded at the time of the admission physical examination.

Interpretive Guidelines:

Upon admission, the patient shall receive a thorough history and physical examination with all indicated laboratory examinations. These investigations shall be sufficient to discover all structural, functional, systemic and metabolic disorders. A thorough history of the patient's past physical disorders, head trauma, accidents, substance dependence/abuse, exposure to toxic agents, tumors, infections, seizures or temporary loss of consciousness, and headaches, will alert the physician to look for the presence of continuing pathology or possible sequelae any of which may turn out to be significant and pertinent to the present mental illness. Equally important is a thorough physical examination to look for signs of any current illness since psychotic symptoms may be due to a general medical condition or substance related disorder.

The screening neurological examination

As part of the physical examination, the physician will perform a "screening" neurological examination. While there is no precise definition of a screening neurological examination in medical practice such examination is expected to assess gross function of the various divisions of the central nervous system as opposite to detailed, fine testing of each division. Gross testing of Cranial Nerves II through XII shall be included. Statements such as "Cranial Nerves II to XII intact" are not acceptable. These areas may be found in various parts of the physical examination and not just grouped specifically under the neurological.

Complete neurological examination.

A complete, comprehensive neurological examination includes a review of the patient's history, physical examination and for psychiatric patients, a review of the psychiatric evaluation. The neurologist/psychiatrist himself/herself also takes a history to obtain the necessary information not already available in the medical record or referral form. The neurological examination is a detailed, orderly survey of the various sections of the nervous system. As an example, whereas a simple reading of a printed page will be sufficient to assess grossly the patient's sight (cranial nerve II) in a complete neurological examination, the neurologist may test visual acuity with a Snellen chart, perform a fundoscopic examination of both eyes (sometimes after dilating the pupils) and he/she will examine the patient's visual fields. In the examination of the motor system, the power of muscle groups of the extremities, the neck and trunk are tested. Where an indication of diminished strength is noted, testing of smaller muscle groups and even individual muscles are tested. In complete neurological examinations, all the systems are examined, but the physician will emphasize even more the areas pertinent to the problem for which the examination was requested.

Surveyor Guidance:

Did the presence of an abnormal physical finding or laboratory finding justify the need for further diagnostic testing, or for the development of a concurrent diagnosis? If the finding justified further follow-up in either situation, was such follow-up done?

Is there evidence that a screening neurological examination was done and recorded at the time of the physical examination?

Was the screening neurological or history indicative of possible involvement (tremors, paralysis, motor weakness or muscle atrophy, severe headaches, seizures, head trauma?

If indicated, was a complete, comprehensive neurological exam ordered, completed and recorded in the medical record in a timely manner?

If an identified physical illness requires immediate treatment, is the treatment being given?

How will an identified physical illness be likely to impact on the patient's eventual outcome? To what extent has this potential impact been addressed by the team?

The purpose of this regulation is to provide an understanding of what caused the patient to be admitted and the patient's response to admission.

The psychiatric hospital records the statements and reason for admission given by family and by others, as well as the patient (preferably verbatim), with informant identified, in a variety of locations, e.g., in transfer and admission notes from the physician, nurses and social workers.

Records shall not contain vague, ill-defined reports from unknown sources. Records shall record "who," "what," "where," "when," and "why" as applicable.

Can the patient describe problems, stresses, situations experienced prior to admission, or do they still exist?

Who is the informant?

Did the informant witness the patient's behavior? If not, on what basis has the informant come

to know the patient's behavior?

Has staff elicited whether the patient has exhibited similar behavior previously? If so, what was different this time to make admission necessary?

Were there other changes/events in the patient's environment (death, separations of significant others) which contributed to the need for admission? If so, has staff explored how these will impact in the patient's treatment? Has this been addressed by the treatment team?

Has there been an interruption or change in the patient's medication which may have been a factor in the patient's admission?

TREATMENT PLAN (PH-TP)

The treatment plan is derived from the information contained in the psychiatric evaluation and in the assessments/diagnostic data collected by the total treatment team. Based on the assessment summaries formulated by team members of various disciplines, the treatment team identifies which patient disabilities will be treated during admission.

SR.1 Each patient shall have an individual, patient centered, comprehensive treatment plan based on:

SR.1a An inventory of the patient's strengths and disabilities;

SR.1b Information gained from assessing/evaluating the patient; and,

SR.1c Collaboration with the patient, as appropriate.

SR.2 The written treatment plan shall include:

SR.2a A substantiated diagnosis;

SR.2b Short-term and long-range goals;

SR.2c The specific treatment modalities utilized;

SR.2d The responsibilities of each member of the treatment team; and,

SR.2e Documentation that justifies the diagnosis as well as the treatment and rehabilitation activities carried out.

SR.3 The patient, and family, if applicable, is involved in developing the treatment plan and goals of treatment.

SR.3a The patient shall be made aware of his/her diagnosis.

SR.4 A preliminary treatment plan shall be included in the medical record within twenty-four hours of admission.

SR.4a The treatment plan shall be completed in a timeframe appropriate to the patient

population served.

SR.4b The organization shall define appropriate timeframes.

SR.5 Treatment received by the patient shall be documented in such a way to assure that all active therapeutic efforts are included.

SR.6 There shall be evidence of periodic review of the patient's response and progress toward meeting planned goals.

SR.6a If the patient has made progress toward meeting goals, or if there is a lack of progress, the review shall justify:

SR.6a(1) Continuing with the current goals and approaches; or,

SR.6a(2) Revising the treatment plan to increase the possibility of a successful treatment outcome.

SR.6b The psychiatric hospital will identify the time frame for periodic review of each program offered as intensity of service will be a consideration of the intervals required.

SR.7 The responsibilities of each member of the treatment team are defined and the patient is aware of the staff responsible for various aspects of treatment.

SR.7a Identification of the staff shall be recorded in a manner that includes the name and discipline of the individual.

SR.7a(1) If other professionals or paraprofessionals provide care, the psychiatric hospital shall decide the manner with which it will identify them on the treatment plan.

SR.7a(2) The patient, as well as family/significant others, shall be aware of the staff responsible for various aspects of treatment, as applicable.

Interpretive Guidelines:

The expected length of time to complete a treatment plan varies with the psychiatric population served. For example, in psychiatric hospitals with a shorter length of stay (measured in days or weeks), the expectation is that the treatment plan be completed within a timeframe that allows for collection of the information necessary to determine appropriate psychiatric care for the patient (e.g., within 72 hours of a 7-day hospitalization). Similarly, in organizations that provide long-term or mandated care (e.g., civil or involuntary commitments measured in months or years), the expectation is that that the treatment plan be completed within a timeframe that allows for the collection of information necessary to meet the requirements of the commitment and determine appropriate psychiatric care for the patient (e.g., within 10 days).

The patient and treatment team collaboratively develop the patient's treatment plan. The treatment plan is the outline of what the psychiatric hospital (or alternative services) has committed itself to do for the patient, based on an assessment of the patient's needs. The psychiatric hospital selects its format for treatment plans and treatment plan updates.

*The **substantiated diagnosis** serves as the basis for treatment interventions. A substantiated diagnosis is the diagnosis identified by the treatment team to be the primary focus upon which treatment planning will be based. It evolves from the synthesis of data from various disciplines.*

At the time of admission, the patient may have been given an initial diagnosis or a rule-out diagnosis. At the time of treatment planning, a substantiated diagnosis shall be recorded. It may be the same as the initial diagnosis, or, based on new information and assessment, it may differ.

Rule-out diagnoses, by themselves are not acceptable as a substantiated diagnosis.

Data to substantiate the diagnosis may be found in, but is not limited to, the psychiatric evaluation, the medical history and physical examination, laboratory tests, medical and other psychological consults, assessments done by disciplines involved in patient evaluations and information supplied from other sources such as community agencies and significant others.

Treatment planning depends on several variables; whether the admission is limited to crisis intervention, short-term treatment or long-term treatment. The briefer the length of stay, the fewer disciplines may be involved in the patient's treatment.

There shall be evidence of periodic review of the patient's response and progress toward meeting planned goals. If the patient has made progress toward meeting goals, or if there is a lack of progress, the review shall justify: (1) continuing with the current goals and approaches; or (2) revising the treatment plan to increase the possibility of a successful treatment outcome.

Based on the problems identified for treatment, short-term and long-range goals are developed. Whether the use of short-term or a combination of short-term and long-range goals is appropriate is dependent on the patient's length of stay.

Short-term and long-range goals include specific dates for expected achievement. As goals are achieved, the treatment plan shall be revised. When a goal is modified, changed or discontinued without achievement, the plan shall be reviewed for relevancy, and updated as needed.

In crisis intervention and short-term treatment there may be only one timeframe for treatment goals. As the length of stay increases (often because of the long-term chronic nature of the patient's illness), both long-range and short-term goals are needed.

The long-range goal is achieved through the development of a series of short-term goals, e.g., smaller, logical sequential steps which will result in reaching the long-range goal. Both the short-term and long-range goals shall be stated as expected behavioral outcomes for the patient. Goals shall be related to the problems identified for treatment. Goals shall be written as observable, measurable patient behaviors to be achieved. Discharge criteria may be included as long-range goals.

There are no "correct" number of staff who comprise the treatment team. The disciplines involved in the patient's treatment depend upon the problems to be treated, the short-term and long-range goals and the treatment approaches and modalities used to achieve the goals.

Surveyor Guidance:

- *Review organization policy/procedure to determine organization requirements*

regarding timeframes for completion of treatment plan

- *Determine if any state regulations regarding timeframes for the completion of treatment plans exist*
    - *Interview staff*
    - *Review regulations as appropriate*

Treatment planning depends on several variables; whether the admission is limited to crisis intervention, short-term treatment or long-term treatment. The briefer the length of stay, the fewer disciplines may be involved in the patient's treatment.

Consideration shall be given to the type of psychiatric program(s) under review to determine the timeframe for treatment plan review. The interval within which treatment plan reviews are conducted is determined by the psychiatric hospital or alternate service areas, however, the review system shall be sufficiently responsive to ensure the treatment plan is reviewed: whenever a goal(s) has been accomplished; when a patient is regressing; when a patient is failing to progress; or when a patient requires a new treatment goal.

The treatment plan shall be individualized and shall not show a predictable sameness with all other treatment plans. When packaged plans or programs are used there shall be individual adaptations in the plan. What specific problems will be treated during the patient's admission?

Does the treatment plan identify and precisely describe problem behaviors rather than generalized statements (e.g., "paranoid," "aggressive," "depressed") or generic terminology (e.g., "alteration in thought process," "ineffective coping," "alteration in mood")?

Physical problems shall be identified and included in the treatment plan if they require treatment or interfere with treatment.

Treatment plan goals need to be related to the problems being treated. Goals shall be specific, measurable and objective.

Modalities include all the active treatment measures provided to the patient. It describes the treatment that will be provided to the patient. It describes the treatment that will be provided by various staff.

A daily schedule of unit activities does not, in itself, constitute planned modalities of treatment. It is expected that when a patient attends various treatment modalities/activities, it is a part of individualized planning with a specific purpose and focus for that patient.

Observation of staff implementing treatment, both in structured and non-structured settings, is a major criterion to determine whether active treatment is being provided in accordance with planned treatment.

Observe to see if qualified staff are following the methods, approaches and staff intervention as stated and have the staff explain the focus of the modality that they have provided.

Are observed treatment methods, approaches and interventions from all disciplines included in the plan?

Is the patient included in the decision-making, whenever possible? How does the patient get to know his/her treatment plan?

Does the patient know his/her diagnosis?

What did the patient contribute to the formulation of the treatment plan? Goals of treatment?

Are the patients able to name the staff responsible for implementing their treatment? Is this information consistent with the treatment plan?

PROGRESS NOTES (PH-PN)

Progress notes shall be recorded by the physicians, psychologists, or other licensed independent practitioner(s) responsible for the care of the patient.

SR.1 The progress note shall provide adequate documentation to justify the diagnosis and the treatment and rehabilitation activities carried out.

SR.1a Progress notes shall reflect the patient's response to treatment and relate to the identified problems, goals and objectives on the treatment plan.

SR.1b The treatment received by the patient shall be documented in such a way as to assure that all active therapeutic efforts are included.

SR.2 Members of the treatment team who are significantly involved in active treatment modalities shall also document progress in the notes. Progress notes (or other documentation) are written by the following:

SR.2a Nurse;

SR.2b Social worker; and,

SR.2c When appropriate, others significantly involved in active treatment modalities.

SR.3 The frequency of progress notes is determined by the condition of the patient, treatment and rehabilitation activities carried out, and organization policy regarding minimum timeframes for the frequency of inpatient progress notes. At a minimum, progress notes shall be recorded at least weekly for the first 2 months and at least once a month thereafter. Progress notes shall contain:

SR.3a Recommendations for revisions in the treatment plan as indicated; and,

SR.3b A precise assessment of the patient's progress in accordance with the original or revised treatment plan.

SR.4 Frequency of progress notes for services/settings other than in-patient services, shall be documented at each service episode.

Interpretive Guidelines:

Active treatment is an essential requirement for inpatient psychiatric care. Active treatment is a

clinical process involving ongoing assessment, diagnosis, intervention, evaluation of care and treatment, and planning for discharge and aftercare, under the direction of a psychiatrist. The medical record shall indicate that the psychiatric hospital adheres to the patient's right to be counseled about medication, its intended effects, and the potential side effects. If the patient requires, because of danger to self or others, a more restrictive environment, the psychiatric hospital shall indicate that the staff attempted to care for the patient in the least restrictive setting before progressing to a more restrictive setting.

***Guidance for clarification between treatment notes and progress notes**. The recording of progress is evidence of individual patient performance. Specifically, the progress notes recorded by the professional staff, or others responsible for the patient's treatment, shall give a chronological picture of the patient's progress or lack of progress towards attaining short and long-range goals outlined in the individual treatment plan. Progress notes shall relate to the goals of the treatment plan. Notes that state, "patient slept well" or "no complaints" constitute observations and do not indicate how the patient is responding to treatment and progressing towards set goals. Frequency alone does not determine the adequacy of progress notes. Expect to see greater frequency when patients are more acutely ill and/or in a crisis of some kind. Notes shall be dated and signed (signature and title or discipline).*

Surveyor Guidance:

When the progress and treatment notes are reviewed, the content of the notes shall relate to the treatment plan. The notes shall indicate what the staff is doing to carry out the treatment plan and the patient's response to the interventions.

Are the treatment notes relative to the identified problems? Are the treatment notes indicative of the patient's response to treatment and do the progress notes relate to specific patient problems or progress?

<u>Clarification of the types of notes found in the medical record.</u>

Treatment notes are recordings in the medical record that indicate provision of, and a patient's response to, a specific modality. This modality may be drug therapy, individual, family, marital, or group therapy, art therapy, recreational therapy, and any specialized therapy ordered by the physician, or anyone credentialed by the psychiatric hospital, in accordance with the State law, to write orders in the medical record.

A combined treatment and progress note may be written.

Progress notes are recordings in the medical record that are written by persons directly responsible for the care and active treatment of the patient. Progress notes give a chronological picture of how the patient is progressing toward the accomplishment of the individual goals in the treatment plan. These are frequently shift notes, weekly notes, or monthly notes.

If the patient receives medication, does the patient understand the reason for the medication? The name of the medication? The dose prescribed? The time of administration? The desired effects? The potential side effects?

If medication is changed, is there a rationale for the change?

Are staff members recording their observations relative to the patient's response to the

treatment modalities, including medication?

Is there evidence the patient was afforded the opportunity to participate in his/her plan of care?

What progress has the patient made? Has the patient achieved his/her optimal level of functioning? If not, why? Are these reasons/barriers reflected in the current treatment plan? Do treatment and progress notes support these insights?

Does the observed status of the patient in the various treatment modalities correspond to the progress note reports of status?

Do all treatment team members document their observations and interventions so that the information is available to the entire team?

If a restrictive procedure is used (e.g., restraint and/or seclusion), is there evidence that attempts were made systematically to treat the patient in the least restrictive manner?

Is there evidence that the rights of the patient were protected while in the restrictive setting in accordance with Federal and State law and accepted standards of practice?

Are the physicians who are significantly involved in active treatment modalities/interventions actually documenting progress?

Do the progress notes relate to the goals of the treatment plan? Do they include precise statements of progress?

Is there a correlation between what is observed by the surveyor and what is described in the notes?

Do the notes give a clear picture of the patient's progress or lack thereof, during the length of stay?

In reviewing the patient's progress, are aftercare/discharge plans being evaluated?

DISCHARGE PLANNING (PH-DP)

SR.1 The record of each patient who has been discharged shall have a discharge summary that includes:

SR.1a A recapitulation of the patient's episode of care;

SR.1b Recommendations from appropriate services concerning follow-up or aftercare; and,

SR.1c A brief summary of the patient's condition on discharge.

SR.2 There shall be a transition plan for outpatient services that includes a description of the support needed to prevent a recurrence of symptoms.

SR.2a The patient shall receive a copy of the transition plan.

SR.3 The organization shall evaluate the effectiveness of the discharge planning process as part of the QMS (see QM.7).

SR.3a Any patient readmission within 10 days of discharge shall trigger an evaluation of the patient's original discharge plan.

Interpretive Guidelines:

The record of each patient who has been discharged shall indicate the extent to which goals established in the patient's treatment plan have been met.

As part of discharge planning, staff shall consider the discharge alternatives addressed in the psychosocial assessment and the extent to which the goals in the treatment plan have been met.

The discharge summary shall contain a recapitulation of the patient's episode of care, which is a summary of the circumstances and rationale for admission, and a synopsis of accomplishments achieved as reflected through the treatment plan. This summary includes the reasons for admission, treatment achieved during the episode of care, a baseline of the psychiatric, physical and social functioning of the patient at the time of discharge, and evidence of the patient/family response to the treatment interventions.

For outpatient services, the transition plan and/or discharge summary may be a combined document as long as it is clear whether the information describes the transition or pre-discharge planning or identifies the person's discharge from the program.

The patient's discharge summary shall describe the services and supports that are appropriate to the patient's needs and that will be effective on the day of discharge. This may include the following:

- *A complete description of arrangements with treatment and other community resources for the provision of follow-up services. Reference shall be made to prior verbal and written communication and exchange of information;*
- *Any psychiatric, medical/physical treatment;*
- *Medications, as applicable;*
- *Specific appointment date(s) and names and addresses of the service provider(s);*
- *Housing/living arrangement;*
- *Economic/financial status or plan, e.g., supplemental security income benefits;*
- *Recreational and leisure resources; and,*
- *A complete description of the involvement of family and significant others with the patient after discharge.*

Surveyor Guidance:

How does the discharge planning process verify appointment source(s), dates and addresses?

How was the patient involved in the discharge and aftercare planning process?

Were discharge related documents made available to the patient, family, community treatment source and/or any other appropriate sources?

Is there indication that the discharge planning process included the participation of multidisciplinary staff and the patient? Have the results been communicated to the post-discharge treatment entity?

Is there evidence that contact with the post-discharge treatment entity included communication of treatment recommendations (including information regarding the patient's medications)?

Is a contact person named, and does the patient have a specific appointment date and time for the initial follow-up visit?

PERSONNEL RESOURCES (PH-PR)

The psychiatric hospital providing psychiatric services shall have adequate numbers of qualified professional and support staff to evaluate patients, formulate written, individualized comprehensive treatment plans, provide active treatment measures, and engage in discharge planning.

The psychiatric hospital shall be adequately staffed with qualified mental health professionals and support staff to carry out an intensive and comprehensive active treatment program and to protect and promote the physical and mental health of the patients. Adequate numbers are defined to mean the numbers, and deployment, of staff with qualifications to evaluate, plan, implement, and document active treatment.

The psychiatric hospital is responsible for organizing available staff and administrative duties along with patient appointments, treatment plan meetings, treatment sessions, activities, materials, equipment and patient assignments to wards, units and groups in such a way that results in patients achieving the maximum therapeutic benefit.

SR.1 The psychiatric hospital shall employ or undertake to provide adequate numbers of qualified professional, technical, and consultative personnel to:

SR.1a Evaluate Patients;

SR.1b Formulate written individualized, comprehensive treatment plans;

SR.1c Provide active treatment measures; and,

SR.1d Engage in discharge planning.

Interpretive Guidelines:

The patient, together with all relevant professionals caring for the patient, shall be expected to participate in the discharge planning process. Staffing shall be sufficient to facilitate this outcome, to the maximum extent possible.

Staffing shall be sufficient so that members of the patient's treatment team and others responsible for evaluation and assessment can contribute their respective data for consideration in the formulation of the treatment plan.

Surveyor Guidance:

Is there adequate staff to assure that the admission work-ups (assessment, diagnostic data gathering) are completed in a timely manner?

Is there evidence that there is continuing evaluation of the patient's progress and response to treatment?

Are evaluations delayed or absent?

Was there sufficient discipline participation at the treatment team meeting to assure formulation of a treatment plan that meets the patient's individualized needs?

What problems prevent staff members from attending treatment meetings? Do they relate to staffing?

Are the assessments/evaluations absent or delayed to the extent that they are not useful to the treatment team for the purpose of planning individualized treatment?

Active treatment occurs when the patient receives treatment interventions that are delivered under the direction of a physician, and which are specific to patient strengths, disabilities, and problems identified in the treatment plan. Treatment interventions and other services are furnished in accordance with accepted standards of professional practice. Although the active treatment process shall be identifiable in documentation, it shall be first and foremost observable and evident in daily practice.

Treatment interventions need to be individualized, in that the patient receives assistance with resolving or ameliorating the problems/circumstances that led to admission. Expect to see treatment focused on the unique needs of individual patients. For example, several patients may be referred to "Anger Management Group," but the focus of discussion and therapeutic intervention may differ depending on the individual patient's particular issue regarding managing anger.

Whether structure shall be imposed by staff or whether the patient can direct his or her own activities for periods of time (without staff supervision), is based on the patient's ability to engage in constructive, appropriate behavior (without engaging in harm to self or others). Be certain that the patient's time on the unit is maximized toward the further development of appropriate desired outcomes, including but not limited to leisure and recreation.

Through observation, interviews and record reviews, can you determine that patients receive active treatment?

Is the distribution of staff consistent with patient needs? Is appropriate staffing sufficient to carry out treatment plans?

Does the patient attend therapies that are relevant to the identified problems that led to the patient's admission?

Are staff absences and/or vacancies preventing the patient from receiving active treatment? Are patients not attending therapeutic activities off the unit because there is no staff to escort them? Are therapeutic groups not available on the unit for patients who are not able to go off the unit?

Are patients observed not engaged in activities while staff attend to administrative tasks?

Are active treatment sessions or activities carried out at discrete time intervals exclusively? Or is active treatment implemented as the patient's needs emerge during the day, as well?

Does a review of quality assurance data reveal a pattern of serious incidents occurring on particular shifts and/or days of the week?

What do patients report to the surveyor are their treatment modalities?

Do patient interviews indicate that patients believe the treatment being provided is helpful?

Does the scheduling of activities and their content relate directly to the patient's treatment objectives or are the activities/content generalized, non-therapeutic "time-fillers"?

Can staff describe how their activities relate to the patient's treatment objectives?

At any point in time, in any of the patient's experiences in the psychiatric hospital is the thrust of the patient's treatment plan observable during the staff and/or patient interactions?

Is there a consistent, observable pattern of evidence that staff provide, reinforce and otherwise implement measures to achieve active treatment objectives?

MEDICAL STAFF (PH-MS)

SR.1 Inpatient psychiatric services shall be under the supervision of a clinical director, service chief, or equivalent who is qualified to provide the leadership required for an intensive treatment program.

SR.1a The clinical director, service chief or equivalent shall meet the training and experience requirements for examination by the American Board of Psychiatry and Neurology, or the American Osteopathic Board of Neurology and Psychiatry.

SR.1b If no certification, evidence that the clinical director, service chief or equivalent took the Boards would satisfy the requirement of PH-MS (SR.1a) that the clinical director, service chief or equivalent met the training and experience requirements for examination by American Board of Psychiatry and Neurology or the American Osteopathic Board of Neurology and Psychiatry.

SR.2 The clinical director is ultimately responsible for the medical and psychiatric care that is provided to patients.

SR.2a The clinical director shall monitor and evaluate the quality and appropriateness of services and treatment provided by the medical staff.

SR.2b Services and treatment prescribed to patients shall be in accordance with

appropriate and acceptable standards of practice.

SR.2c In states that allow psychologists to have admitting privileges, it is still the responsibility of the clinical director to oversee the quality of the patient's treatment.

SR.2d Doctor of Medicine or Osteopathy and other appropriate professional personnel shall be available to provide necessary medical and surgical diagnostic and treatment services. If medical and surgical diagnostic services and treatment are not available within the psychiatric hospital, the psychiatric hospital shall have an agreement with an outside source of these services to ensure that they are immediately available, or a satisfactory agreement shall be established for transferring patients to a general hospital that participates in the Medicare program.

SR.3 The clinical director shall ascertain that quality improvement programs are in place to monitor all areas of patient care and shall implement educational programs for all levels of staff.

SR.4 The number and qualifications of Doctor of Medicine and Osteopathy shall be adequate to provide essential psychiatric services.

SR.5 If outpatient behavioral health services are provided, all medically supervised programs will have a medical director who is a Doctor of Medicine or Osteopathy.

SR.5a For outpatient services such as outpatient detoxification and IOP, there is a psychiatrist available 24hours a day/7days a week.

Interpretive Guidelines:

Inpatient psychiatric services include the following functions of which the clinical director is responsible for maintaining: admission interviews, assessments and evaluations; psychiatric and medical work-ups; treatment team leadership; medication management; on-call provision of emergency psychiatric and medical treatment; provision of individual, group and family therapies; provision of clinical supervision to other professionals and paraprofessionals; provision of medical and psychiatric educational workshops and conferences for all staff; and provision of consultation to staff for clinical and/or administrative matters.

The number and qualifications of Doctor of Medicine and Osteopathy shall be adequate to provide essential psychiatric services.

The number of full-time, part-time and consulting staff, who are board certified within each category and their availability to the psychiatric hospital shall be adequate to provide psychiatric services, as described above. Adequacy is considered in light of the following:

- *Number of admissions, discharges and current patients by treatment units;*
- *Size of the psychiatric hospital;*
- *Geographic proximity of the wards and units;*

- *Organization and kinds of treatment services rendered to the patients;*
- *Availability of the physician coverage on evening, nights and weekends;*
- *Availability of physicians to participate in treatment planning;*
- *Availability of psychiatrists to consult with non-psychiatric physicians about psychotropic medication regimens; and,*
- *Availability of physicians to consult with multi-disciplinary staff about treatment issues.*

When outpatient behavioral health services are provided, all medically supervised programs will have a medical director who is a physician, to ensure that proper care is provided. These services may include but not be limited to medically supervised detoxification, and intensive outpatient or residential or any other program model that serves patients with medical needs.

Surveyor Guidance:

How many staff are board certified? Fully trained? How many full-time/part-time specialties are represented? How are medical staff deployed? To what programs/units are they assigned? Why?

How much time do physicians spend on the units? Based on observations, interviews, and medical record reviews is coverage adequate to meet the needs of sampled patients? To meet the needs of other patients observed during the survey?

If outpatient services are medically supervised, is there a physician available 24/7?

Contracts or other arrangements with individuals and/or providers assure that medical and surgical services are available to meet the needs of the patients. Review the medical and surgical services provided by the psychiatric hospital during the interview with the clinical director. Discuss contract or arrangements with the clinical director for services provided off grounds.

NURSING SERVICES (PH-NS)

The psychiatric hospital shall have a qualified director of psychiatric nursing services. In addition to the director of nursing, there shall be adequate numbers of registered nurses, licensed practical nurses, and mental health workers to provide necessary nursing care.

SR.1 The director of psychiatric nursing services shall be a registered nurse who has a master's degree in psychiatric or mental health nursing or its equivalent from a school of nursing accredited by the National League for Nursing or be qualified by education and experience in the care of the mentally ill.

SR.1a If the director of psychiatric nursing services has less than a master's degree in Psychiatric Nursing, there shall be evidence of experience and on-going training in psychiatric nursing. (e.g., Documented consultation from a nurse with a master's degree in Psychiatric Nursing constitutes on-going training).

SR.1b The director of psychiatric nursing services shall demonstrate competence to participate in the interdisciplinary formulation of individual treatment plans; to give skilled nursing care and therapy; and to direct, monitor, and evaluate the nursing care furnished.

SR.2 There shall be adequate numbers of registered nurses, licensed practical nurses, and mental health workers to provide the nursing care necessary under each patient's active treatment program and to maintain progress notes on each patient.

SR.2a The inpatient staffing pattern shall insure the availability of a registered professional nurse 24 hours each day.

Interpretive Guidelines:

Psychiatric nursing functions include the following: supervision of paraprofessional staff; assessment, planning, provision, and evaluation of psychiatric nursing care to patients; medication teaching; management of the therapeutic milieu; provision of mandatory and voluntary in-service training to all staff; and provision of specialized treatments and therapies, such as individual, group and family therapies, that require the clinical expertise of a professional psychiatric nurse.

Determine that there is a qualified Director of Nursing (DON) providing the required leadership and supervision for the psychiatric nursing department.

The evaluation of sufficient numbers and level of RNs, LPNs and mental health workers is based on the patient characteristics as seen in structured observations of patients in the sample and other patients in the psychiatric hospital, patient interviews, and as evidenced in medical records and other data related to patients (e.g., incident reports, seclusion/restraint reports).

Patient care assignments shall be appropriate to the skills and qualifications of the nursing personnel providing patient care.

There shall be evidence that all nursing personnel have education, experience and/or training in psychiatric care. Mental health workers spend the majority of their workday interacting with patients. Expect to see evidence that they are receiving on-going supervision and training. Mental health workers shall be assigned patient care duties and therapeutic modalities that reflect their educational level, psychiatric training, and experience.

Surveyor Guidance:

During the interview with the DON, assess his/her educational background and psychiatric nursing and leadership skills.

Are nursing assessments completed on all patients?

Do the multidisciplinary treatment plans reflect nursing input which include specific nursing interventions for nursing problems (e.g., violence toward self/others, physical/medical crises)?

Is nursing care evaluated by an R.N., with changes in the care based on the patient's progress or lack thereof?

Are intrusive techniques (e.g., seclusion, restraint, electroconvulsive therapy (ECT), and/or medical procedures) and patient incidents (e.g. medication errors, patient falls, patient-to-patient and patient-to-staff injuries) monitored in accordance with psychiatric hospital policy, State statutes and safe nursing practice?

Are nursing personnel observed relating to patients in a therapeutic manner?

Based on structured observations of the patients in the sample and other patients in the psychiatric hospital, patient and staff interviews and medical record review, ascertain that nursing services are provided in accordance with safe, acceptable standards of nursing practice.

Information obtained from the DON would include: implementation of continuous quality improvement programs; provision of orientation, in-service and continuing education programs for nursing personnel especially in the areas of psychiatric nursing, nursing process, prevention and management of violence, CPR and Universal Precautions.

The staffing, including levels of nursing personnel, shall be reviewed for the day(s) of the survey and evaluated based on the level of needs presented by the patients. Additional staffing patterns shall be reviewed if a problem or concern is evidenced. Decisions regarding extent of additional data (number of wards and dates) to be reviewed shall be based on the degree of problem/concern. Patient need assessment/patient acuity shall be reviewed for any wards as deemed necessary based on problems/concerns found in the sampling review.

Expect to see evidence of orientation programs as well as ongoing continuing education programs for Licensed Practical Nurses and mental health workers that stress individualized treatment interventions.

If your observations and/or interviews indicate a staffing problem, you may want to consider the following variables in assessing adequacy of nursing personnel coverage:

- *Organization and types of services provided to patients by the nursing department;*
- *Number and levels of nursing care needs of patients, including average length of stay, acuity of patients and nursing care requirements;*
- *Number and levels of nursing personnel based on the roles and functions required of nursing;*
- *Number of suicidal/assaultive patients;*
- *Seclusion/restraint incidents;*
- *Number of admissions and discharges;*
- *Number and type of accidents and/or injuries;*
- *Amount and complexity of medication regimens;*
- *Medication errors;*

- *Use of P.R.N. (as needed) medications;*
- *Medical (physical) procedures;*
- *Assignment and utilization of "pool" nursing personnel (those staff who are hired through a contract service and are not employees of the psychiatric hospital). Contractual staff shall receive orientation and training necessary for assigned functions, and shall be supervised by employees of the psychiatric hospital;*
- *Availability of RNs to supervise/consult with nursing/non-nursing personnel about patient care;*
- *Availability of RNs to assess and implement care in crisis situations;*
- *Availability of RNs to interact with patients in structured activities; and,*
- *Involvement of patients with personnel.*

PSYCHOLOGICAL SERVICES (PH-PS)

SR.1 The psychiatric hospital shall provide or have available psychological services to meet the needs of the patients.

Interpretive Guidelines:

Psychology services may include the following: diagnostic testing and diagnostic formulations on request from physicians; provision of individual, group and family therapies; participation in multi-disciplinary treatment conferences; and program development and evaluation.

The number of full-time, part-time, or consulting psychologists shall be adequate to provide necessary services to patients. Arrangements with outside resources shall assure that necessary patient services will be provided.

Surveyor Guidance:

Determine if the individual patients have a need for psychological services or testing and if they were provided. Determine if any of the patients reviewed had a need for psychological services, but none were requested.

Policies, program narratives and interviews shall indicate and describe the various types of psychological services that are offered for the populations and various settings that the psychiatric hospital serves. (e.g., assessments, individual therapy, family therapy, testing)

If tests are performed, determine if the results are reported in sufficient time to be integrated in the patient's active treatment and treatment plan.

How does the psychiatric hospital or Psychological Service Department determine whether or not: it meets the needs of patients? Its services are underutilized or over-utilized?

SOCIAL WORK SERVICES (PH-SS)

Social work services are specifically intended to prevent, treat and increase social and emotional functioning during and following an episode of acute illness or exacerbation of chronic mental illness. Social work services shall provide patients with a comprehensive assessment as well as a variety of therapeutic modalities that are an integral part of each patient's individualized treatment plan.

Social workers focus on psychosocial factors including family relationships; living arrangements; patient's developmental history, as appropriate; and economic, cultural, religious, educational, and vocational background as they impinge on the understanding, treatment, and relapse prevention of the psychiatric disorder. As members of the interdisciplinary team, social workers contribute to program development and treatment planning, review all patients and collaborate in the development and maintenance of the therapeutic milieu.

SR.1 Social work services are provided to patients and their families to ensure that a patient's illness, recovery, and safe transition from one care setting to another are considered within the context of his or her bio-psychosocial needs.

SR.1a Social work services shall be furnished in accordance with accepted standards of practice and established policies and procedures.

SR.1b The social work policies for service provision to the patient describe the organizational structure of the department (program) and the range of services performed by the department.

SR.2 There shall be a director of social work services who monitors and evaluates the quality and appropriateness of social work services furnished.

SR.2a The director of the social work department or service shall have a master's degree from an accredited school of social work or shall be qualified by education and experience in the social work services needs of the mentally ill.

SR.2a(1) If the director does not hold a master's degree in social work, at least one staff member shall have this qualification.

SR.3 The duties, functions, and responsibilities of the director of social work shall be clearly delineated and documented in the psychiatric hospital's policies and procedures.

SR.3a When staff other than a social worker perform delineated social service duties, the Director of Social Work or a master's level social worker (MSW) qualified supervisory staff member shall be involved to oversee the quality and appropriateness of service provided.

SR.4 The social work staff shall complete a comprehensive psychosocial assessment on each patient that is admitted (See PH-PA).

SR.5 Social work staff responsibilities shall include, but are not limited to, participating in discharge, planning, arranging for follow-up care, and developing mechanisms for exchange of appropriate information with sources outside the psychiatric hospital.

SR.5a For outpatient programs, social work services responsibilities shall include coordination of case management services.

Interpretive Guidelines:

Social work Services are provided based on a body of established social work knowledge, technical expertise, and humanistic values that allow for the provision of a specialized, unique, and individualized plan of care for each patient. The social services staff shall have the capacity to provide assistance in a sensitive and supportive manner to patients based on knowledge of human behavior, observational, and communication skills. With this foundation, the social worker establishes therapeutic relationships, assesses complex psychosocial problems, selects problem solving interventions and helps patients function effectively.

Social work functions may include the following functions: Intake or admission screening, psychosocial assessment of a newly admitted patient; developing an update or detailed re-assessment of the patient; high-social risk case finding; contact with family and others significant in the patient's life. Such functions may include patient and family education, support, and advocacy; providing coordination/liaison with community-based social and mental health agencies regarding the pre-admission status of the patient; participating as a member of the treatment team in development of treatment planning and subsequent planned interventions (modalities). Such modalities may include supportive, individual, couple, family, or group therapy, aimed at meeting specified goals identified in the treatment plan.

Treatment and discharge planning activities, liaison/follow-up efforts shall be based upon the goals, including discharge goals, and staff responsibilities specified in the treatment plan.

Social work contact with the patient, family, and significant others shall occur during, or as soon as possible, after the admission. High-risk case finding shall result in significant data being available for early integration into the treatment plan and subsequent social work action as indicated. The treatment team shall consider, for possible inclusion into the patient's treatment plan, the anticipated social work role and expected interventions as recommended in the psychosocial assessment.

Continuity of care is an important social work principle and may be demonstrated through case management and a major role in discharge planning. Activities, in conjunction with the patient wishes, may include contact with patient's family, identifying and assisting in referral of the patient to community-based agencies at the time of discharge. Finally, post-discharge follow-up may be done to assure that linkage of the patient with community resources has occurred to reduce re-admission.

Surveyor Guidance:

The duties, functions, and responsibilities of the director of social services/social work shall be clearly delineated and documented in the psychiatric hospital's policies and procedures. If the director is not MSW qualified and at least one staff member is MSW qualified, verify the duties, functions, and responsibilities of the MSW.

How does the director periodically audit the quality of social work services furnished?

What are the outcomes of audits conducted? What percentage of psychosocial assessments was completed and available in written form at the time of the interdisciplinary treatment plan?

How does the patient's social needs as addressed by the social worker in the psychosocial assessment compare against the goals developed in the interdisciplinary treatment plan?

Has social work staff provided active treatment in accordance with the patient's treatment plan?

Accepted standards of practice are based on policy statements adopted by the National Association of Social Workers and a definition of social work practice in health care adapted by the Consortium of Health Care Social Work Organizations.

Determine who completed the assessment required by 42 CFR Section 482.61(a)(4) (See PH-SS (SR.4)) and initiated preliminary discharge planning.

Patient and staff interviews, structured observations and review of selected medical records yield the information necessary to determine how well social work has met the needs of the patients. The surveyor shall evaluate these data to determine adequacy of qualified and support staff deployed to patient areas and their duties.

Accepted standards of practice are based on policy statements adopted by the National Association of Social Workers and a definition of social work practice in health care adapted by the Consortium of Health Care Social Work Organizations. Staff shall adhere to the psychiatric hospital's personnel requirements.

What are the director's qualifications, experience and scope of duties within this position?

If a MSW staff member, other than the director, is performing any of these duties, what are this staff member's experience and scope of duties performed? Why were these duties delegated?

Are social work staff routinely involved in providing services to the patient that are identified in the treatment plan?

To what extent do social work staff provide discharge planning services to the patient in the way of: supportive individual, couple, family, or group therapy focused on discharge goals of the patient? Carrying out a liaison role with community resource providers?

Have social work staff assured that adequate information is provided to post-discharge patient service providers?

PSYCHOSOCIAL ASSESSMENT (PH-PA)

The purpose of the psychosocial assessment is to determine the current baseline social functioning (strengths and deficits) of the patient, from which treatment interventions and discharge plans are to be formulated.

Patient length of stay is a key factor influencing psychiatric hospital documentation policy (e.g., establishing timeframes for completion, documentation, and filing of the psychosocial assessment, and treatment planning in the medical record).

A psychosocial assessment shall be completed on all patients within a timeframe appropriate to the patient population served. The organization shall define appropriate timeframes for completion of the psychosocial assessment. Key components to be addressed include:

SR.1 Factual and Historical Information:

SR.1a Specific reasons for the patient's admission or readmission;

SR.1b A description of the patient's past and present bio-psychosocial functioning;

SR.1c Family and marital history, dynamics, and patient's relationships with family and significant others;

SR.1d Pertinent religious and cultural factors;

SR.1e History of physical, sexual and emotional abuse;

SR.1f Significant aspects of psychiatric, medical, and substance abuse history and treatment as presented by family members and significant others;

SR.1g Educational, vocational, employment, and military service history;

SR.1h Identification of community resources including previously used treatment sources; and,

SR.1i Identification of present environmental and financial needs.

SR.2 Social Evaluation to include:

SR.2a Patient strengths and deficits;

SR.2b The psychosocial assessment identifies immediate high-risk issues (suicide/homicide/other) that may require immediate intervention or could present as barriers to the patient returning to an optimal level of functioning or being transitioned into a lower level of care, as appropriate.

SR.3 The findings of the psychosocial assessment are integrated into the patient's individualized interdisciplinary treatment plan, as appropriate. Conclusions and recommendations from the historical and social evaluation sections shall result in the development of recommendations related to the following areas:

SR.3a Anticipated necessary steps for discharge to occur;

SR.3b High-risk patient and/or family psychosocial issues requiring early treatment planning and immediate intervention regardless of the patient's length of stay;

SR.3c Specific community resources/ support systems for utilization in discharge planning (e.g., housing, living arrangements, financial aid, and aftercare treatment sources); and,

SR.3d Anticipated social work role(s) in treatment, case management and/or discharge planning.

Interpretive Guidelines:

The expected length of time to complete a psychosocial assessment (inclusive of cultural,

religious, and family issues) varies with the psychiatric population served. For example, in psychiatric hospitals with a shorter length of stay (measured in days or weeks), the expectation is that the psychosocial assessment be completed within a timeframe that allows for collection of the information necessary to determine appropriate psychiatric care and treatment planning for the patient (e.g., within 72 hours of a 7-day hospitalization). Similarly, in organizations that provide long-term or mandated care (e.g., civil or involuntary commitments measured in months or years), the expectation is that that the psychosocial assessment be completed within a timeframe that allows for the collection of information necessary to meet the requirements of the commitment and determine appropriate psychiatric care and treatment planning for the patient (e.g., within 10 days).

Surveyor Guidance:

- *Review organization policy/procedure to determine organization requirements regarding timeframes for completion of the psychosocial assessment*
- *Determine if any state regulations regarding timeframes for the completion of the psychosocial assessment exist*
    - *Interview staff*
    - *Review regulations as appropriate*

Determine if the psychosocial assessment indicates clear identification of the informants(s) and sources of information and whether information is considered reliable. There shall be some indication of patient participation to the extent possible in provision of data relative to treatment and discharge planning. Integration of significant data including identified high-risk psychosocial issues (problems) into the treatment plan shall be in evidence.

THERAPEUTIC ACTIVITIES (PH-TA)

SR.1 The psychiatric hospital shall provide a therapeutic activities program.

SR.1a There shall be daily therapeutic activities.

SR.2 The therapeutic activities program shall be appropriate to the needs and interests of patients and be directed toward restoring and maintaining optimal levels of physical and psychosocial functioning.

SR.2a Therapeutic activities provided shall be appropriate to the needs of diverse populations and consider: age, level of functioning, and reflective of program as well as individual patient's goals and objectives.

SR.3 The number of qualified therapists, support personnel, and consultants shall be adequate to provide comprehensive therapeutic activities consistent with each patient's active treatment program.

SR.4 Assessments shall be performed and documented within the designated time frames of the program policies by the appropriate discipline therapist.

SR.5 There shall be an established monitoring and evaluation mechanisms to conduct

consistent, timely review of the quality and appropriateness of therapeutic and rehabilitative services.

Interpretive Guidelines:

A variety of therapeutic and rehabilitative activities are selectively used as therapeutic tools in providing active treatment to the psychiatric patient. Therapeutic activities focus upon the development and maintenance of adaptive skills that will improve the patient's functioning.

In contrast, leisure activities provide the patient with individualized opportunities to acquire knowledge, skills and attitudes about meaningful leisure involvement and experiences. A patient may need treatment and/or remediation of functional behavior(s) prior to leisure involvement. However, for some psychiatric patients, the priority need may be for leisure education and activities.

The organization is responsible for ensuring the consistent availability and provision of individualized therapeutic activities and rehabilitative services based on patient needs.

The selection of individualized therapeutic and rehabilitative staff modalities shall be based on patient need and goals set in the patient's treatment plan. Rehabilitative services may include educational, occupational, recreational, physical, art, dance, music, and speech therapies and vocational rehabilitation evaluation and counseling.

There are many disciplines that serve patients in the therapeutic activities department. Staff may include but are not limited to the following: educational instructors, registered occupational therapist/certified occupational therapy assistant, certified therapeutic recreation specialist, certified therapeutic recreation assistant, speech-language pathologist has certificate of clinical competence, registered and certified music therapist, registered art therapist, and registered physical therapist. The qualified vocational specialist may perform duties of a rehabilitation counselor, vocational evaluator, or a work adjustment specialist.

Qualified staff shall complete their respective discipline assessments for use in multidisciplinary treatment planning. Specific role(s) and modalities to be implemented by rehabilitative staff shall be determined by goals set in the patient's treatment plan.

Qualified therapists who provide clinical services and administrative staff shall utilize established monitoring and evaluation mechanisms to conduct consistent timely review of the quality and appropriateness of therapeutic and rehabilitative services delivered to patients.

Surveyor Guidance:

Determine if there is evidence in the medical records that therapeutic activities are included in the individual treatment plans. Staff shall be familiar with the goals and staff interventions described in the patient's treatment plan and determining the patient's response. If a patient had a need for therapeutic activities, were their needs considered, addressed and met?

Look on the posted unit schedule and determine if activities are offered as listed. Determine if the interventions and activities are of sufficient frequency and intensity to achieve maximum therapeutic benefit. Determine if patient needs are met consistently at all times including evenings and weekends. Determine if current activity schedules are clearly posted for patient and staff reference and observe selected activities. Are the scheduled activities related to the

particular patient area and specific treatment needs of patients?

Determine the qualifications, experience, duties and responsibilities of the Therapeutic Activities Director, discipline supervisors and other therapists. Qualifications shall match the therapeutic needs of the various populations served. Considerations as to population age, diagnosis, level of functioning and theme of the various programs (example: short term crisis stabilization, rehabilitation, residential).

ABOUT DNV

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