



NATIONAL INTEGRATED ACCREDITATION FOR HEALTHCARE ORGANIZATIONS (NIAHO®)

**Interpretive Guidelines and Surveyor Guidance for Critical Access Hospitals-
Revision 18**

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Use of NIAHO® Accreditation Requirements, Interpretive Guidelines and Surveyor Guidance for Critical Access Hospitals

Effective Date

NIAHO® Accreditation Requirements, Interpretive Guidelines and Surveyor Guidance for Critical Access Hospital document, Revision 18

Effective Date: July 15, 2018

National Professional Organizations- Standards of Practice

Standards of practice of the national professional organizations referenced in this NIAHO® Accreditation Requirements Interpretive Guidelines and Surveyor Guidance for [Critical Access Hospitals \(NIAHO® CAH\)](#) document are consultative and considered in the accreditation decision.

Federal Laws, Rules and Regulations

The most current version of Federal law and the Code of Federal Regulations referenced in this NIAHO® CAH document are incorporated herein by reference and constitute NIAHO® accreditation requirements.

This NIAHO® CAH document is based upon the Centers for Medicare and Medicaid (CMS) Conditions of Participation for Critical Access Hospitals 42 CFR Section 485.606 and State Operations Manual Regulations and Interpretive Guidelines for Critical Access Hospitals. These Interpretive Guidelines also are periodically updated based on notices distributed from CMS. [CAH's](#) participating in the Medicare and Medicaid programs are expected to comply with current Conditions of Participation ([CoP](#)). When new or revised requirements are published, [CAHs](#) are expected to demonstrate compliance in a time frame consistent with the effective date published by CMS in the Federal Register.

Life Safety Code®

The Life Safety Code® of the National Fire Protection Association referenced in this NIAHO® [CAH](#) document are incorporated herein by reference and constitute NIAHO® accreditation requirements.

GLOSSARY

AANA	American Association of Nurse Anesthetists (AANA)
ACS	American College of Surgeons
ACIP	CDC's Advisory Committee on Immunization Practices
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
APP	Advanced Practice Provider
ASA	American Society of Anesthesiologists
ASHP	American Society of Health-System Pharmacists
CAH	Critical Access Hospital
CDC	Centers for Disease Control and Prevention
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
Direct Services	Unless the context indicates otherwise, means services provided by employed staff of the CAH, not services provided through arrangements or agreements.
DOT	United States Department of Transportation
DPU	Distinct Part Unit
ECFMG	Educational Commission for Foreign Medical Graduates
FDA	Food and Drug Administration
HAI	Healthcare Associated Infections
HHA	Home Health Agency
HICPAC	CDC's Healthcare Infection Control Practices Advisory Committee
HVAC	Heating Ventilating and Air Conditioning

ISMP	Institute for Safe Medication Practices
ISO	International Organization of Standardization
LPN	Licensed Practical Nurse
LVN	Licensed Vocational Nurse
LSC	Life Safety Code® of the National Fire Protection Association
NFPA	National Fire Protection Association
NLN	National League for Nursing
NP	Nurse Practitioner
NPDB	National Practitioner Data Bank
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
PRN (prn)	Pro re nata, as the occasion arises, when necessary.
PU	Psychiatric Unit. Inpatient psychiatric services provided in a separate and distinct part unit of the CAH.
QIO	Quality Improvement Organization
QMS	Quality Management System
QLP	Qualified Licensed Practitioner
Resident	Person receiving post- hospital SNF care in the CAH.
RHC	Rural Health Clinic
RO	Regional Office
RU	Rehabilitation Unit. Inpatient rehabilitation services provided in a separate and distinct part unit of the CAH.
Rural Health Network	An organization that includes at least one hospital that the State has designated or plans to designate as a CAH, and at least one hospital that furnishes acute care (hospital) services.
Satellite Facility	A satellite facility is a part of a hospital that provides inpatient services in a building also used by another hospital, or in one or more entire buildings located on the same campus as buildings used by another hospital.
Secretary	Secretary of the Department of Health and Human Service
SHALL	The word "shall" indicates a requirement. The intended definition of the word "shall" is "must."
SGNA	Society of Gastroenterology Nurses and Associates

SHEA	Society for Healthcare Epidemiology of America
SMDA	Safe Medical Devices Act of 1990
SNF	Skilled Nursing Facility
SOP	Standard Operating Procedure
SR	Standard Requirement

QUALITY MANAGEMENT SYSTEM (QM)

QM.1 QUALITY MANAGEMENT SYSTEM

The governing body (or organized group or individual who assumes full legal authority and responsibility for operations of the CAH), medical staff, and administrative officials are responsible and accountable for ensuring that the CAH implements and maintains an effective quality management system (QMS). This QMS shall ensure that corrective and preventive actions taken by the CAH are implemented, measured and monitored.

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

- SR.1 The CAH must develop, implement and maintain an ongoing QMS for managing quality, performance and patient safety. As a part of the QMS, the CAH must periodically evaluate (at least once annually) the processes, functions and areas of the organization to determine the appropriate utilization of services, ensure that policies have been followed, and necessary changes are made when identified. The scope of this review will include, but not be limited to:
 - SR.1a Utilization of services provided by the CAH including the number of patients served and the volume of services provided.
 - SR.1b Review of a representative sample of both open and closed clinical records.
 - SR.1c Review of the CAH's policies and procedures.
 - SR.1d When the CAH participates in a Quality Improvement Organization (QIO), the CAH must demonstrate that information and supporting documentation is provided to the QIO as required.
 - SR.1d (1) The CAH will review and consider the findings and/or recommendations of the evaluation of the QIO and implements the appropriate corrective/preventive action as necessary.
- SR.2 The CAH must implement CAH-wide quality assessment and performance improvement efforts to evaluate the appropriateness of the diagnosis, treatment, outcomes, quality of care and patient safety. Corrective and preventive actions shall be documented, implemented and evaluated for effectiveness. Quality assessment and performance improvement efforts will include, but not be limited to:
 - SR.2a Evaluation of patient care services and other services provided affecting patient health and safety;
 - SR.2b Evaluation of healthcare associated infections and medication therapy;
 - SR.2c Evaluation of the quality and appropriateness of the diagnosis and treatment provided by nurse practitioners, clinical nurse specialists, and physician assistants and evaluated by a member of the CAH who is a doctor or medicine or osteopathy.
 - SR.2d Evaluation of the quality and appropriateness of the diagnosis and treatment provided by doctors or medicine or osteopathy at the CAH, or in the case of distant-site physicians and practitioners providing telemedicine services to the CAH's patients under a written agreement between the CAH and a distant-site hospital, the distant-site hospital; or in the case of distant-site physicians and practitioners providing telemedicine services to the CAH's patients under a written agreement between the CAH and a distant-site telemedicine entity. This evaluation will be conducted by at least:
 - SR.2d (1) One hospital that is a member of the network, when applicable;
 - SR.2d (2) One QIO or equivalent organization; or,

- SR.2d (3) One other appropriately quality entity identified in the State rural healthcare plan.
- SR.3 The organization will assure that adequate resources are allocated for measuring, assessing, improving, and sustaining the CAH's performance and reducing risk to patients.
- SR.4 s one of the quality improvement initiatives, the CAH may 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.

QM.2 ISO 9001 QUALITY MANAGEMENT SYSTEM

- SR.1 Compliance with the ISO 9001 standard must occur within three (3) years after the initial deemed NIAHO® accreditation. The CAH shall either demonstrate compliance with the ISO 9001 Quality Management System principles through a NIAHO® CAH accreditation survey or maintain Certification through an Accredited Registrar. Only certificates covered by an accreditation by an IAF MLA (International Accreditation Forum Multilateral Recognition Agreement) signatory shall be eligible. The CAH shall maintain ISO 9001 compliance or formal Certification 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 Must have certified or conducted a pre-assessment at a minimum of twelve (12) hospitals.
- SR.3 The CAH will initiate and continue implementation of the ISO 9001 methodology to achieve compliance or certification as stated in QM.1, SR.1. At a minimum, the CAH must be able to demonstrate at the time of the NIAHO® CAH Accreditation survey evidence of the following:
- SR.3a Risk based thinking: through leadership commitment and involvement, the organization shall establish and maintain a process to identify and address the needs and expectations of interested parties, both internal and external. The necessary processes and controls shall be planned and implemented to ensure that appropriate actions are taken to address relevant risks and opportunities.
- 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 Audits: the CAH will initiate a process for conducting internal process- based audits of its processes and prepare corrective/preventive action plans to be implemented and a means to verify such actions to be effective;
- SR.3d Nonconformity and Corrective Action: when nonconformity occurs, the CAH will have a mechanism in place to document and monitor actions taken to address improvement and changes, where appropriate.
- SR.3e The CAH will initiate a process to establish measurable quality objectives and periodically review progress toward meeting these objectives; and
- SR.3f Appropriate information has been submitted to the Quality Management Oversight group for determination of the effectiveness of the QMS as required in QM.6 SR.1.

Interpretive Guidelines:

The ISO 9001 requirements are assessed during each survey of the CAH. The CAH has 3 years from the initial

deemed NIAHO® CAH accreditation to achieved compliance or certification to ISO 9001. If the CAH is currently certified to ISO 9001, the Registrar that currently certifies the CAH must be verified using current criteria established under SR.2a and SR.2b. This should be verified prior to the CAH's accreditation survey.

The CAH shall demonstrate that aspects consistent with ISO 9001 methodologies identified in SR.3a-SR.3f (above) are present. This may not be *at a* level of compliance with ISO 9001 but will be in place in some manner. If the survey team is conducting the annual ISO periodic survey during the NIAHO® CAH survey, the survey team will assess the applicable ISO 9001 requirements and review the status of findings and corrective action(s) taken to validate that they have been implemented.

Surveyor Guidance:

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

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

If the CAH is already certified to ISO 9001 and the survey team is not conducting the periodic annual survey required by ISO at the time of the NIAHO® CAH survey, the lead surveyor will verify that the Registrar is an Accredited Registrar in accordance with QM.1, SR.2.

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

QM.3 QUALITY OUTLINE/PLAN

The CAH shall outline the methodology, practice and related policies for addressing how quality and performance are measured, monitored, analyzed and continually improved to improve health outcomes and reduce risks for patients.

Interpretive Guidelines:

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

Surveyor Guidance:

The CAH can document conformance in a variety of ways. An example would include a Quality Manual or Performance Improvement / Quality Management Plan. Verify that the CAH has clearly defined how they measure quality and performance. The monitoring methods, data analysis and effectiveness of action(s) taken will be verified.

QM.4 MANAGEMENT REPRESENTATIVE

A management representative shall be 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 as a 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 there is a defined scope of responsibilities for this individual.

QM.5 DOCUMENTATION AND QUALITY MANAGEMENT OVERSIGHT

Variations, deficiencies or non-conformities identified by the CAH as well as findings or recommendations of the QIO shall be addressed. Appropriate corrective or preventive action will be determined, applied, and documented in accordance with the QMS of the CAH. Documentation of activities may take the form of a Failure, Mode and Effect Analysis, Root Cause Analysis, Performance Reports, Non-Conformity Report, specific Improvement Project analysis, etc. This documentation shall become a part of the Quality Management Oversight performed at regular intervals, at a minimum of once annually.

Interpretive Guidelines:

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

The results of these activities are communicated to senior leadership, usually conducted as a part of the Quality Management Oversight process.

Quality Management Oversight is defined as the formal evaluation by the interdisciplinary group described in QM.6, SR.1 of the status, adequacy and effectiveness of the QMS. The Quality Management Oversight process may or may not be the same process as formal ISO 9001 Management Review.

Surveyor Guidance:

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

QM.6 SYSTEM REQUIREMENTS

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

- SR.1 Interdisciplinary group to oversee the QMS with representation from/for Senior Leadership, Medical Staff, Nursing, Quality/ Risk Management (Management Representative), Physical Environment/ Safety, Pharmacy Services, and Ancillary Services. This interdisciplinary group shall conduct Quality Management Oversight regarding the effectiveness of the QMS.
- SR.2 The CAH shall define and document the QMS in place, to include clinical and non-clinical services;
- SR.3 Statement of the Quality Policy;
- SR.4 Measurable Quality Objectives; and,
- SR.5 Goal Measurement / Prioritization of activities to include:
 - SR.5a Focus on high-risk, problem-prone areas, processes or functions,
 - SR.5b Consideration of the incidence, prevalence and severity of problems in these areas, processes or functions,
 - SR.5c Health outcomes and improvement of patient safety and quality of care.

Interpretive Guidelines:

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 Manual or other similar document outlines the process that the CAH has in place. The Quality Manual will include or reference the policies and procedures for the QMS, Quality Policy, and Quality Objectives. The CAH must carry out Quality Management Oversight which encompasses determination of the effectiveness of the QMS.

The Quality Management Oversight Process may or may not be the same process as formal ISO 9001 Management Review.

Surveyor Guidance:

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

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

QM.7 MEASUREMENT, MONITORING, ANALYSIS

The CAH shall evaluate organized services and processes, both direct and supportive, including services provided by contracted services. The interdisciplinary group referred to in QM.6, SR.1, also known as the Quality Management Oversight group, shall conduct these evaluations. The monitoring shall include internal reviews of key processes as defined by the CAH at scheduled intervals, not to exceed one year, and review of data related to these processes. Measurement, monitoring and analysis of processes throughout the CAH requires established measures that have the ability to detect variation, identify problem processes, identify both positive and negative outcomes, and effectiveness of actions taken to improve performance and/or reduce risks. The governing body of the organization must define the frequency and detail of the measurement. Those functions to be measured at a minimum must include the following (as applicable):

- SR.1 Evaluation of patient care services and other services provided affecting patient health and safety, quality and appropriateness of the diagnosis and treatment (including outcomes) provided by the PA, NP and CNS clinical staff. This evaluation must be performed by a CAH staff member who is a doctor of medicine or osteopathy or by another doctor of medicine or osteopathy under contract with the CAH.
- SR.2 Credentialing and quality and appropriateness of diagnosis and treatment (including outcomes) provided by Physicians. This credentialing and clinical review must be performed by:
 - SR.2a Representative(s) of a hospital that is a member of the network, if applicable;
 - SR.2b A QIO (or equivalent) entity; or,
 - SR.2c An entity qualified by the State rural health care plan.
- SR.3 Threats to patient safety (e.g. falls, pt. identification, injuries);
- SR.4 Medication therapy/medication use: to include medication reconciliation, high-risk medications, lookalike sound-alike medications and the use of dangerous abbreviations;
- SR.5 Operative and invasive procedures (including wrong site/wrong patient/wrong procedure surgery);
- SR.6 Anesthesia/moderate sedation adverse events;
- SR.7 Blood and blood components;
- SR.8 Restraint use/seclusion;
- SR.9 Effectiveness of pain management system;
- SR.10 Infection prevention and control system, including HAI;
- SR.11 Utilization Management System;

- SR.12 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 CAH);
- SR.13 Customer satisfaction, both clinical and support areas;
- SR.14 Discrepant pathology reports;
- SR.15 Unanticipated deaths;
- SR.16 Adverse events/near misses;
- SR.17 Readmissions and unplanned returns to surgery (as defined by the CAH);
- SR.18 Critical and/or pertinent processes, both clinical and supportive;
- SR.19 Medical record delinquency; and,
- SR.20 Physical Environment Management Systems.

Interpretive Guidelines:

In order for the CAH to continually improve its QMS, the services and processes must be measured to determine their effectiveness. Through an internal review mechanism, the CAH 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, there are several listed above that must be measured for the CAH to determine the effectiveness of these processes for continual improvement and preserving the safety of the patients and staff.

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

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

If the CAH produces a law, regulation, or standard of practice from a nationally recognized organization, evaluate whether the CAH'S policies and procedures reflect the law, regulation, or standard of practice. Then, evaluate whether the CAH'S actual practice reflects their policies and procedures, as well as the law, regulation or standard of practice.

There is no specific requirement to preclude a CAH from obtaining review of quality measure through arrangement. Whether the CAH has an internal process in place or by arrangement, all of the requirements for evaluation of quality measures must be met. If a CAH chooses to have an internal process, this should be facility wide, including departments and all services provided under contract as prioritized by the organization. For services provided to the CAH under contract, there should be established channels of communication between the contractor and CAH staff.

Other qualified entities could include another CAH or any licensed firms, businesses, or agencies that provide credentialing and evaluations services. The location for these other qualified entities is not limited to local entities.

Agreements for evaluation of measurement need to include medical record review as part of the determination of the quality and medical necessity of medical care at the CAH.

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

Surveyor Guidance:

The CAH can demonstrate the effectiveness of its Quality Management System through the analysis of data and follow up where variation exists in order to implement corrective/preventive action. Evaluate the internal review process and subsequent effectiveness of action(s) taken to improve performance. The CAH will be assessed according to its ability

to effectively monitor and measure those areas listed above.

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

Review a copy of the CAH quality plan and other documentation regarding quality measurement and monitoring activities, (e.g., meeting notes from quality committees, reports produced by the quality management director and/or quality committees, if designated, and follow-up communication relative to corrective actions) to become familiar with the scope, methodology and [organization](#) of the CAH quality measurement and monitoring program.

How does the CAH ensure that the yearly program evaluation includes a review of CAH services as prioritized by the organization, the number of patients served and the volume of services provided?

Who is responsible to evaluate CAH patient care services and how are they evaluated?

How does the CAH ensure that a doctor of medicine or osteopathy evaluates the quality of care provided by mid-level practitioners in the CAH?

- What evidence demonstrates that there is an ongoing evaluation of care provided by mid-level practitioners (e.g., reports, periodic written evaluation, and quality committee meeting notes)?
- How does the reviewing MD/DO inform the CAH if he/she determines that there are problems relative to the diagnosis and treatment provided by mid-level practitioners?

What other services are evaluated?

How does the CAH ensure quality assurance data is provided to the medical staff and governing body?

Review policies and procedures to determine how information is to be obtained, utilized, and how confidentiality of information will be maintained.

What methodology does the CAH use to evaluate nosocomial infections and medications therapy?

QM.8 PATIENT SAFETY SYSTEM

- SR.1 The CAH 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 CAH's [Patient Safety System](#) shall [be documented and shall](#) address the following:
- SR.2a Detection;
 - SR.2b Preventative and corrective action;
 - SR.2c Defined processes to reduce risk;
 - SR.2d Implementation of action plans;
 - SR.2e On-going measurement to ensure action effectiveness;
 - SR.2f Management review of response and resource allocation utilizing the results of patient adverse events and other data analysis; and,
 - SR.2g Policy and procedure of informing patients and/or their families about unexpected adverse events.

Interpretive Guidelines:

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

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

Surveyor Guidance:

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

When such incidents occur, a process must be in place to address customer (patient) communication, how the patients are informed and their right to know the circumstances of events. Such communication does not imply wrongdoing on the part of the CAH 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 CAH is acting responsibly and will promote the safest environment possible.

GOVERNING BODY / CHIEF EXECUTIVE (GB)

GB.1 LEGAL RESPONSIBILITY

There must be an effective governing body or an individual responsible (e.g. Chief Executive) that is legally responsible for the conduct of the CAH to ensure that policies governing the operation of the CAH are defined, implemented and monitored to ensure that such policies are administered to provide quality healthcare in a safe and effective manner.

If an individual has been designated to be responsible for the conduct of the CAH, this individual will be qualified through appropriately defined education and experience. (Reference to this individual responsible is herein referred to as "Chief Executive" where applicable.) Only one individual may be designated as the Chief Executive of the CAH.

The governing body or individual is responsible for all services provided in the organization including all contracted services. The governing body or individual who assumes full legal authority and responsibility for operations of the CAH must carry out the functions specified.

The governing body or Chief Executive for the CAH shall ensure that healthcare services are furnished in accordance with appropriate written policies that are consistent with applicable State law.

- SR.1 The governing body or individual who assumes full legal authority and responsibility for operations of the CAH, medical staff, and administrative officials (which may include the chief financial officer, nurse executive and other leadership staff) are responsible and accountable for ensuring that:
 - SR1a The CAH is in compliance with all applicable Federal, State and local laws and regulations and in accordance with organization policies and procedures regarding the health and safety of its patients;
 - SR1b The CAH is licensed in accordance with all applicable Federal, State and local laws and regulations;
 - SR.1b (1) If the State does not license the hospital, the CAH will be approved as meeting standards for licensing established by the agency of the State or locality responsible for licensing hospitals.
 - SR.1c The CAH is designated and certified as a critical access hospital (CAH) in accordance with 42 CFR Sections 485.606; 485.608, and 485.627(a).
 - SR.1c (1) Except as permitted for CAHs having distinct part units under 42 CFR Section 485.647, the CAH maintains no more than 25 inpatient beds. Inpatient beds may be used for either inpatient or swing-bed services.
 - SR.1c (2) The CAH provides acute inpatient care for a period that does not exceed, on an annual average basis, 96 hours per patient.
 - SR.1d The personnel working in the CAH are properly licensed, certified, registered or otherwise meet all applicable Federal, State and local laws and regulations; and,
 - SR.1e Criteria that includes aspects of individual character, competence, training, experience and judgment is established for the selection of individuals working for the organization, directly or under contract, and/or appointed through the formal medical staff appointment process.

Interpretive Guidelines:

There should only be one governing body responsible for the day-to-day operation of the CAH. 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 CAH must provide written documentation that identifies the individual or individuals that are responsible for the conduct of the CAH operations.

Section 1820(c)(2)(B)(iii) of the Social Security Act, codified at 42 USC 1395i-4(c)(2)(B)(iii) limits a CAH to a maximum of 25 inpatient beds that can be used for inpatient acute care or swing bed services. The statute also requires CAHs to provide inpatient acute care limited, on an annual average basis, to 96 hours per patient (see interpretive guidelines for §485.620(b)).

Section 1820(c)(2)(E) of the Act also permits a CAH to operate a 10-bed psychiatric distinct part unit (DPU) and a 10-bed rehabilitation DPU, without counting these beds toward the 25-bed inpatient limit. The limit applies to the number of inpatient beds; not to the number of inpatients on any given day. CAHs that were larger hospitals prior to converting to CAH status may not maintain more than 25 inpatient beds, plus a maximum of 10 psychiatric DPU inpatient beds, and 10 rehabilitation DPU inpatient beds.

Observation Services

Observation beds are not included in the 25-bed maximum, or in the calculation of the average annual acute care patient length of stay. This makes it essential for surveyors to determine that CAHs with observation beds are using them appropriately, and not as a means to circumvent the CAH size and length-of-stay limits.

Inappropriate use of observation services also subjects Medicare beneficiaries and other patients to an increased payment liability that could have been avoided, had the patient been properly admitted as an inpatient. Depending on the terms of their health insurance coverage, other CAH patients may also face similar increased and avoidable costs when inappropriately placed in an observation status.

Observation care is a well-defined set of specific, clinically appropriate services that include ongoing short-term treatment, assessment, and reassessment, that are provided before a decision can be made regarding whether a patient will require further treatment as an inpatient or may be safely discharged. Observation status is commonly assigned to patients with unexpectedly prolonged recovery after outpatient surgery, and to patients who present to the emergency department and who then require a significant period of treatment or monitoring before a clinical decision is made concerning their next placement. The CAH should ensure that once there is sufficient information to render this clinical decision, the patient should be expeditiously admitted, appropriately transferred, or discharged.

A patient may be in an observation status even though the CAH furnishes the patient overnight accommodation, food, and nursing care.

*Observation services are **NOT** appropriate:*

- As a substitute for an inpatient admission;
- For continuous monitoring;
- For medically stable patients who need diagnostic testing or outpatient procedures (e.g., blood transfusion, chemotherapy, dialysis) that are routinely provided in an outpatient setting;
- For patients awaiting nursing home placement;
- To be used as a convenience to the patient, his or her family, the CAH, or the CAH's staff;
- For routine prep or recovery prior to or following diagnostic or surgical services; or as a routine
- "stop" between the emergency department and an inpatient admission.

*Observation services **BEGIN** and **END** with an order by a doctor of medicine or osteopathy or other qualified licensed practitioner of the CAH.*

The order for observation services must be written prior to initiation of the service, as documented by a dated and timed order in the patient's medical record. The order may not be backdated. Orders should be clear for the level of care intended, such as "admit to inpatient" or "admit for observation."

Observation services end when the physician or other qualified licensed practitioner orders an inpatient admission, a transfer to another health care facility, or discharge. The inpatient stay begins on the date and time of the new order.

Standing orders for observation services are not acceptable, since it is not necessary to employ observation services for every patient in a given category, e.g., every emergency department patient, in order to reach a clinical decision about the appropriate next step in the patient's care.

Medicare generally will not pay for observation services lasting more than 48 hours. However, some States may have more stringent limits in their licensure or other regulatory requirements, e.g., 24 hours. In such cases the more stringent limit on the length of an observation stay applies to Medicare beneficiaries as well.

The CAHs must provide appropriate documentation upon surveyor request to show that an observation bed is not an inpatient bed. The CAH must be able to document that it has specific clinical criteria for admission to, and discharge from, the observation service, and that these criteria are clearly distinguishable from those used for inpatient admission and discharge. CMS expects a CAH to employ the same type of clinical criteria for observation versus inpatient status for all patients, regardless of their payer status. For example, if a CAH were routinely placing only Medicare beneficiaries in its dedicated observation unit, then this would suggest that non-clinical criteria were being used in the decision to admit versus place in observation status. This would not only call the observation bed status into question but would violate the CAH's provider agreement. (See 42 CFR 489.53(c)(2).)

CMS expects there to be a reasonable relationship between the size of the CAH's inpatient and observation operations. For example, a 10-bed observation unit in a 25-bed CAH might be disproportionately large, and the surveyor must determine whether the observation unit is actually functioning as an inpatient overflow unit. A CAH observation unit that routinely operates at a high occupancy rate could also be an indicator of the need to probe further.

Other Types of Beds

Other bed types that do not count toward the 25-inpatient bed limit include:

- Examination or procedure tables;
- Stretchers;
- Operating room tables;
- Beds in a surgical recovery room used exclusively for surgical patients during recovery from anesthesia;
- Beds in an obstetric delivery room used exclusively for OB patients in active labor and delivery of newborn infants (do count beds in birthing rooms where the patient remains after giving birth);
- Newborn bassinets and isolettes used for well-baby boarders;
- Stretchers in emergency departments; and
- Inpatient beds in Medicare-certified distinct part rehabilitation or psychiatric units.

Hospice Services

A CAH can dedicate beds to a hospice under arrangement, but the beds must count as part of the maximum bed count. The computation contributing to the 96-hour annual average length of stay does not apply to hospice patients. The hospice patient can be admitted to the CAH for any care involved in their hospice treatment plan or for respite care.

Medicare does not reimburse the CAH for the hospice CAH benefit. Medicare reimburses the hospice. The CAH must negotiate payment for services from the hospice through an agreement.

The governing body (or responsible individual) must determine, in accordance with State law, which categories of practitioners are eligible candidates for appointment to the medical staff.

It is the responsibility of the governing body (or responsible individual) to appoint, with the advice of the medical staff, the individual practitioners to the medical staff. After considering medical staff recommendations, and in accordance with established CAH medical staff criteria and State and Federal laws and regulations, the governing

body (or responsible individual) decides whether or not to appoint new medical staff members or to continue current members of the medical staff.

All CAH patients must be under the care of a member of the medical staff or under the care of a practitioner who is under the supervision of a member of the medical staff. All patient care is provided by or in accordance with the orders of a practitioner granted privileges to provide or order that care and is in accordance with State law.

All staff required by the State to be licensed must possess a current license. The CAH must ensure that these personnel are in compliance with the State's licensure laws. The laws requiring licensure vary from state to state.

There are wide variations in the States' practice acts relative to the extent to which MD/DOs may delegate responsibilities to nurse practitioners, clinical nurse specialists, and physician assistants. Some states have updated their practice acts to include definitions and specific references to permitted/prohibited activities, supervision/guidance required by a MD/DO, and local situations in which nurse practitioners, clinical nurse specialists, and physician assistants may function

Criteria for selection of both new medical staff members and selection of current medical staff members for continued membership must be based on: Individual character; Individual competence; Individual training; Individual experience; and Individual judgment

Surveyor Guidance:

Prior to conducting the survey, determine what professional specialists provide patient care services at the CAH and review State practice act requirements. Also, determine whether the CAH is subject to licensure requirements and verify that the licensing agency has approved the CAH as meeting the standards for licensure as set forth by the agency of the State or locality responsible for licensing CAHs.

CAHs must meet the requirements of 42 CFR Section 485.610 (Status and Location). The appropriate CMS Regional Office is responsible for notifying the Accreditation Organization that the CAH remains compliant with location and distance requirements prior to DNV GL conducting a CAH accreditation or reaccreditation survey. If the survey team becomes aware of any possible non-compliance relative to location or status, the Team Leader must notify Accreditation Services immediately to clarify the organization's CAH status. Possible non-conformances may include but are not limited to:

- Location and distance:
 - The CAH must be located more than a 35-mile drive (or in the case of mountainous terrain or in areas with only secondary roads available, a 15-mile drive) from any other CAH or hospital.
 - If the CAH is located on an island:
 - *The island must be entirely surrounded by water and not accessible by any roads*
 - *The CAH is the only hospital or CAH on the island*
- IHS or Tribal hospitals are the exception in that CMS considers only proximity to other IHS and Tribal CAHs and hospitals in determining whether the location requirement is met.
- Status:
 - *The CAH that relocates must continue to meet Necessary Provider requirements as per 42 CFR Section 485.610(d) and continue to:*
 - *Serve at least 75% of the original service area;*
 - *Provide at least 75% of the same services; and,*
 - *Staff at 75% of the same staff (including medical staff, contracted staff, and employees) as was at original location.*

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

Review the defined requirements including education and experience required of the individual responsible (e.g. chief executive officer) for the CAH. This may be in the form of a job description or other document that adequately describes the scope of responsibilities for this individual.

Interview the CAH leadership to determine the reporting structure regarding how information flows to and from the governing body or individual responsible for the CAH. The reporting structure may include written reports, presentations by staff at board meetings, or other means.

Interview the individual responsible (e.g. chief executive officer) or appropriate individual, to determine whether the CAH is in compliance with Federal laws related to patient health and safety. For example, if the CAH has been convicted of violating a Federal law such as denying people with disabilities access to care, verify that satisfactory corrections have been made to bring the CAH into compliance with that law.

Review documentation and verify that the governing body (or responsible individual) has determined and stated the categories of practitioners that are eligible candidates for appointment to the medical staff.

GB.2 DISCLOSURE

- SR.1 The CAH shall publicly disclose (or otherwise have available to the public upon request) the names and address of its owners or those persons or entities with a controlling interest in the CAH or in any subcontractor in which the CAH has a direct or indirect ownership interest of five percent or more in accordance 42 CFR 420, subpart C.
- SR.2 The CAH shall publicly disclose (or otherwise have available to the public upon request) the name of the person principally responsible for the operation of the CAH and the person responsible for the medical direction of the CAH.
- SR.3 Physician-owned CAHs provide written notice to their patients at the beginning of each patient's CAH inpatient stay or outpatient visit stating that the CAH is physician-owned, in order to assist the patient in making an informed decision about his or her care as per the requirements of 42 CFR Section 489.20(u)(1).
 - SR.3a Physicians are required to disclose to their patients at the time of referral if they (or their immediate family members) have an ownership or investment interest in the hospitals to which they refer patients for treatment.

Surveyor Guidance:

Review CAH policy for reporting changes of ownership.

How does the CAH implement its policy or procedure for reporting changes in ownership to the State agency?

How does the CAH implement its policy or procedure for reporting changes in operating officials to the State agency?

How does the CAH implement its policy or procedure for reporting changes in medical director to the State agency?

Surveyors are not required to make an independent determination regarding whether a CAH meets the Medicare definition of "physician-owned," but they must ask whether the CAH is physician-owned.

GB.3 INSTITUTIONAL PLAN AND BUDGET

- SR.1 The organization shall have an overall plan that includes an operating budget that contains anticipated income and expenses and is prepared according to generally accepted accounting principles. The plan shall be reviewed and updated as appropriate.
- SR.2 The plan must provide for identification of capital expenditures to include and identify anticipated sources of financing as needed to account for (when deemed necessary) for:

- SR.2a Acquisition of land;
- SR.2b Improvement of land, buildings and equipment; or,
- SR.2c Replacement, modernization or expansion of buildings or equipment.
- SR.3 The plan must be approved by governing body or individual who assumes full legal authority and responsibility for operations of the CAH for the organization.
- SR.4 If required, the plan must be submitted for review in accordance with or, as applicable, to the appropriate health planning agency in the State.
- SR.5 If required, the plan must be submitted for review in accordance with or, as applicable, to the appropriate health planning agency in the State, and if determined that the capital expenditures for services and facilities that are needed in order to operate efficiently and economically and that are not otherwise readily accessible because:
 - SR.5a The facilities do not provide common services at the same site;
 - SR.5b The facilities are not available under a contract of reasonable duration;
 - SR.5c Full and equal medical staff privileges in the facilities are not available;
 - SR.5d Arrangements with these facilities are not administratively feasible; or,
 - SR.5e The purchase of these services is more costly than if the HMO or CMP provided the services directly.

Surveyor Guidance:

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

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

GB.4 AGREEMENTS

- SR.1 If the CAH is a member of a rural health network as defined in 42 CFR Section 485.603, the CAH will have an agreement with at least one hospital that is a member of the network for the following:
 - SR.1a Patient referral and transfer;
 - SR.1b The development, use and readily accessible communications systems of the network including the means for sharing patient data, telemetry and medical record electronically if the network is operating such an electronic system; and,
 - SR.1c Provides for emergency and nonemergency transportation between the network facility and the hospital.
- SR.2 If the CAH is a member of a rural health network as defined in 42 CFR Section 485.603, the CAH will have an agreement to provide for credentialing and quality assurance with at least:
 - SR.2a One hospital that is a member of the network;
 - SR.2b One QIO or equivalent entity; or,

SR.2c One other appropriate and qualified entity identified in the State rural health plan.

SR.3 **RESERVED**

SR.4 When telemedicine services are furnished to the CAH'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 CAH and as such, in accordance with 42 CFR Section 485.635 (c)(4)(iii), furnishes the contracted services in a manner that permits the hospital to comply with all applicable conditions of participation for the contracted services, including, but not limited to, the requirements of 42 CFR Section 485.616(c)(2) with regard to the distant-site telemedicine entity's physicians and practitioners providing telemedicine services. The governing body of the CAH whose patients are receiving the telemedicine services may grant privileges to physicians and practitioners employed by the distant-site telemedicine entity based on such hospital's medical staff recommendations; such staff recommendations may rely on information provided by the distant-site telemedicine entity. The CAH's governing body or responsible individual must ensure, through its written agreement with the distant-site telemedicine entity, that the provisions under Section MS.17 Telemedicine (SR.1 – SR.1d) have been met.

SR.5 When telemedicine services are furnished to the hospital's patients through an agreement with a distant-site hospital, the agreement is written and that it specifies that it is the responsibility of the governing body of the distant-site hospital to meet the requirements of 485.616(c)(2) with regard to the distant-site hospital's physicians and practitioners providing telemedicine services. The governing body of the CAH whose patients are receiving the telemedicine services may grant privileges based on its medical staff recommendations that rely on information provided by the distant-site hospital. The CAH's governing body or responsible individual must ensure, through its written agreement with the distant-site telemedicine entity, that the provisions under Section MS.17 Telemedicine (SR.2 – SR.2d) have been met.

The distant-site hospital must meet the following requirements:

- SR.5a Determine, in accordance with State law, which categories of practitioners are eligible candidates for appointment to the medical staff.
- SR.5b Appoint members of the medical staff after considering the recommendations of the existing members of the medical staff.
- SR.5c Assure that the medical staff has bylaws.
- SR.5d Approve medical staff bylaws and other medical staff rules and regulations.
- SR.5e Ensure that the medical staff is accountable to the governing body for the quality of care provided to patients.
- SR.5f Ensure the criteria for selection are individual character, competence, training, experience, and judgment.
- SR.5g 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.

Interpretive Guidelines:

Section 485.603 defines a rural health network as an organization that includes at least one hospital that the State has designated or plans to designate as a CAH, and at least one hospital that furnishes acute care (hospital) services.

Surveyor Guidance:

Verify that the CAH has an agreement in place with a hospital as a member of the network, QIO or equivalent entity of other appropriately qualified entity.

If the CAH is a member of a rural health network having a communications system, request a copy of the agreement.

How does the CAH demonstrate that it participates with other hospitals and facilities in the network communications system for sharing patient medical information?

How does the CAH ensure the effectiveness of its means for communications other hospitals and facilities?

Discuss/Ascertain if there have been difficulties regarding communication with network members and how such issues are dealt with under the agreement(s). If so, ask how the CAH deals with communication delays.

How does the network's communications system compare with any available communications equipment in the CAH?

When the network communications system is not in operation, how does the CAH communicate and share patient data with other network members?

Review any policies and procedures related to the operation of any communications system. Review any written agreements with the local EMS service.

GB.5 CONTRACTED SERVICES

- SR.1 The CAH has agreements or arrangements (as appropriate) with one or more providers or suppliers participating under Medicare to furnish other services to its patients, including:
- SR.1a Services of doctors of medicine or osteopathy;
 - SR.1b Additional or specialized diagnostic and clinical laboratory services that are not available at the CAH; and,
 - SR.1c Food and other services to meet inpatients' nutritional needs to the extent these services are not provided directly by the CAH.
- SR.2 The governing body or individual who assumes full legal authority and responsibility for operations of the CAH is **responsible for** services provided by the CAH whether or not they are furnished under arrangement or contract. The CAH shall have a description of the services provided directly and those provided through an agreement or arrangement (contract services). **The CAH's written patient care policies must describe the types of health care services that are available at the CAH, including whether those services are furnished by CAH staff or through agreements or arrangements. The types of health services described must include services provided both on-site and off-site.** The CAH must have a means to evaluate and select contracted services (including joint ventures or shared services) (and non-contracted services) entities/individuals based on their ability to supply products and/or services in accordance with the CAH's requirements. The CAH will have a method in place for determining the criteria for selection, evaluation, and re-evaluation shall be established. The criteria for selection will include the requirement that the contracted entity or individual to provide the products/services in a safe and effective manner and comply with all applicable NIAHO® standards, and standards required for all contracted services. **At a minimum, the CAH shall evaluate each contracted service at defined intervals. Where indicated, the CAH will take appropriate action to address variation.**
- (Note: If the organization participates/contracts and provided products and/or services through a Group Purchasing Organization (GPO) or similar service, the selection, criteria, evaluation and re-evaluation may be completed by the GPO or service responsible. When required by the CAH, there will be a process in place for the CAH to be provided necessary information to ensure that such products/services meet the needs and requirements of the CAH as well as ensuring compliance with all applicable NIAHO® standards.)
- SR.3 A documented list of contracted companies and individuals, including their scope/nature of services shall be maintained.
- SR.3a If the agreements or arrangements are not in writing, the CAH is able to present evidence that patients referred by the CAH are being accepted and treated.

Interpretive Guidelines:

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

When services are provided by a contracted entity, the governing body must identify the criteria for selection and procurement of services, and the means of evaluating the contracted entity. [Evaluation timeframes/intervals shall be established.](#)

The CAH will prioritize the review of contracted [services based on the concept of risk based thinking with an emphasis on those contracted services related to patient care.](#) [Contracts determined to be in this category will have established evaluation processes that are comparable to the evaluation processes of similar services that are provided directly by the CAH.](#) Other contracts will be assessed in accordance with the organization's policy as defined. It is not the expectation that such contracts as that for cable television or plumbing, for example, would be assessed in the same manner as those related to patient care services. However, if services provided under contract will have an impact in some manner for patient care services, the organization will review these services and monitor the appropriate measures to ensure the expectations of the organization and needs of the patient are being met.

- The governing body (or individual responsible) must take actions through the CAH's quality program to: assess the services furnished directly by CAH staff and 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

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.

Individual agreements or arrangements should be well defined, but need not be contractual. They should describe routine procedures (e.g., for obtaining outside laboratory tests); and there should be evidence in the agreement or arrangement that the governing body (or responsible individual) is responsible for these services provided under agreement or arrangement. Individual agreements or arrangements should be revised when the nature and scope of services provided has changed.

Laboratories that provide additional diagnostic and clinical laboratory services to a CAH by agreement or arrangement must be in compliance with CLIA requirements in 42 CFR Part 493. These laboratories will be surveyed separately for compliance with Part 493.

Surveyor Guidance:

[Determine that the CAH has documented information related to the services that are carried out by a contracted entity and the scope of their responsibilities. Assess the organizations process for determining and applying criteria for selection, evaluation, monitoring of performance, and re-evaluation of contracted services. Review documented information to verify that the CAH is in compliance with established processes identified in the CAH's policies and procedures, including verification that established evaluation timeframes/intervals are being met.](#)

Review the list of contracted services and verify that there is a delineation of contractor responsibility.

Review any arrangements or agreements to determine if the nature and scope of services defined is being provided to CAH patients and is in compliance with the CAH CoPs and NIAHO® requirements.

How does the CAH ensure, (e.g., through operating policies and procedures, by-laws etc.) that the individual responsible for its operations is responsible for all services provided through arrangements or agreements? How does the CAH ensure that it has arrangements or agreements with one or more MD/DOs to meet its requirements at §485.631(b)?

MEDICAL STAFF (MS)

MS.1 ORGANIZED MEDICAL STAFF

The CAH shall have an organized medical staff composed of licensed doctors of medicine or osteopathy (reference to "physician" in a section of these requirements shall be recognized as a doctor of medicine or osteopathy). The medical staff may include physician assistants, nurse practitioners, clinical nurse specialists, or QLPs in accordance with State law.

- SR.1 The CAH shall have medical staff that is appropriate to provide the services offered. The medical staff must be available at all times to provide the offered services when the CAH is in operation.
- SR.2 The medical staff shall include at least one doctor of medicine or osteopathy. The medical staff may also include physician assistants (PA), nurse practitioners (NP), or clinical nurse specialists (CNS).
- SR.3 The medical staff provides supervision to all ancillary staff.
- SR.4 The CAH shall have a medical staff that is appropriate to provide the services offered.

Interpretive Guidelines:

A CAH may operate with a MD/DO on staff as well as with any combination of mid-level practitioners.

CAHs are to provide "those diagnostic and therapeutic services and supplies that are commonly furnished in "a physician's office" such as low intensity outpatient services. In order to demonstrate compliance, a CAH must demonstrate that a practitioner is physically present and prepared to treat patients at the CAH when patients present at the CAH outpatient clinic during announced hours of outpatient clinic operation. This requirement does not mean the CAH must have a practitioner physically present in the facility 24 hours per day, nor does it require their presence 24 hours per day when the CAH has inpatients, including swing-bed patients

Surveyor Guidance:

Review lists or other documentation identifying the names of all staff MD/DOs, nurse practitioners, clinical nurse specialists and physician assistants on the CAH staff.

Review work schedules showing normal CAH hours of operation and coverage by members of the CAH staff.

Use CAH organization charts and staff interviews to determine how the CAH ensures that the professional staff supervises all ancillary personnel.

How does the CAH ensure that staff coverage is sufficient to provide essential services at the facility (e.g., emergency services, direct services, and nursing services)?

Review staffing schedules and daily census records

If the CAH does not have regular announced hours of operation, ask the individual who is principally responsible for the operation of the CAH, when the CAH is open to the public to provide outpatient services.

What kinds of arrangements have been made by the CAH to ensure that a practitioner is available on site at all times the CAH operates to furnish patient care services?

MS.2 ACCOUNTABILITY / RESPONSIBILITY

The CAH shall identify an MD/DO (identified as the Medical Director, Chief Medical Officer, Chief of Staff or as designated by the Medical Staff and as identified under 42 CFR Section 485.631(b) herein referenced as "Medical Director") approved by and accountable to the governing body (or individual who assumes full legal authority and responsibility for operations of the CAH) and shall be responsible for the conduct of medical staff, quality of the medical care provided to patients and provide direction of the CAH healthcare activities and consultation for, and medical supervision of healthcare staff.

Note: The CAH may recognize this individual responsible for the medical staff to be identified under the same or similar title. The CAH may also recognize a committee for oversight of the medical staff (e.g., Medical Executive Committee) under the direction of the Medical Director, and approved by the governing body or individual who assumes full legal authority and responsibility for operations of the CAH. If the CAH has such a committee in place, the majority of the members of the committee shall be primarily composed of doctors of medicine or osteopathy, and include the individual who assumes full legal authority and responsibility for operations of the CAH and Nurse Executive/Leader of the CAH.

This doctor of medicine or osteopathy is accountable for:

- SR.1 Developing, reviewing, revising and implementing the CAH's written policies for services provided by the CAH in conjunction with physician assistant(s) and/or nurse practitioner(s); and,
- SR.2 Reviewing medical records, medical orders, and providing medical services to CAH patients in conjunction with physician assistant(s) and/or nurse practitioner(s).
- SR.3 Periodically reviewing and signing the records of all inpatients cared for by nurse practitioners, clinical nurse specialists, certified nurse midwives, or physician assistants.
- SR.4 Periodically reviewing and signing a sample of outpatient records of patients cared for by nurse practitioners, clinical nurse specialists, certified nurse midwives, or physician assistants according to the policies of the CAH and according to current standards of practice where State law requires record reviews or co-signatures, or both, by a collaborating physician. The frequency of such review activity will be determined by CAH policy.
- SR.5 Ensuring that a doctor of medicine or osteopathy is present for sufficient periods of time to provide effective medical services, medical direction, consultation, and supervision of services provided by the CAH.
 - SR.5a A doctor of medicine or osteopathy is not required to make an onsite visit if no patients have received treatment since the last site visit.
 - SR.5b A doctor of medicine or osteopathy shall be readily available by radio or telephone for medical emergencies, consultation and referrals.

Interpretive Guidelines:

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

The CAH is to identify a doctor of medicine or osteopathy (identified as the Medical Director, Chief Medical Officer, and Chief of Staff or as designated under the Medical Staff. This individual must be approved by and accountable to the governing body (or individual who assumes full legal authority and responsibility for operations of the CAH) and shall be responsible for the conduct of medical staff, quality of the medical care provided to patients and provide direction of the CAH healthcare activities and consultation for, and medical supervision of healthcare staff.

The CAH may recognize this individual responsible for the medical staff to be identified under the same or similar title. The CAH may also recognize a committee for oversight of the medical staff (e.g. Medical Executive Committee) under the direction of the Medical Director and approved by the governing body or individual who assumes full legal authority and responsibility for operations of the CAH. If the CAH has such a committee in place, the majority of the members of the committee shall be primarily composed of doctors of medicine or osteopathy, and include the individual who assumes full legal authority and responsibility for operations of the CAH and Nurse Executive/Leader of the CAH.

All patients must be under the care of a member of the medical staff or under the care of a practitioner who is directly under the supervision of a member of the medical staff. All patient care is provided by or in accordance with the orders of a practitioner who meets the medical staff criteria and procedures for the privileges granted, who has been granted privileges in accordance with those criteria by the governing body, and who is working within the scope of those granted privileges.

There will be a process in place to for developing, reviewing, revising and implementing the CAH's written clinical policies for services, medical records, clinical orders and other medical services provided by the CAH in conjunction with physician assistant(s) and/or nurse practitioner(s)

There will be a process in place for periodically reviewing and signing the records of all inpatients/outpatients cared for by nurse practitioners, clinical nurse specialists, certified nurse midwives, or physician assistants according to the policies of the CAH and according to current standards of practice where State law requires record reviews or co-signatures, or both, by a collaborating physician.

*There will be a doctor of medicine or osteopathy be physically present in the CAH for sufficient periods of time to provide effective medical services supervision, **direction**, and consultation.*

Surveyor Guidance:

Verify that the governing body is accountable for the medical staff and the quality of patient care services. Validate the process by which the governing body monitors the quality of medical care provided to patients.

Verify that an individual doctor of medicine or osteopathy is responsible for the conduct and organization of the medical staff.

Review the CAH policy delineating frequency of MD/DO reviews of patient records.

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

Evaluate how written clinical policies are developed, reviewed, revised and implemented for services provided by the CAH.

Evaluate the process in place for periodically reviewing and signing the records of all inpatients/outpatients cared for by nurse practitioners, clinical nurse specialists, certified nurse midwives, or physician assistants.

Evaluate the effectiveness and timeliness of MD/DO on-site supervision, consultation, and medical direction. Verify that there are policies and procedures for transferring patients to other facilities.

MS.3 PHYSICIAN ASSISTANT, NURSE PRACTITIONER, CLINICAL NURSE SPECIALIST

A physician assistant, nurse practitioner and/or clinical nurse specialist shall:

- SR.1 Participate in the development, review, revising and implementation of written policies for services provided by the CAH.
- SR.2 Participate in the periodic review of medical records in conjunction with the doctor or medicine or osteopathy.
- SR.3 Perform clinical services that are not being performed by a doctor or medicine or osteopathy in accordance with CAH policies.
 - SR.3a Refer those patients who require clinical services not provided by the CAH and arrange for the maintenance and transfer of medical records.
 - SR.3b Notify a Physician on the CAH clinical staff when a patient is admitted as an inpatient.

Interpretive Guidelines:

The CAH regulations do permit licensed mid-level practitioners, in accordance with State law, to admit patients to a CAH. However, CMS regulations do require that Medicare and Medicaid patients be under the care of an MD/DO if admitted by a mid-level practitioner and the patient has 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. Evidence of being under the care of an MD/DO must be in the patient's medical record. If a CAH allows a mid-level practitioner to admit and care for patients, as allowed by State law, the governing body (or responsible individual) and medical staff would have to establish policies and bylaws to ensure patient safety. As applicable, the patient's

medical record must demonstrate MD/DO responsibility/care.

Surveyor Guidance:

If mid-level practitioners admit patients, verify that every Medicare/Medicaid patient is being monitored by an MD/DO who is responsible for any medical problem outside the scope of practice of the admitting practitioners.

Evaluate clinical services being performed by physician assistants, nurse practitioners and/or clinical nurse specialists.

How does the CAH ensure that an MD/DO is available by telephone or radio contact for consultation, assistance and/or patient referral?

What evidence demonstrates that an MD/DO provides medical direction for the CAH's health care activities and is available for consultation and supervision of the CAH health care staff?

What evidence demonstrates that there is involvement of physician assistants, nurse practitioners and/or clinical nurse specialists regarding periodic review of patient records and written clinical policies?

- Interview any mid-level professional staff to ascertain their level of involvement in CAH policy development, execution, and periodic review.

MS.4 MEDICAL STAFF AND HEALTH PROFESSIONAL PARTICIPATION

The Medical Director, in conjunction with physician assistant(s) and/or nurse practitioner(s), shall participate in a manner to ensure the effective oversight of:

- SR.1 Medication management practices;
- SR.2 Infection prevention and control oversight;
- SR.3 Tissue review;
- SR.4 Utilization review;
- SR.5 Medical record review; and,
- SR.6 Quality Management System.
- SR.7 Reports and recommendations from these activities shall be prepared and shared with the governing body (or individual who assumes full legal authority and responsibility for operations of the CAH) of the CAH.

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 CAH:

- 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.5 MEDICAL STAFF BYLAWS, RULES AND REGULATIONS

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

Interpretive Guidelines:

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

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

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

The governing body (or responsible individual) must ensure that the medical staff is accountable to the governing body (or responsible individual) for the quality of care provided to patients. The governing body (or responsible individual) is responsible for the conduct of the CAH and this conduct would include the quality of care provided to patients.

Surveyor Guidance:

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

Review the process the CAH has defined for addressing how bylaws, rules and regulation revisions are made and approved by the medical staff and governing body (or individual responsible).

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

MS.6 APPOINTMENT

The governing body (or individual who assumes full legal authority and responsibility for operations of the CAH) shall determine, in accordance with State law, which practitioners are eligible candidates for appointment to the medical staff and describe the qualifications to be met by a candidate in order for the medical staff to recommend that the governing body (or individual who assumes full legal authority and responsibility for operations of the CAH) appoint the candidate.

Those qualifications shall include the following:

- SR.1 Initial appointment to the medical staff:
 - SR.1a Primary source verification of licensure, education, specific training, experience, and current competence; (AMA Master Profile [or Osteopathic Physician Profile Report from American Osteopathic Information Association](#) is acceptable)
 - SR.1a (1) Verification of ECFMG (as applicable);
 - SR.1b Current Federal Narcotics Registration Certificate (DEA) number (as applicable);
 - SR.1c Peer recommendation(s);
 - SR.1d Review of involvement in any professional liability action;
 - SR.1e If available, review of individual performance data and,
 - SR.1f Receipt of database profiles through professional sources (e.g., AMA, AOA, NPDB, OIG, Medicare/Medicaid Exclusions)
- SR.2 Reappointment to the medical staff:
 - SR.2a Primary source verification of licensure and current competence (AMA Master Profile [or Osteopathic Physician Profile Report from American Osteopathic Information Association](#) is acceptable);
 - SR.2b Federal Narcotics Registration Certificate (DEA) number (if required);
 - SR.2c Review of involvement in any professional liability action; and,
 - SR.2d Review of individual performance data for variation from benchmark. Variation shall go to Peer Review for determination of validity, written explanation of findings and, if appropriate, an action plan to include improvement strategies.
 - SR.2e Receipt of database profiles through professional sources (e.g. AMA, AOA, NPDB, OIG Medicare/Medicaid Exclusions).

Surveyor Guidance:

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

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

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

MS.7 PERFORMANCE DATA

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

Areas required to be measured (as applicable) include:

- SR.1 Blood use (may include AABB transfusion criteria);
- SR.2 Prescribing of medications: Prescribing patterns, trends, errors and appropriateness of prescribing for Drug Use Evaluations;

- SR.3 Operative and invasive procedures: appropriateness and outcomes;
- SR.4 Anesthesia and Moderate Sedation Adverse events;
- SR.5 Appropriateness of care for non-invasive procedures/interventions;
- SR.6 Utilization data;
- SR.7 Significant deviations from established standards of practice; and,
- SR.8 Timely and legible completion of patients' medical records.
- SR.9 Any variant should be analyzed for statistical significance.

Interpretive Guidelines:

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

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

Surveyor Guidance:

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

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

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

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

Advanced Practice Providers (APP) are often included as Medical Staff members. In those instances, MS.7 applies to the APP as well. Verify that the CAH has implemented a process for the review of APP performance data. Given that much of the work of APPs is attributed to the supervising provider, APP performance data might be collected in a manner different from that of the MD/ DO members of the Medical Staff (e.g., 360° evaluations, robust chart supervising Physician's review) combined with CAH Medical Staff review.

If the required information is not available for review, document that a CAH representative (e.g., Quality Management representative, Nursing Leadership, etc.) confirmed that the information was not available and include that information in the nonconformance evidence statement.

MS.8 CONTINUING EDUCATION

All individuals with clinical privileges shall participate in continuing education (as required) that is at least in part related to their clinical privileges.

- SR.1 This documentation shall be considered in decisions about reappointment or renewal or revision of clinical privileges.
- SR.2 Action on an individual's application for appointment /reappointment or initial or subsequent clinical privileges is withheld until the information is available and verified (when required).

Surveyor Guidance:

Review documentation to determine how the CAH considers continuing education in relation to maintaining clinical privileges.

MS.9 GOVERNING BODY / CHIEF EXECUTIVE ROLE

- SR.1 The governing body, Chief Executive, (or individual who assumes full legal authority and responsibility for operations of the CAH) 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 (or individual who assumes full legal authority and responsibility for operations of the CAH) for the quality of care provided to patients.
- SR.2 The governing body (or individual who assumes full legal authority and responsibility for operations of the CAH) may elect to delegate the authority to render initial appointment, reappointment, and renewal or modification of clinical privileges decisions to a committee identified by the governing body (or individual who assumes full legal authority and responsibility for operations of the CAH).
- SR.3 A complete application for appointment to the medical staff shall be acted on within a reasonable period of time, as specified in the medical staff bylaws, rules and regulations.

Interpretive Guidelines:

The governing body (or individual responsible), 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 (or individual responsible) 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.

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 (or individual responsible) is involved in appointments of medical staff members.

MS.10 CLINICAL PRIVILEGES

- SR.1 The medical staff bylaws, rules and regulations shall include criteria for determining the privileges to be granted to individual practitioners and a procedure for applying the criteria to those individuals that request privileges.
- SR.2 Appointment or reappointments to the medical staff and the granting, renewal, or revision of clinical privileges shall be made for a period defined by State law or if permitted by State law, not to exceed three years.
- SR.3 All individuals who are permitted by the CAH and by law to provide patient care services independently in the CAH shall have delineated clinical privileges.
- SR.4 There shall be a provision in the medical staff bylaws for a mechanism to ensure that all individuals with clinical privileges provide services only within the scope of privileges granted.
- SR.5 If available and/or required by the medical staff to hold or maintain clinical privileges, include a review of individual performance data variation from criteria determined by the medical staff to

identify need for training or proctoring that may be required.

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

Interpretive Guidelines:

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

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

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

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

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

Surveyor Guidance:

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

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

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

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.

Review any agreements related to credentialing or quality assurance to determine the level of assistance to be provided and the responsibilities of the CAH.

How is information obtained to be included in the periodic evaluation? How does the CAH conduct the periodic evaluation?

Who is responsible for conducting the periodic evaluation?

How is clinical performance of mid-level practitioners evaluated?

MS.11 TEMPORARY CLINICAL PRIVILEGES

When dictated by urgent patient care need or when an application is complete without any negative or adverse information the medical staff, with the approval of the governing body (or individual who assumes full legal authority and responsibility for operations of the CAH), 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 one hundred twenty (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 (6) 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 individual who assumes full legal authority and responsibility for operations of the CAH or designee may grant temporary clinical privileges on the recommendation of a member of 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

Surveyor Guidance:

Review and verify that the CAH 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.12 CORRECTIVE OR REHABILITATION ACTION

The medical staff bylaws, rules and regulations 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 CAH operations. The doctor of medicine or osteopathy responsible for the medical staff, or governing body (or individual who assumes full legal authority and responsibility for operations of the CAH), 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 CAH. The medical staff must provide a mechanism for managing the process for taking corrective or rehabilitative action when a practitioner's conduct is in question. An officer of the medical staff, CEO or any officer of the governing body 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 CAH 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 CAH 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.13 ADMISSION REQUIREMENTS

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

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

- SR.1 The governing body (or individual who assumes full legal authority and responsibility for operations of the CAH) 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 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 The governing body (or individual who assumes full legal authority and responsibility for operations

of the CAH) shall ensure that:

- SR.2a A doctor of medicine or osteopathy shall be readily available by radio or telephone for medical emergencies, consultation and referrals. If the CAH maintains a Distinct Part Unit for Rehabilitation and/or Psychiatric patients, the CAH is required to have a doctor of medicine or osteopathy on duty or on call at all times.
- SR.2b A physician assistant, nurse practitioner and/or clinical nurse specialist shall notify a doctor of medicine or osteopathy on the CAH clinical staff when a patient is admitted as an inpatient, in accordance with State law.
- SR.2c 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 SR 1b-1f (above) as that scope of practice is defined by the medical staff and State law.

Interpretive Guidelines:

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

The governing body (or individual responsible) must ensure that a doctor of medicine or osteopathy shall be readily available by radio or telephone for medical emergencies, consultation and referrals. The governing body must also ensure a doctor of medicine or osteopathy is responsible for the care of each patient with respect to any medical or psychiatric problem that is present on admission or develops during hospitalization and is not within the scope of practice of the licensed practitioners specified and within the scope of practice is defined by the medical staff and State law.

The CAH regulations do permit licensed mid-level practitioners, as allowed by the State, to admit patients to a CAH. However, CMS regulations do require that Medicare and Medicaid patients be under the care of an MD/DO if admitted by a mid-level practitioner and the patient has 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. Evidence of being under the care of an MD/DO must be in the patient's medical record. If a CAH allows a mid-level practitioner to admit and care for patients, as allowed by State law, the governing body (or responsible individual) and medical staff would have to establish policies and bylaws to ensure patient safety. As applicable, the patient's medical record must demonstrate MD/DO responsibility/care.

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 (or individual responsible) and as permitted by State law.

Although the practitioners that are licensed and permitted by State law to admit patients, in some CAHs, the admission of patients must be done under the service of specific practitioners as defined in the medical staff bylaws, rules and regulations. Verify the CAH'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 the governing body (or individual responsible) 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 CAH.

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

MS.14 MEDICAL RECORD MAINTENANCE

- SR.1 The medical staff bylaws, rules or regulations 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, rules or regulations shall require that the medical staff in conjunction with physician assistant(s) and/or nurse practitioner(s) at regular intervals to review and analyze medical records of the patients for adequacy and quality of care.

Interpretive Guidelines:

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

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

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

Surveyor Guidance:

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

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

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

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

MS.15 HISTORY AND PHYSICAL

- SR.1 The medical staff bylaws, rules or regulations 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 twenty-four (24) hours after an admission or registration, **and prior to any high-risk procedure, surgery, procedures requiring anesthesia services, or other procedures requiring an H&P.**
- 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.
- SR.1b This examination and update of the patient's current medical condition shall be completed and placed in the medical record within twenty-four (24) hours after admission or registration, **but and prior to any high-risk procedure, surgery, or other procedures requiring anesthesia services, or other procedures requiring an H&P. Any H&P update of the patient's current medical condition shall document:**
- SR.1b (i) That the patient has been examined;
 - SR.1b (ii) That the H&P has been reviewed;
 - SR.1b (iii) Any changes in the patient's condition, or,
 - Sr.1b (iv) That "no change" has occurred in the patient's condition since the H&P was

completed.

- SR.2 All or part of the H&P may be delegated to other practitioners in accordance with State law and CAH policy. The responsible physician must review, approve, and authenticate the H&P.
- SR.3 The content of the H&P examination and applicability shall be determined by the medical staff and may be done by the individuals described in MS.15, SR. 2. The content of the H&P examination will be determined by an assessment of the patient's condition and any co- morbidities in relation to the reason for admission or surgery. This H&P examination must be in the medical record within 24 hours of admission and prior to any high-risk procedure, surgery, procedures requiring anesthesia services or other procedures requiring an H&P.

Interpretive Guidelines:

The medical record must be completed by an authorized practitioner and contain an H&P as required for all inpatients and applicable outpatients. The H&P must be performed no more than thirty (30) days prior to admission or registration or within 24 hours after admission, and prior to any high-risk procedure, surgery procedures requiring anesthesia services or other procedures requiring an H&P.

The H&P must be placed in the patient's medical record within twenty-four (24) hours of admission and prior to any high-risk procedure, surgery, procedures requiring anesthesia services or other procedures requiring an H&P. In the event that the H & P is completed less than thirty (30) days prior to admission, the CAH must ensure that this H&P is updated to document any changes in the patient's condition.

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

The practitioner completing the update is responsible for ensuring that the H&P documented in the medical record is complete and accurate.

- The completed H&P must be authenticated by the practitioner who conducted the H&P.
 - If the H&P is performed when the patient arrives at the CAH and the H&P is not placed on the medical record immediately following completion (e.g. pending transcription), it is expected that the practitioner who conducts the H&P will document in the patient's medical record that the H&P was completed and dictated within 24 hours following admission.
 - Authentication includes dating and timing of this medical record entry. Therefore, it is not necessary to document the time the H&P was physically placed in the medical record.

A doctor of medicine or osteopathy or alternatively, qualified licensed practitioner may perform an H&P if so privileged by the medical staff and permitted by State law and scope of practice.

If the patient is admitted only for oral or maxillofacial surgery, the H&P may be performed by an oral and maxillofacial surgeon who has been granted such privileges by the medical staff, in accordance with State law.

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

Surveyor Guidance:

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

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

- Surgical patients
- At least one per in-patient unit or clinical tracer
- Procedures requiring an H&P by CAH policy

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 CAH policy
 - In some cases, the CAH 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 CAH 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 prior to any high-risk procedure, surgery, procedure requiring anesthesia services, or other procedures requiring an H&P.

Verify that documentation of the H&P was placed in the medical record within 24 hours after admission or registration, and prior to any high-risk procedure, surgery, procedure requiring anesthesia services, or other procedures requiring an H&P.

- Where the H&P is completed within 30 days before admission or registration, the CAH must ensure that the H&P is updated to document any changes in the patient's condition prior to all cases involving any high-risk procedure, surgery, procedure requiring anesthesia services, or other procedures requiring an H&P.

MS.16 CONSULTATION

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

Interpretive Guidelines:

Guidelines for the medical management of health problems should include a description of the scope of medical acts that may be performed by the mid-level practitioners. Guidelines represent an agreement between the MD/DO providing the CAH'S medical direction and the CAH'S mid-level practitioners relative to the privileges and limits of those acts of medical diagnosis and treatment that may be undertaken with direct MD/DO supervision. Guidelines should describe the regimens to follow and also stipulate the condition in the illness or health care management when consultation or referral is required.

Regardless of the format used by the CAH for its medical management guidelines, they should include the following essential elements:

- They should be comprehensive enough to cover most health problems that patients usually refer to a MD/DO;
- They should describe the medical procedures available to the PA, NP and/or CNS;
- They should describe the medical conditions, signs, or developments that require consultation or referral; and
- They should be compatible with State laws.

Surveyor Guidance:

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

What evidence demonstrates that the CAH'S guidelines for medical management of health problems accurately reflect the actual clinical capabilities of the facility?

What evidence demonstrates that the guidelines are followed?

MS.17 TELEMEDICINE

- SR.1 When telemedicine services are furnished to the CAH's patients through an agreement with a distant-site telemedicine entity, the governing body of the CAH whose patients are receiving the telemedicine services may choose to rely upon the credentialing and privileging decisions made by the distant-site telemedicine entity when making recommendations on privileges for the individual distant-site physicians and practitioners providing such services, if the CAH's governing body ensures, through its written agreement with the distant-site telemedicine entity, that the distant-site telemedicine entity furnishes services that, in accordance with requirements stated above, permit the CAH to comply with all applicable CoP for the contracted services. The CAH's governing body must also ensure, through its written agreement with the distant-site telemedicine entity, that all of the following provisions are met:
- SR.1a The distant-site telemedicine entity's medical staff credentialing and privileging process and standards at least meet the standards stated in 42 CFR Section 485.616(c)(1).
 - SR.1b The individual distant-site physician or practitioner is privileged at the distant-site telemedicine entity providing the telemedicine services. [The distant-site](#) provides the CAH with a current list of the distant-site physician's or practitioner's privileges at the distant-site telemedicine entity.
 - SR.1c The individual distant-site physician or practitioner holds a license issued or recognized by the State in which the CAH whose patients are receiving such telemedicine services is located.
 - SR.1d With respect to a distant-site physician or practitioner, who holds current privileges at the CAH whose patients are receiving the telemedicine services, the CAH has evidence of an internal review of the distant-site physician's or practitioner's performance of these privileges and sends the distant-site telemedicine entity such performance information for use in the periodic appraisal of the distant-site physician or practitioner. At a minimum, this information must include all adverse events that result from the telemedicine services provided by the distant-site physician or practitioner to the CAH's patients, and all complaints the CAH has received about the distant-site physician or practitioner.
 - SR.1e [The distant-site telemedicine entity may or may not be a Medicare- participating provider or supplier. This is at the discretion of the CAH to require this as a condition of the agreement with the distant-site entity.](#)
- SR.2 When telemedicine services are furnished to the CAH's patients through an agreement with a distant-site hospital, the governing body of the CAH whose patients are receiving the telemedicine services may choose to 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 CAH's governing body ensures, through its written agreement with the distant-site hospital, that all of the following provisions are met:
- SR.2a The distant-site hospital providing the telemedicine services is a Medicare-participating hospital.
 - SR.2b The individual distant-site physician or practitioner is privileged at the distant-site hospital providing the telemedicine services, which provides a current list of the distant-site physician's or practitioner's privileges at the distant-site hospital.

- SR.2c The individual distant-site physician or practitioner holds a license issued or recognized by the State in which the CAH whose patients are receiving the telemedicine services is located.
- SR.2d With respect to a distant-site physician or practitioner, who holds current privileges at the CAH whose patients are receiving the telemedicine services, the CAH has evidence of an internal review of the distant-site physician's or practitioner's performance of these privileges and sends the distant-site CAH such performance information for use in the periodic appraisal of the distant-site physician or practitioner. At a minimum, this information must include all adverse events that result from the telemedicine services provided by the distant-site physician or practitioner to the CAH's patients and all complaints the CAH has received about the distant-site physician or practitioner.
- SR.3 The CAH 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 CAH, the criteria for determining privileges and the procedure for applying the criteria are also subject to these requirements.

Interpretive Guidelines:

While CAHs may use third-party credentialing verification organizations to compile and verify the credentials of practitioners applying for privileges, the CAH'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 CAH or using its services to meet all applicable CoPs, particularly those requirements related to the credentialing and privileging of practitioners providing telemedicine services to the patients of a CAH

Surveyor Guidance:

Review agreement with any distance-site telemedicine providers.

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

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

NURSING SERVICES (NS)

NS.1 NURSING SERVICE

- SR.1 The CAH must have a well-organized nursing service with a plan of administrative authority and delineation of responsibilities for delivery of patient care.
- SR.2 There shall be 24-hour nursing services and a registered nurse must provide (or assign to other personnel) the nursing care of each patient, including patients at a SNF level of care in a swing-bed CAH. The care must be provided in accordance with the patient's needs and the specialized qualifications and competence of the staff available.
 - SR.2a A registered nurse (or physician assistant when permitted by State law) must supervise and evaluate the nursing care for each patient, including patients in SNF swing beds.
- SR.3 The nursing service must develop and maintain a procedure to ensure that nursing personnel for whom licensure is required have a valid and current licensure. Nursing services must be provided or supervised by a registered nurse.
- SR.4 There shall be adequate numbers of RNs, LPN/LVNs, supervisory, and other staff to provide nursing care to all patients as needed. A registered nurse must be immediately available for the bedside care of every patient, as required by State law.
 - SR.4a At least one registered nurse, clinical nurse specialist or LPN/LVN is on duty when one or more inpatients are present.
- SR.5 A registered nurse shall make any decisions regarding delegation of nursing care to other nursing staff, based on individual patient need and staff qualifications.
- SR.6 Non-employee licensed nurses who are working in the CAH must adhere to the policies and procedures of the CAH. The nurse executive/leader must provide for the adequate supervision and evaluation of the clinical activities of non-employee nursing personnel that occur within the responsibility of the nursing service.

Interpretive Guidelines:

The CAH must have a well-organized nursing service, under the direction of a registered nurse and must provide on-site nursing services 24 hours a day, seven (7) days a week with at least one (1) registered nurse (RN) providing or supervising the service 24 hours a day, 7 days a week.

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

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

The CAH and the nurse executive/leader are responsible for the clinical activities of all nursing to include the clinical activities of all non-CAH nursing personnel (contract, agency, or volunteer).

If services are provided by contracted (non-employee) staff, the nurse executive/leader must supervise and evaluate the clinical activities being performed by these individual(s). The non-employee staff are required to adhere to the policies and procedures of the CAH and will receive an orientation regarding the CAH's policies and procedures prior to working on-site for the CAH.

The CAH and the nurse executive/leader ensure that all CAH nursing staff and each non-CAH nursing staff person is adequately trained and oriented, is adequately supervised, that their clinical activities are evaluated, and that all nursing personnel know the CAH policies and procedures. An appropriately qualified CAH-employed RN should conduct the supervision and evaluation of the clinical activities of each non-CAH nursing staff.

The nursing service ensures that patient needs are met by ongoing assessments of patients' needs and provides

nursing staff to meet those needs. There must be sufficient personnel to respond to the appropriate medical needs and care of the patient population being serviced.

An RN must make all patient care assignments. The nurse executive/leader and the CAH are to ensure that nursing personnel with the appropriate education, experience, licensure, competence and specialized qualifications are assigned to provide nursing care for each patient in accordance with the individual needs of each patient.

Staffing:

The CAH must provide nursing services 24 hours a day, 7 days a week. An LPN/LVN can provide nursing services if an RN (or PA where State law permits) supervises that care. The RN (or PA where State law permits) must be immediately available for the bedside care of those patients, Evaluation would include assessing the patient's care needs as well as the patient's response to interventions.

(Exception for small and rural hospitals: CMS Conditions of Participation §488.54 sets forth certain conditions under which rural hospitals of 50 beds or fewer may be granted a temporary waiver of the 24-hour registered nurse requirement by the regional office.)

The CAH must have met the criteria for this exception to apply. Definitions:

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

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

Surveyor Guidance:

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

- CAH organizational chart(s) for nursing services for all locations where the CAH provides nursing services;
- Job descriptions or description of responsibilities for all nursing personnel including the nurse executive/leader.

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

Review samples of the following documentation:

- Nursing care plans;
- Medical records;
- Accident and investigative reports;
- Staffing schedules;
- Nursing policies and procedures; and,
- Internal survey reports.

Interview patients to verify how nursing care has been provided. Secure CAH 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.

Review nursing staff schedules to ensure that a registered nurse, clinical nurse specialist or licensed practical nurse is

on duty whenever the CAH has one or more inpatients. Determine that there are written staffing schedules that correlate to the number and acuity of patients.

Review the nursing assignments. Did an RN make the assignments? Determine that the assignments take into consideration the complexity of patient care needs and the competence and specialized qualifications of the nursing staff.

Determine that a registered nurse (or PA where State law permits) supervises and evaluates the nursing care for each patient?

When contracted (non-employee) personnel are used by the CAH, these individuals must adhere to the practices, policies and procedures of the CAH. Verify the process for orienting these contracted individuals to the CAH, 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.

- Interview one or more temporary staff, if available, to determine if they are adequately familiar with CAH nursing requirements

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

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

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

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

Observe the nursing care in progress to determine the adequacy of staffing and to assess the delivery of care. Other sources of information to use in the evaluation of the nursing services are: nursing care plans, medical records, accident and investigative reports, staffing schedules, nursing policies and procedures, credentialing and training files (including contracted staff), and QA activities and reports.

Interview the registered nurse responsible for supervising the nursing care of the patients and ask the following-

- How are the specialized needs of patients determined? Who makes this determination?
- How is staff assigned?
- How is staff monitored to ensure that appropriately qualified staff provides the care needed?
- How does the CAH ensure that care provided meets the needs of each patient?
- If temporary nursing staff is utilized, how are these staff oriented and supervised relative to CAH nursing procedures?

NS.2 NURSE EXECUTIVE/LEADER

- SR.1 The CAH will designate a nurse executive/leader that is a licensed registered nurse responsible for the operation nursing services, including determining the types and numbers of staff necessary to provide nursing care for all patient care areas of the CAH and standards of nursing practice.

Interpretive Guidelines:

The nurse executive/leader is a member of senior leadership and must be appropriately qualified. It is preferable that the nurse executive/leader possess a nursing master's degree (MSN), is actively pursuing a master's degree, or has demonstrated the equivalent experience in comparable positions. The CAH may have only one nursing service CAH-

wide and the single nursing service must be under the direction of one RN.

The nurse executive/leader is responsible for the overall management and evaluation of nursing care in the CAH, including, but not limited to:

- Development and maintenance of nursing policies and procedures;
- Supervision of nursing staff, either directly, or, depending on the size of the CAH, indirectly through other nursing managers; and,
- Ongoing review and analysis of the quality of nursing care.

Operation of service:

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

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

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

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

- Although specific titles may vary, the hierarchy of the nursing service will include some variation of:
 - Assistant/Associate Directors(s)
 - Supervisors/Coordinators
 - Charge Nurses/Nurse Managers
 - Staff Nurses
 - Unit Secretaries/Clerks
 - Nursing Assistants/Aides

Surveyor Guidance:

Review the nurse executive/leader job description and verify that he or she has the appropriate education, licensure and experience for this position in the CAH for operation of the nursing service.

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

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

Verify that the nurse executive/leader 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 CAH;
- 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.

Interview the nurse executive/leader to determine if he/she has the necessary knowledge, experience and capabilities to properly supervise and administer the service.

NS.3 ASSESSMENT AND PLAN OF CARE

A nursing care plan must be developed and kept current for each inpatient.

- SR.1 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.2 Nursing staff shall complete an assessment of a patient's condition within twenty-four hours of admission to an inpatient setting.
- SR.2a The nursing assessment will include but not be limited to:
- SR.2a (i) Allergies
 - SR.2a (iii) Admitting problem
 - SR.2a (iv) History of pain and current status
 - SR.2a (v) Preexisting or other conditions (e.g. Pregnancy, COPD, Diabetes)
 - SR.2a (vi) Current medications (what time last dose, including any illicit drugs)
 - SR.2a (vii) ADL needs
 - SR.2a (viii) Dietary Requirements
 - SR.2a (ix) All other requirements per hospital nursing policies
- SR.2b Nursing staff will complete an assessment according to the hospital nursing policies in all other areas of the organization. (Outpatient, clinics, surgical centers etc.).
- SR.3 Nursing staff will reassess the patient at regular time defined intervals and if the patient's condition changes.
- SR.3a The patient's plan of care is reviewed and revised, as necessary, when the patient's condition has changed.

Interpretive Guidelines:

A nursing assessment will be completed within 24 hours of admission to an inpatient setting and according to hospital policies in other areas of the organization such as clinics, outpatient surgery etc. While the list of requirements to be included in the initial nursing assessment is specific, the complete nursing assessment should reflect the philosophy of the nursing department on patient care. The use of nursing diagnosis, pathways or clinical guidelines are allowed and encouraged if they meet the minimum requirements. All nursing assessments should collect enough data for the nurse to be able to develop a plan of care to keep the patient safe and address the presenting and relevant concomitant conditions. A plan of care begins within twenty-four (24) hours of admission of the patient. The plan of care includes planning the patient's care from admission through discharge and the respective care processes involved. If interdisciplinary findings are indicated, these shall also be a part of the plan of care and documented in the medical record. The plan of care is based on assessing the patient's nursing care needs (not solely those needs related to the admitting diagnosis), developing appropriate goals, nursing interventions in response to those needs,

and evaluating the patient's progress toward those goals.

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

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

Surveyor Guidance:

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

- Are the plans initiated as soon as possible after admission for each patient?
- Does the plan reflect findings of the assessments and outlines the patient goals and as appropriate includes both, physiological and psychosocial factors;
- Has the discharge planning process been initiated?
- Is the plan consistent with the attending practitioner's plan for medical care?
- Does the plan includes appropriate interdisciplinary assessments and documentation of findings (as applicable); and,
- Has the plan been revised as necessary to meet the needs of the patient changes?
- Are the plans implemented?

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

Review the process for determining how nursing assignments and staffing is 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.

STAFFING MANAGEMENT (SM)

SM.1 PROFESSIONAL SCOPE

The CAH shall have a policy and practice to ensure that all clinical staff, including contract staff, shall function within the limits of their scope of service as defined by their professional practice act, State law, and CAH policy. Within this policy, the CAH will have a process in place outlining and verifying that each staff member possesses a valid and current license or certification as required by the CAH and Federal and State law. This includes clinical nurse specialists, nurse practitioners and physician assistants. This written policy shall be strictly enforced, and compliance data reported to Quality Management Oversight.

- SR.1 Clinical Nurse Specialist: A CNS must be a person who performs the services of a clinical nurse specialist as authorized by the State. The Clinical Nurse Specialist will:
- SR.1a Be a registered nurse licensed to practice nursing in the State in which the clinical nurse specialist services are performed in accordance with State nurse licensing laws and regulations; and,
 - SR.1b Hold a masters or doctoral degree (doctorate level) in a defined clinical area of nursing from an accredited educational institution.
- SR.2 Nurse Practitioner: A nurse practitioner must be a registered professional nurse currently licensed to practice in the State, who meets the State's requirements governing the qualification of nurse practitioners, and who meets one of the following conditions:
- SR.2a Is currently certified as a primary care nurse practitioner by the American Nurses' Association or by the National Board of Pediatric Nurse Practitioners and Associates.
 - SR.2b Has successfully completed a 1 academic year program that:
 - Prepares registered nurses to perform an expanded role in the delivery of primary care;
 - Includes at least 4 months (in the aggregate) of classroom instruction and a component of supervised clinical practice; and
 - Awards a degree, diploma, or certificate to persons who successfully complete the program.
 - SR.2c Has successfully completed a formal educational program (for preparing registered nurses to perform an expanded role in the delivery of primary care) that does not meet the requirements of SM.1; SR.2 and has been performing an expanded role in the delivery of primary care for at least 12 consecutive months during the 18-month period immediately preceding June 25, 1993.
- SR.3 Physician Assistant: A PA must be a person who meets the applicable State requirements governing the qualifications for assistants to primary care physicians, and who meets at least one of the following conditions:
- SR.3a Is currently certified by the National Commission on Certification of Physician Assistants to assist primary care physicians.
 - SR.3b Has satisfactorily completed a program for preparing physician assistants that:
 - Was at least one academic year in length;
 - Consisted of supervised clinical practice and at least 4 months (in the aggregate) of classroom instruction directed toward preparing students to deliver health care; and
 - Was accredited by the American Medical Association's Committee on Allied Health Education and Accreditation.

- SR.3c Has satisfactorily completed a formal educational program (for preparing physician assistants) that does not meet the requirements of SM.1; SR.3 and has been assisting primary care physicians for at least 12 consecutive months during the 18-month period immediately preceding June 25, 1993.

Surveyor Guidance:

Review and validate the CAH's policy and practice for verifying the current licensure and/or certification of all staff members as required by the CAH, and Federal and State law.

Verify the process in place to enforce compliance and that data regarding validations and expirations is shared with Quality Management Oversight.

Verify for those personnel required to be licensed by the State, that the CAH has established, and follows, procedures for determining that personnel providing patient care services are properly licensed.

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

Check a sample of personnel files to verify that licensure information is up to date. Verify that appropriate categories of staff and personnel are licensed in accordance with State requirements. Verify state licensure compliance of the direct care personnel, as well as administrators and supervisory personnel, and any contracted personnel.

SM.2 DETERMINING AND MODIFYING STAFFING

The CAH will have a method for determining and modifying staffing to ensure effective patient care and process outcomes, including any untoward patient events or process failures.

Interpretive Guidelines:

The CAH will develop a method for determining and modifying staffing. Staffing will be validated through periodic reporting of variance from core staffing and outline the justification and link for that justification with patient and process outcomes, including any untoward patient events or process failures. Validation of staffing monitors will be completed at least monthly and reported to Quality Management Oversight.

Surveyor Guidance:

Review and verify the method(s) used by the CAH for determining and modifying staffing.

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

SM.3 JOB DESCRIPTION

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

Surveyor Guidance:

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

SM.4 ORIENTATION

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

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

Interpretive Guidelines:

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

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

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

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

Surveyor Guidance:

Review the orientation process and issues addressed as a part of the orientation of staff (including contract staff) Verify that staff (including contract staff) receive the appropriate orientation before working independently

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

SM.5 STAFF EVALUATIONS

- SR.1 The CAH will have a method for evaluating the performance/competency of all staff, whether clinical or supportive, including contract staff to objectively measure the ability of staff to perform all job duties as outlined in the job description.
- SR.2 The staff shall be objectively evaluated to validate competence and identify opportunities for improvement. The following may be taken into consideration as a part of this evaluation process:
- SR.2a Variations and problem processes identified through the analysis of outcomes measurement as required by the Quality Management System;
 - SR.2b High-risk, low volume procedures;
 - SR.2c New technology/equipment/processes;
 - SR.2d Customer satisfaction feedback;
 - SR.2e Scheduled training session outcomes;

- SR.2f Staff learning needs assessments that include variations identified through prior staff performance measurement;
 - SR.2g Staff feedback;
 - SR.2h Medical staff feedback;
 - SR.2i Requirements of Federal or State law, and,
 - SR.2j Other indicators as determined by the organization
- SR.3 Evaluation of contract staff may be modified based on CAH outcomes and frequency of service of the individual and conducted in accordance with the policies of the CAH.
- SR.4 The CAH shall define a timeframe, not to exceed one calendar year, and a policy and practice for the evaluation of individual staff members and have a process for sharing information with those staff members that allows for staff feedback.
- SR.5 The CAH 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 CAH policy.

Interpretive Guidelines:

The CAH must continually evaluate the performance/competency of staff. This process of evaluation will include the use of indicators that will objectively measure the ability of staff to perform all job duties as outlined in the job description. These indicators may be taken into consideration as a part of this evaluation process may include:

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

The CAH shall validate staff competency as per the CAH's defined timeframe, no less than once per each calendar year, share the indicator measurements of individual staff members with those staff members in a method that allows for staff feedback.

The CAH may modify indicator measurement for contract staff based on CAH outcomes and frequency of service of the individual. This measurement modification must take place no less than every calendar year and shall be justified by data analysis.

The CAH shall aggregate the objective performance data for individual staff and within each job classification to identify variations for further training, coaching, and mentoring.

In order to continually improving the fulfillment of their job responsibilities, the CAH 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 CAH policy.

Surveyor Guidance:

The intent of the requirement is to ensure the staff member, whether clinical or supportive, (including contract staff, students, and volunteers) has a listing of job responsibilities and is aware of the duties required as well as the required experience, educational and physical requirements, supervision if applicable, and job expectations for the position.

The above information might be found in different documentation across the CAH and not just in an all-inclusive job description located in the individual's HR file (e.g., scope of service, department orientation, evaluation forms).

If the required information is not available for review, document that a CAH representative (e.g., Quality Management representative, Nursing Leadership, etc.) confirmed that the information was available and include that information in the nonconformance evidence statement.

In a sampling of patient records, verify that the CAH a performance/competency evaluation includes appropriate measures as stated within the Interpretive Guidelines (above).

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

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

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

SERVICE PROVISION (SP)

SP.1 SERVICES

The CAH provides those diagnostic and therapeutic services and supplies that are commonly furnished in a physician's office or at another entry point into the health care delivery system, such as a low intensity hospital outpatient department or emergency department. These CAH services include medical history, physical examination, specimen collection, assessment of health status, and treatment for a variety of medical conditions. The CAH furnishes [the following](#) acute care inpatient services:

- SR.1 Laboratory (as defined in standards under Laboratory Services (LS));
- SR.2 Radiology (as defined in standards under Medical Imaging (MI));
- SR.3 Emergency (as defined in standards under Emergency Services (ED));

Interpretive Guidelines:

The CAH must provide those services that are commonly furnished in a physician's office or other point of entry such as a low intensity outpatient or emergency room services.

Surveyor Guidance:

Verify that the CAH is providing services that are commonly furnished in a physician's office such as diagnostic services and emergency care. Such services include but are not limited to: taking a patient's medical history; conducting a physical examination of the patient; specimen collection, assessment of health status, and treatment for a variety of medical conditions.

Verify that the CAH provides acute care inpatient services. Verify that sufficient staff are available to provide care.

Verify that the types and number of qualified personnel are appropriate for the types and numbers of patients receiving care and the complexity of services offered.

SP.2 COMMITTEE INVOLVEMENT

All CAH clinical policies will be developed [and reviewed](#) with the involvement of a committee that is comprised of at least one (1) CAH Physician and at least one (1) PA, NP or CNS if the CAH has PAs, NPs or CNSs on its clinical staff.

Interpretive Guidelines:

A CAH with a full-time MD/DO is not required to have a mid-level practitioner on staff and would not have to obtain the services of a mid-level practitioner on a contractual or voluntary basis to participate in writing the facility's health care services policies

Surveyor Guidance:

Review CAH health care services policies and sampled records.

Observe staff delivering health care services to patients.

What evidence indicates that patients are receiving care in accordance with written policies for health care services consistent with applicable State law?

Review any meeting minutes to determine group composition and to ascertain the extent of the group's interactions with the CAH.

Interview the nurse executive/leader to determine the extent of his/her interactions with this group concerning policy Development.

SP.3 PERIODIC REVIEW

All services and policies shall be periodically reviewed and evaluated **as necessary, but** at least annually, by the group of professional personnel as stated in SP.2 and in accordance with the CAH's QMS.

Surveyor Guidance:

Review the meeting notes and policy and procedure books to verify that the patient care policies are reviewed on an annual basis by the professional group

What evidence demonstrates that the health care policies of the CAH are evaluated, reviewed and/or revised as part of the annual program evaluation?

SURGICAL SERVICES (SS)

SS.1 ORGANIZATION

- SR.1 If the CAH provides surgical services, the scope of surgical services shall be defined in writing and approved by the medical staff to be well organized, appropriate to the scope of the services offered, performed in a safe manner and provided accordance with applicable Federal and State Laws and acceptable standards of practice and recommendations of National standards of practice of AORN, CDC, APIC, ASA, AANA and other professional organizations are applicable to surgical services.
- SR.2 If outpatient surgical services are offered, the services must be consistent in quality with inpatient surgical services in accordance with the complexity of services offered.
- SR.3 The CAH must develop and implement policies and procedures for providing surgical services that are in accordance with acceptable standards of medical practice and surgical patient care. Policies and procedures shall include at least the following:
- SR.3a Aseptic surveillance and practice, including scrub techniques;
 - SR.3b Identification of infected and non-infected cases;
 - SR.3c Housekeeping requirements/procedures;
 - SR.3d Customer satisfaction feedback;
 - SR.3e 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;
 - SR.3f Conducting surgical counts in accordance with accepted standards of practice. The CAH will have a process in place to ensure that no foreign bodies are retained in patients following surgical procedures;
 - SR.3g The scheduling of patients for surgery; SR.3h Patient care requirements including:
 - SR.3h (i) Pre-operative testing
 - SR.3h (ii) Clinical procedures
 - SR.3h (iii) Patient identification procedure and site verification process
 - SR.3i Resuscitative techniques;
 - SR.3j How the DNR status is addressed when indicated in the patient's records;
 - SR.3k Handling, care and labeling of surgical specimens;
 - SR.3l 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.3m Sterilization and disinfection procedures;
 - SR.3n Handling infections and biomedical/medical waste;
 - SR.3o Monitoring of temperature and humidity
 - SR.3p Safety practices (e.g., fire safety, site marking, time-outs, etc.); and, SR.3q Acceptable operating room attire.

Interpretive Guidelines:

If the CAH provides any surgical services, they must be organized and staffed in such a manner to ensure the health and safety of patients and be in accordance with acceptable standards of practice. These standards of practice include the American College of Surgeons, Association of Operating Room Nurses, Centers for Disease Control, Association for Professionals in Infection Control and Epidemiology, American Society of Anesthesiologists, American Association of Nurse Anesthetists, Association of Perioperative Registered Nurses Association and other professional organizations that are applicable to the scope and complexity of surgical services provided. Additionally, the CAHs outpatient surgical services must be integrated with the CAHs inpatient surgical service.

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

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

The scope of surgical services provided by the CAH should be defined in writing and approved by the governing body or responsible individual.

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

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

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

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

- Aseptic and sterile surveillance and practice, including scrub techniques;
- Identification of infected and non-infected cases;
- Housekeeping requirements/procedures;
- Duties of scrub and circulating nurse. These may be defined within a job description, but may vary depending on the cases for which these staff members are involved;
- Conducting surgical counts in accordance with accepted standards of practice. The CAH will have a process in place to ensure that no foreign bodies are retained in patients following surgical procedures;
- The scheduling of patients for surgery;
- Patient care requirements
- Pre-operative testing
- Clinical procedures
- Patient identification procedure and site verification process
- Resuscitative techniques;
- How the DNR status is addressed when indicated in the patient's records;
- Handling, care and labeling procedures of surgical specimens;

- Malignant hyperthermia;
- Procedure-specific or in general protocols that are appropriate for all surgical procedures performed. This will include a list of equipment, materials, and supplies necessary to properly carry out the surgical services provided;
- Sterilization and disinfection procedures; and,
- Handling infections and biomedical/medical waste;
- Monitoring of temperature and humidity
- Safety practices (e.g., fire safety, site marking, time-outs, etc.); and,
- Acceptable operating room attire

Surveyor Guidance:

Review and verify the extent of surgical services provided by the CAH and verify that services are in accordance with acceptable standards of practice. In order to do this appropriately, request the use of proper attire (gown, cap, and other attire as required by the CAH) 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 [SS.1](#) and the Interpretive Guidelines.

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

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

Verify that the operating room has appropriate cleaning between surgical cases and appropriate terminal cleaning

Verify that the CAH 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 CAH's biomedical equipment/clinical engineering program.

Verify that there is a process in place for handling sterilized materials and that these materials are packaged, labeled, and stored in a manner that ensures sterility (e.g., in a moisture and dust-controlled environment and policies and procedures for expiration dates have been developed and are followed in accordance with accepted standards of practice.)

SS.2 STAFFING AND SUPERVISION

- SR.1 Surgical services shall be supervised by either a registered nurse with appropriate experience, (or PA if permitted by state law), or by a doctor of medicine or osteopathy.
- SR.2 Under the supervision of a registered nurse (or PA if permitted by state law), the following personnel may serve as "scrub nurses":
 - SR.2a Registered nurses (or PAs if permitted by state law);
 - SR.2b LPN/LVNs; and,
 - SR.2c Surgical technologists (operating room technicians).
- SR.3 Qualified RNs (or PAs if permitted by state law) shall perform circulating duties in the operating room. If a qualified RN (or PAs if permitted by state law) is present who is immediately available to respond to emergencies, LPN/LVNs and STs may assist in circulatory duties under the supervision of that RN (or PAs if permitted by state law), if State law and medical staff policies and

procedures permit.

Interpretive Guidelines:

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

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

Qualified RNs must perform circulating duties in the operating room. If a qualified registered nurse is present in the operating suite who is immediately available to respond to emergencies, LPN/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 CAH's CAH organizational chart regarding surgical services to confirm that there are lines of authority and delegation of responsibility indicated within surgical services.

Verify that an RN or an MD/DO 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 CAH maintains appropriate staffing schedules to provide adequate staff and RN supervision.

Verify in situations where LPN/LVNs and STs are permitted to assist with circulating duties that a qualified RN supervisor is immediately available to respond to emergencies. If LPN/LVNs and STs are performing circulating duties, verify that they do so in accordance with applicable State laws and approved medical staff policies and procedures

SS.3 PRACTITIONER PRIVILEGES

- SR.1 The CAH shall designate the practitioners to perform surgical procedures. Surgical procedures shall be performed only by the following practitioners:
 - SR.1a Doctors of medicine or osteopathy including osteopathic practitioners recognized under §1101(a)(7) of the Social Security Act;
 - SR.1b Doctors of dental surgery or dental medicine; or,
 - SR.1c Doctors of podiatric medicine.
- SR.2 All practitioners performing surgery shall have surgical privileges established by the CAH's department of surgery and medical staff and approved by the governing body (or individual who assumes full legal authority and responsibility for operations of the CAH). Surgical privileges shall correspond with the established competencies of each practitioner.
- SR.3 A current roster of practitioners with surgical privileges shall be maintained by the department of surgery by the CAH.
- SR.4 Privileges for general surgery and surgical subspecialties defined with established criteria approved by the medical staff and in accordance with the approved policies and procedures of the CAH, and in accordance with State law.

Interpretive Guidelines:

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

The medical staff bylaws must include criteria for determining the privileges to be granted to an individual practitioner and a procedure for applying the criteria to individuals requesting privileges. Specific criteria for privileges for general surgery and surgical subspecialties should be clearly defined.

Surgical privileges shall correspond with the established competencies of each practitioner and should be periodically reviewed and updated.

The CAH must specify the surgical privileges for each practitioner that performs surgical tasks. This would include practitioners such as MD/DOs, dentists, oral surgeons, podiatrists, RN first assistants, nurse practitioners, surgical physician assistants, surgical technicians, etc. 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 in the same OR in line of sight) 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 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.

A current roster listing each practitioner's specific surgical privileges must be available in the surgical suite and area/location where the scheduling of surgical procedures is completed. The CAH will also be able to determine the surgeons with suspended surgical privileges or whose surgical privileges have been restricted and this information must also be retained in these areas/locations.

Surveyor Guidance:

Validate the CAH's method for reviewing practitioners' surgical privileges. This method should require verification of practitioner training, experience, health status, and performance. Confirm that the CAH provides a current roster listing each practitioner's specific surgical privileges and that the roster is available in the surgical suite and the area where the scheduling of surgical procedures is done.

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

SS.4 HISTORY AND PHYSICAL

- SR.1 Except in emergencies, there must be a complete H&P in the medical record of every patient prior to surgery or procedure requiring anesthesia services.
 - SR.1a A complete history and physical examination must be completed and documented no more than thirty (30) days before or twenty-four (24) hours after admission or registration.
 - SR.1b When the history and physical is completed within thirty (30) days prior to admission or registration, an updated medical record entry documenting an examination for any changes in the patient's condition must be completed and documented in the patient's medical record within twenty-four (24) hours after admission or registration, and prior to surgery or procedure requiring anesthesia services.
- SR.2 An MD/DO shall perform the H&P examination. Alternatively, a PA or advance practice nurse may perform an H&P if permitted by State law and scope of practice. The responsible physician must review and approve the H&P in accordance with the policy of the CAH and State law.
- SR.3 The content of the H&P examination and applicability shall be determined in accordance with the policy of the CAH and may be done by the individuals described in SS.4, 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 surgery. The H&P must be in the medical record prior to surgery.
- SR.4 If the H&P has been dictated but not yet present in the patient's medical record, the practitioner who admitted the patient shall write a statement to that effect as well as an admission note in the medical record. Such circumstance is acceptable only in a medical emergency and is not applicable for a scheduled surgery.

- SR.5 A properly executed informed consent form for the surgery shall be in the patient's medical record before surgery except in an extreme medical emergency. A properly executed informed consent form contains at least the following:
- SR.5a Name of patient, and when appropriate, patient's authorized representative;
 - SR.5b Name of CAH;
 - SR.5c Description of the proposed surgical procedure(s), including anesthesia to be used;
 - SR.5d Name of practitioner(s) performing the procedure(s) or important aspects of the procedure(s), as well as the name(s) and specific significant surgical tasks that will be 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.);
 - SR.5e Signature of patient or his/her authorized representative;
 - SR.5f Date and time consent is obtained;
 - SR.5g Statement that procedure(s) was explained to patient or legal guardian;
 - SR.5h Signature of professional person witnessing the consent; and,
 - SR.5i Name/signature of person who explained the procedure to the patient or guardian.

Interpretive Guidelines:

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

All or part of the H&P may be delegated to other practitioners in accordance with State law and CAH policy, but the surgeon must sign the H&P and assume full responsibility for the H&P. This means that a nurse practitioner or a physician assistant, meeting these criteria, may perform the H&P.

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, BP, and vital signs.

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

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

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

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

these practitioners are working under the primary surgeon's supervision.

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

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

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

- That it is anticipated that physicians who are in approved post graduate residency training programs will perform portions of the surgery, based upon their availability and level of competence
- That it will be decided at the time of the surgery which residents will participate and their manner of participation, and that this will depend on the availability of the residents with the necessary competence; knowledge the operating practitioner/teaching surgeon has of the resident's skill set; and the patient's condition.
- That residents performing surgical tasks will be under the supervision of the operating practitioner/teaching surgeon.
- Whether, based on the resident's level of competence, the operating practitioner/teaching surgeon will not be physically present in the same operating room for some or all of the surgical tasks performed by residents.

Surveyor Guidance:

In a sampling of medical records of surgical patients, determine if a complete H&P 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 the H&P was within the specified time frame and appropriate documentation noted.

- Verify the content and completeness of the H&P per CAH policy
 - In some cases, the CAH 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 CAH 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, but prior to in all cases involving surgery or procedures requiring anesthesia services

or moderate/conscious sedation.

- Verify this documentation of the H&P was placed in the medical record within 24 hours after admission or registration, but prior to in all cases involving surgery or procedures requiring anesthesia services or moderate/conscious sedation.
- 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 CAH must ensure that this H&P is updated to document any changes in the patient's condition (see [MS.15, SR.1](#)).

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

Ascertain that the completed forms contain at least the information specified in [SS.4, SR.5](#) and Interpretive Guidelines (above).

Verify that the CAH's informed consent policies address the circumstances when a surgery would be considered an emergency and thus not require an informed consent form be placed in the medical record prior to surgery.

SS.5 AVAILABLE EQUIPMENT

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

- SR.1 On-Call system;
- SR.2 Cardiac monitor;
- SR.3 Resuscitator;
- SR.4 Defibrillator;
- SR.5 Suction equipment;
- SR.6 Tracheotomy set; and,
- SR.7 Malignant Hyperthermia (MH) rescue materials
 - SR.7a [Dantrolene sufficient to treat an MH episode must be available for all anesthetizing locations within 10 minutes of the decision to treat for MH;](#)
 - SR.7b Dantrolene must be available for all anesthetizing locations where MH trigger agents are used; [and,](#)
 - SR.7c Required components to safely administer Dantrolene must be readily accessible

Interpretive Guidelines:

All facilities, including ambulatory surgery centers and offices, where MH triggering anesthetics (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”

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

Surveyor Guidance:

Review and verify that the CAH has equipment immediately available to each surgical suite to include, at least, those items as listed above in SR.1 – SR.7.

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

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

SS.6 OPERATING ROOM REGISTER

The operating room register shall be complete and current.

- SR.1 The operating room register will include at least the following information:
 - SR.1a Patient’s name;
 - SR.1b Patient’s CAH 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.

Interpretive Guidelines:

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

- Patient’s name;
- Patient’s CAH identification number;
- Date of the operation/procedure;
- Inclusive or total time of the operation/procedure;
- Name of the surgeon and any assistant(s);
- Name of nursing personnel (scrub and circulating);
- Type of anesthesia used and name of the administering practitioner;

- Operation/procedure performed;
- Pre-and post-op diagnosis; and,
- Age of patient.

Surveyor Guidance:

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

SS.7 POST-OPERATIVE CARE

- SR.1 There shall be adequate provision for immediate post-operative care.
- SR.2 Equipment, clinical staff, and plan of care provisions as well as criteria for discharge shall be developed and adopted by the medical staff and nurse executive/leader designees.

Interpretive Guidelines:

The CAH will make adequate provisions for immediate post-operative care. These provisions are as follows: Post-operative care is provided in accordance with acceptable standards of practice; and,

The post-operative care area or recovery room is a separate area of the CAH [with access limited to authorized personnel](#).

The CAH will provide the appropriate equipment and clinical staff to adequately address the patients' plan of care appropriate to the complexity of services provided.

The CAH will develop criteria for the discharge from the post-operative care area that have been approved by the medical staff and nurse executive/leader.

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

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

Surveyor Guidance:

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

Review and verify that the CAH 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;
 - 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 procedures 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 that require anesthesia services (excluding minimal or moderate sedation or topical analgesics, which are not considered to be “anesthesia”) require an operative report or a postoperative/post-procedure note if the operative report is not immediately available.
- 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 and placed on the patient’s chart before transfer to the next level of care, an immediate postoperative/post procedure note is required to be documented. The note shall include identification or description of:
- SR.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 medical record; it is acceptable if referred to and authenticated as accurate by the attending surgeon.

Interpretive Guidelines:

The intent of the immediate operative report or postoperative/post-procedure note is to ensure that the next provider of care has the information necessary to make further appropriate care decisions.

The hospital may, in some circumstances, choose to require a postoperative/post procedure note in other settings or for specific high-risk procedures when anesthesia services are not required.

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 postoperative/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.

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

- Name and CAH identification number of the patient;
- Date and times of the surgery;
- Name(s) of the surgeon(s) and assistants or other practitioners who performed surgical tasks (even when performing those tasks under supervision);
- Pre-operative and post-operative diagnosis;
- Name of the specific surgical procedure(s) performed;
- Type of anesthesia administered;
- Complications;
- A description of techniques, findings, and tissues removed or altered;
- Surgeons or practitioners name(s) and a description of the specific significant surgical tasks that were conducted by practitioners other than the primary surgeon/practitioner (significant surgical procedures include: opening and closing, harvesting grafts, dissecting tissue, removing tissue, implanting devices, altering tissues); and,
- Prosthetic devices, grafts, tissues, transplants, or devices implanted.

In the event there is a delay in dictation turnaround regarding the operative report, an immediate written postoperative note is required to include the elements as described in SS.8, SR.4. This information must be available in the medical record, and, as applicable, 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 the Interpretive Guidelines for SS.8.

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.1a – SR.1h (above).

In the event that there is no delay in dictation during the time the surveyor is on-site, validate that the CAH has a process in place for the immediate postoperative note to be written and that this is enforced by the CAH.

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. <https://www.facs.org/about-acs/statements/stonprin>.

ANESTHESIA SERVICES (AS)

AS.1 ORGANIZATION

- SR.1 Anesthesia services shall be provided in an organized manner. [The medical staff shall appoint an appropriately qualified practitioner to direct anesthesia services in accordance with State law.](#) The CAH is responsible for all anesthesia services administered.
- SR.2 Anesthesia services shall be appropriate to the scope of the services offered.

Interpretive Guidelines:

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

"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.

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.

"Anesthesia services" in a CAH subject to the anesthesia administration requirements:

- General anesthesia: A drug-induced loss of consciousness during which patients are not arousable, even by painful stimulation. The ability to independently maintain ventilator 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 CAH that are 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 CAH must ensure that procedures are in place to rescue patients whose level of sedation becomes deeper than initially intended, for example, patients who inadvertently enter a state of Deep Sedation/Analgesia when moderate sedation was intended. "Rescue" from a deeper level of sedation than intended requires an intervention by a practitioner with expertise in airway management and advanced life support. The qualified practitioner corrects adverse physiologic consequences of the deeper-than-intended level of sedation and returns the patient to the originally intended level of sedation.

Anesthesia services throughout the CAH (including all departments in all campuses and off-site locations where anesthesia services are provided) must be organized into one anesthesia service, under the direction of a qualified 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 (DPU);
- Outpatient surgery areas;
- Special procedures area (e.g., endoscopy suite, pain management clinic, etc.)

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

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

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 the anesthesia/sedation services are under the direction of an MD/DO (or other appropriately qualified practitioner in accordance with State law).

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 (or other appropriately qualified practitioner in accordance with State law) 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 (or individual responsible).

Review the CAH's anesthesia policies and procedures.

- Do they address who may provide anesthesia services in each setting where such services are furnished, and are these policies in compliance with the regulations?
- Do they apply in all CAH locations where anesthesia services are provided?

Verify that anesthesia services are integrated into the CAH's QMS oversight.

AS.2 ADMINISTRATION

Anesthesia shall only be administered by the following:

- SR.1 A qualified anesthesiologist or a doctor of medicine or osteopathy (other than an anesthesiologist including an osteopathic practitioner recognized under section 1101(a)(7) of the Act);
- 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), who is under the supervision of the operating practitioner or of an anesthesiologist who is immediately available if needed;
- SR.3a State exemption: A CAH may be exempted from the requirement for physician supervision of CRNAs if the State in which the CAH is located in accordance with State law or regulation or 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 for CRNAs. The letter from the Governor must attest that he or she has consulted with the State Boards of Medicine and Nursing about issues related to access to and the quality of anesthesia services in the State and has concluded that it is in the best interests of the State's citizens to opt-out of the current physician supervision requirement, and that the opt-out is consistent with State law.
- SR.3b 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.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 if needed.

SR.5 A supervised trainee in an approved educational program, as described in §413.85 or 413.86.

Interpretive Guidelines:

The CAH's medical staff will define the criteria and qualifications for those physicians who have privileges for administering anesthesia/sedation in accordance with State laws and acceptable standards of practice. AS.2, SR.1 – SR.5 defines those physicians and other practitioners who can administer anesthesia/sedation.

Anesthesia Services Policies

The medical staff bylaws or rules and regulations must include criteria for determining the anesthesia service privileges to be granted to an individual practitioner and a procedure for applying the criteria to individuals requesting privileges, as required for any type of anesthesia services, including those not subject to the anesthesia administration requirements. The CAH's governing body (or individual responsible) must approve the specific anesthesia service privileges for each practitioner who furnishes anesthesia services, addressing the type of supervision, if any, required. The privileges granted must be in accordance with State law and CAH policy. The type and complexity of procedures for which the practitioner may administer anesthesia must be specified in the privileges granted to the individual practitioner.

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.

Guidelines for Developing Policy Regarding Immediate Availability:

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 CAH should 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."

Who May Administer Anesthesia

Topical/local anesthetics, minimal sedation, 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 CAH must have policies and procedures, consistent with State scope of practice law, governing the provision of these types of anesthesia services. Further, the CAH must assure that all anesthesia services are provided in a safe, well-organized manner by qualified personnel.

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

- A qualified anesthesiologist;
- An MD or DO (other than an anesthesiologist);
- A dentist, oral surgeon or podiatrist who is qualified to administer anesthesia under State law;
- A CRNA who is supervised by the operating practitioner or by an anesthesiologist who is immediately

- available if needed; 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 CAH's anesthesia services policies must address the circumstances under which an MD or DO who is not an anesthesiologist, a dentist, oral surgeon or podiatrist is permitted to administer anesthesia. In the case of a dentist, oral surgeon or podiatrist, administration of anesthesia must be permissible under State law and comply with all State requirements concerning qualifications. The CAH 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 CAH is located in a State that has chosen to opt out of the CRNA supervision requirements, a CRNA administering general, regional and monitored anesthesia must be supervised either by the operating practitioner who is performing the procedure, or by an anesthesiologist who is immediately available.

The CAH 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 CAH is located in a State where law or regulation permits or where the Governor has submitted a letter to CMS attesting that he or she has consulted with State Boards of Medicine and Nursing about issues related to access to and the quality of anesthesia services in the State and has concluded that it is in the best interests of the State's citizens to opt-out of the current physician supervision requirement, and that the opt-out is consistent with State law, then a CAH may permit a CRNA to administer anesthesia without operating practitioner or anesthesiologist supervision (A list of States that have opted out of the CRNA supervision requirement may be found at <https://www.cms.gov/Regulations-and-Guidance/Legislation/CFCsAndCoPs/Spotlight.html>).

A CRNA is defined in §410.69(b) as a "registered nurse who: (1) is licensed as a registered professional nurse by the State in which the nurse practices; (2) meets any licensure requirements the State imposes with respect to non-physician anesthetists; (3) has graduated from a nurse anesthesia educational program that meets the standards of the Council on Accreditation of Nurse Anesthesia Programs, or such other accreditation organization as may be designated by the Secretary; and (4) meets the following criteria: (i) has passed a certification examination of the Council on Certification of Nurse Anesthetists, the Council on Recertification of Nurse

Anesthetists, or any other certification organization that may be designated by the Secretary; or (ii) is a graduate of a program described in paragraph (3) of this definition and within 24 months after that graduation meets the requirements of paragraph (4)(i) of this definition."

Administration by an anesthesiologist's assistant

An anesthesiologist's assistant may administer anesthesia when under the direct supervision of an anesthesiologist. The anesthesiologist must be immediately available if needed. An anesthesiologist is considered "immediately available" to assist the anesthesiologist's assistant under the anesthesiologist's supervision only if he/she is physically located within the same area as the anesthesiologist's assistant, e.g., in the same operative suite, or in the same labor and delivery unit, or in the same procedure room, and not otherwise occupied in a way that prevents him/her from immediately conducting hands-on intervention, if needed.

An anesthesiologist's assistant is defined in §410.69(b) as a "...person who – (1) works under the direction of an anesthesiologist; (2) is in compliance with all applicable requirements of State law, including any licensure requirements the State imposes on non-physician anesthetists; and (3) is a graduate of a medical school-based anesthesiologist's assistant education program that – (A) is accredited by the Committee on Allied Health Education and Accreditation; and (B) includes approximately two years of specialized basic science and clinical education in anesthesia at a level that builds on a premedical undergraduate science background."

Surveyor Guidance:

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

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

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

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

Review the qualifications of individuals authorized to administer general anesthesia, regional anesthesia and monitored anesthesia, including deep sedation/analgesia to determine if they satisfy the requirements.

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

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

Determine if the state is an “opt-out state” and therefore permits CRNAs to administer anesthesia without supervision. As of February 2017, seventeen States and the U.S. Territory Guam have chosen to opt-out of the CRNA physician supervision regulation. The States are: California, Iowa, Nebraska, Idaho, Minnesota, New Hampshire, New Mexico, Kansas, North Dakota, Washington, Alaska, Oregon, South Dakota, Wisconsin, Montana, Colorado, and Kentucky.

Review the CAH’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 CAH’s anesthesia service policies.

AS.3 POLICIES AND PROCEDURES

- SR.1 Policies on anesthesia/sedation procedures must include the delineation of pre-anesthesia and post- anesthesia responsibilities.
- SR.2 The policies must ensure that the following are provided for each patient:
 - SR.2a A pre-anesthesia or pre-sedation evaluation must be performed for each patient who will receive general, regional or monitored anesthesia. Patients who will be receiving moderate sedation must be monitored and evaluated before, during and after a procedure by a trained practitioner, however a pre-anesthesia evaluation is not required because moderate sedation is not considered to be “anesthesia” and is not subject to this requirement. This evaluation will include a documented airway assessment, anesthesia risk assessment, and anesthesia drug and allergy history, by an individual qualified and

privileged to administer anesthesia/sedation, immediately before or a procedure requiring anesthesia services.SR.2c (3)

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

SR.2c For inpatient or outpatient surgery, a post-anesthesia evaluation for proper anesthesia recovery is completed and documented within 48 hours after surgery or prior to discharge if less than 48 hours by the individual who administers the anesthesia or, if approved by the medical staff, by any individual qualified and credentialed to administer anesthesia or as identified in AS.2 SR.3.

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

SR.2c(1)i Respiratory function, including respiratory rate, airway patency, and oxygen saturation;

SR.2c(1)ii Cardiovascular function, including pulse rate and blood pressure;

SR.2c(1)iii Mental status;

SR.2c(1)iv Temperature;

SR.2c(1)v Pain;

SR.2c(1)vi Nausea and vomiting; and,

SR.2c(1)vii Postoperative hydration. Depending on the specific surgery or procedure performed, additional types of monitoring and assessment may be necessary.

SR.2c (2) 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.2c(3) A post-anesthesia evaluation for anesthesia recovery is required for each patient who will receive general, regional or monitored anesthesia. Patients who will be receiving moderate sedation must be monitored and evaluated before, during and after a procedure by a trained practitioner, however, a post-anesthesia evaluation is not required because moderate sedation is not considered to be "anesthesia" and is not subject to this requirement. This evaluation must be completed in accordance with State law and CAH policies and procedures approved by the medical staff and reflect current standards of care.

SR.2c(4) If the patient is discharged less than 48 hours after the procedure, completion and documentation of the post-anesthesia evaluation is still required. This is the case regardless of whether the procedure is performed on an inpatient or outpatient basis or when the patient is discharged

SR.2d All anesthesia patients shall be discharged from the CAH in the company of a responsible adult unless exempted by the clinician who performed the surgical procedure.

Interpretive Guidelines:

Pre-anesthesia evaluation:

A pre-anesthesia evaluation must be performed for each patient who receives general, regional or monitored anesthesia. While current practice dictates that the patient receiving moderate sedation be monitored and evaluated before, during, and after the procedure by trained practitioners, a pre-anesthesia evaluation is not required because moderate sedation is not considered to be "anesthesia", and thus is not subject to this requirement.

The evaluation must be performed by someone qualified to administer anesthesia, e.g., only by:

- A qualified anesthesiologist;
- A doctor of medicine or osteopathy (other than an anesthesiologist);
- A dentist, oral surgeon, or podiatrist who is qualified to administer anesthesia under State law;
- A certified registered nurse anesthetist (CRNA), who, unless exempted in accordance AS.2 SR.3, is under the supervision of the operating practitioner or of an anesthesiologist who is immediately available if needed; or
- An anesthesiologist's assistant who is under the supervision of an anesthesiologist who's immediately available if needed.

Although the requirement provides broad authority to physicians to delegate tasks to other qualified medical personnel, the requirements do not permit delegation of the pre-anesthesia evaluation to practitioners who are not qualified to administer anesthesia.

The pre-anesthesia evaluation must be performed within 48 hours prior to any inpatient or outpatient surgery or procedure requiring anesthesia services. The delivery of the first dose of medication(s) for the purpose of inducing anesthesia, as defined above, marks the end of the 48-hour timeframe.

In accordance with current standards of anesthesia care, the pre-anesthesia evaluation of the patient includes, at a minimum:

- Review of the medical history, including anesthesia, drug and allergy history;
- Interview and examination of the patient;
- Notation of anesthesia risk according to established standards of practice (e.g. ASA classification of risk);
- Identification of potential anesthesia problems, particularly those that may suggest potential complications or contraindications to the planned procedure (e.g., difficult airway, ongoing infection, limited intravascular access);
- Additional pre-anesthesia evaluation, if applicable and as required in accordance with standard practice prior to administering anesthesia (e.g., stress tests, additional specialist consultation);
- Development of the plan for the patient's anesthesia care, including the type of medications for induction, maintenance and post-operative care and discussion with the patient (or patient's representative) of the risks and benefits of the delivery of anesthesia.

Intraoperative anesthesia record:

There must be an intraoperative anesthesia record or report for each patient who receives general, regional or monitored anesthesia. While current practice dictates that the patient receiving moderate sedation be monitored and evaluated before, during, and after the procedure by trained practitioners, an intraoperative anesthesia report is not required because, as explained above, moderate sedation is not "anesthesia". Current standard of care stipulates that an intraoperative anesthesia record, at a minimum, includes:

- Name and CAH identification number of the patient;
- Name(s) of practitioner who administered anesthesia, 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 agents;
- Techniques(s) used and patient position(s), including the insertion/use of any intravascular or airway devices;
- Name and amounts of IV fluids, including blood or blood products if applicable;
- Timed-based documentation of vital signs as well as oxygenation and ventilation parameters;
- 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 evaluation:

A post-anesthesia evaluation must be completed and documented no later than 48 hours after surgery or a procedure requiring anesthesia services. The evaluation is required any time general, regional, or monitored anesthesia has been administered to the patient. While current practice dictates that the patient receiving moderate (conscious) sedation be monitored and evaluated before, during, and after the procedure by trained practitioners, a post-anesthesia evaluation is not required.

The evaluation must be completed and documented must be administered only by any practitioner who is qualified to administer anesthesia.

- A qualified anesthesiologist;
- A doctor of medicine or osteopathy (other than an anesthesiologist);
- A dentist, oral surgeon, or podiatrist who is qualified to administer anesthesia under State law
- A certified registered nurse anesthetist (CRNA), who, unless exempted in accordance with paragraph (c) of §485.639, is under the supervision of the operating practitioner or of an anesthesiologist who is immediately available if needed; or
- An anesthesiologist's assistant who is under the supervision of an anesthesiologist who is immediately available if needed.

Although the requirement provides broad authority to physicians to delegate tasks to other qualified medical personnel, the requirements do not permit delegation of the post-anesthesia evaluation to practitioners who are not qualified to administer anesthesia.

The calculation of the 48-hour timeframe begins at the point the patient is moved into the designated recovery area. Except in cases where post-operative sedation is necessary for the optimum medical care of the patient (e.g., ICU), the evaluation generally would not be performed immediately at the point of movement from the operative area to the designated recovery area. Accepted standards of anesthesia care indicate that the evaluation may not begin until the patient is sufficiently recovered from the acute administration of the anesthesia so as to participate in the evaluation, e.g., answer questions appropriately, perform simple tasks, etc. The evaluation can occur in the PACU/ICU or other designated recovery location. For outpatients, the post- anesthesia evaluation must be completed prior to the patient's discharge. The elements of an adequate post- anesthesia evaluation should be clearly documented and conform to current standards of anesthesia care, including:

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

- Nausea and vomiting; and,
- Postoperative hydration.
- Depending on the specific surgery or procedure performed, additional types of monitoring and assessment may be necessary.

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.

Surveyor Guidance:

Review a sample of inpatient and outpatient medical records for patients who had surgery or a procedure requiring administration of anesthesia.

Determine whether each patient had a pre-anesthesia and post-operative evaluation by a practitioner qualified to administer anesthesia and includes the requirements as described above.

Determine that the pre-anesthesia evaluation was performed within 48 hours prior to the delivery of the first dose of medication(s) given for the purpose of inducing anesthesia for the surgery or a procedure requiring anesthesia services.

Review records to determine that each patient has an intraoperative anesthesia record that includes the elements described above.

Review a sample of medical records for patients who had surgery or a procedure requiring general, regional or monitored anesthesia to determine whether a post anesthesia evaluation was written for each patient.

Determine whether the evaluation was performed within 48 hours after the surgery or procedure

EMERGENCY SERVICES (ED)

The CAH provides emergency care services necessary to meet the needs of inpatients and outpatients. There shall be written policies and procedures for handling medical emergencies.

ED.1 ORGANIZATION

- SR.1 The CAH shall provide Emergency Services and be available twenty-four (24) hours a day, seven (7) days per week.
- SR.2 The CAH shall provide direct emergency medical services to meet the emergency needs of its patients as a first response to common life-threatening injuries and acute illness in accordance with acceptable standards of practice.
- SR.3 Emergency Services shall be organized and integrated with other departments under the direction and supervision of a qualified member of the medical staff or other appropriately qualified practitioner.
- SR.4 The medical staff shall be responsible for developing and maintaining policies and procedures governing the emergency medical care delivered.

Interpretive Guidelines:

The CAH "makes available 24-hour emergency services." This does not mean that the CAH must remain open 24 hours a day when it does not have inpatients (including swing-bed patients). A CAH that does not have inpatients may close with no staff present, provided that it has an effective system in place to meet the requirement. The system must ensure that a practitioner with training and experience in emergency care is on call and immediately available by telephone or radio, and available on site within 30 minutes, (or 1 hour in certain frontier areas), 24 hours a day.

In addition to these items, the CAH must maintain the types, quality and numbers of supplies, drugs and biologicals, blood and blood products, and equipment required by state and local law and in accordance with accepted standards of practice.

All emergency services must be provided as a direct service in the CAH. The ED cannot be a provider-based off-site location. Emergency needs of patients must be met in accordance with acceptable standards of practice.

Acceptable standards of practice include maintaining compliance with applicable Federal and State laws, regulations, and guidelines governing all services provided in the CAH'S emergency department, as well as any standards and recommendations promoted by or established by nationally recognized professional organizations such as the American Medical Association, American Association for Respiratory Care, American Society of Emergency Medicine, American College of Surgeons, American Nursing Association, etc.

The CAH's emergency services must be integrated with the other departments of the CAH (e.g. surgical services, laboratory, ICU, diagnostic services) and be accessible in the delivery of emergency care for patients.

The CAH'S emergency services must be integrated into the CAH-wide QMS.

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 as well as delineating the qualifications a medical staff member must possess in order to be granted privileges for the provision of emergency care services in accordance with Federal and State law.

The medical staff will ensure that policies and procedures are developed and implemented to govern the emergency services provided.

Emergency care necessary to meet the needs of its inpatients and outpatients would include the provision of respiratory services as needed by the CAH'S emergency patients. When respiratory services are provided, those services must be provided in accordance with acceptable standards of practice. The scope of diagnostic and/or

therapeutic respiratory services offered by the CAH should be defined in writing and approved by the medical staff.

The CAH has the responsibility and must abide by the Emergency Treatment and Labor Act (EMTALA). It is intended to reinforce that the EMTALA responsibility of the CAH with a dedicated emergency department begins when an individual arrives on CAH property (ambulance arrival) and not when the CAH "accepts" the individual from the gurney. An individual is considered to have "presented" to the CAH when her or she arrives at the CAH's dedicated emergency department or on CAH 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 CAH, whether by EMS or otherwise, the CAH 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 CAH 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 CAH provides medical treatment that minimizes risks to an individual's health and the receiving CAH has the capability and capacity to accept the patient at the time the transfer is effectuated. A CAH 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 CAH policy or practice that relies on calling 9-1-1 in order for EMS to substitute its emergency response capabilities for when the CAH is required to maintain as stated above. The CAH may not rely on 9-1-1 to provide appraisal and initial treatment of medical emergencies that occur at the CAH.

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 any respiratory services provided) and that they are evaluated and updated on an ongoing basis no less than once per year.

Review and validate the coordination and communication between the Emergency Department and other CAH services/departments (e.g. laboratory, diagnostic services, surgical services).

Ascertain by record review of patients admitted through the emergency department, interviews with staff, patients, and families, and/or observations that ED services were made available to patients presenting on a 24-hour a day basis. How does the CAH ensure that emergency services are made available on a 24-hour a day basis?

Review any policies and procedures for emergency services in the CAH. What evidence indicates that the CAH is capable of providing necessary emergency care for its inpatients and outpatients?

Determine if the CAH provides any degree of respiratory care services and that the type and amount of respiratory care provided meets the needs of the patients and is delivered in accordance with acceptable standards of practice.

Review the CAH policies and procedures to verify that the scope of the diagnostic and/or therapeutic respiratory care services provided is defined in writing and approved by the medical staff.

If blood gases or other laboratory tests are performed as part of the delivery of respiratory services, verify that there is a current CLIA certificate.

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;
- Prevention of contamination and cross infection; and,
- Provision of emergency respiratory services.

ED.2 STAFFING

- SR.1 Adequate medical and nursing staff qualified in emergency care must be present to meet the written emergency procedures and needs determined by the CAH.
- SR.1a Except as specified under 42 CFR Section 485.618 (d)(2), a doctor of medicine or osteopathy, physician assistant, nurse practitioner, or clinical nurse specialist, with training or experience in emergency care shall be on call at all times and immediately available by telephone or two-way radio and available onsite within thirty (30) minutes.
- SR.1b A doctor of medicine or osteopathy, physician assistant, nurse practitioner, or clinical nurse specialist with training or experience in emergency care shall be on call at all times and immediately available by telephone or two-way radio and available onsite within thirty (30) minutes if the CAH is located in an area designated:
- As a frontier area;
 - Or in an area that meets the criteria for a remote location adopted by the State in its rural health care plan, and approved by CMS under section 1820(b) of the Act;
 - The State has determined, under criteria in its rural health plan, that allowing emergency response time longer than 30 minutes is the only feasible method of providing emergency care to residents of the area served by the CAH; or
 - The State maintains documentation showing the response time of up to 60 minutes at a particular CAH it designates is justified because other available alternatives would increase the time needed to stabilize a patient in an emergency.
- SR.2 A qualified clinician shall perform patient triage upon presentation to the emergency department.
- SR.3 A registered nurse with training and experience in emergency care can be utilized to conduct specific medical screening examinations only if:
- SR.3a The registered nurse is on site and immediately available at the CAH when a patient requests medical care; and
- SR.3b The nature of the patient's request for medical care is within the scope of practice of a registered nurse and consistent with applicable State laws and the CAH's bylaws or rules and regulations.
- SR.3c The CAH has no greater than 10 beds;
- SR.3d The CAH is located in an area designated as a frontier area or remote location as described in ED.2; SR.1b;
- SR.3e The State in which the CAH is located in accordance with State law or regulation or submits a letter to CMS signed by the Governor, following consultation on the issue of using RNs on a temporary basis as a part of their State rural health plan with the State Boards of Medicine and Nursing, and in accordance with State law, requesting that a registered nurse with training and experience in emergency care be included in the list of personnel specified in ED.2. The letter from the Governor must attest that he or she has consulted with the State Boards of Medicine and Nursing about issues related to access to and the quality of emergency services in the State. The letter from the Governor must also describe the circumstances and duration of the temporary request to include registered nurses on the list of personnel specified in ED.2.
- SR.3f Once the Governor submits a letter specified in as stated in SR.3e above, a CAH must submit documentation to the State survey agency demonstrating that is has been unable, due to the shortage of such personnel in the area, to provide adequate coverage as specified under this requirement.

- SR.3g The request, as specified in SR.3e above, and the withdrawal of the request may be submitted at any time, and are effective upon submission.

Interpretive Guidelines:

The CAH must ensure that a qualified member of the medical staff is on premises and available to supervise the provision of emergency services at all times.

The CAH 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 CAH must staff the emergency department with the appropriate numbers and types of professionals and other staff who possess the skills, education, certifications, specialized training and experience in emergency care when emergency services are provided.

The CAH must work with Federal, State and local agencies and officials in order to identify risks to the community (e.g., natural disasters, mass casualties, terrorist acts), to anticipate demands and resources needed by the CAH emergency services, and accordingly, develop plans and methods to address and coordinate anticipated needs.

When State laws are more stringent and require more stringent staffing or expanded operational hours, the CAH must staff its emergency department in accordance with state laws. For example, if State law requires the CAH emergency department be open and be staffed with a MD/DO 24/7 then the CAH must comply.

Surveyor Guidance:

Verify that a qualified member of the medical staff is on premises and available to supervise the provision of emergency services at all times.

Verify that the appropriate numbers and types of professionals and other staff who possess the skills, education, certifications, specialized training and experience in emergency care when emergency services are provided.

Review staffing schedules to determine that the number and type of staff available is appropriate to the volume and types of treatments furnished.

Review on-call schedules to determine how the CAH ensures that a qualified staff member is on call 24 hours a day and available on site at the CAH within 30 minutes, or 60 minutes in certain frontier areas.

What documentation demonstrates that a MD/DO, NP, PA, CNS or RN (as allowed under SR.3) with emergency training or experience has been on call and available on site at the CAH within 30 or 60 minutes, as appropriate?

Interview staff to determine how the CAH staff is knowledgeable of who is on call.

Review and validate the processes in place to demonstrate that the CAH 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 CAH emergency services.

ED.3 EQUIPMENT, SUPPLIES and MEDICATION

Equipment, supplies, and medication used in treating emergency cases are kept at the CAH and are readily available for treating emergency cases.

- SR.1 Drugs and biologicals commonly used in life-saving procedures shall be provided at a minimum to include:
- SR.1a Analgesics;
 - SR.1b Local Anesthetics;
 - SR.1c Antibiotics;
 - SR.1d Anticonvulsants;

- SR.1e Antidotes and emetics;
 - SR.1f Serums and toxoids;
 - SR.1g Antiarrhythmics;
 - SR.1h Cardiac glycosides;
 - SR.1i Antihypertensives;
 - SR.1j Diuretics;
 - SR.1k Electrolytes and replacement solutions.
- SR.2 Equipment and supplies (adult and pediatric sizes) shall be provided at a minimum to include:
- SR.2a Airways, endotracheal and nasogastric tubes;
 - SR.2b Ambubag, valve and masks;
 - SR.2c Oxygen;
 - SR.2d Immobilization devices and splints;
 - SR.2e Tourniquets;
 - SR.2f Suction machine and related supplies;
 - SR.2g IV therapy supplies;
 - SR.2h Defibrillator and cardiac monitor; and,
 - SR.2i Chest tubes and indwelling catheters.

Interpretive Guidelines:

The CAH must provide the appropriate equipment and qualified personnel necessary to furnish all services offered in a safe manner in accordance with acceptable standards of practice.

There should be written policies for the delivery of any services provided. The policies and procedures must be developed and approved by the medical staff and include the participation of any mid-level practitioners working in the ED. The written policies should address the following services, as appropriate:

- The qualifications, including job title, licensure requirements, education, training and experience of personnel authorized to perform each type of respiratory care service and whether they may perform it without supervision;
- Equipment assembly and operation;
- Safety practices, including infection control measures;
- Handling, storage, and dispensing of therapeutic gases;
- 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;
- Administration of medications; and,
- Procedures for obtaining and analyzing blood samples (arterial blood gases).

In addition to these items, the CAH must maintain the types, quality and numbers of supplies, drugs and biologicals, blood and blood products, and equipment required by State and local law and in accordance with accepted standards of practice

Surveyor Guidance:

How does the CAH ensure that the required equipment, supplies and medications are always readily available in the CAH?

Interview staff and tour the ER to ascertain compliance and ability to provide emergency services. How does the CAH ensure that staff knows where drugs and biologicals are stored?

How does the CAH ensure that staff knows where emergency equipment and supplies are stored?

Determine when the last time emergency supplies were used and who is responsible for monitoring supplies? Examine sterilized equipment (e.g., tracheostomy sets) for expiration dates when applicable

Examine equipment to determine if it is working order. For example, check the force of the vacuum (suction) equipment to see that it is in operating condition. Determine if there is there an equipment maintenance schedule for equipment. Ask staff if equipment has ever failed to work when needed.

ED.4 BLOOD AND BLOOD PRODUCTS

The CAH shall provide, directly or under arrangement or agreement for:

- SR.1 Services for the procurement, safeguarding, and transfusion of blood, including the availability of blood products for emergencies on a 24 hour a day basis.
- SR.2 Storage of blood and blood products that meet the requirements of 42 CFR 493, subpart K:
 - SR.2a Storage of blood and blood products shall be under the control and supervision of a pathologist or other qualified doctor of medicine or osteopathy.
 - SR.2b If blood banking services are provided under arrangement or agreement, such services will be approved by the medical staff of the CAH, the governing body (or individual who assumes full legal authority and responsibility for operations of the CAH) for the CAH.

Surveyor Guidance:

If blood banking services are provided on site, what evidence shows that the blood facility is under the control and supervision of a pathologist or other qualified MD/DO?

For blood banking services provided under arrangement, what evidence shows that the CAH medical staff and the person responsible for CAH operations have approved the arrangement?

ED.5 EMERGENCY RESPONSE SYSTEM

The CAH shall establish a relationship with available emergency response systems that provide for a doctor of medicine or osteopathy to be continually available by telephone or two-way radio to receive emergency calls, triage patients and refer patients to the CAH or other appropriate location for treatment.

Interpretive Guidelines:

The CAH, not the local ambulance service, is responsible for ensuring that an effective procedure is in place to meet this requirement.

Surveyor Guidance:

Verify that the CAH has policies and procedures in place to ensure an MD/DO is available by telephone or radio, on a 24-hour a day basis to receive emergency calls and provide medical direction in emergency situations?

Interview staff to see how an MD/DO is contacted when emergency instructions are needed.

ED.6 OFF-CAMPUS DEPARTMENTS

The medical staff shall have written policies and procedures for appraising and referring emergencies that occur in off-campus departments where emergency services are not provided.

Interpretive Guidelines:

This requirement applies to off-campus departments that do not provide emergency services.

The CAH will implement written policies and procedures for appraising and referring emergencies that occur in off-campus departments. This includes emergencies involving patients, staff, visitors or others or individuals who come to those locations seeking/requiring emergency care.

Initial treatment and stabilization of patients requiring emergency care must be provided within the capabilities and complexities of services provided and the staff on-site at these off-campus departments.

Surveyor Guidance:

Review and validate that written policies and procedures address the appraisal and referral of medical emergencies that occur in off-campus departments. As appropriate, when visiting the off-campus departments, validate that the staff are aware of these policies and procedures.

- Interview staff to ensure they are aware of the policies and procedures for managing medical emergencies
- Discuss with staff their role and responsibilities if such an emergency is encountered how they will respond and the this is consistent with the policies and procedures in place
- 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.

MEDICATION MANAGEMENT (MM)

MM.1 MANAGEMENT PRACTICES

The CAH shall have a pharmacy service (provided directly or through agreement or arrangement) with written policies and procedures to ensure effective medication management practices that meet the needs of the patients.

- SR.1 The pharmacy service will be directed by a full time, part time, or consulting registered pharmacist responsible for developing, supervising, and coordinating all the activities of the pharmacy services. The pharmacy service must have an adequate number of qualified personnel to ensure effective medication management services, including emergency services.
- SR.2 Medications and biologicals will be prepared and administered [in accordance with Federal, State, and local requirements, recommendations of professional organizations and accepted professional principles \(e.g., ASHP, USP, ISMP\)](#).
- SR.3 All drugs and biologicals, and intravenous medications, shall be administered by or under the supervision of a registered nurse, doctor or medicine or osteopathy, or, where permitted by State law, a physician assistant, in accordance with written and signed orders, accepted standards of practice, and Federal and State laws. All drugs and biologicals, and intravenous medications shall be administered only upon the orders of the practitioner responsible for the care of the patient in accordance with approved medical staff policies and procedures, and accepted standards of practice.
- SR.4 All compounding, packaging, and dispensing of medication shall be under the direction/supervision of a pharmacist.
- SR.5 [All personnel involved in the compounding of pharmaceuticals shall receive training and evaluation based upon the complexity of the compounding performed.](#)
- SR.6 [The CAH must 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.6a [The CAH must establish and follow written Standard Operating Procedures \(SOPs\) for compounded sterile preparation \(CSP\). The SOPs must ensure that the entire compounding operation is well designed, functions as designed, and will yield CSPs that are safe for administration to patients.](#)
- SR.7 All drugs and biologicals must be controlled, secured and distributed in accordance with applicable standards of practice and consistent with Federal and State law at all times.
 - SR.7a Drugs listed as Schedule II, III, IV, and V of the Comprehensive Drug Abuse Prevention and Control Act of 1970 must be kept locked within a secure area.
 - SR.7b Only personnel authorized by the pharmacy service shall have access to locked areas.
- SR.8 Outdated, mislabeled, or otherwise unusable medications shall not be available for patient use.
- SR.9 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.10 Blood transfusions and intravenous medications must be administered in accordance with State law and approved medical staff policies and procedures. If blood transfusions and intravenous medications are administered by personnel other than doctors of medicine or osteopathy, the personnel must have special training to perform these duties.

Interpretive Guidelines:

The CAH must have a system that ensures that medication orders sent to the pharmacy and medications provided to patients promptly

All medication management practices, including preparation and administration, shall be administered by or under the supervision of nursing or other qualified personnel (where permitted by State law a PA) in accordance with applicable Federal and State laws.

Drugs and biologicals must be prepared and administered in accordance with:

- Federal and State laws;
- The orders of the practitioner or practitioners responsible for the patient's care; and,
- Accepted standards of practice.

The CAH shall have a pharmacy service administered in accordance with accepted professional principles and directed by a single full time, part time, or consulting registered pharmacist responsible for developing, supervising, and coordinating all the activities of the pharmacy services. The job description or the written agreement for the responsibilities of the pharmacist should be clearly defined and include development, supervision and coordination of all the activities of 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.ihl.org/ihl>); or the Infusion Nurses Society (<http://www.ins1.org>).

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

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

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

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.

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

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

Consistent with accepted professional principles, CAHs must demonstrate appropriate storage and preparation of medications under proper conditions of sanitation, temperature, light, moisture, ventilation, segregation, and security as outlined in 42 CFR Section 485.635(a)(3)(iv) Interpretive Guidelines.

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

Medication Security

- CAH 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.

- All drugs and biologicals must be kept in a locked room or container in a manner that prevents tampering and diversion. If the container is mobile or readily portable (Nursing Medication Carts, Anesthesia Carts, and Other Medication Carts) when not in use, it must be stored in a locked room, monitored location, or secured location that will ensure the security of the drugs or biologicals. That person must monitor the cart and be aware of other people's activities near the cart. He/she is responsible for the security of the drugs and biologicals in the cart.
- 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 operational the operating room would not be considered secure and all drugs and biologicals are expected to be locked.

Drugs and biologicals must be controlled and distributed in accordance with manufacturer's directions and State and Federal requirements.

As appropriate, patients may need to self-administer non-controlled drugs and biologicals, the CAH 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 CAH 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 CAH by patients and their families
- Investigational medications
- Sample medications
- Practices to minimize and prevent medication errors based on professional standards of practice including;
 - Proactive review and analysis of external alerts, internal practice variances and adverse drug events
 - Labeling of medications
 - High-alert medications - dosing limits, administration guidelines, packaging, labeling and storage;
 - Guidelines/criteria for selection from a menu of medication options addressing similar indications for use e.g. pain meds

- Limiting the variety of medication-related devices and equipment. For Example, limit the types of general-purpose infusion pumps to one or two;
- Availability of up-to-date medication information;
- Availability of pharmacy expertise. Pharmacist available on-call when pharmacy does not operate 24 hours a day;
- Avoidance of dangerous abbreviations;
- Alert systems for look-like and sound-alike drug names;
- Use of facility approved pre-printed order sheets whenever possible;
- That orders to “resume previous orders” are prohibited;
- A voluntary, non-punitive, reporting system to monitor and report adverse drug events (including medication errors and adverse drug reactions);
- The preparation, distribution, administration and proper disposal of hazardous medications;
- Drug recalls;
- That patient-specific information is readily accessible to all individuals involved in provision of pharmaceutical care. The patient information must be sufficient to properly order, prepare, dispense, administer and monitor medications as appropriate;
- Identification of when weight-based dosing for pediatric populations is required;
- Other relevant performance improvement activities.

The pharmacy should participate in CAH decisions about emergency medication kits. The supply and provision of emergency medications stored in the kits must be consistent with standards of practice and appropriate for a specified age group or disease treatment as well as consistent with applicable Federal and State laws.

The pharmacy should be involved in the evaluation, use and monitoring of drug delivery systems, administration devices and automated drug-dispensing machines. The evaluation and monitoring should include the potential for medication errors.

Surveyor Guidance:

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

Review and verify the job description or the written agreement to see that the responsibilities of the pharmacist are clearly defined and include development, supervision and coordination of all the activities of pharmacy services.

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

Verify that the pharmaceutical services are provided by staff sufficient in number and training to provide quality services, including 24 hour, 7-day emergency coverage, or there is an arrangement for emergency services, as determined by the needs of the patients and as specified by the medical staff.

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

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

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

- Verify the process for ensuring correct patient identification.
- Review the process for how medications are administered and how the nursing staff ensure the medications are taken when PO.
- Review the process followed when medications are not given on time and what action(s) are taken.

Verify that the CAH maintains policies and procedures, approved by the medical staff, that identify who is authorized to administer medications, the nursing and other personnel (if other than nursing) administering medications are appropriately training or licensed, function under supervision as required and that the policies are followed and are in accordance with Federal and State laws.

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.

In the review of patient care areas:

- Verify the process for patient identification.
- Review and verify that the labels of individual medications conform to State laws.
- Review and verify that medications prescribed for a patient include:
 - Patient's full name;
 - The prescriber's name;
 - Strength and quantity of the drug dispensed; and,
 - Appropriate accessory and cautionary statements are included as well as the expiration date.

Each floor stock drug container is expected to be labeled with the name and strength of the drug, lot and control number equivalent, and expiration date. Appropriate accessory and cautionary statements are included as well as the expiration date and/or, if applicable, a BUD. It should be noted that, for multi-dose medication vials with antimicrobial preservatives which have been opened or entered (e.g., needle-punctured), the USP standard is that the BUD is 28 days, unless otherwise specified by the manufacturer. In addition, where applicable, each patient's individual drug container is expected to be labeled with the patient's full name and quantity of the drug dispensed.

- *If the unit dose system is utilized, each single unit dose package is expected to be labeled with the name and strength of the drug, lot and control number equivalent, expiration date and/or, if applicable, a BUD.*

Review the CAH policies and procedures governing patient self-administration of drugs and biologicals. Review the transfusions and intravenous medications practices:

- Verify that training is provided to staff in some manner for administering blood transfusions and intravenous medication practices
- Review the course content to ensure that the following information is included at a

minimum:

- Fluid and electrolyte balance
- Blood components
- Venipuncture techniques, returned demonstration and supervised practice

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

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

Is there a method to periodically review and evaluate the actual implementation of pharmaceutical policies and procedures by staff?

Verify through interviews of pharmacy and CAH staff, observation of on-site dispensing operations and review of pharmacy records that compounding, dispensing and packaging of drugs and biologicals are performed under the supervision of a pharmacist, in accordance with applicable laws.

MM.2 FORMULARY

The CAH pharmacy service, in conjunction with the medical staff, shall select a list of medications to be available within the CAH. The list shall be available to appropriate staff at all times.

Interpretive Guidelines:

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

The formulary lists medications for dispensing or administration that the CAH maintains or that are readily available. In accordance with accepted standards of practice, the medical staff, in consultation with the pharmacy service, should develop written criteria for determining what medications are available for dispensing or administration. At a minimum, the criteria include the indication for use, effectiveness, risks (including propensity for medication errors, abuse potential, and adverse events), and costs.

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

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

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

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

Surveyor Guidance:

Verify that the pharmacy has an established formulary that of medications that are available in the CAH. Verify that there is a process for creation and periodic review of a formulary system.

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

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

MM.3 SCHEDULED DRUGS

- SR.1 Current and accurate records must be kept of the receipt and disposition of all scheduled drugs, and in compliance with all Federal and State documentation requirements.
- SR.2 Abuses and losses of controlled substances must be reported, in accordance with applicable Federal and State laws, to the individual responsible for the pharmaceutical service, and to the governing body (or individual who assumes full legal authority and responsibility for operations of the CAH), as appropriate.

Interpretive Guidelines:

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

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

- Accountability procedures to ensure control of the distribution, use, and disposition;
- Current and accurate receipt and disposition;
- Ability to trace the process for moving scheduled drugs throughout the service from the point of entry into the CAH to the point of departure either through administration to the patient, destruction or return to the manufacture;
- Identify 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 CAH must develop and implement policies and procedures to minimize abuses and losses of controlled substances. These procedures must outline, in accordance with applicable Federal and State laws, the reporting process to the individual responsible for the pharmaceutical service, and to the individual who assumes full legal authority and responsibility for operations of the CAH 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 CAH 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 CAH to address these discrepancies.

Validate the CAH 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.

Review reports of pharmaceutical services to determine if there are reported problems with controlled drugs and what actions have been taken to correct the situation.

Interview the Pharmacy Director, pharmacist and pharmacy employees to determine their understanding of the controlled drug policies. Is there a policy and procedure for handling controlled drug discrepancies?

MM.4 MEDICATION ORDERS

All medication orders shall:

- SR.1 Include the name of the drug, the dosage and frequency of administration and the route of administration.
- SR.2 Be in writing and signed, including date and time, by the practitioner or practitioners responsible for the care of the patient and authorized to write such orders by CAH policy and in accordance with State law.
- SR.3 Telephone or verbal orders are to be used infrequently and when used must be accepted only by personnel authorized by the medical staff and in accordance with Federal and State law.
- SR.4 Verbal orders must be signed or initialed by the prescribing practitioner must be authenticated in accordance with Federal and State law. If there is not State law that designates a specific timeframe for the authentication of verbal orders, the orders must be authenticated at the time of the next practitioner visit or by another practitioner responsible for the care of the patient.

Interpretive Guidelines:

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

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

- Name of prescriber.

The CAH should establish policies and procedures that:

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

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

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

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

All orders for drugs and biologicals, including verbal orders, must be legible, timed, dated and authenticated with a signature by the practitioner or practitioners responsible

It is acceptable for a covering practitioner to co-sign the verbal order of the ordering practitioner. The signature indicates that the covering practitioner assumes responsibility for his/her colleague's order as being complete, accurate and final. This practice must be addressed in the CAH'S policy. However, a qualified practitioner such as a physician assistant or nurse practitioner may not "co-sign" a MD/DO's verbal order or otherwise authenticate a medical record entry for the MD/DO who gave the verbal order. When used, verbal orders must be used infrequently. Therefore, it is not acceptable to allow covering practitioners to authenticate verbal orders for convenience or to make this common practice.

The ordering practitioner or practitioner responsible for the care of the patient must date and time the order at the time he or she signs the order and must sign a verbal order as soon as possible which would be the earlier of the following:

- The next time the prescribing practitioner provides care to the patient, assesses the patient, or documents information in the patient's medical record, or
- The prescribing practitioner signs or initials the verbal order within time frames consistent with Federal and State law or regulation and CAH policy.

Surveyor Guidance:

In a sampling of patient records, validate that all drug orders, including verbal orders, contain the elements as described in the Interpretive Guidelines (above) 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 and CAH policy. If there is not a State law in place, verify that these orders are authenticated next time the prescribing practitioner provides care to the patient, assesses the patient, or documents information in the patient's medical record.

Verify their process for handling of verbal orders and there have been measures put in place to effectively reduce these when possible.

MM.5 REVIEW OF MEDICATION ORDERS

A licensed pharmacist must review all medication orders (except in emergency situations) prior to administration of the first dose to a patient. If these individuals are not available at that time, the following shall occur:

- SR.1 The practitioner caring for the patient must determine the urgency of administration.
- SR.2 When a pharmacist is not available medications shall be retrieved from the pharmacy or storage area (including automated dispensing) only by licensed staff designated by the pharmacy service and approved by the medical staff, in accordance with principles of patient safety and Federal and State law.
- SR.3 The licensed individual that obtains the medication shall have an orientation to the storage area for the medication.
- SR.4 All high-risk medications in this area shall be segregated and unavailable. High-risk medications may only be retrieved from the pharmacy (including automated dispensing) under the direction of qualified Pharmacy personnel when determined necessary on the orders of the practitioner responsible for the care of the patient.
- SR.5 There shall be a documented protocol requiring that this licensed individual have access to appropriate information to process the order in a formal manner. Information shall include:
 - SR.5a Potential drug-drug interactions;
 - SR.5b Potential allergies or cross sensitivities;
 - SR.5c Proper dose ranges; and,
 - SR.5d Proper indications for administration.
 - SR.5e Other contraindications (pregnancy, breast feeding etc.)
- SR.6 The licensed individual shall follow the pharmacy protocol for removal of a drug from the pharmacy so that the pharmacist can verify the removed drug upon next arrival at the facility.
- SR.7 The removal of the medication must be documented, tracked and trended and the results analyzed to determine need for additional medication storage resources and appropriateness of any pharmacy after-hour practices, as appropriate.

Interpretive Guidelines:

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

Review of medication orders should include:

- Therapeutic appropriateness of a patient's medication regimen;
- Therapeutic duplication in the patient's medication regimen;
- Appropriateness of the drug, dose, frequency, route and method of administration;
- Real or potential medication-medication, medication-food, medication-laboratory test and medication-disease interactions;
- Real or potential allergies or sensitivities;

- Variation from CAH criteria for use; and,
- Other contraindications (pregnancy, breast feeding etc.)

Note: Routine after-hours access to the pharmacy by non-pharmacists for access to medication should be minimized and eliminated as much as possible. The use of well-designed night cabinets, after-hours medication carts, and other methods may preclude the need for non-pharmacist to enter the pharmacy. Policies and procedures should be consistent with Federal and State law.

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

- The practitioner caring for the patient must determine the urgency of administration;
- The medications shall be retrieved from the pharmacy or 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;
- The licensed individual that obtains the medication shall have an orientation to the storage area for the medication;
- The CAH arranges for a qualified pharmacist to be available either on-call or at another location (e.g. 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;
- These 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 this area shall be segregated and unavailable. Protocols should be in place under the direction of the pharmacy for retrieval of high-risk medications from the pharmacy (including automated dispensing) when necessary;
- There shall be a documented protocol requiring that this licensed individual have access to appropriate information to process the order in a formal manner. Information shall include:
 - Potential drug-drug interactions;
 - Potential allergies or cross sensitivities;
 - Proper dose ranges, and
 - Proper indications for administration.
- The licensed individual shall follow the pharmacy protocol for removal of a drug from the pharmacy so that the pharmacist can verify the removed drug upon next arrival at the facility.
- The removal of the medication must be documented, tracked and trended and the results analyzed to determine need for additional pharmacy staff or medication storage resources and appropriateness of any pharmacy after-hour practices.

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

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

The effects of medication(s) on patients are monitored to assure medication therapy is appropriate and minimizes the

occurrence of adverse events. That monitoring process includes:

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

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

Surveyor Guidance:

Verify through a sampling of pharmacy records that documents the process when the pharmacist is not available, drugs are removed from the pharmacy (drug storage area) only by a designated individual (in accordance with State law, if applicable) and only in amounts sufficient for immediate therapeutic needs.

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

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

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

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

Determine that there is a policy for the safeguarding, transferring and availability of keys to the locked storage area.

Identify and assess the quality assurance procedures for the preparation of sterile products.

MM.6 OVERSIGHT

- SR.1 The CAH pharmacy service, in conjunction with the medical staff, is responsible for developing policies and procedures that minimize drug errors.
- SR.2 There shall be procedures for reporting transfusion reactions, adverse drug reactions, and errors in prescribing, preparing, and administering of drugs for trending and analysis.
- SR.3 Drug preparation, administration, and prescribing errors, adverse drug reactions, incompatibilities and transfusion reactions shall be immediately reported to the attending physician and to the CAH quality management oversight.

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 CAH 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 should be immediately reported to the patient's attending physician, or when appropriate the covering physician. When the covering physician is notified due to the attending physician not being available, the patient's attending physician must be notified as soon as he/she is available.

In accordance with 42 CFR Section 485.635(a)(3)(v), the CAH must have a system for staff to report adverse drug reactions and medication administration errors. The pharmacy service is expected to assess all such reports to

determine if problems or errors in pharmacy services caused or contributed to the adverse reaction or medication administration error. Where such problems or errors are identified, the CAH is expected to take effective action to address the identified issues.

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

The facility must have a method to measure the effectiveness of its reporting system to identify 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 CAH. Such methods may 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.

In addition to broad scope definitions, the facility must also proactively identify medication errors and adverse drug reactions. Proactive identification includes observation of medication passes, concurrent and retrospective review of patient's clinical records, ADR surveillance team, implementation of medication usage evaluations for high-alert drugs and identification of indicator drugs or "patient signals" that, when ordered, or noted automatically generate a drug regimen review for a potential adverse drug event.

In the case of ADRs or medication administration errors that are not caught before they reach the patient, a "report" must be made to a practitioner responsible for the care of the patient. Documentation of the error or reaction, including notification to the practitioner, must be in the patient's medical record.

The CAH should have a means to incorporate external alerts and/or recommendations from national associations and governmental agencies for review and facility policy and procedure revision consideration. National associations could include Institute for Safe Medications Practice, National Coordination Council for Medication Error Reporting and Prevention. Governmental agencies may include; Food and Drug Administration, Med Watch Program, and Agency for Health Care Research and Quality.

Surveyor Guidance:

Verify that policies and procedures are developed in order to minimize medication errors, adverse drug reactions, and drug incompatibilities. These policies and procedures must include the involvement and approval of the medical staff.

Validate that the CAH 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 CAH'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 CAH. If the perception is such that medication errors are considered under-reported, determine the action(s) the CAH 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.

Determine if only voluntary reporting is used for detection of ADRs, and ADEs, or if proactive identification is utilized. Proactive identification includes observation of medication passes, concurrent and retrospective review of patient's clinical records, implementation of medication usage evaluations for high-alert drugs, and identification of indicator drugs that, when ordered, automatically generate a drug regimen review for a potential adverse drug event.

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.

Is there a process to report serious adverse drug reactions to the Federal Med-Watch program?

Check the quality management activities to determine if the administration of drugs is regularly monitored. The monitoring should include reports of medication irregularities or errors and corrective action taken.

Upon review of patient clinical record are issues with regard to provision of pharmaceutical services identified? Is the facility aware of the issues? Was there a failure to implement a policy and procedure?

Determine whether staff development programs on drug therapy are available to facility staff to cover such topics as new drugs added to the formulary, how to resolve drug therapy problems, and other general information as the need arises.

Interview facility staff (nursing, pharmacy and medicine) to ascertain awareness of the facilities policy on reporting and documentation of medication errors and adverse drug reactions.

MM.7 AVAILABLE INFORMATION

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

Surveyor Guidance:

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

Examine the sources of drug information available at the nursing station and/or drug storage area and determine if they are current.

LABORATORY SERVICES (LS)

LS.1 SERVICES

- SR.1 The CAH shall provide basic laboratory services that are essential to the immediate diagnosis and treatment of the patient. These services shall meet the standards imposed under section 353 of the Public Health Services Act (42 U.S.C. 236a). The CAH must have a valid CLIA certificate for those tests required under SR.2 as well as other tests that may be performed.
- SR.2 The CAH shall have the capability to perform the following services at a minimum:
- SR.2a Chemical examination of urine by stick or tablet or both (including urine ketones);
 - SR.2b Hemoglobin or hematocrit;
 - SR.2c Blood glucose;
 - SR.2d Examination of stool specimens for occult blood;
 - SR.2e Pregnancy tests; and,
 - SR.2f Primary culturing for transmittal to a certified laboratory.
- SR.3 Blood and blood products involving the procurement, safekeeping and transfusion shall be available, directly or under arrangement, twenty-four (24) hours a day as follows:
- SR.3a blood storage facilities shall meet the requirements of 42 CFR 493, subpart K, and are under the control and supervision of a pathologist or qualified doctor of medicine or osteopathy. Blood storage facilities provided under arrangement shall be approved by the CAH medical staff and the person responsible for the operation of the CAH.
- SR.4 The CAH shall ensure that all laboratory services provided to its patients are performed in a laboratory certified in accordance with 42 CFR §493.
- SR.5 A documented scope of laboratory services shall be available to the medical staff.

Interpretive Guidelines:

Basic laboratory services must be provided directly at the CAH campus by CAH staff in order to facilitate the immediate diagnosis and treatment of the patient. The CAH must have a current Clinical Laboratory Improvement Act (CLIA) certificate or waiver for all tests performed.

The provision of laboratory services that exceed the requirements for basic laboratory services is an optional requirement.

The CAH must maintain, or have available, adequate laboratory services whenever its patients need those services. The CAH may maintain laboratory services at the CAH 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 CAH will have a documented scope and complexity of the laboratory services available. This will include the capability to perform necessary laboratory studies twenty-four (24) hours a day, 7 days a week. The medical staff should determine which laboratory services are to be immediately available to meet the emergency laboratory needs of patients who may be currently at the CAH or those patients who may arrive at the CAH in an emergency condition and whether provided directly or through a contractual arrangement, these services must be provided in accordance with Clinical Laboratory Improvement Act (CLIA) requirements. The CAH 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 collection, preservation, transportation, receipt, and reporting of tissue specimen results.

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.

Verify that the laboratory has the appropriate CLIA certificate or waiver for the tests performed in the CAH laboratory.

Review a sampling of records such as worksheets, and determine if the services, including emergency services, are provided in accordance with the CAH'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.

Verify that the CAH has a procedure in place for obtaining tests that are needed but unavailable at the CAH laboratory.

Verify that the CAH has written policies and procedures to ensure that all laboratory results are recorded in the medical record.

MEDICAL IMAGING (MI)

MI.1 SERVICES

The CAH shall provide diagnostic radiology services that meet professionally approved standards and federal and state laws for radiation safety. The CAH shall have personnel qualified in accordance with State law staff to use radiology equipment, perform radiology procedures and meet requirements according to patient needs and prevention of exposure to radiation hazards.

Interpretive Guidelines:

Radiological services furnished by the CAH may be provided by CAH staff or under arrangement. The CAH must maintain and have available diagnostic radiological services to support the services the CAH provides to meet the needs of its patients. These services must be readily available at all times that the CAH provides services, including emergency services. The CAH 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).

All radiological services provided by the CAH, including diagnostic, therapeutic, and nuclear medicine, must be provided in accordance with acceptable standards of practice and must meet professionally approved standards for safety. The scope and complexity of radiological services offered should be specified in writing and approved by the governing body (or responsible individual).

Acceptable standards of practice include maintaining compliance with applicable Federal and State laws, regulations and guidelines governing radiology services, including facility licensure and/or certification requirements, as well as any standards and recommendations promoted by nationally recognized professional CAHs (e.g., the American Medical Association, American College of Radiology, etc.). 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.

All radiology services provided by the CAH (diagnostic and therapeutic, if offered) must meet acceptable standards of practice and professionally approved standards for safety and personnel qualifications.

Qualified Radiologic Personnel

There should be written policies that are developed and approved by the governing body or responsible individual and are consistent with State law, that designate which personnel are qualified to use the radiological equipment, administer procedures, and which studies require interpretation by a radiologist.

When telemedicine is used to provide teleradiology services, radiologists who interpret radiological tests must satisfy the telemedicine privileging requirements under §485.616(c)(3).

In addition to radiologists, there are other types of healthcare personnel who, depending on State law and the scope and complexity of the CAH's radiologic services, may be involved in the delivery of radiologic services in the CAH, including radiologic technologists and medical physicists. Radiologic technologists perform diagnostic imaging examinations and administer radiation therapy treatments. They are educated in anatomy, patient positioning, examination techniques, equipment protocols, radiation safety, radiation protection and basic patient care.

Surveyor Guidance:

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

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

The CAH 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.

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

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.2 RADIATION PROTECTION

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

Interpretive Guidelines:

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

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

- Adequate shielding for patients, personnel and facilities;
- Labeling of radioactive materials, waste, and hazardous areas;
- Transportation of radioactive materials between locations within the CAH;
- Securing radioactive materials, including determining limitations of access to radioactive materials;
- Testing and maintenance of equipment for prevention of radiation hazards;
- Maintenance monitoring and measuring devices for equipment;
- Proper storage of radiation monitoring badges when not in use;
- Storage and disposal of radio nuclides and radio pharmaceuticals as well as radioactive waste; and,
- Methods of identifying patients who may be pregnant.

The CAH must implement and ensure compliance with its established safety standards.

The CAH shall require any staff member who may be exposed to radiation or working near radiation sources wear badges to identify levels for amount of radiation exposure. This includes certain radiology technologists, radiologists, nursing and maintenance staff.

Surveyor Guidance:

*Review locations where radiological services are provided. During this review, assess the following:
Safety measures are implemented for patients and staff;*

- Verify that patient shielding (aprons, etc.) are properly maintained and routinely inspected by the CAH and review the records for the most recent inspection of the aprons;
- Review the storage of hazardous materials and process if there is any exposure and the protocol followed when this occurs;
- Verify that the CAH requires periodic checks on all radiology personnel and any other CAH 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 CAH – review the records related to these

checks; and,

- Verify that appropriate staff have a device to detect radiation and that it is worn appropriately without interference to detect radiation.
- Verify that hazardous materials are stored properly in a safe manner.
- Review the organization and functioning of the radiation safety program including policies and systems used to identify and resolve safety issues.
- Ask if the CAH 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 must also be notified).

MI.3 EQUIPMENT

- SR.1 Periodic inspection of equipment shall be performed, at least minimally according to manufacturer's recommendations. Hazards shall be identified and promptly corrected.
- SR.2 Documentation of preventative maintenance and repairs of radiology equipment shall be maintained.

Interpretive Guidelines:

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

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

Radiology services must be provided only on the order of practitioners with clinical privileges or, consistent with state law, of other practitioners approved by the medical staff and the governing body (or individual who assumes full legal authority and responsibility for operations of the CAH) and authorized to order the services.

Surveyor Guidance:

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

MI.5 SUPERVISION

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.

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

Interpretive Guidelines:

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

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

In the event that the CAH contracts for telemedicine to be used including the radiologist who interprets radiology tests, the CAH has a process in place to verify the radiologist interpreting the radiological test is licensed and/or meets the other applicable standards that are required by State or local laws in both the State where the practitioner is located and the State where the patient is located OR is subjected to the credentialing and privileging process through the medical staff to be approved for providing this service for the CAH.

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

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

Surveyor Guidance:

Review the Radiologist's credentialing file to verify that he or she has met the qualifications established by the medical staff for appointment. If these services are provided by a contracted entity, the survey team will verify that the CAH 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 CAH.

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.

DIETARY SERVICES (DS)

The CAH shall have dietary services (provided directly or through agreement or arrangement) with written policies and procedures to ensure effective services are provided to meet the nutritional needs of the patients.

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. The CAH shall have written policies and procedures in place for provision of these services that have been approved by the medical staff and are consistent with applicable State law.
- SR.2 The CAH shall ensure that there is the appropriate management and support for dietary services provided. 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 CAH. This full-time person shall have the qualifications, experience and training defined by the CAH and appropriate for the position.
- SR.3 The full-time person responsible for the management of Dietary Services shall ensure that the appropriate administrative and technical personnel are competent and adequate to carry out this process for the CAH.
- SR.4 The CAH shall have a qualified dietitian in the CAH who is available to address issues, concerns and patient care planning. This dietitian shall be employed by the CAH on a full-time or part-time basis or contracted as a consultant for the CAH and available as needed.

Interpretive Guidelines:

The nutritional needs of the patients are met in accordance with practitioners' orders, acceptable standards of practice, and the CAH being in compliance with Federal and State licensure requirements for dietary personnel as well as food service standards, laws and regulations. These activities are carried out by dietary services. This can be completed with qualified CAH staff or through a contractual basis with a nutrition management company. If the CAH utilized a nutrition management company, the CAH is responsible for the quality of arranged services on the same basis as if CAH employees were providing these services.

The full-time individual responsible for dietary services employee on staff or under contract will be authorized and have the delegated responsibility for these services from the CAH's governing body and medical staff. The responsibilities of the responsible individual in this role will include operational management, implementing training and education for dietary staff, and assuring that there are policies and procedures developed and implemented to address at least the following:

- Orientation, work assignments, supervision of work and personnel performance;
- Safety practices for food handling;
- Provision for emergency food supplies; and,
- Supervision of the menu planning function, purchasing of foods and supplies, and retention of required records.
- Dietary service QA program.

Policies and Procedures for Dietary Services

The CAH should have written policies and procedures that address at least the following:

- Availability of a diet manual and therapeutic diet menus to meet patients' nutritional needs;
- Frequency of meals served;

- Process for ordering and delivery of food to respective patient areas;
- Accommodation of non-routine occurrences (e.g., parenteral nutrition (tube feeding), total parenteral nutrition, peripheral parenteral nutrition, change in diet orders, early/late trays, nutritional supplements, etc.); and,
- Guidelines for acceptable hygiene practices of food service personnel and the sanitation protocols for the preparation and cleaning areas.
- Integration of the dietary service into the CAH-wide quality management oversight and Infection Control programs;

The full-time individual responsible for dietary services must demonstrate he or she has the qualifications necessary to manage the service to include education, experience and/or training appropriate to the scope and complexity of the food service operations.

Qualified Dietitian

The CAH must have a qualified dietitian to supervise the nutritional aspects of patient care. The dietitian can be part of the CAH staff or work under contract (may be full or part time) and is responsible for all inpatient nutrition including swing bed services. This individual shall have met the required education, experience, and training defined by the CAH and medical staff, and, where applicable, the State licensure or registration when applicable.

The dietitian's responsibilities include, but are not limited to:

- Approving menus and nutritional supplements provided to patients;
- Provide dietary counseling to patients and those responsible for the patient upon discharge;
- Performing and documenting nutritional assessments;
- Evaluating patient tolerance to therapeutic diets as appropriate;
- Collaborating with other CAH 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 CAH must 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 food and dietary service has been clearly delineated. The personnel file for this individual should be reviewed.
- Review the dietitian's personnel file to determine that he or she is qualified for this role and has an appropriate job description to verify he or she has the experience, specialized training, and required licensure or certification (as required by State law).
- If the dietitian is not full-time, determine the frequency in which the nutritional needs of the patients are assessed, and that the CAH 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 if they have appropriate credentials as required and have received adequate training and are competent in their respective duties.

Ask the CAH to demonstrate what national standard is being followed regarding menus prepared to meet the nutritional needs of their patients.

DS.2 SERVICES AND DIETS

Dietary services shall be provided, and menus/diets offered that meet the needs of the patients.

The following criteria shall be applied:

- SR.1 All menus/diets offered must meet the needs of the patients
- SR.2 All therapeutic diets shall be prescribed by a practitioner or practitioners responsible for the care of the patient; **OR by a qualified dietitian or qualified nutritional professional when permitted under State law and when granted such privileges by the medical staff.**
- SR.3 All nutritional needs of inpatients shall be met in accordance with recognized dietary practices and the orders of the practitioner or practitioners responsible for the care of the patients and that the requirements of 42 CFR Section 483.25(g) is met with respect to inpatients receiving post hospital SNF care.

Interpretive Guidelines:

Menus provided by the CAH must be nutritionally balanced and meet the special needs of the patients. Current menus available to patients will be posted or readily available in the food preparation area.

Review the screening criteria to identify patients at nutritional risk and how the process is carried out from assessment and re-assessment to ensure that their nutritional needs are being met.

The following represent examples of patients who require nutritional assessment. The CAH may define additional criteria for the provision of nutritional assessments:

- *All patients requiring artificial nutrition by any means (e.g., parenteral nutrition (tube feeding), total parenteral nutrition, or peripheral parenteral nutrition);*
- *Patients whose medical condition or physical status (current or future status based upon care plan) interferes with their ability to ingest, digest or absorb nutrients;*
- *Patients whose diagnosis or presenting signs/symptoms indicates a compromised nutritional status (e.g., anorexia nervosa, bulimia, electrolyte imbalances, dysphagia, malabsorption, end stage organ diseases, etc.); and,*
- *Patients whose medical condition is directly impacted by their nutritional intake (e.g., diabetes, congestive heart failure, food/drug interactions, etc.).*

For all therapeutic diets provided to patients as a result of a nutritional assessment or as prescribed, such diets should be:

- *Prescribed in writing by a qualified practitioner, qualified dietitian, or **qualified nutritional professional**;*
- *Documented in the patient's medical record (include the patient's tolerance to the diet); and,*
- *And evaluated for nutritional adequacy to meet the patient's needs.*

In the event a patient refuses the food served, the patient should be offered an appropriate substitute that is of equal nutritional value in order to meet their nutritional needs. Religious beliefs should also be taken into consideration if applicable

Current national standards for recommended dietary allowances will be referenced (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 medical records to verify where therapeutic diet orders are prescribed and authenticated by the practitioner(s) responsible for the care of the patient. In the sampling of medical records reviewed, verify that:

- The patient's nutritional needs have been met;
- The appropriate therapeutic diets have been ordered; and,
- The patient's dietary intake and nutritional status is being monitored and re-assessed as appropriate.
- *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.*

The CAH 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 CAH shall maintain a diet manual (written or electronically) that defines the current therapeutic diets used by the CAH.
- SR.2 The diet manual shall be reviewed at least annually by a dietitian (full-time, part-time or contracted) and group of professional personnel that includes one or more doctors of medicine or osteopathy and one or more physician assistants, nurse practitioners, or clinical nurse specialists.
- SR.3 The diet 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 (whether written or available electronically) must be reviewed by the dietitian and the medical staff. This therapeutic diet manual should be reviewed at least annually. The therapeutic diet manual must be readily available to all medical, nursing and food service personnel.

Surveyor Guidance:

Review the therapeutic diet manual to determine that it is current and readily available to all appropriate staff. The therapeutic diet manual should include the diets currently available to patients and meet current national standards, such as RDA or DRI. The therapeutic diet manual should be referenced as necessary when such diets are prescribed.

Verify that the therapeutic diet manual has been approved by the medical staff and a qualified dietitian is in accordance with the current national standards, such as RDA or DRI; includes the different types of therapeutic diets routinely ordered at the CAH; and is consistently used as guidance for ordering and preparing patient diets.

REHABILITATION SERVICES (RS)

If the CAH provides rehabilitation therapy services to patients (directly or through agreement or arrangement), the following requirements will apply:

RS.1 ORGANIZATION

- SR.1 Physical therapy, occupational therapy, audiology or speech pathology services, the service(s) shall be provided by qualified staff in accordance with State Law, consistent with the requirements for therapy services under 42 CFR Section 409.17, and in a manner, that ensures the patient's health and safety. The CAH shall have written policies and procedures in place for provision of these services that have been approved by the medical staff, are consistent with applicable State law, and reflect accepted standards of practice.

Interpretive Guidelines:

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

The scope of rehabilitation services offered by the CAH, either directly or under contract, should be defined in written policies and procedures and approved by the Medical staff.

If a CAH provides any degree of rehabilitative services to its patients, either directly or under arrangement, either inpatient or outpatient, the services must be organized and staffed to ensure the health and safety of patients. This includes providing rehabilitative services in accordance with practitioner orders and acceptable standards of practice

The CAH will adhere to acceptable standards of practice include compliance with any applicable Federal or State laws, regulations or guidelines, as well as standards and recommendations promoted by nationally recognized professional CAHs (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 CAH or through a contractual arrangement.
- Validate that these services are provided in a manner that ensures the patient's health and safety.
- Verify that rehabilitation services are integrated into the CAH's QMS oversight.

RS.2 MANAGEMENT AND SUPPORT

- SR.1 The CAH shall ensure that there is the appropriate management and support for rehabilitation therapy services. These requirements shall include:
- SR.1a A director/manager who has the responsibility for the management, direction and accountability for ensuring services are carried throughout the CAH;
- SR.1b The director/manager shall have the qualifications, experience and/or training defined by the CAH and appropriate for this position;
- SR.1c Staff who meet the qualifications as defined by the medical staff and CAH and consistent with State law shall be performed by qualified physical therapists, physical therapists assistants, occupational therapists, occupational therapist assistants, speech- language pathologists, or audiologists. (as defined in § 484.4 Personnel qualifications.)

Interpretive Guidelines:

The CAH must manage and support the service(s) as necessary to maintain the level provided. In order to support these services, the appropriate equipment and qualified personnel must be in place and follow acceptable standards

of practice.

The rehabilitation services offered must be under the direction of a qualified individual that will have the accountability, qualifications, and experience appropriate for this position. The staff (employed or contracted) shall meet the required qualifications, as defined by the CAH to provide these services.

The director may be part-time, full-time, and/or under contract. If part-time, the time spent directing the service should be appropriate with the scope of services provided.

The medical staff must define in writing the required qualifications and competencies for rehabilitation staff in each program or service offered. At least one qualified professional, of the applicable discipline, must be on site when needed to:

- Perform an initial evaluation of each patient for whom rehabilitative services were ordered;
- Initiate the plan of treatment based on the initial evaluation, input from family/caregivers and in accordance with the orders of the practitioner responsible for the care of the patient; and
- Supervise supportive personnel when they furnish services

Surveyor Guidance:

- Review the CAH's policies and procedures to verify that the scope of rehabilitation services offered is defined in writing and these services are under the direction of a qualified individual.
- Verify that staff providing rehabilitative services meet the qualifications as defined by the medical staff and CAH and consistent with State law shall be performed by qualified physical therapists, physical therapists assistants, occupational therapists, occupational therapist assistants, speech-language pathologists, or audiologists. (as defined in § 484.4 Personnel qualifications.)
- If the director of the service does not work full-time, determine that the number of hours spent working is appropriate to the scope of services provided.
- If services are provided under a contractual arrangement, determine that the agreement requires the staff to be appropriately qualified (as listed above) and scope of services provided.
- Sample personnel files to verify current licensure, certifications and ongoing training, consistent with applicable State laws.
- Review medical records to verify that a qualified professional evaluates the patient and initiates the treatment under medical orders and direction for each episode.

RS.3 TREATMENT PLAN

The CAH shall have a written treatment plan that is in accordance with the practitioner's orders who are authorized by the medical staff to order the services in accordance with the CAH's policies and procedures and State laws. The orders, treatment plan and results, notes and other related documentation shall be maintained in the patient's medical record.

- SR.1 The treatment plan and the personnel qualifications must be in accordance with national acceptable standards of practice and must also meet the requirements of [42 CFR Section 409.17](#) which specifies the following rehabilitation services plan of care requirements:
 - SR.1a Establishment of the plan: "The plan must be established before treatment begins by one of the following: (1) A physician; (2) A nurse practitioner, a clinical nurse specialist or a physician assistant; (3) The physical therapist furnishing the physical therapy services; (4) A speech-language pathologist furnishing the speech-language pathology services; (5) An occupational therapist furnishing the occupational therapy services."
 - SR.1b Content of the plan: "The plan: (1) Prescribes the type, amount, frequency, and duration of the physical therapy, occupational therapy, or speech-language pathology services to be

furnished to the individual; and (2) Indicates the diagnosis and anticipated goals.”

SR.1c Changes in the plan: “Any changes in the plan are implemented in accordance with the provider’s policies and procedures.”

Interpretive Guidelines:

The CAH shall have an individualized plan of treatment, based on the patient’s specific rehabilitation needs, input from family/caregivers and therapeutic treatment goals for the patient that are documented in the patient’s record prior to the initiation of treatment. At a minimum, this treatment plan will include:

- The order from the practitioner for the service(s) in collaboration with individuals qualified to provide the service(s);
- The type, amount, frequency and duration of services;
- Measurable short-term and long-term goals, results and notes; and,
- Reviews and revisions, as necessary, to account for changes in the patient’s response to therapeutic intervention.

Changes to the treatment plan must be documented in writing and supported by clinical record information such as evaluation, test results, interdisciplinary staff conferences or practitioner orders.

NOTE: THE ACTIVITIES DESCRIBED IN THE WRITTEN PLAN OF TREATMENT MUST BE WITHIN THE SCOPE OF PRACTICE, STATE LICENSURE, OR CERTIFICATIONS OF THE INDIVIDUAL PERFORMING THE ACTIVITY.

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 treatment established in writing prior to the beginning of treatment and there are stated short-term and long-term goals for the patient.
- Verify that changes in the treatment plan are documented in the patient’s medical record to
- include the evaluation, test results, or orders, and practitioner approvals of changes.

RESPIRATORY CARE SERVICES (RC)

If the CAH provides respiratory care services to patients (directly or through agreement or arrangement), the following requirements will apply:

RC.1 ORGANIZATION

- SR.1 Respiratory care services provided at the CAH shall be appropriate to the scope and complexity of the services offered and be delivered in accordance with medical staff directives. The CAH shall have written policies and procedures in place for provision of these services that have been approved by the medical staff and are consistent with applicable State law.
- SR.2 The individual responsible for the supervision of respiratory care services will be a doctor of medicine or osteopathy with the knowledge, experience, and capabilities to administer the service properly.
- SR.3 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 CAH provides respiratory care services to patients, the service will be appropriate to the scope and complexity of the services offered. Respiratory care services shall be delivered in accordance with medical staff directives and acceptable standards of practice.

Standards of practice include compliance with applicable standards that are set forth in Federal or State laws, regulations or guidelines, as well as standards and recommendations promoted by nationally recognized professional CAHs (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 CAH must provide the appropriate equipment and types and numbers of qualified personnel necessary to furnish the services offered by the CAH in accordance with acceptable standards of practice.

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

Surveyor Guidance:

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

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

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 PHYSICIAN ORDER

An order from a doctor of medicine or osteopathy is required for the provision of respiratory treatments and

interventions in accordance with the hospital's policies and procedures and State laws.

Surveyor Guidance:

Sample medical records of patients receiving respiratory services to verify that services are provided only upon the orders of a doctor of medicine or osteopathy, and that the services are provided in accordance with those orders.

RC.3 POLICIES OR PROTOCOLS

Written policies or protocols shall specify:

- SR.1 Which personnel are qualified to perform specific procedures; and,
- SR.2 The amount of supervision required

Interpretive Guidelines:

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

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

- The qualifications, licensure (consistent with State law), education, training and experience of personnel authorized to perform each type of respiratory care service and whether they may perform services without supervision; and,
- The type of personnel qualified to provide the direct supervision.

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

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

INFECTION PREVENTION AND CONTROL (IC)

IC.1 INFECTION PREVENTION AND CONTROL SYSTEM

The CAH shall have, as required and/or recommended by the CDC, CMS, OSHA and related professional organizations (e.g., APIC), an Infection Prevention and Control System to ensure the safety of patients, healthcare workers, volunteers, contract workers and visitors. This system shall provide the means for the identification, prevention, control, investigation, reporting, and avoidance of the transmission of infections and communicable diseases.

- SR.1 The CAH, through its governing body or individual who assumes full legal authority and responsibility for operations of the CAH, Medical Director and nurse executive/leader shall ensure that the Infection Prevention and Control System and associated activities/processes adequately address issues identified throughout the CAH.
- SR.2 The CAH shall designate an individual(s) (e.g., infection control officer(s), infection prevention practitioner) to be responsible for the ongoing development, implementation, and maintenance of the Infection Prevention and Control System.
 - SR.2a Any designated infection prevention practitioner shall have completed a course in basic surveillance by a recognized body or have documented evidence of supervision by a qualified infection prevention practitioner.
 - SR.2b The infection prevention practitioner must demonstrate evidence of pertinent continuing education related to infection prevention, minimally every two years; and
 - SR.2c The designated Infection Control Officer participates in the CAH's Antimicrobial Stewardship Program to minimize the risk of development and transmission of multidrug-resistant organisms (MDROs) within the CAH.
- SR.3 The CAH's Infection Prevention and Control System shall have documented processes, policies and procedures to define how infections and communicable diseases are prevented, controlled and investigated throughout the CAH including, but not limited to:
 - SR.3a Designation of individual(s) responsible for Infection Prevention and Control activities;
 - SR.3b Process for ongoing monitoring for infection 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;
 - 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.3i Reduction and containment of medical costs; and,
 - SR.3j Contributions to the reduction of mortality and morbidity.
- SR.4 The CAH must have a process in place to address potential exposure incidents:
 - SR.4a The CAH must 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 must have a written Exposure Control Plan that is reviewed annually
- SR.4b The Infection Prevention and Control System shall have a tuberculosis (TB) screening program that ensures:
- SR.4b (1) All CAH personnel 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.4b (3) Respiratory fit testing is provided according to State and Federal regulations.
- SR.4c 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.
- SR.5 High Level Disinfection of Reusable Instruments and Devices is accomplished in a manner consistent with CAH 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 recommendation of related professional organizations (e.g., AORN, SGNA, etc.).
- SR.5a CAH policy ensures a reliable, high quality process for endoscope reprocessing which minimizes infection risks.
- SR.5b The CAH has a process in place to identify which endoscope was used on a patient for each procedure (traceability).
- SR.6 The Infection Prevention and Control System 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 populations 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 CAH to take corrective or preventive actions.

Interpretive Guidelines:

The CAH must maintain an Infection Prevention and Control System 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, helminthes, and prions.
- Communicable disease – a disease associated with an agent that can be transmitted from one host

to another.

- Infection control professional – a person whose primary training is in either nursing, medical technology, microbiology, or epidemiology and who has acquired specialized training in infection control.
- 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).

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 CAH that covers patients and CAH staff. The Infection Prevention and Control System must be continually evaluated for effectiveness and when necessary, corrective and/or preventive action must 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.

The CAH must provide for and maintain a sanitary environment to avoid the sources and transmission of infections and communicable diseases. All areas of the CAH must be regularly cleaned and sanitary including all CAH units, campuses and off-site locations (as applicable). The [Infection Prevention and Control System](#) surveillance program will include [processes for the](#) monitoring of housekeeping and maintenance (including when applicable areas of the CAH are under repair, renovation or construction) as well as any other activities to ensure the CAH maintains a sanitary environment.

The CAH must provide adequate resources to accomplish the activities of the [Infection Prevention and Control System](#) – when assessing the need for resources, the CAH should consider the patient population and complexity of services provided as a part of the process for evaluation and provision of resources.

The CAH shall have a documented process, policies and procedures to define how infections and communicable diseases are prevented, controlled and investigated throughout the CAH. These policies and procedures will include:

- Maintenance of a sanitary physical environment, including;
 - Ventilation and water quality control issues
 - Safe air handling systems in areas of special ventilation, such as operating rooms, intensive care units, and isolation rooms
 - Food sanitation, storage and handling
 - Cleaning and disinfecting surfaces, carpeting, and furniture
 - Textiles reprocessing, storage and distribution
 - Disposal of regulated and non-regulated waste
 - Pest control

No items shall be stored under any sink in a Healthcare Facility except where the organization has developed a written policy that specifically identifies the items that are permissible to be stored under sinks. Procedures to identify and maintain areas under sinks used for storage must be part of the Infection Prevention and Control System Plan. No patient care items are permitted to be stored under sinks in any policy.

**The accepted NIAHO definition of healthcare facilities*

NFPA 99: "buildings or portions of buildings in which medical, dental, psychiatric, nursing, obstetrical, or surgical care are provided."

NFPA 70 and 70E adds more to this definition: "Health care facilities include, but are not limited to hospitals, nursing homes, limited care facilities, clinics, medical and dental offices, and ambulatory care centers." NFPA 45 and 5000 include in addition: "whether permanent or movable."

- Measures related to CAH 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
 - Staff orientation and on-going training regarding the prevention and control of infections and communicable diseases as appropriate including:
 - *Exposure to blood borne pathogens*
- 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 infection 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 CAH-acquired infection risks mitigation measures
 - Promotion of hand washing hygiene among all staff and employees, including use of alcohol-based hand sanitizer measures, specific to prevention of infections caused by
 - Multi-Drug - resistant organisms (MDRO). This applies to, but is not limited to, organisms such as methicillin-resistant staphylococcus aureus (MRSA), clostridium difficile (C.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)

- Safe Injection Practice Program
- Isolation procedures and requirements for immuno-suppressed patients
- 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 CAH and community
- Active Surveillance methods for:
 - Obtaining and reviewing data on infections and communicable diseases selected for monitoring
 - Monitoring and evaluating practices of asepsis
 - Authority and indications for obtaining microbiological cultures from patients and the environment as indicated
- A designated Infection Control Officer and his/ her scope of responsibilities;
 - Development and implementation of infection control measures
 - Mitigation of risks associated with patient infections and risks contributing to healthcare-acquired infections
 - Program evaluation and revisions (as necessary)
 - Coordination as required by law with Federal, State, and local emergency preparedness and health authorities to address communicable disease threats, bioterrorism, and outbreaks
 - Compliance with the requirements for reporting to local health authorities
- Roles and responsibilities for infection prevention and control within the CAH and how various committees and departments interface with the Infection Prevention and Control System,
- The CAH leaders are responsible for implementing and ensuring corrective/preventive action(s) are implemented and effective in addressing infection prevention and control issues.
- A process for identifying, reporting, investigating preventing, controlling infections and communicable diseases; to include both inpatient and outpatient populations as well as CAH staff;
- Records to be maintained and controlled to account for incidents related to infections and communicable diseases;
 - Log of incidents related to infections and communicable diseases is maintained (safe and secure from unauthorized access, up-to-date, and readily accessible and retrievable) and documents infections and communicable diseases in patients and staff (patient care staff and non-patient care staff, including employees, contract staff and volunteers).
 - *To protect privacy, the CAH may use codes instead of names in the log with a*

separate reference document to interpret codes to address these incidents

- *Although not required, the CAH 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 with identified communicable diseases that local, State or Federal health agencies require to be reported*
 - *Patients of staff identified by laboratory cultures as colonized or infected with multi drug-resistant organisms (MDROs), as defined by the CAH*
 - *Patients who meet CDC criteria for requiring isolation precautions during their hospitalization*
 - *Patients or staff with signs and symptoms that have been requested be reported or recorded by local, State or Federal health agencies*
 - *Patients or staff who are known or suspected to be infected with epidemiologically- significant pathogens that are identified by the CAH or local, State or Federal health agencies*
- How infections and communicable diseases are measured and analyzed to identify any patterns or trends;
- A process for adequately addressing issues identified throughout the CAH and for the prevention, correction, improvement and training programs to address these issues;
- A means of reporting data/information at least quarterly to the CAH oversight group responsible for the infection prevention and control function (e.g. Infection Protection and Control Committee);
- How education of patients, family members and caregivers about infections and communicable diseases is conducted;
- Orientation of all new CAH personnel to infections, communicable diseases, and to the Infection Prevention and Control System; and,
- A procedure for meeting the reporting requirements of the local health authority as required.

The chief executive officer (CEO, or individual who assumes full legal authority and responsibility for operations of the CAH), the medical staff and the nurse executive/leader, must ensure that the CAH-wide QMS oversight and staff in-service training programs address problems identified through the Infection Prevention and Control System.

The chief executive officer (CEO, or individual who assumes full legal authority and responsibility for operations of the CAH), the medical staff, and the nurse executive/leader are responsible for implementing corrective action plans to address problems identified by the infection control officer(s). These plans should be evaluated for effectiveness and revised if needed, and documentation concerning corrective actions and outcomes should be maintained.

Surveyor Guidance:

- Interview the infection control officer to verify the scope and activities of the CAH's Infection Prevention and Control System and CAH issues regarding infection prevention and control.
- Review the personnel file of the infection control officer(s) to verify that he or she is qualified through education, training, experience, and certification or licensure to oversee the Infection Prevention and Control System.
- Review and validate that appropriate policies and procedures have been developed and implemented to identify, prevent, monitor, report, investigate and measure the control of infections and

communicable diseases.

- Mitigation of risks associated with patient infections present on admission
- Mitigation of risks contributing to healthcare-associated infections
- Determine whether the Infection Prevention and Control System is CAH-wide and identifies all CAH locations and take these various locations into account under the program and there is active surveillance in place.
- Review how areas of the CAH are monitored to include: areas where food is stored, prepared and served, refrigerators, ice machines; air handlers, autoclave rooms/areas, ventilation systems, inpatient rooms, patient care areas, laboratory, surgical areas, supply storage and where equipment is stored and cleaned.
- During the survey, all surveyors should observe the sanitary condition of the physical environment, cleanliness of rooms, surfaces, patient equipment, air inlets, mechanical rooms, food service activities, treatment and procedure areas, surgical areas, central supply and storage areas, etc.
- Review the (Infection Prevention and Control Committee) meeting minutes to evaluate compliance with requirements and follow-up on corrective and preventive actions taken.
- Review a sampling or records for incidents related to infections and communicable diseases, including those identified through employee health services to ensure that these were acted upon and corrective action taken to minimize risks. Also, review compliance with reporting requirements to the local health authority.
- Verify that a log is maintained of incidents related to infections and communicable diseases and is easily accessible and retrievable by the infection control officer and other appropriate staff
- Verify that there is coordination with Federal, State and local emergency preparedness and health authorities as required by law to address communicable disease threats, bioterrorism, and outbreaks
- Verify that the Infection Prevention and Control System is under the scope of the CAH QMS and whether infection prevention and control issues are reported to the Medical Staff, Leadership and Nursing to ensure that corrective action(s) are implemented and effective.
- Review the on-going evaluation of the Infection Prevention and Control System and revisions made to the program based in part on this evaluation

DISCHARGE PLANNING (DC)

DC.1 DISCHARGE PLANNING EVALUATION

The CAH shall have a process in place to appropriate plan for discharge of patients

- SR.1 The CAH shall appropriately identify patients who may risk for negative outcomes without adequate discharge planning to account for the patient's needs with the likelihood of needing post-hospitalization services and of the availability of services.
- SR.2 The CAH shall determine the likelihood of a patient's capacity for self-care or of the possibility of the patient being cared for in the environment from which he or she entered the CAH.
- SR.3 As needed, the patient and family members or interested persons shall be educated to prepare them for post-hospitalization care of the patient.
- SR.4 The CAH shall provide the means to inform the patient or the patient's family of their freedom to choose among participating Medicare providers of post-hospitalization care services, and must, when possible, respect patient and family preferences when they are expressed.
- SR.5 The CAH shall make the appropriate arrangements for patients as necessary before discharge, and unnecessary delays in discharge are avoided.
- SR.6 The CAH shall document appropriate information within the patient's medical record to be used when forming the discharge plan with the patient or individual acting on his or her behalf.
 - SR.6a The results of the discharge planning evaluations must be discussed with the patient or individual acting on their behalf.
- SR.7 If the results of the discharge evaluation so indicate, or at the request of the patient's physician, a registered nurse, social worker, or other appropriately qualified personnel shall develop, or supervise the development of a discharge plan and associated educational materials.
- SR.8 If the CAH transfers or refers patients, the CAH will provide necessary medical information, to appropriate facilities, agencies, or outpatient services, as needed.
- SR.9 If the CAH determines a referral is medically appropriate, the CAH shall provide the patient a list of Medicare-participating providers that are available and serve the geographical area where the patient resides. The CAH shall document in the medical record that the patient (or authorized representative) received a copy of the list and was advised of his/her freedom of choice.
 - SR.9a The CAH must respect the choice of the patient or authorized representative except in unusual circumstances. The CAH may not lead, direct, specify or otherwise limit the selection of qualified Medicare-participating providers.
 - SR.9b The CAH must identify in writing any Medicare-participating providers to which the patient is referred in which the CAH has a disclosable financial interest and any Medicare-participating providers that has a disclosable financial interest in the CAH. Disclosable financial interests are defined by 42 CFR §420, Subpart C.
- SR.10 The discharge planning process shall be periodically reevaluated on an on-going basis. The reassessment must include a review of the discharge plans to ensure that they are responsive to discharge needs of patients.
- SR.11 As needed, the patient and family members or interested persons shall be counseled to prepare them for post-hospital care.

Interpretive Guidelines:

The discharge planning process will identify the following factors when patients are leaving the CAH setting: functional

status; cognitive ability of the patient; and, family support.

The CAH should have a screening process in place to identify patients who are at risk of requiring post-CAH service. The CAH needs to ensure the availability of services that the patient may need and determine the patient's ability for self-care or care to be provided by another party when necessary.

The discharge planning process will be initiated in a timely manner in order for arrangements to be made for the patient prior to discharge.

When the discharge planning evaluation has determined that a referral is medically appropriate for the patient. The patient has the freedom of choice for the providers on the list and the CAH can take no part in leading, directing or otherwise limit the selection of a qualified HHA or SNF.

When patients are transferred, or referred to another provider, the necessary medical information must be communicated to these providers as needed. This includes arranging for necessary post-CAH services and care and educating patient/family/caregivers/community providers about post-CAH care plans.

The documentation associated with the discharge planning process will be included as a part of the patient's medical record as a means of coordinating communication with other providers involved in the patient's care throughout the CAH. The patient's physician, a registered nurse, social worker, and/or other qualified staff member will be responsible for the development of information and materials to implement the discharge plan for the patient.

Surveyor Guidance:

Verify that the discharge planning is effective and an inherent part of the patient care delivery system through the following means:

- Interview staff to determine how patients are identified and require discharge planning;
- Review the CAH's policy and procedures to verify that at-risk patients are provided discharge planning;

Sample records to see when the discharge planning process is initiated, the roles of individuals involved in the process, reassessments as needed and the implementation of the discharge plan.

*Sample patient records to verify that **there is** objective evidence regarding the implementation of the discharge plan, including communication of information to the patient (when possible) and the next provider.*

Interview staff responsible for the patient's care to determine the discharge planning process and how it has been implemented. The following may be asked of the staff regarding this process:

- How are the patient's rights, confidentiality, refusal, and preference considered?
- Is there documentation that care instruction has been communicated to the post CAH care setting where the patient is being referred?

Verify that the CAH includes the discharge planning process within the quality management system and this process is effective

UTILIZATION REVIEW (UR)

UR.1 UTILIZATION REVIEW PROCESS

CMS has determined that the UR procedures established by the State under title XIX of the Act are superior to the procedures required in UR.1, and has required hospitals in that State to meet the UR plan requirements under §456.50 through §456.245

The CAH shall have a process in place (either directly or through agreement or arrangement) for review and evaluation to ensure appropriate utilization of services provided by the CAH organizational and medical staff services to patients, particularly those patients entitled to benefits under both Medicare and Medicaid.

This review and evaluation process regarding the appropriate utilization of services to promote the most efficient use of available health facilities and services will include at a minimum:

- SR.1 Medical necessity of admissions and extended stays;
 - SR.1a For organizations paid under the prospective payment system, all patients whose length of stay is considered an outlier must be reviewed.
 - SR.1a (1) If the CAH with DPU is paid for inpatient hospital services under the prospective payment system set forth in 42 C.F.R. Part 412 must conduct review of duration of stays need review only cases that they reasonably assume to be outlier cases based on extended length of stay, as described in §412.80(a)(1)(i)
 - SR.1a (2) If the CAH with DPU not paid under the prospective payment system, the UR committee must review all cases reasonably assumed by the hospital to be outlier cases because the extended length of stay exceeds the threshold criteria for the diagnosis, as described in §412.80(a)(1)(i). The hospital is not required to review an extended stay that does not exceed the outlier threshold for the diagnosis.
 - SR.1a (3) If the CAH with DPU not paid under the prospective payment system, the UR committee must make a periodic review, as specified in the UR plan, of each current inpatient receiving hospital services during a continuous period of extended duration. The scheduling of the periodic reviews may
 - SR.1a(3)(i) Be the same for all cases; or
 - SR.1a(3)(ii) Differ for different classes of cases.
- SR.2 Medical necessity of professional services.
- SR.3 Professional services furnished, including medications.
 - SR.3a If the CAH with DPU that are paid for inpatient hospital services under the prospective payment system set forth in 42 C.F.R. Part 412 must conduct review of professional services need review only cases that they reasonably assume to be outlier cases based on extraordinarily high costs, as described in §412.80(a)(1)(ii).
- SR.4 Appropriateness of setting;
- SR.5 If the CAH with DPU, in addition to the meeting the hospital accreditation requirements under UR.3 (SR.2) above, the CAH is required to meet the requirements described in §482.12(c) for determination of admissions or continued stays is not medically necessary.

Interpretive Guidelines:

The CAH UR process should include a delineation of the responsibilities and authority for those involved in the performance of UR activities, define the requirement for all review findings to be reported to the Quality Management

Oversight or QIO as defined, and ensure that there is no conflict of interest (financial or otherwise) by those individuals participating in the review.

Surveyor Guidance:

Verify that the CAH has a utilization review plan for those services furnished by the CAH 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 for the CAH UR process.

How does the CAH ensure that mid-level practitioners at the CAH participate with an MD/DO in the review of their patients' health records?

Review for any conflicts of interest or CAH 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.

Sample case reviews of where decisions involving admissions, extended stay and professional services that were deemed to be not medically necessary and verify the decision-making and notification process to all respective parties.

Verify that the CAH's UR process encompasses a periodic review of each current inpatient receiving CAH services of extended duration and that the review is carried out as specified as a part of the CAH's UR activities.

Note: Do not apply these UR requirements if any of the following situations apply:

- A Quality Improvement CAH (QIO) has assumed binding review for the CAH;
- 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 CAHs in that State to meet them. In these cases, the State requirements are applied to both Medicare and the Medicaid patients. The State requirements will then be used for survey in those States.

PATIENT RIGHTS (PR)

PR.1 NONDISCRIMINATION

- SR.1 The CAH 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 CAH 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 CAH is located.

INTERPRETIVE GUIDELINES:

In compliance with Section 1557 of the Affordable Care Act:

- The CAH will post information notifying patients about their rights
- The CAH will post information notifying patients with limited English proficiency (LEP) about the right to receive communication assistance.
- The CAH is also required to post taglines in the top 15 languages spoken by individuals with LEP in the states in which the covered entity operates, advising consumers of the availability of free language assistance services.

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 CAH 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;
- SR.3 Information to the patient or family of patient care and to involve the patient and family to make informed decisions regarding their care planning and treatment, including the requesting and/or refusing treatment, their health status, not to be construed as a demand for the provision of

- SR.4 treatment or services deemed medically unnecessary or inappropriate;
Prompt notification of the patient and his/her representative of patient choice and to promptly notify the patient's physician of admission;
- SR.5 Personal privacy;
- SR.6 Provision of care in a safe setting;
- SR.7 Freedom from all forms of abuse or harassment;
- SR.8 Confidentiality of clinical records;
- SR.9 Patient access to clinical records as quickly as record keeping system permits; and,
 - SR.9a The CAH must not impede the legitimate efforts of individuals to gain access to their own clinical records and must actively seek to meet these requests as quickly as the record keeping system permits.
- SR.10 Procedure for submission of a written or verbal grievance. (See PR.5 Grievance Procedure)
- SR.11 Pain Management

Interpretive Guidelines:

This standard requires that whenever possible, the CAH informs each patient and/or legal representative of the patient's rights in advance of providing or discontinuing care. The CAH will inform both inpatients and outpatients of their rights to include the elements as described in SR.1 – SR.11.

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 CAH.

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 and CAHs to provide written and oral notification under specified guidelines.

All CAHs are required to provide the MOON beginning no later than March 8, 2017.
<https://www.cms.gov/Medicare/Medicare-General-Information/BNI/index.html?redirect=/bni/>

The CAH 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 CAH may decide it is most effective to bundle the patients' rights and advance directives notice with these existing notices.

The CAH must include the patient or their legal representative in the development, implementation and revision of his/her plan of care.

A patient may elect to delegate his or her right to make informed decisions to another person. To the degree permitted by State law, and to the maximum extent practical, the CAH must respect the patient's wishes and follow these accordingly. If the patient is unconscious or otherwise incapacitated and unable to make a decision, the CAH must consult the patient's advance directives, medical durable power of attorney or patient representative, if any of these individuals are available. In the advance directive or the medical power of attorney, the patient may provide guidance as to his or her wishes in certain situations or may delegate decision-making to another individual as permitted by State law. If such an individual has been selected by the patient, or if a person willing and able under applicable State law is available to make treatment decisions, relevant information should be provided to the representative so that informed health care decisions can be made for the patient. However, as soon as the patient is able to be informed of his or her rights, the CAH 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 CAH, or personal information such as name, age, address, income, health information without prior consent from the patient. The CAH 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 practitioner or other staff visits the patient to discuss clinical care issues or conduct any examination.

A patient's right to privacy may be limited in situations where a person must be continuously observed, such as when restrained or in seclusion when immediate and serious risk to harm him/herself (such as when the patient is under suicide precautions or special observation status) or others exists.

The CAH staff should follow current standards of practice for patient environmental safety, infection control, and security. The CAH must protect vulnerable patients, including newborns and children.

The CAH must ensure that patients are free from all forms of abuse, neglect, or harassment. The CAH must have mechanisms/methods in place that ensure patients are free of all forms of abuse, neglect, or harassment.

The CAH must assure that any incidents of abuse, neglect or harassment are reported and analyzed, and the appropriate corrective, remedial or disciplinary action occurs, in accordance with applicable local, State, or Federal law.

Definition: Abuse is defined as the willful infliction of injury, unreasonable confinement, intimidation, or punishment, with resulting physical harm, pain, or mental anguish. This includes staff neglect or indifference to infliction of injury or intimidation of one patient by another. Neglect, for the purpose of this requirement, is considered a form of abuse and is defined as the failure to provide goods and services necessary to avoid physical harm, mental anguish, or mental illness.

The CAH must have sufficient safeguards in place to ensure that access to all information regarding patients is limited to those individuals designated by law, regulation, and policy; or duly authorized as having a need to know. No unauthorized access or dissemination of clinical records is permitted. Clinical records are kept secure and are only viewed when necessary by those persons having a part in the patient's care.

Confidentiality applies to both central records and clinical record information that may be kept at other locations in the CAH, such as, patient units, radiology, laboratories, patient clinics, record storage areas, data systems, etc.

Surveyor Guidance:

Verify the CAH's policy for notifying all patients of their rights, both inpatient and outpatient.

Review the information that is provided to patients by the CAH. Verify the method(s) used to inform patients of their rights.

Interview patients (with CAH and patient permission) to determine how the CAH has informed them about their rights.

Validate that the CAH 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 CAH 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 CAH 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 CAH has a system in place to assure that a patient's family and practitioner are contacted as soon as can be reasonably expected after the patient is admitted (unless the patient requests that this not be done).

In the review of patient care areas, verify that patients are provided privacy during examinations, procedures, treatments, surgery, personal hygiene activities and discussions about their health status/care and other appropriate situations.

Review and validate patient and staff incident and accident reports to identify any incidents or patterns of incidents concerning a safe environment.

In review of areas where infants and children are inpatients, verify the security protections (such as alarms, arm banding systems) in place. Determine how these protections are tested and where corrective/preventive action(s) have been implemented.

Review and validate the system in place to protect patients from abuse, neglect and harassment of all forms, whether from staff, other patients, visitors or other persons. Review and verify that the CAH has a written procedure for investigating allegations of abuse and neglect including methods to protect patients from abuse,

Verify that the CAH 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 CAH 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.

PR.3 ADVANCE DIRECTIVE

The CAH must allow the patient to formulate advance directives and to have CAH staff and practitioners comply with the advance directives in accordance with Federal and State law, rules and regulations. [The organization must maintain written policies in accordance with 42 CFR Section 489.102 requirements for providers.](#)

- SR.1 The CAH shall document in the patient's medical record whether or not the patient has executed an advance directive.
- SR.2 The CAH shall not condition the provision of care or otherwise discriminate based on the execution of the advance directive.
- SR.3 The CAH shall ensure compliance with State law regarding the provision of an advance directive.
- SR.4 The CAH 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:

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.

The patient (inpatient or outpatient) has the right to formulate advance directives and to have CAH 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 CFR 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.

The hospital should also provide the advance directive notices to outpatients (or their representatives) that are in the emergency department, who are in an observation status, or who are undergoing same-day surgery. The notice should be presented at the time of registration. Notice is not required for other outpatients, given that they are unlikely to become incapacitated.

42 CFR Section 489.102 also requires that the CAH provide community education regarding advance directives and that the CAH must document its efforts.

The CAH must communicate its policies regarding the implementation of advance directives, including a clear and precise statement of limitation if the CAH 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 CAH must document in a prominent part of the patient's medical record whether or not the patient has executed an advance directive.

The CAH must not condition the provision of care or otherwise discriminate against an individual on the basis of whether or not the patient has executed an advance directive.

The CAH must ensure compliance with State law regarding the provision of an advance directive and inform individuals that complaints concerning the advance directive requirements may be filed with the State survey agency and this accreditation body.

When the advance directive exists, and is not in the patient's medical record, a written policy must be in place to address the follow-up and compliance. When necessary, the CAH 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 CAH has complied with the patient's advance directive notice requirements.

Review and verify the CAH has a procedure in place to allow patients to formulate an advance directive or to update their current advance directive.

Verify that the CAH educates its staff regarding advance directives.

Verify the extent the CAH provides education for the patient population (inpatient and outpatient) regarding

one's rights under State law to formulate advance directives.

PR.4 LANGUAGE AND COMMUNICATION

The CAH 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 CAH policy and practice provides for competent individuals to interpret as needed for individuals who do not speak English as their primary language or provide alternative communication aids for those who are deaf, blind, or otherwise impaired.

Interpretive Guidelines:

The CAH 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 CAH's obligation to communicate with patients requires that the CAH 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 CAH has alternative means, such as written materials, signs, or interpreters, to communicate patients' rights, when necessary.

Verify how the CAH meets the needs of these diverse patients.

PR.5 INFORMED CONSENT

The CAH shall obtain an informed written consent from each patient or authorized representative for the provision of medical and/or surgical care except in medical emergencies. The consent shall include an explanation of risks, benefits, and alternatives for high-risk procedures, sedation, and other procedures or services, as defined by the medical staff and State law.

Interpretive Guidelines:

All patients receiving either inpatient or outpatient care must complete an informed written consent form for all procedures and treatments specified by the CAH's medical staff, or State or Federal laws or regulations. In the event of a medical emergency, the CAH is not required to obtain a written consent, but timely efforts should be made to obtain an informed written consent from the patient's authorized representative.

The procedures/treatments which will require the CAH to obtain patient written consent will at least include: high-risk procedures (including blood transfusions); sedation; participation in research projects; and, filming or videotaping.

Definition elements: Informed consent means the patient or patient representative is given (in a language or means of communication he/she understands) the information, explanations of risks, benefits and alternatives, needed in order to consent to a procedure or treatment. Informed consent would include that the patient is informed as to who will actually perform planned surgical interventions. When practitioners other than the primary surgeon will perform important parts of the surgical procedures, even when under the primary surgeon's supervision, the patient must be informed of who these other practitioners are, as well as, what important tasks each will carry out. We recognize that at the time of the surgery, unforeseen circumstances may require changing which individual practitioners actually are involved in conducting the surgery.

A properly executed informed consent form contains at least the following:

- Name of patient, and when appropriate, patient's legal guardian;
- Name of CAH;
- Name of specific procedure(s) or medical treatment);

- Name of the responsible practitioner who is performing the procedure(s) or administering the medical treatment;
- Risks;
- Alternative procedures, treatments or therapies;
- Signature of patient or legal representative;
- Date and time consent form is signed;
- 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 the individual witnessing the consent;
- Name of person who explained the procedure to the patient or guardian.

Situations where the patient consents to a procedure and information was withheld from the patient, where if the patient had been informed of that information, the patient may not have consented to the procedure or made the same decisions would not be considered informed consent.

Surveyor Guidance:

Verify that the medical staff has specified which procedures or treatments require a written informed consent. Verify that medical records contain consent forms for all procedures or treatments as required by CAH policy. In a sampling of patient records, review and validate that consent forms are properly executed and contain at least the information identified above.

PR.6 GRIEVANCE PROCEDURE

The CAH shall develop and implement a formal grievance procedure that provides for the following:

- SR.1 *A list of whom to contact;*
- SR.2 *The governing body's review and resolution of grievances or the written delegation of this function to an appropriate person or committee;*
- SR.3 *A referral process for quality of care issues to the Utilization Review, Quality Management or Peer Review functions, as appropriate; and,*
- SR.4 *Specification of reasonable timeframes for review and response to grievances.*
- SR.5 *Grievance resolutions must be in writing and directed to the patient. The grievance resolution shall include the following:*
 - SR.5a CAH contact person;
 - SR.5b Steps taken to investigate;
 - SR.5c Results of the grievance process; and,
 - SR.5d Date of completion.

Interpretive Guideline:

The CAH must develop and implement a formal grievance procedure to identify the process that will be followed and the required correspondence, including grievance resolution, to be provided to the patient.

Definition elements: A "patient grievance" is a formal or informal written or verbal complaint that is made to the CAH by a patient, or the patient's representative, when a patient issue cannot be resolved promptly by staff present. If a complaint cannot be resolved promptly by staff present or is referred to a complaint coordinator, patient advocate, or CAH management, it is to be considered a grievance.

The patient should have reasonable expectations of care and services and the facility should address those expectations in a timely, reasonable, and consistent manner. Regardless of the nature of the grievance, the CAH should make sure that it is responding to the substance of each grievance while identifying, investigating, and resolving any deeper, systemic problems indicated by the grievance. A written response is required for the initial acknowledgement of the grievance (which may or may not include the resolution) within the timeframe of 7 to 10 days. If the grievance is not resolved, the investigation is not complete, or if the corrective action is still being evaluated, the CAH's response should address that the CAH is still working to resolve the complaint and states that the CAH will follow-up with another written response within a specified timeframe (depending on what actions the CAH may have to take). Not all grievances must be in writing if the CAH is addressing a relatively minor request from a patient and that it can be immediately resolved. When appropriate, the grievance resolution will include:

- Identification of the CAH's contact person;
- Steps taken to investigate;
- Results of the grievance process; and,
- Date of completion.

The CAH must inform the patient and/or the patient's legal guardian/representative of the internal grievance process, including whom to contact to file a grievance (complaint). As part of its notification of patient rights, the CAH must inform the patient that he/she may submit a grievance with the State agency (the State agency that has licensure survey responsibility for the CAH) directly, regardless of whether he/she has first used the CAH's grievance process. The CAH must provide the patient or the patient's representative a phone number and address for submitting a grievance with the State agency.

The CAH is required to have procedures for referring Medicare beneficiary concerns to the assigned Quality Improvement CAH (QIO) at the beneficiary's request if they have a complaint regarding quality of care, disagree with a coverage decision, or they wish to appeal premature discharge; additionally, CAHs must inform all beneficiaries of this right.

Surveyor Guidance:

Review and verify the CAH's policies and procedures to assure that its grievance process encourages all personnel to alert appropriate staff concerning any patient grievance and that the CAH's governing body has approved the grievance process.

Verify that the CAH's process assure that grievances involving situations or practices that place the patient in immediate danger, are resolved in a timely manner.

Verify that information is provided to patients to explain the CAH's grievance procedures.

Verify that time frames are established to review and respond to patient grievances. Verify that the CAH 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 explain the CAH'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.

A restraint does not include devices, such as orthopedically prescribed devices, surgical dressings or bandages, protective helmets, or other methods that involve the physical holding of a patient for the purpose of conducting routine physical examinations or tests, or to protect the patient from falling out of bed, or to permit the patient to participate in activities without the risk of physical harm (this does not include a physical escort).

SR.1b A restraint includes a drug or medication used as a restriction to manage the patient's behavior or restrict the patient's freedom of movement and is not a standard treatment or dosage for the patient's condition.

SR.1c Seclusion is the involuntary confinement of a patient alone in a room or area from which the patient is physically prevented from leaving. A situation where a patient is restricted to a room or area alone and staff are physically intervening to prevent the patient from leaving the room or area is also considered seclusion.

Seclusion may only be used for the management of violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others.

Interpretive Guidelines:

An object may be a restraint by functional definition. Anything that prevents the patient access to his or her body, moving their arms, legs, or ambulating in a normal manner is a restraint.

A device is considered a restraint if it is applied to someone who is physically able to get up and they are prevented from doing so. Under this definition, many commonly used CAH 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.
- Side Rails
- 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 CAH 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 CAH and its staff are responsible for providing safe and appropriate care to the patient.
- A voluntary mechanical support used to achieve proper body position, balance, or alignment so as to allow greater freedom of mobility than would be possible without the use of such a mechanical support. Some patients lack the ability to walk without the use of leg braces, to sit upright without neck, head or back braces.
- A medically necessary and voluntary positioning or securing device used to maintain the position, limit mobility or temporarily immobilize during medical, dental, diagnostic, or surgical procedures is not considered a restraint.
- Physically holding a patient during a forced psychotropic medication procedure is considered physical restraint and is not included in this exception.
- Recovery from anesthesia that occurs when the patient is in the intensive care unit or recovery room is considered part of the surgical procedure; therefore, medically necessary restraint use in this setting would not need to meet the requirements of this standard. However, if the intervention is maintained when the patient is transferred to another unit or recovers from the effects of the anesthesia (whichever occurs first), a restraint order would be necessary and the requirements of the standard(s) must be followed.
- Age or developmentally appropriate protective safety interventions (such as stroller safety belts, swing safety belts, high chair lap belts, raised crib rails, and crib covers) that a safety-conscious child care provider outside a health care setting would utilize to protect an infant, toddler, or preschool-aged child would not be considered restraint or seclusion for the purposes of this

standard. The use of these safety interventions needs to be addressed in the CAH's policies or procedures

Drugs Used as a Restraint

If the use of the medication for the patient meets the definition of a drug used as a restraint, the assessment, monitoring and documentation requirements apply. The use of PRN orders is prohibited for drugs or medications that are being used as restraints.

The standard is not intended to interfere with the clinical treatment of patients who need medication in appropriate doses that are standard medical or psychiatric treatment for the patient's condition. Medications such as the following are not considered restraints when based on the assessed needs of the particular patient with careful monitoring to minimize adverse effects.

- Therapeutic doses of psychotropic medication for patients who are suffering from serious mental illness to improve their level of functioning so that they can more actively participate in their treatment.
- Therapeutic doses of anti-anxiety medications to calm the patient who is anxious.
- Appropriate doses of sleeping medication prescribed to treat insomnia.
- Appropriate doses of analgesic medication ordered for pain management.

Therefore, a notation that certain medications are a standard treatment for a patient's medical or psychiatric conditions and are NOT subject to the requirements of the restraint standard is acceptable in the following circumstances:

- The medication is used within the pharmaceutical parameters approved by the Food and Drug Administration (FDA) and the manufacturer for the indications it is manufactured and labeled to address, including listed dosage parameters.
- The use of the medication follows national practice standards established or recognized by the medical community and/or professional medical association or CAH.
- 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 QLP's knowledge of that patient's expected and actual response to the medication.

An additional component of "standard treatment" for a medication is the expectation that the standard use of a medication to treat the patient's condition enables the patient to more effectively or appropriately function in the world around them than would be possible without the use of the medication. If the overall effect of a medication is to reduce the patient's ability to effectively or appropriately interact with the world around the patient, then the medication is not being used as a standard treatment for the patient's condition.

- Example: "A patient has Sundowner's Syndrome, a syndrome in which a patient's dementia becomes more apparent at the end of the day than the beginning of the day. The patient may become agitated, angry, or anxious at sundown. This may lead to wandering, pacing the floors, or other nervous behaviors. The unit's staff find the patient's behavior bothersome and ask the physician to order a high dose of a sedative to keep him in bed. The patient has no medical symptoms or condition that indicates that he needs a sedative. In this case, for this patient, the sedative is being used as a restraint for staff convenience. Such use is not permitted by the regulation. The regulation does not allow a drug to be used to restrain the patient for staff convenience, to coerce or discipline the patient, or as a method of retaliation."
- The standard supports existing State laws that provide more vigorous promotion of the patient's choice and rights. Therefore, when a State's law prohibits the administration of drugs against the wishes of the patient without a court order, the State law applies.

Seclusion

Seclusion can only be used in emergency situations if needed to ensure the immediate safety of the patient exhibiting violent or self-destructive behavior (and others) and less restrictive interventions have been determined to be ineffective.

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. When the patient is in seclusion, the judgment to remove the patient from seclusion 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.

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 would not be considered seclusion.

- SR.2 The CAH will keep the patient safe and protect their rights when restraint or seclusion are applied.
 - SR.2a The CAH 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. States are free to impose requirements by statutes or regulations that are more restrictive than those specified under PR.6.
 - SR.2b Restraint or seclusion may only be imposed to ensure the immediate physical safety of the patient, staff or others and must be discontinued at the earliest possible time.
 - SR.2c Restraint or seclusion may only be used when less restrictive interventions have been determined to be ineffective to protect the patient or others from harm.
 - SR.2d The type or technique of restraint or seclusion used must be the least restrictive intervention that will be effective to protect the patient or others from harm.
 - SR.2e The use of restraint or seclusion must be in accordance with a written modification to the patient’s plan of care, and implemented in accordance with safe and appropriate restraint and seclusion techniques as determined by CAH policy in accordance with State law.
 - SR.2f Restraint and seclusion may not be used simultaneously, unless the patient is continually monitored, face-to-face, by an assigned, trained staff member; or continually monitored by trained staff using both video and audio equipment.
 - SR.2f (1) This monitoring must be in close proximity to the patient.
 - SR.2f (2) For the purposes of this provision, ‘continually’ means ongoing without interruption.

Interpretive Guidelines:

Restraint or seclusion must not be used unless it is to meet the patient’s individual clinical needs. The uses of restraint or seclusion should be discontinued as soon as possible.

Restraint use associated with non-violent or non-self-destructive behavior may be indicated, but only when it directly supports medical healing.

When a patient’s violent or self-destructive behavior presents an immediate and serious danger to the patient or others, immediate action is needed. While staff should be mindful of using the least intrusive intervention, it is critical that staff considers all interventions available to them and that the intervention selected be effective in protecting the patient or others from harm.

A patient may experience a severe medication reaction that causes him or her to become violent or a patient may be withdrawing from alcohol and having delirium tremens (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 CAH should consider whether he/she has a medical condition or symptom that indicates a current need for a protective intervention to prevent the patient from walking or getting out of bed. A restraint must not serve as a substitute for adequate staffing to monitor patients.

Comprehensive assessment of the patient and the environment, in conjunction with individualized patient care planning, should be used to determine those interventions that will best ensure the patient's safety and well-being with the least risk

The most appropriate intervention that will ensure the safety of the patient is to be selected following a comprehensive assessment of the patient, the environment, and the patient's individualized treatment plan.

CAH 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). CAH 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 CAH 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 CAH policy. The plan should reflect an individualized approach that is in the best interest of the patient and promotes the patient's health, safety, dignity, self-respect, and self-worth

The risks associated with any intervention must be considered within the context of an ongoing process of assessment, intervention, evaluation, and re-evaluation.

- The use of restraint or seclusion interventions must never act as a barrier to the provision of safe and appropriate care, treatments, and other interventions to meet the needs of the patient.

Surveyor Guidance:

Review CAH 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 practitioners are permitted to order restraints.

- Verify that the CAH has defined who has the authority to discontinue restraints (based on State law and CAH policies) and under what circumstances restraints are to be discontinued.
- Review and validate that when there is evidence of prolonged restraint, as defined by the CAH, and if possible, actions taken to reduce to eliminate the use of restraints must be analyzed by the treatment team.

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 invasive measures before applying restraint or seclusion.

Interview CAH 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 CAH 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 CAH policy and reflects continuous assessment, intervention, evaluation, and reassessment as required.

SR.3 Order for Restraint or Seclusion:

- SR.3a The use of restraint or seclusion must be in accordance with the order of a physician or other QLP who is responsible for the care of the patient and is authorized to order restraint or seclusion by CAH policy in accordance with State law.
- SR.3b An order for restraint or seclusion must be obtained prior to the application of restraints, except in emergency situations when the need for intervention may occur quickly;
 - SR.3b (1) *In these emergency application situations, the order must be obtained either during the emergency application of the restraint or seclusion, or immediately (within a few minutes) after the restraint or seclusion has been applied.*
- 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 physician or other QLP who is responsible for the care of the patient must be consulted as soon as possible if restraint or seclusion is not ordered by the patient's attending physician.
- SR.3e Each order for restraint or seclusion used to manage violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others may only be renewed in accordance with the following limits:
 - SR.3e (1) Orders are limited to 4 hours for adults 18 years of age or older; 2 hours for children and adolescents 9 to 17 years of age; and 1 hour for children under 9 years of age.
 - SR.3e (2) The restraint or seclusion order may only be renewed in accordance with these limits for up to a total of 24 hours unless superseded by State law that is more restrictive.
 - SR.3e (3) After 24 hours, and before writing a new order for the use of restraint or seclusion for the management of violent or self-destructive behavior a physician or other QLP (if allowed by State law) must see and assess the patient.

SR.3e (4) If the restraint or seclusion is discontinued prior to the expiration of the order, a new order must be obtained prior to re-initiation of the restraint or seclusion.

SR.3f Each order for restraint used to ensure the physical safety of the non-violent or non-self-destructive patient may be renewed as authorized by CAH policy.

Interpretive Guidelines:

A QLP is any individual permitted by State law and CAH 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 CAH policy.

The standard requires that a physician or other QLP 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 must be obtained either during the emergency application of the restraint or seclusion, or immediately (within a few minutes) after the restraint or seclusion has been applied. The failure to immediately obtain an order is viewed as the application of restraint or seclusion without an order. The hospital should address this process in its restraint and seclusion policies and procedures. The policies and procedures should specify who can initiate the emergency application of restraint or seclusion prior to obtaining an order from a physician or other QLP.

When the restraint or seclusion is not ordered by the patients attending physician, the order must be followed by consultation with the patient's treating physician as soon as possible.

Consultation ensures that the physician who has overall responsibility and authority for the management and care of the patient is aware of and involved in the intervention. This also promotes continuity of care and elicits information from the attending physician that might be relevant in choosing the most appropriate intervention for the patient.

Medical staff policies determine who is considered the treating (attending) physician. 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. CAH 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 must 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 must be delegated to another physician, who would then be considered the attending physician.

The attending practitioner must be able to conduct both a physical and psychological assessment of the patient in accordance with State law, their scope of practice, and CAH policy

When implementing a protocol that includes the use of an intervention that meets the definition of a restraint, a separate order must be obtained for the restraint.

The patient's medical record must include documentation of an individualized patient assessment indicating that the patient's symptoms and diagnosis meet use-triggering criteria listed in the protocol. Restraint or seclusion use is an exception, not a routine response to a certain condition or behavior.

CAHs 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, the order must be obtained either during the emergency application of the restraint or seclusion, or immediately after the restraint has been applied. The CAH should address this process in its restraint policies and procedures.
- CAH procedures shall specify who can initiate the use of restraint or seclusion in an emergency prior to obtaining an order from a physician or other QLP.

Time limits on the length of each order only apply when restraint or seclusion are used to manage violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others.

- The length-of-order requirement identifies critical points at which there is mandatory contact with a physician or QLP responsible for the care of the patient.
- A trained RN can reassess the patient when the original order is about to expire, and then contact the physician or other QLP to obtain direction as to whether to renew the order and whether other steps are to be taken.
- If a patient remains in restraint or seclusion for the management of violent or self-destructive behavior 24-hours after the original order, a face-to-face assessment by a physician or other QLP must occur before a new order for the continued use of restraint or seclusion is written.

*The regulation does not require the ordering LIP to be physically present to re-evaluate the need for continuing restraint for non-violent and non-self-destructive behaviors. Hospitals have the flexibility to determine time frames for the restraint of the non-violent, non-self-destructive patient. These time frames should be addressed in policies and procedures. **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 must be discontinued at the earliest possible time (see PR.7, SR.2b).***

Surveyor Guidance:

Review the medical records of patients that required restraint or seclusion to verify that:

- The attending physician was consulted of the need for restraint or seclusion, as soon as possible, according to CAH policy
- The attending physician was contacted prior to the expiration of orders for restraint or seclusion

SR.4 One Hour Face-to-Face Evaluation.

The condition of the patient must be continuously assessed, monitored, and reevaluated.

SR.4a When restraint or seclusion is used to manage violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others, a physician or other QLP, or a RN or PA trained in accordance with the requirements specified under PR.7 must see the patient face-to-face within 1-hour after the initiation of the intervention to evaluate:

SR.4a (1) The patient's immediate situation;

SR.4a (2) The patient's reaction to the intervention;

SR.4a (3) The patient's medical and behavioral condition; and,

SR.4a (4) The need to continue or terminate the restraint or seclusion.

SR.4b If the 1-hour face-to-face evaluation is conducted by a trained RN or PA, the attending physician or other QLP responsible for the care of the patient must be consulted as soon

as possible after completion of the evaluation.

Interpretive Guidelines:

The 1-hour face-to-face evaluation includes both a physical and behavioral assessment of the patient. Therefore, the practitioner who conducts this evaluation must be able to complete both a physical and behavioral assessment of the patient in accordance with State law, his or her scope of practice, and hospital policy. An evaluation of the patient's medical condition would include a complete review of systems assessment, behavioral assessment, as well as review and assessment of the patient's history, drugs and medications, most recent lab results, etc. The purpose is to complete a comprehensive review of the patient's condition to determine if other factors, such as drug or medication interactions, electrolyte imbalances, hypoxia, sepsis, etc., are contributing to the patient's violent or self-destructive behavior.

When a trained RN or PA conducts the 1-hour evaluation, the physician is consulted, but is not required to come to the hospital to see and evaluate the patient 1-hour after the initiation of the restraint or seclusion.

The physician can determine the need for immediate or further onsite evaluation based upon the patient's symptoms, condition, and history.

Telephone consultation may be acceptable for this consultation.

The 1-hour face-to-face evaluation only applies when restraints, use of a medication as a restraint, or seclusion are used to manage violent or self-destructive behavior.

If a patient's violent or self-destructive behavior is resolved and the restraint or seclusion is discontinued before the practitioner arrives to perform the one hour face to face evaluation, a practitioner is still required to see the patient face to face within one hour after the initiation of the intervention. Ending the intervention prior to the 1-hour point does not mean that the mandated assessment and consultation are no longer necessary. The patient's behavior warranted the use of a restraint or seclusion which indicates a serious change in a patient's condition and must be assessed.

State law (by statute or regulation) regarding the 1-hour face-to-face evaluation should be followed if more e than these requirements.

Surveyor Guidance:

Validate the competency of personnel conducting the 1-hour face-to-face evaluation. The 1-hour face-to-face evaluation includes both a physical and behavioral assessment of the patient.

Therefore, the practitioner who conducts this evaluation must be able to complete both a physical and behavioral assessment of the patient in accordance with State law, his or her scope of practice, and hospital policy

Generally, practitioners such as social workers, psychologists and other mental health workers are not qualified to conduct a physical assessment, nor is it in their scope of practice.

Review a sampling of medical record for patients where restraint or seclusion was applied and review documentation to confirm that:

- The patient received a face-to-face medical and behavioral evaluation within 1 hour of the intervention by an appropriate person identified in hospital policy
- Consultation with the attending physician has taken place as soon as possible following the 1-hour face-to-face evaluation
- The patient's condition and reaction to the intervention was documented.

SR.5 Assessment, Monitoring, and Evaluation of the Restrained or Secluded Patient

SR.5a The condition of patients in restraint or seclusion is monitored and assessed by a physician, other licensed independent practitioner or trained staff at an interval determined by CAH policy, at least every 24 hours.

- SR.5a (1) CAH 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) CAH policies guide staff in how to determine an appropriate interval for assessment and monitoring based on the individual needs of the patient, the patient's condition, and the type of restraint used (for example, every 15 minutes).
- SR.5b Restraint or seclusion must be discontinued at the earliest possible time, regardless of the length of time identified in the order.
- SR.5c If restraint and seclusion are used simultaneously, the patient must be continually monitored, face-to-face, by an assigned, trained staff member; or continually monitored by trained staff using both video and audio equipment.
- SR.5c (1) This monitoring must be in close proximity to the patient.
- SR.5c (2) For the purposes of this provision, "continually" means ongoing without interruption.

Interpretive Guidelines:

All restraint interventions must be based on the individual clinical needs of a particular patient at a particular time as demonstrated by documented ongoing assessments of that patient.

Ongoing assessment and monitoring of the patient's condition are crucial for prevention of patient injury.

- The selection of an intervention and determination of the necessary frequency and level of assessment and monitoring should be individualized, taking into consideration variables such as the patient's condition, cognitive status, risks associated with the use of the chosen intervention, and other relevant factors.
- Staff determines the appropriate level of monitoring and frequency of assessment based on CAH policy, an individualized patient assessment, and type of intervention used.
- The attending physician should be kept informed about the patient's status.

After 24 hours, a face-to-face assessment by a physician or other QLP must occur before a new order is written for restraints or seclusion for the violent or self-destructive patient.

Restraint or seclusion must be ended at the earliest possible time, regardless of the length of time identified in the order.

- Restraint or seclusion may only be employed while the unsafe situation continues. Once the unsafe situation ends, the use of restraint or seclusion should be discontinued.

If restraint or seclusion is discontinued prior to the expiration of the original order, a new order must be obtained prior to reinitiating the use of restraint or seclusion

- Staff cannot discontinue an order and then restart it because that would constitute a PRN order.
- A temporary release that occurs for the purpose of caring for a patient's needs, for example, toileting, feeding, and range of motion, is not considered a discontinuation of the intervention.
- Example: When a trial period of observation out of restraints is initiated and the patient again exhibits the symptoms that prompted the prior use of restraints, and the patient is placed in restraint again, a new order would be required. This episode cannot be considered as part of the original episode/order as it would be considered a PRN order which is not permitted.

- Example: A patient is released from restraint or seclusion. If this patient later exhibits violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others that can only be handled through the use of restraint or seclusion, a new order would be required.
- Example: When patient's behavior responds to the intervention in 20 minutes, the restraint or seclusion should be discontinued, even if the order was given for up to 4 hours.

All requirements specified under this standard apply in the simultaneous use of restraint and seclusion

- Continual face-to-face monitoring (that is, moment to moment) is only required when restraint and seclusion are used simultaneously to address violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others.
- Monitoring in "close proximity" to the patient is intended to ensure that staff is immediately available to intervene and render appropriate interventions to meet the patient's needs.

The use of PRN orders for drugs or medications is only prohibited when a drug or medication is being used as a restraint.

EXCEPTIONS

Geri chair. *If a patient requires the use of a Geri chair with the tray locked in place in order for the patient to safely be out of bed, a standing or PRN order is permitted. Given that a patient may be out of bed in a Geri chair several times a day, it is not necessary to obtain a new order each time.*

Raised side rails. *If a patient's status requires that all bedrails be raised (restraint) while the patient is in bed, a standing or PRN order is permitted. It is not necessary to obtain a new order each time the patient is returned to bed after being out of bed.*

Repetitive self-mutilating behavior. *If a patient is diagnosed with a chronic medical or psychiatric condition, such as Lesch-Nyham Syndrome, and the patient engages in repetitive self-mutilating behavior, a standing or PRN order for restraint to be applied in accordance with specific parameters established in the treatment plan would be permitted. Since the use of restraints to prevent self-injury is needed for these types of rare, severe, medical and psychiatric conditions, the specific requirements (1-hour face-to-face evaluation, time-limited orders, and evaluation every 24 hours before renewal of the order) for the management of violent or self-destructive behavior do not apply.*

Surveyor Guidance:

In a sampling of medical records of patients where restraint or seclusion has been applied review and validate that

- The patient was monitored and reassessed according to timeframes defined by CAH policy
- The patient was reassessed according to criteria established by CAH policy

SR.6 Documentation in the Medical Record

SR.6a When restraint or seclusion is used, there must be documentation in the patient's medical record of the following:

- SR.6a (1) A description of the patient's behavior and the intervention used;
- SR.6a (2) Alternatives or other less restrictive interventions attempted (as applicable);
- SR.6a (3) The patient's condition or symptom(s) that warranted the use of the restraint or seclusion; and,
- SR.6a (4) The patient's response to the intervention(s) used, including the rationale for continued use of the intervention;
- SR.6a (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 CAH 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 CAH policy.
- SR.6b In addition, staff must document in the patient’s medical record the date and time any death associated with restraint or seclusion use was reported to CMS, as required. (see section on Report of Death)

Interpretive Guidelines:

Patient care staff must be able to demonstrate that the restraint or seclusion intervention is the least restrictive intervention that protects the patient’s safety. Patient care staff must demonstrate through their documentation that the use of restraint or seclusion is based on individual assessment of the patient the assessments and documentation of these assessments must be ongoing in order to demonstrate a continued need for restraint or seclusion.

Surveyor Guidance:

Verify and validate that there is documentation of ongoing patient assessment (e.g. skin integrity, circulation, respiration, intake and output, weight, hygiene, injury).

In a sampling of patient records, where restraint or seclusion was applied during their CAH 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
- Monitoring and assessment activities
- Modification of the patient’s plan of care based on the assessment and evaluation of the patient

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 CAH’s QMS (See also QM.7.SR.6)
- SR.7b Evidence of prolonged restraint, as defined by the CAH, and, if possible, actions taken to reduce or eliminate the use of restraints must be analyzed by the treatment team.
- SR.7c [Aggregate data regarding the use of restraint must be collected and analyzed for the identification of patterns and trends. Intensive analysis must be implemented in the event a patient is injured through the use of restraint or a staff member is injured through the application of a restraint.](#)

Interpretative Guidelines:

The data collected will be aggregated and analyzed to ensure that only clinically necessary restraints are used with a focus on patient safety.

Actions are to be implemented to ensure that standards for restraint or seclusion are applied appropriately as they relate to the patient with non-violent/ non-self-destructive behavior and the patient with violent/self- destructive behavior.

As a means of documenting this assessment and monitoring, the use of restraints must be recorded within a log or other data collection mechanism for monitoring. The documentation must include identification of:

- Shift;
- Date, time of order;
- Staff who initiated the process;
- The length of each episode;
- Date and time each episode was initiated;
- Day of the week each episode was initiated;
- Type of restraint or seclusion used (including physical restraint or drug used as restraint);
- Compliance with requirements defined in the standards;
- Whether injuries were sustained by the individual or staff;
- Age of individual; and,
- Gender of individual.

Data must be analyzed for the identification of patterns and trends including:

- Patterns of excessive use
- Use of physical restraint or drugs used as restraint to substitute for adequate staffing, monitoring, assessment, or investigation of the reasons behind patient behavior such as wandering or getting up in the night, which may be indicative of unmet patient care needs
- Opportunities for improving compliance with the requirements of the standards

Twenty-four hours of restraint or seclusion for the management of violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others is an extreme measure which could potentially seriously harm the patient. When there is evidence of prolonged restraint, as defined by the CAH, and, if possible, actions taken to reduce or eliminate the use of restraints must be analyzed and presented for management review.

Intensive analysis must be implemented in the event a patient is injured through the use of restraint or a staff member is injured through the application of a restraint.

Surveyor Guidance:

Review the aggregate data regarding the use of restraints and seclusion to see if the CAH has identified patterns and trends.

Confirm that the CAH can demonstrate implementation of corrective or preventive action where analysis of data reflects variation.

Verify the CAH had conducted an intensive analysis in the event a patient is injured through the use of restraint or a staff member is injured through the application of a restraint.

PR.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 must be trained and able to demonstrate competency in the application of restraints, implementation of seclusion, monitoring, assessment, and providing care for a patient in restraint

or seclusion

- SR.1a Training must occur before performing any of these actions, as part of orientation, and subsequently on a periodic basis consistent with CAH policy.
- SR.2 In order to limit the use of restraint or seclusion, the CAH **must require appropriate staff to have education, training, and demonstrated knowledge based on the specific needs of the patient population in at least the following:**
 - SR.2a Techniques to identify staff and patient behaviors, events, and environmental factors that may trigger circumstances that require restraint or seclusion;
 - SR.2b The use of non-physical intervention skills, including de-escalation and dealing with aggressive behavior;
 - SR.2c Choosing the least restrictive intervention based on an individualized assessment of the patient's medical or behavioral status or condition;
 - SR.2d The safe application and use of all types of restraint or seclusion used in the CAH, 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 CAH policy associated with the evaluation of the patient; and;
 - SR.2g **The use of first aid techniques and certification in the use of cardiopulmonary resuscitation, including recertification requirements.**
- SR.3 At a minimum, physicians and other QLP's authorized to order restraint or seclusion by CAH policy in accordance with State law must have a working knowledge of the CAH policy regarding the use of restraint or seclusion.
 - SR.3a Physician and other QLP training requirements must be specified in CAH policy.
- SR.4 Individuals providing staff training must be qualified as evidenced by education, training, and experience in techniques used to address patients' behaviors.
- SR.5 The CAH must document in the staff personnel records that the training and demonstration of competency were successfully completed.
- SR.6 Registered Nurses and Physician Assistants that are selected to perform face-to-face evaluations of patients that exhibit violent or self-destructive behaviors are identified and trained in the expectations of this role, specifically how to evaluate and document the:
 - SR.6a Patient's immediate situation;
 - SR.6b Patient's reaction to intervention
 - SR.6c Patients medical and behavioral condition including a review of systems, patient history, medications, and lab results; and,
 - SR.6d Need to continue or terminate the restraint or seclusion

Interpretive Guidelines:

Staff who have direct contact with patients must be trained and able to demonstrate competency before applying

restraints, implementing seclusion, providing care for a patient in restraint or seclusion, or with assessing and monitoring the condition of the restrained or secluded patient.

- The facility identifies the appropriate clinical staff that must be trained in the application, monitoring, patient care, and discontinuation of restraint or seclusion.
- Non-nursing staff must be included to the extent that they are involved with restraint use.
- Application of restraint or seclusion by an untrained staff member, including contract staff, would constitute a violation of this requirement.

Hospitals are required to provide a safe environment for the patients in their care. When restraint or seclusion techniques are used, patients are placed at a higher risk for injuries or even death. Hospitals must require appropriate staff (all staff who apply restraint or seclusion, monitor, access or provide care for a patient in restraint or seclusion) to receive education and training in the use of first aid techniques as well as training and certification in the use of cardiopulmonary resuscitation.

Training must be comprehensive and must involve demonstration and return demonstration.

The written training curriculum reflects the defined competency skill sets defined for each level of clinical personnel.

- The CAH 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.
- CAH policies and emergency procedures for managing violent or self-destructive behaviors in included in the training curriculum as determined appropriate.
- It is appropriate to have different levels of training for different individuals depending upon their involvement with restraints.

The training curriculum is reviewed annually and revised as indicated, incorporating relevant findings from QA/PI activities.

Accurate recordkeeping of training sessions, including titles of the employees who attend must be stored onsite where the actual documents will be easily accessible for review. In order to ensure that the employee training is complete, all the required components of the program must be covered

Registered Nurses and Physician assistants, nurse practitioners and/or clinical nurse specialists that are selected to perform 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:

1. *Patient's immediate situation;*
2. *Patient's reaction to intervention*
3. *Patients medical and behavioral condition including a review of systems, patient history, medications, and lab results; and,*
4. *Need to continue or terminate the restraint or seclusion*

Surveyor Guidance:

Review CAH policy and training records to verify:

- Competency skill sets for clinical staff are identified
- Training content and frequency are identified to meet the standard.
- Trainers are qualified as evidenced by education, training, and experience.
- All staff that applies or monitors restraint or seclusion, including Physical Therapy, Radiology, and

Respiratory Care staff receive training and have demonstrated competency related to use of restraint and seclusion.

- Policy describes training requirements for physicians and licensed independent practitioners
- Training has been provided for the medical staff, QLP's and CAH staff as defined

Review and validate that the CAH has documented instructional training for the use of all restraint techniques used and the alternatives to the use of restraint and seclusion

Review selected personnel files to verify that clinical staff have demonstrated appropriate competency

PR.9 RESTRAINT OR SECLUSION: REPORT OF DEATH

- SR.1 CAH's must report deaths associated with the use of restraint or seclusion in accordance State Law (if applicable). [CAHs with rehabilitation and/or psychiatric DPUs must report deaths associated with the use of restraint or seclusion directly to their CMS Regional Office in accordance with 42 CFR 482.13\(g\), the Conditions of Participation, and the State Operations Manual. Form CMS-10455 \(<http://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS10455.pdf>\) is used to report deaths associated with the use of restraint or seclusion.](#)
- SR.2 Staff must document in the patient's medical record the date and time the death was reported.

Surveyor Guidance:

When required under CMS or in accordance with State law, review the CAH 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 or in accordance with State law when required.

PR.10 PATIENT VISITATION RIGHTS

- SR.1 The hospital must have written policies and procedures regarding the visitation rights of patients, including those setting forth any clinically necessary or reasonable restriction or limitation that the hospital may need to place on such rights and the reasons for the clinical restriction or limitation. A CAH must:
- SR.1a Inform each patient (or support person, where appropriate) of his or her visitation rights, including any clinical restriction or limitation on such rights, in advance of furnishing patient care whenever possible.
- SR.1b Inform each patient (or support person, where appropriate) of the right, subject to his or her consent, to receive the visitors whom he or she designates, including, but not limited to, a spouse, a domestic partner (including a same-sex domestic partner), another family member, or a friend, and his or her right to withdraw or deny such consent at any time.
- SR.1c Not restrict, limit, or otherwise deny visitation privileges on the basis of race, color, national origin, religion, sex, sexual orientation, gender identity, or disability.
- SR.1d Ensure that all visitors enjoy full and equal visitation privileges consistent with patient preferences.

Interpretive Guidelines:

Patient visitation rights

The CAH must have developed written policies and procedures regarding the visitation rights of patients, including those setting forth any clinically necessary or reasonable restriction or limitation that the hospital may need to place on such rights and the reasons for the clinical restriction or limitation.

A CAH must (1) Inform each patient (or representative, where appropriate) of his or her visitation rights, including any clinical restriction or limitation on such rights, when he or she is informed of his or her other rights under 485.635(f). (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:

Review the CAH policies on visitation and validate that the policies delineate any reasonable clinical restrictions or limitations, if needed.

Verify that the CAH 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.

MEDICAL RECORDS SERVICE (MR)

MR.1 MEDICAL RECORD SYSTEM

- SR.1 Administrative responsibility for medical records shall rest with the medical record service of the CAH, or through agreement if applicable. The CAH will designate a member of the professional staff with the responsibility for maintaining records.
- SR.2 The CAH 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.
- SR.3 The medical record service will ensure that all records are legible, complete, accurately documented, readily accessible and systematically organized.

Interpretive Guidelines:

The CAH must have administrative responsibility for all medical records- both inpatient and outpatient. The medical record service shall reflect the scope and complexities of services offered.

Definition: "Medical records" refers to the written documents, computerized electronic information, radiology film and scans, laboratory reports and pathology slides, videos, audio recordings, and other forms of information regarding the condition of a patient.

Surveyor Guidance:

Verify that the medical records service is defined to meet the needs of the CAH and the patients with respect to the scope and complexities of services.

MR.2 COMPLETE MEDICAL RECORD

- SR.1 The CAH shall maintain an accurately written, promptly completed medical record for each inpatient and outpatient.
- SR.2 The CAH shall have a process for providing services for the completion, filing, and retrieval of the medical record. The process for completion of the medical record must address timeframes.
- SR.3 Authenticity and security of all record entries shall be safeguarded.

Interpretive Guidelines:

The CAH must maintain a medical record for each inpatient and outpatient evaluated or treated in any part or location of the CAH.

The CAH must ensure that all medical records accurately and completely document all orders, test results, evaluations, care plans, treatments, interventions, care provided and the patient's response to those treatments, interventions and care.

The CAH 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 CAH must ensure there is a process in place to protect and retrieve these records in a timely manner.

The record must be completed promptly after discharge in accordance with State law and CAH policy but no later than thirty (30) days following discharge.

A unit record for both inpatients and outpatients may be used; however, when two different systems are used they must be appropriately cross referenced. When a patient reimbursement status changes from acute care services to swing bed services, a single medical record may be used for both stays as long as the record is sectioned separately. Both sections must include admission and discharge orders, progress notes, nursing notes, graphics, laboratory support documents, any other pertinent documents, and discharge summaries.

The medical record must be accessible. The CAH must have a medical record system that allows the medical record of any patient, inpatient or outpatient, evaluated and/or treated at any location of the CAH within the past 6 years to be accessible by appropriate staff, 24-hours a day, 7 days a week, whenever that medical record may be needed.

Surveyor Guidance:

Review the area(s) where medical records are maintained by the CAH.

Verify that a medical record is maintained for each person treated or receiving care.

Verify that medical records are stored and maintained in area(s) that ensure the records are secure, protected from damage by flood, fire, and other casualties, and access is limited to authorized staff.

Verify that the CAH has a process to ensure that records are accurate, completed promptly, easily retrieved and readily accessible in all area(s) where medical records are maintained.

MR.3 RETENTION

- SR.1 Medical records (original or legally reproduced form) shall be retained for a period of at least six (6) years, or longer if required by State statute or if 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 six (6) years, or more if required by state or local laws. These records may be in the form of a hard copy, microfilm, computer memory, or other electronic storage media. The CAH must have a process to promptly retrieve the complete medical record of every individual evaluated or treated in accordance with Federal and State law and regulations. Certain medical records may have retention requirements that exceed six (6) years (e.g., FDA, OSHA, and EPA).

The medical record must be properly filed and retained. The CAH must have a medical recording system that ensures the prompt retrieval of any medical record, of any patient evaluated or treated at any location of the CAH within the past 6 years.

The CAH must have a system of patient records, pertinent medical information, author identification, and record maintenance that ensures the integrity of the authentication and protects the security of all record entries. The medical record system must correctly identify the author of every medical record entry. The medical record system must protect the security of all medical record entries. The medical record system must ensure that medical record entries are not lost, stolen, destroyed, altered, or reproduced in an unauthorized manner. All locations where medical records are stored or maintained must ensure the integrity, security and protection of the records.

Surveyor Guidance:

Verify that the control of medical record is in place and these records are retained for at least 6 years, or more if required by State or local laws.

Verify that the CAH uses a coding and indexing system that allows for timely retrieval of patient records by diagnosis and procedures.

MR.4 CONFIDENTIALITY

- SR.1 Confidentiality of patient records shall be assured 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 CAH 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 CAH only in accordance with federal or state laws, court orders, or subpoenas.

Interpretive Guidelines:

The CAH must have a means of ensuring that access to all information regarding patient's records is limited to those individuals designated by law, regulation, and policy or duly authorized as having a need to know. The process must be designed to protect improper or inadvertent release of private information to unauthorized individuals. This includes open patient records for patients who are currently inpatients in the CAH and outpatients in outpatient clinics.

Patient information will include; patient paper records, video, audio, and/or computer stored information.

If the CAH uses computer entries, there must be a security system in place to ensure the integrity of the record system; to ensure that the author of each entry is correctly identified; to ensure that record entries are not altered or lost; that limits access to medical records to only authorized persons; and ensures that records are not released to unauthorized individuals. For the purposes of this regulation, electronic signatures comply with those medical record entries that include a requirement for a signature.

The CAH will maintain a compliance program as required under the Health Insurance Portability and Accountability Act (HIPAA).

Surveyor Guidance:

Verify that the CAH has a means of ensuring that access to patients' records is limited to those individuals designated by law, regulation, and policy or duly authorized as having a need to know.

Validate the policy and procedure for release of patient information and verify that copies of medical records and other confidential patient information are released outside the CAH only upon written authorization of the patient, legal guardian, or person with an appropriate "power of attorney" to act on the patient's behalf, or only if there is a properly executed subpoena or court order, or as mandated by Federal and State law.

Verify the methods in place to prevent unauthorized persons from gaining physical access or electronic access to information in patient records.

Validate the CAH's current practices in place for protecting and securing the confidentiality of patient records. Observe the CAH'S security practices for patient records. Are patient records left unsecured or unattended? Are patient records unsecured or unattended in hallways, patient rooms, nurse's stations, or on counters where an unauthorized person could gain access to patient records?

Verify the elements of the CAH's compliance program as required under (HIPAA).

MR.5 RECORD CONTENT

For each patient receiving healthcare services, the CAH will ensure the following, as applicable:

- SR.1 The medical record shall contain information to include:
 - SR.1a Accurate identification of the patient and social data;
 - SR.1b Properly executed consents for treatment (including informed consent forms when applicable);
 - SR.1c Pertinent medical history;

- SR.1d Assessment of the health status and healthcare needs of the patient;
 - SR.1e Brief summary of the episode;
 - SR.1f Disposition of the patient;
 - SR.1g Education/instructions to the patient;
 - SR.1h Justification for admission and continued hospitalization;
 - SR.1i Support the diagnosis;
 - SR.1j Reports of physical examinations, diagnostic and laboratory tests results (including clinical laboratory services and consultative findings);
 - SR.1k Report of treatments and medications;
 - SR.1l Description of the patient's progress through nursing documentation and progress notes (including vital signs, response to medications and treatment, complications, and other pertinent information necessary to monitor the patient's progress); and,
 - SR.1m All orders of doctors of medicine or osteopathy or other practitioners.
- SR.2 All entries shall be:
- SR.2a Legible, complete, dated and timed; and,
 - SR.2b Authenticated by the person responsible for providing or evaluating the services provided consistent with CAH policy.
- SR.3 Authentication may include written signatures or initials. Electronic authentication is permissible.
- SR.4 All orders must be dated, timed and authenticated promptly by the prescribing practitioner.
- SR.5 Verbal orders must be authenticated in accordance CAH policy and with Federal and State law.
- SR.5a Telephone or verbal orders are to be used infrequently and when used must be accepted only by personnel authorized by the medical staff and in accordance with Federal and State law.
 - SR.5b Verbal orders must be signed or initialed by the prescribing practitioner must be authenticated in accordance with Federal and State law. If there is not State law that designates a specific timeframe for the authentication of verbal orders, the orders must be authenticated at the time of the next practitioner visit or by another practitioner responsible for the care of the patient.

Interpretive Guidelines:

The medical record must contain information such as notes, documentation, records, reports, recordings, test results, and assessments to:

- Justify admission and continued hospitalization;
- Support the diagnosis; and,
- Describe the patient's progress and response to medications and services.

All entries in the patient's medical record (information/documentation regarding evaluations, interventions, care provided, services, care plans, discharge plans, and the patient's response to those activities, laboratory reports, test results, consults, assessments, radiology reports, dictated notes, etc. must be promptly filed in the patient's medical record in order to be available to the physician and other care providers.

Entries in the medical record may be made only by individuals as specified in CAH and medical staff policies. All entries in the medical record must be timed, dated, and authenticated, and a method established to identify the author. The identification may include written signatures, initials, computer key, or other code.

When rubber stamps are authorized, the individual whose signature the stamp represents shall place in the administrative offices of the CAH a signed statement to the effect that he/she is the only one who has the stamp and uses it. There shall be no delegation to another individual. A list of computer or other codes and written signatures must be readily available and maintained under adequate safeguards. There shall be sanctions for improper or unauthorized use of stamp, computer key, or other code signatures. The CAH must have policies and procedures in place and operational before an electronic medical record system would be deemed acceptable.

The parts of the medical record that are the responsibility of the MD/DO must be authenticated by this individual. When non-MD/DOs have been approved for such duties as taking medical histories or documenting aspects of physical examination, such information shall be appropriately authenticated by the responsible MD/DO. Any entries in the medical record by house staff or non-MD/DOs that require counter signing by supervisory or attending medical staff members shall be defined in the medical staff rules and regulations.

These entries must be legible, complete, dated, timed and authenticated by the person responsible for prescribing the services or by another practitioner who is responsible for the patient's care. This individual must be authorized to write orders in accordance with CAH policy and State law.

Where a practitioner has written a set of orders or is using a preprinted order set contained on one page, or on several pages, the physician must 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.

Although verbal and telephone orders should be minimized when possible, for such orders, these must be in accordance with Federal and State law and authenticated. If there is not State law that designates a specific timeframe for the authentication of verbal orders, the orders must be authenticated at the time of the next practitioner visit or by another practitioner responsible for the care of the patient or earlier if required by State law.

However, a State law that substitutes for authentication of the verbal order another mechanism, such as a read-back and verify requirement, where the receiver of the order reads the order back to the ordering practitioner to verify its accuracy, does not qualify for the State law exception. The expectation is that CAH policies and procedures for verbal orders will include a read-back and verify process, in addition to specifying a timeframe for authentication of the orders. For example, in a State with a law that requires verification of a verbal order within a specified timeframe only when the read-back and verify process is not used, CAHs in that State would still be required to authenticate all verbal orders at the time of the next practitioner visit or by another practitioner responsible for the care of the patient or earlier if required by State law.

Verify their process for handling of verbal orders and there have been measures put in place to effectively reduce these when possible.

A system of auto-authentication in which a MD/DO or other practitioner authenticates a report before transcription is not consistent with these requirements. There must be a method of determining that the practitioner did, in fact, authenticate the document after it was transcribed

Surveyor Guidance:

Review a sample of medical records during the survey. Validate that that MR.5 is consistently applied throughout the CAH.

Determine if there is a State law that defines the specific timeframe requirement for verbal order authentication.

Verify that the CAH has policies and procedures in place for addressing verbal orders including a process for read-back and verification to ensure accuracy of such orders.

Interview staff and review examples of verbal orders to verify this process for authentication and the read-back and verification process.

Verify that within each medical record reviewed, the appropriate information is stated, timed, dated and

authenticated by the appropriate individual(s) and supports the diagnosis, treatment and other services provided to the patient.

Verify that the department maintains a current list of authenticated signatures, written initials, codes, and stamps when such are used for authorship identification.

Verify that computer or other code signatures are authorized by the CAH'S governing body and that a list of these codes is maintained under adequate safeguards by the CAH administration.

Verify that the CAH'S policies and procedures provide for appropriate sanctions for unauthorized or improper use of the computer codes.

Examine the CAH'S policies and procedures for using the system and determine if documents are being authenticated after transcription.

For sampled records, are there dated and authenticated signatures by appropriate MD/DOs and/or mid-level practitioners, as needed?

MR.6 IDENTIFICATION OF AUTHORS

The organization shall have a system to identify the author of each entry into the medical record.

Interpretive Guidelines:

The organization shall have a system to identify the author of each entry in the medical record. Entries may be made only by individuals as specified in CAH and medical staff policies.

If the CAH, through the approval of the medical staff and leadership allow rubber stamps, the individual whose signature the stamp represents shall place in the administrative offices of the CAH a signed statement to the effect that he/she is the only one who has the stamp and is the only individual allowed to use it. No other individual can be authorized to use the stamp under any circumstance.

All entries in the medical record must be legible. Any entry in the medical record that is not legible can be misread or misinterpreted and could lead to medical errors or other adverse patient events.

Surveyor Guidance:

Verify that the CAH has a means of identifying authors for each entry in the patient medical record. The organization shall have a policy in place that states who is allowed to document in the medical record and the means for identifying the author. Review a sampling of records to verify the consistency of this process.

In the event that the medical staff and leadership allow stamps to be used, verify that the stamps have been approved and are only used by the individual identified on the stamp.

In the sample of records, validate that all entries in the medical record are legible.

MR.7 REQUIRED DOCUMENTATION

All records must document the following, as appropriate:

- SR.1 All medical records of inpatients and all outpatient medical records for patients having same day surgery or a procedure requiring anesthesia must contain evidence of a physical examination, including a health history, performed no more than thirty (30) days prior to admission or registration or within twenty-four (24) hours after admission:
 - SR.1a The H&P, completed and documented no more than thirty (30) days before admission or registration or twenty-four (24) hours after admission, and prior to any high-risk procedure, surgery, procedures requiring anesthesia services, or other procedures requiring an H&P, must be placed in the patient's medical record within twenty-four (24) hours after admission or registration, and prior to any high-risk procedure, surgery, procedure requiring anesthesia services, or other procedures requiring an H&P.

- SR.1b When the history and physical is completed within thirty (30) days prior to admission or registration, an updated medical record entry documenting an examination for any changes in the patient's condition must be completed and documented in the patient's medical record within twenty-four (24) hours after admission or registration, **and** prior to **any high-risk procedure, surgery, procedures** requiring anesthesia services, **or other procedures requiring an H&P.**
- SR.2 Admitting diagnosis,
- SR.3 Results of all consultative evaluations of the patient and appropriate finding by clinical and other staff involved in the care of the patient,
- SR.4 Documentation of complications, organization acquired infections, and unfavorable reactions to drugs and anesthesia,
- SR.5 Properly executed informed written consent forms for procedures and treatments specified by the medical staff, or by Federal or State law if applicable, signed by the patient or his/her authorized representative,
- SR.6 All practitioners' orders, nursing notes, reports of treatment, medication records, radiology, and laboratory reports, and vital signs and other information necessary to monitor the patient's condition,
- SR.7 Discharge summary with outcome of hospitalization, disposition of case, and provisions for follow up care,
- SR.8 Final diagnosis with completion of medical records within thirty, (30) days following discharge

Interpretive Guidelines:

The medical record must contain a history and physical examination (H&P) for all inpatients and outpatients. The H & P must be performed by an authorized practitioner no more than thirty (30) days prior to admission or within twenty-four (24) hours after admission.

The H & P must be placed in the patient's medical record within twenty-four (24) hours after admission. In the event the H & P is completed within thirty (30) days prior to admission, the CAH must ensure that the H & P is updated to document any changes in the patient's condition.

The patient's medical record must document the following:

- Admitting diagnosis;
- Results of all consultative evaluations of the patient and appropriate finding by clinical and other staff involved in the care of the patient,
- Documentation of complications, organization acquired infections, and unfavorable reactions to drugs and anesthesia;
- Properly executed informed written consent forms for procedures and treatments specified by the medical staff, or by Federal or State law if applicable, signed by the patient or his/her authorized representative;
- A properly executed consent form should reflect the patient consent process. All inpatient and outpatient medical records must contain a properly executed informed consent for prior to conducting any procedure or other type of treatment when informed consent is required. A properly executed consent form must be consistent with CAH policy as well as applicable State and Federal law or regulation and at a minimum contain the following elements
- CAH name where procedure or treatment is to take place

- Description of the procedure or treatment for which consent is being given
- Name of the responsible practitioner performing the procedure or administering treatment
- Statement that the procedure or treatment, including the benefits, risks, and alternative therapies, was explained to the patient or the patient's legal representative
- Signature of the patient or patient's legal representative
- Date and time the informed consent is signed by the patient or patient's legal representative

If there is applicable State law governing the content of the informed consent, then the CAH must comply with those requirements

Additional information may be considered to include as a part of the informed consent form

- Name of the practitioner who conducted the consent
- All practitioners' orders, nursing notes, reports of treatment, medication records, radiology, and laboratory reports, and vital signs and other information necessary to monitor the patient's condition;
- Discharge summary with outcome of hospitalization, disposition of case, and provisions for follow up care; and,
- Final diagnosis with completion of medical records within thirty, (30) days following discharge.

Surveyor Guidance:

Determine that medical records contain a physical examination and medical history completed for each patient by an authorized practitioner.

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

- Verify the content and completeness of the H&P per organization policy
 - In some cases, the organization may accept an H&P that has been completed in the practitioner's office, when this is allowed, verify the process for ensuring that the appropriate documentation is present and completed per the requirements of the organization and the H&P was completed within the required timeframe.
- Verify that the H&P was completed no more than 30 days before or 24 hours after admission or registration and in all cases involving surgery or procedures requiring anesthesia services or moderate/conscious sedation prior to the surgery or procedure.
- Verify this documentation of the H&P was placed in the medical record within 24 hours after admission or registration, and in all cases involving surgery or procedures requiring anesthesia services or moderate/conscious sedation prior to the surgery or procedure
- Where the H&P is completed within 30 days before admission or registration and in all cases involving surgery or procedures requiring anesthesia services or moderate/conscious sedation, the CAH must ensure that this H&P is updated to document any changes in the patient's condition.
 - If there are no changes to the H&P as written, the physician can simply document an update note stating
 - *that the H&P has been reviewed,*

- *that the patient has been examined, and*
- *that the physician concurs with the findings of the H&P completed on the specified date or that "no change" has occurred in the patient's condition since the H&P was completed.*

Review a sample of medical records (inpatient and outpatient) to verify conformance to the appropriate elements specified in the interpretive guidelines.

Verify that the medical staff has specified which procedures and treatments require informed consent.

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

Compare the CAH standard informed consent form to the CAH's policy regarding informed consent to verify that the form is consistent with the policy. If there is applicable State law, verify that the form is consistent with the requirements of that law.

ORGAN, TISSUE AND EYE PROCUREMENT (TO)

TO.1 PROCESS

- SR.1 The CAH shall have a process and written protocols in place for the procurement of organs, tissue, and eyes.
- SR.1a The CAH shall have an agreement with at least one tissue bank and one eye bank to facilitate in the retrieval, processing, preservation, storage and distribution of tissues and eyes, as appropriate to ensure that all usable tissues and eyes are obtained from potential donors and that such an agreement does not interfere with the procurement of organs.

Interpretive Guidelines:

The CAH must have an agreement with at least one tissue bank and at least one eye bank. The OPO may serve as a "gatekeeper" receiving notification about every CAH death and should notify the tissue bank chosen by the CAH about potential tissue and eye donors.

It is not necessary for a CAH to have a separate agreement with a tissue bank if it has an agreement with its OPO to provide tissue procurement services; it is not necessary for a CAH to have a separate agreement with an eye bank if its OPO provides eye procurement services. The CAH is not required to use the OPO for tissue or eye procurement but is free to have an agreement with the tissue bank or eye bank of its choice. The tissue banks and eye banks define "usable tissues" and "usable eyes."

The requirements of this regulation may be satisfied through a single agreement with an OPO that provides services for organ, tissue and eye, or by a separate agreement with another tissue and/or eye bank outside the OPO, chosen by the CAH. The CAH may continue current successful direct arrangements with tissue and eye banks as long as the direct arrangement does not interfere with organ procurement.

Surveyor Guidance:

Verify that the CAH has an agreement with at least one tissue bank and one eye bank that specifies criteria for referral of all individuals who have died in the CAH. The agreement must also acknowledge that it is the OPO's responsibility to determine medical suitability for tissue and eye donation, unless the CAH has an alternative agreement with a different tissue and/or eye bank.

TO.2 ORGAN PROCUREMENT ORGANIZATION (OPO) WRITTEN AGREEMENT

The CAH shall have a written agreement with an OPO designated under 42 CFR Section 486. Per SR.1 through SR.5 (below), this agreement shall:

- SR.1 Contain procurement protocols that have been approved by the CAH's governing body or individual who assumes full legal authority and responsibility for operations of the CAH 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 CAH;
- SR.3 Ensure communication of the policy for organ, tissue and eye procurement to all appropriate areas of the CAH, 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 CAH, 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 CAH for this purpose;
- SR.5 Ensure, in collaboration with the designated OPO, that the family or each potential donor is informed of its options to donate organs, tissues, or eyes, or to decline to donate. The individual designated by the CAH to initiate the request to the family must be an organ procurement

representative or a designated requestor. If a designated requestor is responsible for initiating this request, this individual must have completed a course offered or approved by the OPO that has been designed in conjunction with the tissue and eye bank community in the methodology for approaching potential donor families and requesting organ or tissue donation; and,

- 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.

Definition: The term "organ" means a human kidney, liver, heart, lung, pancreas, or intestines (or multivisceral organs).

Interpretive Guidelines:

The CAH has a process in place for the procurement of organs, tissue, and eyes.

The CAH must have a written agreement with an Organ Procurement CAH (OPO), designated under 42 CFR Part 486. At a minimum, the written agreement must address the following:

- Procurement protocols approved by the governing body and medical staff and criteria for referral, including the referrals of all individuals whose death is imminent or who have died in the CAH 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 CAH-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 CAH;
- Procedures that permit the OPO, tissue bank, and eye bank access to the CAH's death record information according to a designated schedule, e.g., monthly or quarterly;
- Policies that confirm that the CAH 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 CAH will utilize to maintain potential organ donor patients so that the patient organs remain viable.

The CAH must implement a mechanism for communication of the policy for organ, tissue and eye procurement to all appropriate area of the CAH, in addition to any revisions or modifications under a controlled document

CAH must notify the OPO of every death or imminent death in the CAH. When death is imminent, the CAH must notify the OPO both before a potential donor is removed from a ventilator and while the potential donor's organs are still viable. The CAH should have a written policy, developed in coordination with the OPO and approved by the CAH'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 CAH'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 CAH will create a partnership that furthers donation, while respecting the perspective of CAH 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 CAH must contact the OPO by telephone as soon as possible after an individual has died, has been placed on a ventilator due to a severe brain injury, or who has been declared brain dead (ideally within 1 hour). That is, a CAH must notify the OPO while a brain dead or severely brain-injured, ventilator-dependent individual is still attached to the ventilator and as soon as possible after the death of any other individual, including a potential non-heart-beating donor. Even if the CAH does not consider an individual who is not on a ventilator to be a potential donor, the CAH must call the OPO as soon as possible after the death of that individual has occurred.

CAHs may not use "batch reporting" for deaths by providing the OPO with periodic lists of patient deaths, even if instructed to do so by the OPO. If the patient dies during a transfer from one CAH to another, it is the receiving CAH'S responsibility to notify the OPO.

The individual designated by the CAH to initiate the request to a family must be an organ procurement representative, a CAH representative of a tissue or eye bank, or a designated requestor. Any individuals involved in a request for organ, tissue, and eye donation must be formally trained in the donation request process.

Definition: A "designated requestor" is defined as a CAH-designated individual who has completed a course offered or approved by the OPO and designed in conjunction with the tissue and eye bank community.

Surveyor Guidance:

Verify that the CAH has a written agreement, approved by the governing body, and that it addresses all required information.

In a sampling of records, verify that the CAH has implemented its organ procurement policies. Verify that that all designated requestors have completed the required training.

Verify that the CAH 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 CAH-designated requestor regarding his or her approach to donation requests.

Validate that the CAH ensures that all appropriate staff have attended an educational program regarding donation issues and how to work with the OPO, tissue bank, and eye bank.

Review and verify that there are policies and procedures in place to ensure the coordination between facility staff and OPO staff in maintaining the potential donor.

Verify that the organ, tissue, and eye procurement program is integrated into quality management system oversight.

TO.3 RESPECT FOR PATIENT RIGHTS

The organ, tissue and eye procurement policies, procedures and practices shall demonstrate that staff use discretion, sensitivity with 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 CAH personnel.

Surveyor Guidance:

Review the facility complaint file for any relevant complaints

TO.4 DOCUMENTATION

Documents and records of organ procurement will be maintained in the manner directed by the OPO.

Surveyor Guidance:

Review a sampling of documents and records regarding organ procurement

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 facility services appropriate to services provided.

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) Technical 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.

(xii) NFPA 110, Standard for Emergency and Standby Power Systems, 2010 edition, including TIAs to chapter 7, issued August 6, 2009.

(2) [Reserved]

- SR.1 The condition of the physical plant and the overall CAH environment must be developed and maintained through housekeeping and preventive maintenance programs in such a manner that the safety and well-being of patients, visitors, and staff are assured.
- SR.1a All essential mechanical, electrical, and patient-care equipment shall be maintained in safe operating condition.
- SR.1b The premises are clean and orderly where patients and staff can function safely.
- SR.2 The CAH must maintain adequate facilities for its services.
- SR.2a Diagnostic and therapeutic facilities must be located for the safety of patients.

- SR.2b Facilities, supplies, and equipment must be maintained to ensure an acceptable level of safety and quality.
- SR.2c The extent and complexity of facilities must be determined by the services offered.
- SR.3 The CAH shall have a process in place, as required and/or recommended by local, State, and national authorities or related professional organizations, to maintain a safe environment for the CAH's patients, staff, and others.
- SR.4 The CAH shall have written 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 are prevented, controlled, investigated, and reported throughout the CAH.
- SR.5 The CAH shall evaluate the facility's physical environment management systems at least annually. This evaluation shall be forwarded to QMS oversight.
- SR.6 Occurrences, incidents and/or impairments shall be measured and analyzed to identify any patterns or trends.
- SR.7 The CAH, through its senior leadership, shall ensure that the physical environment and associated processes adequately addresses issues identified throughout the CAH and that there are prevention, correction, improvement and training programs to address these issues.
- SR.8 Significant physical environment data/information shall be disseminated regularly to QMS oversight.
- SR.9 Except as otherwise provided in this section, the CAH must meet the applicable provisions and must proceed in accordance with the Health Care Facilities Code (NFPA 99, 2012 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.10 Chapters 7, 8, and 13 of the adopted Health Care Facilities Code do not apply to a CAH.
- SR.11 If application of the Health Care Facilities Code required under PE.1, SR. 9 & 10 would result in unreasonable hardship for the CAH, 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.
- SR.12 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 GL- 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. For this to be permissible, the CAH must obtain from the local and/or state fire prevention agencies (Authority Having Jurisdiction or AHJ) written documentation stating that these areas 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 PE.1, SR.12:

To apply for areas in which smoking is acceptable,

1. *The documented AHJ permission must 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 CAH must 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/permited by the local/state fire prevention agency or AHJ documentation, then the hospital 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 must also include plans and/or processes that will be developed and maintained to demonstrate continual progress in achieving a tobacco-free campus.

Interpretive Guidelines:

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, Standards for Health Care Facilities Code of the National Fire Protection Association 99, 2012 edition, issued August 11, 2011.*
 - (ii) *TIA 12-2 to NFPA 99, issued August 11, 2011.*
 - (iii) *TIA 12-3 to NFPA 99, issued August 9, 2012.*
 - (iv) *TIA 12-4 to NFPA 99, issued March 7, 2013.*
 - (v) *TIA 12-5 to NFPA 99, issued August 1, 2013.*
 - (vi) *TIA 12-6 to NFPA 99, issued March 3, 2014.*
 - (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.*

(2) [Reserved]

- (xii) [58 FR 30671, May 26, 1993, as amended at 62 FR 46036, 46037, Aug. 29, 1997; 68 FR 1387, Jan. 10, 2003; 69 FR 49271, Aug. 11, 2004; 70 FR 15239, Mar. 25, 2005; 71 FR 55341, Sept. 22, 2006; 77 FR 29076, May 16, 2012; 81 FR 26901, May 4, 2016]
- (xiii) Section 1820(c)(2)(B)(iii) of the Social Security Act, codified at 42 USC 1395i-4(c)(2)(B)(iii) limits a CAH to a maximum of 25 inpatient beds that can be used for inpatient acute care or swing bed services. The statute also requires CAHs to provide inpatient acute care limited, on an annual average basis, to 96 hours per patient (see interpretive guidelines for §485.620(b)).
- (xiv) Section 1820(c)(2)(E) of the Act also permits a CAH to operate a 10-bed psychiatric distinct part unit (DPU) and a 10-bed rehabilitation DPU, without counting these beds toward the 25-bed inpatient limit.

The limit applies to the number of inpatient beds; not to the number of inpatients on any given day. CAHs that were larger hospitals prior to converting to CAH status may not maintain more than 25 inpatient beds, plus a maximum of 10 psychiatric DPU inpatient beds, and 10 rehabilitation DPU inpatient beds

This standard shall apply to all locations of the CAH, all campuses, and all off-site facilities, all provider-based activities The CAH's department that is responsible for the CAH's buildings and equipment (both facility equipment and patient care equipment) must be evaluated for maintaining the appropriate work environment and related infrastructure to be safe for all staff, patients and visitors.

The CAH must ensure that the condition of the physical plant and overall CAH environment is developed and maintained in a manner to ensure the safety and wellbeing of patients. This includes ensuring 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 or equipment in need of repair. The routine and preventive maintenance and testing activities should be incorporated into the CAH's quality management oversight.

"Adequate facilities" means the CAH has facilities that are:

- Designed and maintained in accordance with Federal, State and local laws, regulations and guidelines; and
- Designed and maintained to reflect the scope and complexity of the services it offers in accordance with accepted standards of practice.

Certain areas of the CAH may be required to have external sources responsible for maintaining treatment areas and the CAH will ensure that these services are provided to provide a safe environment for all staff, patient and visitors.

The CAH'S departments or services responsible for the CAH'S building and equipment maintenance (both facility equipment and patient care equipment) must be incorporated into the CAH'S quality management oversight and be in compliance with the requirements.

"Clean and orderly" means an uncluttered physical environment where patients and staff can function safely. Equipment and supplies are stored in proper spaces, not in corridors. Spills are not left unattended. There are no floor obstructions. The area is neat and well kept. There is no evidence of peeling paint, visible water leaks, or plumbing problems

Facilities

The CAH must ensure that the condition of the physical plant and overall CAH environment is developed and maintained in a manner that will ensure the safety and wellbeing of patients.

"Clean and orderly" means an uncluttered physical environment where patients and staff can function safely. Equipment and supplies are stored in proper spaces, not in corridors. Spills are not left unattended. There are no floor obstructions. The area is neat and well kept. There is no evidence of peeling paint, visible water leaks, or plumbing

problems

This includes ensuring that routine and preventive maintenance and testing activities are performed as necessary, in accordance with Federal and State laws, regulations, guidelines and manufacturer's recommendations. The routine and preventive maintenance and testing activities should be incorporated into the CAH's quality management oversight process.

"Adequate facilities" means the CAH has facilities that are:

- *Designed and maintained in accordance with Federal, State and local laws, regulations and guidelines; and*
- *Designed and maintained to reflect the scope and complexity of the services it offers in accordance with accepted standards of practice.*

Supplies

The CAH must ensure that supplies are maintained to provide an acceptable level of safety and quality for patients. Among other things, this means that the CAH identifies the supplies required to meet its patients' needs for both day-to-day operations as well as those supplies that are likely to be needed in likely emergency situations, such as mass casualty events resulting from natural disasters, mass trauma, disease outbreaks, etc. Further, the CAH must make adequate provisions to ensure the availability of those supplies when needed.

Supplies must be stored in such a manner to ensure their safety (protection against theft or damage, contamination, or deterioration), as well as that the storage practices do not violate fire codes or otherwise endanger patients (storage of flammables, blocking passageways, storage of contaminated or dangerous materials, safe storage practices for poisons, etc.).

Equipment

In order to ensure all essential mechanical, electrical and patient-care equipment is maintained in safe operating condition, the CAH must identify the essential 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 CAH must make adequate provisions to ensure the availability and reliability of equipment needed for its operations and services. Equipment includes both facility equipment, which supports the physical environment of the CAH (e.g., elevators, generators, air handlers, medical gas systems, air compressors and vacuum systems, electrical systems, etc.) and medical equipment, which are devices intended to be used for diagnostic, therapeutic or monitoring care provided to a patient by the CAH (e.g., IV infusion equipment, ventilators, laboratory equipment, surgical devices, etc.).

All equipment must be inspected and tested for performance and safety before initial use and after major repairs or upgrades. Equipment to be used for the first time should be inspected and tested for performance and safety in accordance with manufacturer recommendations, unless a sufficient amount of maintenance history has been acquired, either based on its contractor's records or available publicly from nationally recognized sources, to determine whether the alteration of initial inspection and testing activities and frequencies would be safe.

All equipment must be inspected, tested, and maintained to ensure their safety, availability and reliability. Equipment maintenance activities may be conducted using CAH personnel, contracted services, or through a combination of CAH personnel and contracted services. Individual(s) responsible for overseeing the development, implementation, and management of equipment maintenance programs and activities must be qualified. The CAH maintains records of CAH personnel qualifications and is able to demonstrate how it assures all personnel, including contracted personnel, are qualified.

All equipment maintenance policies, procedures and programs, as well as specific equipment maintenance inventories, activities and schedules fall under the purview of the CAH's clinical maintenance personnel, safety department personnel or other personnel who have been assigned responsibility for equipment maintenance by CAH leadership.

CAHs comply with this regulation when they follow the manufacturer-recommended maintenance activities and schedule. CAHs may choose to perform maintenance more frequently than the manufacturer recommends but must use the manufacturer-recommended maintenance activities in such cases. When equipment is maintained in

accordance with the manufacturer's recommendations, the CAH must maintain documentation of those recommendations and the CAH's associated maintenance activity for the affected equipment.

Alternate Equipment Management (AEM) Program

A CAH may, under certain conditions, use equipment maintenance activities and frequencies that differ from those recommended by the manufacturer. CAHs that choose to employ alternate maintenance activities and/or schedules must develop, implement, and maintain a documented AEM program to minimize risks to patients and others in the CAH associated with the use of facility or medical equipment. The AEM program must be based on generally accepted standards of practice for facility or medical equipment maintenance. An example of guidelines for a medical equipment maintenance program may be found in the American National Standards Institute/ Association for the Advancement of Medical Instrumentation document: ANSI/AAMI EQ 56:1999/ (R) 2013, Recommended Practice for a Medical Equipment Management Program. Likewise, an example of guidelines for physical plant equipment may be found in the American Society for Healthcare Engineering (ASHE) 2009 document: Maintenance Management for Health Care Facilities. There may be similar documents issued by other nationally recognized organizations which CAHs might choose to reference.

Decision to Place Equipment in an AEM Program

The determination of whether it is safe to perform facility or medical equipment maintenance without following the equipment manufacturer recommendations must be made by qualified personnel, regardless of whether they are CAH employees or contractors. CAHs must be able to verify that qualified personnel, employees or contractors, are making the decisions to place equipment in the AEM program, performing the risk-based assessments, establishing the alternate equipment maintenance requirements, managing the AEM program, and performing the maintenance in accordance with the AEM policies and procedures.

In the case of medical equipment, a clinical or biomedical technician or engineer would be considered qualified. Highly specialized or complex equipment may require specialized knowledge or training in order for personnel to be considered qualified to make a decision to place such equipment in an AEM program.

In the case of facility equipment, a Healthcare Facility Management professional (e.g., facility manager, director of facilities, vice president of facilities) would be considered qualified.

The CAH must maintain records of the qualifications of CAH personnel who make decisions on placing equipment in an AEM program and must be able to demonstrate how they assure contracted personnel making such decisions are qualified.

In determining whether or not to include equipment in an AEM program, and which maintenance strategies to use in developing maintenance activities and frequencies for particular equipment, the CAH must take into account the typical health and safety risks associated with the equipment's use. Note that the risk may vary for the same type of equipment, depending on the patient care setting within the CAH where it is used.

A CAH is expected to identify any equipment in its AEM program which is critical equipment, i.e., biomedical or physical plant equipment for which there is a risk of serious injury or death to a patient or staff person should the equipment fail. Surveyors must focus their review of a CAH's AEM program on critical equipment in that program and the CAH's documentation of the factors and evidence it considered in developing an AEM strategy for that equipment.

Factors for a hospital to consider when evaluating the risks associated with a particular type of equipment include, but are not limited to:

- *How the equipment is used and the likely consequences of equipment failure or malfunction - would failure or malfunction of the equipment hospital-wide or in a particular setting be likely to cause harm to a patient or a staff person?*
- *How serious is the harm likely to be? For example, a slightly miscalibrated scale in an adult internal medicine outpatient clinic might not present significant risk of harm. However, a miscalibrated scale in a neonatal intensive care unit could have very serious consequences for patient care.*
- *How widespread is the harm likely to be? For example, are many patients exposed to the equipment, resulting in harm due to failure impacting more patients or staff? If harm would be widespread, even if the harm to each affected individual is not serious, this would be a cause for concern.*

Information, if available, on the manufacturer's equipment maintenance recommendations, including the rationale for the manufacturer's recommendations;

- Maintenance requirements of the equipment:
 - Are they simple or complex?
 - Are the manufacturer's instructions and procedures available in the CAH, and if so can the CAH explain how and why it is modifying the manufacturer's instructions?
 - If the manufacturer's instructions are not available in the CAH, how does the CAH assess whether the AEM uses appropriate maintenance strategies?
 - How readily can the CAH validate the effectiveness of AEM methods for particular equipment? For example, can the CAH 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 CAH (or its third-party contractor), or on evidence publicly reported by credible sources outside the CAH, which:
 - Provides the number, frequency and nature of previous failures and service requests?
 - Indicates use of an AEM strategy does not result in degraded performance of the equipment?

Generally multiple factors must be considered, since different types of equipment present different combinations of severity of potential harm and likelihood of failure. The CAH is expected to be able to demonstrate to a surveyor the factors it considered in its risk assessment for equipment placed in its AEM program.

Equipment not Eligible for Placement in the AEM Program

Some equipment may not be eligible for placement in the AEM program, for one or more of the following reasons:

- Other Federal law (for example, regulations promulgated by another Federal agency) or State law may require that facility or medical equipment maintenance, inspection and testing be performed strictly in accordance with the manufacturer's recommendations, or may establish other, more stringent maintenance requirements. In these instances, the CAH must comply with these other Federal or State requirements, but State Surveyors conducting Federal surveys assess compliance only with the CAH CoPs.
- Other CoPs require adherence to manufacturer's recommendations and/or set specific standards which preclude their inclusion in an AEM program. For example:
 - The National Fire Protection Association Life Safety Code (LSC) requirements incorporated by reference at 42 CFR 485.623(d) have provisions that are pertinent to equipment maintenance, and compliance with these requirements are assessed on Federal surveys. Further, §485.623(d)(7)(v) requires CAHs to adhere to the manufacturer's maintenance guidelines for alcohol-based hand-rub dispensers. Compliance with these requirements is assessed on Federal surveys.
- Imaging/radiologic equipment, whether used for diagnostic or therapeutic purposes, must be maintained per manufacturer's recommendations.
- The equipment is a medical laser device. It should be noted that for medical lasers the U.S. Food and Drug Administration requires manufacturers to provide a schedule of maintenance and adequate instructions for service adjustments and service procedures to purchasers and, at cost, to any

other parties requesting them.

- New equipment for which sufficient maintenance history, either based on the CAH's own or its contractor's records, or available publicly from nationally recognized sources, is not available to support a risk-based determination must not be immediately included in the AEM program. New equipment must be maintained in accordance with manufacturer recommendations until a sufficient amount of maintenance history has been acquired to determine whether the alteration of maintenance activities or frequencies would be safe. If a CAH later transitions the equipment to a risk-based maintenance regimen different than the manufacturers' recommendations, the CAH must maintain evidence that it has first evaluated the maintenance track record, risks, and tested the alternate regimen.

Alternative Maintenance Frequencies or Activities

Maintenance strategies are various methodologies used for determining the most efficient and effective maintenance activities and frequencies. Manufacturers' recommendations may be based on one or more such strategies. A CAH may also use one or more maintenance strategies for its AEM program in order to determine the appropriate maintenance, inspection, and testing activities and frequencies, based upon the nature of the equipment and the level of risk it presents to patient or staff health and safety. The risk to patient health and safety that is considered in developing alternative maintenance strategies must be explained and documented in the AEM program.

In developing AEM maintenance strategies, CAHs 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 CAH's (or its third-party contractor's) own experience. Maintenance strategies may be applied to groups or to individual pieces of equipment.

The CAH is expected to adhere strictly to the AEM activities or strategies it has developed.

Background Information on Types of Maintenance Strategies

- **Preventive Maintenance (Time-based Maintenance)** – a maintenance strategy where maintenance activities are performed at scheduled time intervals to minimize equipment degradation and reduce instances where there is a loss of performance. Most preventive maintenance is "interval-based maintenance" performed at fixed time intervals (e.g., annual or semi-annual), but may also be "metered maintenance" performed according to metered usage of the equipment (e.g., hours of operation). In either case, the primary focus of preventive maintenance is reliability, not optimization of cost-effectiveness. Maintenance is performed systematically, regardless of whether or not it is needed at the time. Example: Replacing a battery every year, after a set number of uses or after running for a set number of hours, regardless.
- **Predictive Maintenance (Condition-based Maintenance)** – a maintenance strategy that involves periodic or continuous equipment condition monitoring to detect the onset of equipment degradation. This information is used to predict future maintenance requirements and to schedule maintenance at a time just before equipment experiences a loss of performance. Example: Replacing a battery one year after the manufacturer's recommended replacement interval, based on historical monitoring that has determined the battery capacity does not tend to fall below the required performance threshold before this extended time.
- **Reactive Maintenance (Corrective, Breakdown or Run-to-Failure Maintenance)** – a maintenance strategy based upon a "run it until it breaks" philosophy, where maintenance or replacement is performed only after equipment fails or experiences a problem. This strategy may be acceptable for equipment that is disposable or low cost and presents little or no risk to health and safety if it fails. Example: Replacing a battery after equipment failure when the equipment has little negative health and safety consequences associated with a failure and there is a replacement readily available in supply.
- **Reliability-Centered Maintenance** – a maintenance strategy that not only considers equipment condition, but also considers other factors unique to individual pieces of equipment, such as equipment function, consequences of equipment failure, and the operational environment. Maintenance is performed to optimize reliability and cost effectiveness. Example: Replacing a battery in an ambulance defibrillator more frequently than the same model used at a nursing

station, since the one in the ambulance is used more frequently and is charged by an unstable power supply.

Maintenance Tools

Tools (e.g., hand tools, test equipment, software, etc.) necessary for performing equipment maintenance must be available and maintained to ensure that measurements are reliable. Tools used for maintenance are not required to be those specifically recommended by the manufacturer, but tools utilized must be capable of providing results equivalent to those required by the equipment manufacturer.

AEM Program Documentation

For each type of equipment subject to the AEM program, there must be documentation indicating:

- The pertinent types and level of risks to patient or staff health and safety;
- Alternate maintenance activities, and the maintenance strategy and any other rationale used to determine those activities; the differences from the manufacturer's recommended maintenance activities are made explicit, unless the CAH is unable to obtain the manufacturer's maintenance recommendations, due to the age of the equipment or the manufacturer's restricting the availability of its recommendations;
- Alternate maintenance frequencies to be used, if any, and the maintenance strategy and any other rationale used to determine those frequencies. For equipment identified as presenting a very low risk to patient or staff safety, it could be acceptable to not set a particular frequency but instead indicate a less specific approach, for example, an interval range, such as "every 12 – 24 months." It could also be acceptable to employ periodic "departmental sweeps" for such very low risk equipment, where equipment functioning is sampled, and operators are polled about its functionality.
- The date when AEM program maintenance activities were performed and, if applicable, further actions required/taken; and
- Documentation of any equipment failures (not including failures due to operator error), including whether there was resulting harm to an individual. (Note: equipment failure that is due to operator error and which results in an adverse event or near miss must be documented in accordance with the QAPI CoP, as part of the CAH's required tracking of patient safety-related incidents. However, there is no requirement to include operator failures in equipment maintenance documentation.)

When the CAH has multiple identical equipment items, the documentation may be generic to that type of equipment, except that documentation of maintenance activities performed must be specific to each item of equipment.

Evaluating Safety and Effectiveness of the AEM Program

The CAH must have policies and procedures which address the effectiveness of its AEM program. In evaluating the effectiveness of the AEM program, the CAH 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 CAH facility and medical equipment essential to the operation of the CAH, 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 essential 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 CAH, e.g., "15 vacuum cleaners for cleaning patient rooms and common areas."

If the CAH is using an AEM program, the equipment managed through that program must be readily separately identifiable as subject to AEM. Critical equipment, whether in an AEM program or not, must also be readily identified as such.

To facilitate effective management, a well-designed equipment inventory contains the following information for all equipment included. However, CAHs 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 CAH believes may be useful for proper management of the equipment.

This standard shall apply to all locations of the CAH, all campuses, all off-site facilities and all provider-based activities. The CAH's department that is responsible for the CAH's buildings and equipment (both facility equipment and patient care equipment) must be evaluated for maintaining the appropriate work environment and related infrastructure to be safe for all staff, patients and visitors.

Certain areas of the CAH may be required to have external sources responsible for maintaining treatment areas. The CAH will ensure that these services are provided in a safe environment for all staff, patient and visitors.

Surveyor Guidance:

The survey team will delegate one surveyor to review and evaluate the physical environment of the CAH, however, each surveyor, during their respective review of areas within the CAH, should assess the CAH'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 CAH 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 CAH's routine and preventive maintenance schedules to determine that ongoing maintenance inspections are performed and that necessary repairs are completed.

Verify that the CAH has developed and implemented a comprehensive plan to ensure that the safety and wellbeing of patients are assured during emergency situations.

Observe the facility layout and determine if the patient's needs are met. Toilets, sinks, specialized equipment, etc. should be accessible.

Interview personnel in charge of equipment maintenance:

- Determine if the CAH has identified equipment that is essential for both regular operations and in an emergency situation.
- Determine if the CAH has made adequate provisions to ensure the availability of those and equipment when needed.

PE.2 LIFE SAFETY MANAGEMENT

SR.1 Except as otherwise provided in NIAHO® CAH Accreditation Requirements-

SR.1a The CAH must meet the applicable provisions and must 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).

SR.1b Corridor doors and doors to rooms containing flammable or combustible materials must be provided with positive latching hardware. Roller latches are prohibited on such doors.

SR.2 In consideration of a recommendation by the State survey agency or Accrediting Organization or at the discretion of the Secretary, CMS may waive, for periods deemed appropriate, specific provisions of the Life Safety Code, which would result in unreasonable hardship upon a CAH, but only if the waiver will not adversely affect the health and safety of the patients.

SR.2a After consideration of State survey agency findings, CMS may waive specific provisions of the Life Safety Code that, if rigidly applied, would result in unreasonable hardship on the CAH, but only if the waiver does not adversely affect the health and safety of patients.

SR.3 The CAH must have written fire control plans that contain provisions for prompt reporting of fires; extinguishing fires; protection of patients, personnel and guests; evacuation; and cooperation with firefighting and emergency management authorities; including training of staff in the following areas:

SR.3a Use of alarms

SR.3b Transmission of alarm to fire department

SR.3c Response to alarms

SR.3d Isolation of fire

SR.3e Evacuation of immediate area SR.3f Evacuation of smoke compartment

SR.3g Preparation of floors and building for evacuation

SR.3h Extinguishment of fire

SR.4 The Life Safety Management System shall have procedures for the proper routine storage and prompt disposal of trash.

SR.5 The CAH shall maintain written evidence of regular inspection and approval by State or local fire control agencies.

- SR.6 Health care occupancies shall conduct unannounced fire drills, but not less than one (1) drill per shift per calendar quarter that transmits a fire alarm signal and simulates an emergency fire condition. When fire drills are conducted between 9:00 p.m. (2100 hours) and 6:00 a.m. (0600 hours), a coded announcement shall be permitted to be used instead of audible alarms.
- Business occupancies shall conduct at least one unannounced fire drill annually per shift.
- SR.6a Fire drills must be thoroughly documented and evaluate the CAH's knowledge to the items listed in PE.2, SR.3.
- SR.6a (1) At least annually, the CAH shall evaluate the effectiveness of the fire drills. The report of effectiveness shall be forwarded to QMS oversight
- SR.7 The CAH shall address applicable Alternative Life Safety Measures (ALSM) that shall be implemented whenever life safety features, systems, or processes are impaired or deficient are created or occur. Thorough documentation is required.
- SR.7a All alternative life safety measures must be submitted for acceptance by the authority having local jurisdiction. Life safety measures for redundant and/or common minor renovations/repairs/testing may be pre-approved for the specific task by the AHJ.
- SR.8 The CAH shall require that Life Safety systems (e.g., fire suppression, notification, and detection equipment) shall be tested and inspected (including portable systems).
- SR.9 When a sprinkler system is shut down for more than 10 hours, the CAH must:
- SR.9a Evacuate the building or portion of the building affected by the system outage until the system is back in service,
- SR.9b Or, establish a fire watch until the system is back in service.
- SR.10 Buildings must have an outside window or outside door in every sleeping room, and for any building constructed after July 5, 2016 the sill height must not exceed 36 inches above the floor. Windows in atrium walls are considered outside windows for the purposes of this requirement.
- SR.10a The sill height requirement does not apply to newborn nurseries and rooms intended for occupancy for less than 24 hours.
- SR.10b Special nursing care areas of new occupancies shall not exceed 60 inches.
- SR.11 The CAH shall require a process for reviewing the acquisition of bedding, draperies, furnishings and decorations for fire safety.
- SR.12 Construction, Repair, and Improvement operations shall involve the following activities:
- SR.12a During construction, repairs, or improvement operations, or otherwise affecting the space, the Guidelines for Design and Construction of Hospitals and Health Care Facilities, 2014 edition, published by the American Institute of Architects shall be consulted for designing purposes.
- SR.12b The CAH 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.12c 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.12d 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.

Interpretive Guidelines:

*The Life Safety Management System should include in the elements of **SR.3e** a written barrier protection plan for the preservation of the integrity of hospital smoke and fire barriers. The plan shall include:*

- a Name(s) of Responsible hospital staff for barrier protection program*
- b Requirement for written permission for anyone (including all hospital staff, contractors and vendors) to penetrate a smoke or fire barrier wall, ceiling or floor*
- c Input from Infection Control and Prevention Practitioner on critical clinical areas prior to issuance of written permit for performing work on barriers*
- d Establishment of monitoring process to ensure all work is completed correctly*

The CAH, regardless of size or number of beds, shall meet the applicable provisions of the 2012 National Fire Protection Association (NFPA) 101- Life Safety Code (LSC), the 2012 edition of the NFPA 99-Health Care Facilities Code (HCFC) for all inpatient care locations, emergency departments, and outpatient care locations.

Note: In order for SR.3 to be applicable, the appropriate supporting documentation must be in place.

The CAH will maintain and update, as necessary, a fire control plan that includes the elements of SR.3. The CAH will also have supporting documentation to verify the regular inspection and approval by State or local fire control agencies.

The Life Safety Management System shall:

- Address applicable Alternative Life Safety Measures to be implemented whenever life safety systems, processes, or deficiencies are created or occur;
- Require that Life Safety systems (e.g., fire alarm and detection equipment) shall be is tested and inspected (including portable systems);
- Require a process for reviewing bedding, draperies, furnishings and decorations for fire safety; and,
- Require that a tobacco-free policy be developed and enforced campus-wide. Substantial progress toward complete conformity shall be demonstrated over time.

When construction, repairs, or improvement operations affect the space where CAH processes are carried out, the Guidelines for Design and Construction of Hospitals and Health Care Facilities, 2014 edition (or newer revision if in publication), NFPA 101-2000 standards, and State and local building and fire codes shall be used.

When construction, repairs, or improvement operations impacts occupied areas, the CAH will also make provisions to include, as appropriate, infection control practices to be followed, utility requirements, and account for noise and vibration. The CAH may have also implemented appropriate alternative life safety measures which are required to be approved by the authority having local jurisdiction.

The term trash refers to common garbage as well as bio hazardous waste. The storage and disposal of trash must be in accordance with Federal, State and local laws and regulations (i.e., EPA, OSHA, CDC, State environmental, health and safety regulations). The Radiology requirements address handling and storage of radioactive materials.

Medicare-participating CAHs, regardless of size or number of beds, must comply with the CAH/healthcare Life Safety Code requirements for all inpatient care locations. CAH departments and locations such as emergency departments,

outpatient care locations, etc. must comply with CAH/healthcare Life Safety Code Requirements. Additionally, the CAH must be in compliance with all applicable codes referenced in the Life Safety Code, such as NFPA-99: Health Care Facilities.

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 CAH's written fire control plans to verify they contain the required provisions of the Life Safety Code® or State law.

Review and verify that CAH staff has a process in place to report all fires as required to State officials. In the review of respective areas of the CAH, interview staff throughout the facility to verify knowledge of their role and responsibilities during a fire.

Review and validate the documentation of inspection and approval reports from State and local fire control agencies.

Review and validate that the Life Safety Management System addresses the elements as described within the Interpretive Guidelines.

Verify that CAH staff reported all fires as required to State officials.

The surveyor should validate compliance with the inspection, testing, and maintenance of fire detection, notification, and suppression equipment and systems.

Review areas where current construction, repairs, or improvement operations are taking place and validate that the Guidelines for Design and Construction of Hospitals and Health Care Facilities, NFPA 101-2012 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 CAH has made provisions for the respective elements as described in the Interpretive Guidelines (above).

If there is no renovation or construction taking place within the CAH, verify that the CAH follows a process to follow the Guidelines for Design and Construction of Hospitals and Health Care Facilities, implements alternative life safety measures and includes the infection control practitioner and has the resources to account for utility requirements, and eliminating, to the extent possible, noise and vibration.

Validate there was documentation:

- That the means of egress were checked daily.
- That the means of egress were continuously maintained free from obstructions or impediments.
- That an assessment was performed of work relating to the impact on the occupied area(s) shall be conducted and include provisions for infection control, utility requirements, noise, vibration, and alternate life safety measures.
- That the authority having local jurisdiction approved the alternate life safety measures.

Verify that the CAH has developed and implemented policies for the proper storage and disposal of trash. Verify through observation that staff adhere to these policies and that the CAH has signage, as appropriate.

Survey the entire building occupied by the CAH unless there is a 2-hour firewall separating the space designated as the CAH from the remainder of the building. A 2-hour floor slab does not count; it must be a vertical firewall to constitute a separate building or part of a building.

Review staff training documents and in-service records to validate training.

Interview staff throughout the facility to verify their knowledge of their responsibilities during a fire (this is usually done during the LSC survey, but health surveyors may also verify staff knowledge).

PE.3 SAFETY MANAGEMENT

- SR.1 The CAH shall have processes in place to maintain safe and adequate facilities for its services. Diagnostic and therapeutic facilities must be located for the safety of patients and drugs and biologicals are appropriately stored.
- SR.2 The CAH shall require that facilities, supplies, and equipment be maintained and ensure an acceptable level of safety and quality and that the premises are clean and orderly. The extent and complexity of facilities shall be determined by the services offered.
- SR.3 The CAH shall require proper ventilation, light and temperature controls in pharmaceutical, food preparation, and other appropriate areas.
- SR.4 The CAH shall maintain an environment free of hazards and manages staff activities to reduce the risk of occupational related illnesses or injuries.
- SR.5 The CAH shall require periodic surveillance of the CAH 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.

Interpretive Guidelines:

The CAH will maintain safe and adequate facilities that are designed and maintained in accordance with Federal, State and local laws, regulations and guidelines and reflect the scope and complexity of the services it offers in accordance with accepted standards of practice.

The Safety Management System will require:

- That facilities, supplies, and equipment be maintained and ensure an acceptable level of safety and quality;
- The CAH maintains an environment free of hazards and manages staff activities to reduce the risk of occupational related illnesses or injuries; and,
- A process for addressing safety recalls and alerts.

The CAH shall require periodic surveillance of the CAH grounds to observe safety issues that may be identified and take corrective/preventive action(s) as needed.

There must be proper ventilation in at least the following areas:

- Areas using ethylene oxide, nitrous oxide, gluteraldehydes, xylene, pentamidine, or other potentially hazardous substances;
- Locations where oxygen is transferred from one container to another;
- Isolation rooms and reverse isolation rooms (both must be in compliance with Federal and State laws, regulations, and guidelines such as OSHA, CDC, NIH, etc.);
- Pharmaceutical preparation areas (hoods, cabinets, etc.); and
- Laboratory locations.

There must be adequate lighting in all the patient care, food and medication preparation areas.

Temperature, humidity and airflow in the operating rooms must be maintained within acceptable standards to inhibit bacterial growth and prevent infection 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 American Institute of Architects (AIA) should be incorporated into CAH policy.

The CAH must ensure that an appropriate number of refrigerators and/or heating devices are provided and ensure that food and pharmaceuticals are stored properly and in accordance with nationally accepted guidelines (food) and manufacturer's recommendations (pharmaceuticals).

All eyewashes and emergency showers should be tested and maintained according to the ANSI Z358.1-2009 Standard.

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.

Verify that all food and medication preparation areas are well lit and that pharmaceuticals are stored at temperatures recommended by the product manufacturer.

Verify that each operating room has temperature and humidity control mechanisms, reviewing temperature and humidity tracking logs to ensure that appropriate temperature and humidity levels are maintained.

Verify that the CAH is in compliance with ventilation requirements for patients with contagious airborne diseases, such as tuberculosis, patients receiving treatments with hazardous chemical, surgical areas, and other areas where hazardous materials are stored.

Verify that the CAH has developed and implemented a comprehensive plan to ensure the safety and wellbeing of patients during local emergency situations.

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.

PE.4 SECURITY MANAGEMENT

- SR.1 The CAH shall have processes in place that provides for a secure environment.
- SR.2 The CAH shall provide for identification of patients, employees and others.
- SR.3 The CAH shall address issues related to abduction, elopement, visitors, workplace violence, and investigation of property losses.
- SR.4 The CAH shall establish emergency security procedures to include all hazard events.
- SR.5 The CAH shall require vehicular access to emergency service areas.
- SR.6 The CAH shall require a process for reporting and investigating security related issues.

Interpretive Guidelines:

The organization should have a written, comprehensive workplace violence control and prevention program based on guidelines from national authorities such as the OSHA Publication 3148-04R 2015 Guidelines for Preventing Workplace violence for Healthcare and Social Workers

<https://www.osha.gov/Publications/osha3148.pdf>.

Elements of a Workplace Violence Prevention Program should include but not limited to:

- A Clearly Written Company Workplace Violence Policy Statement
- Establishment of a Threat Assessment Team
- Hazard Assessments
- Workplace Hazard Control and Prevention
- Training and Education
- Incident Reporting, Investigation, Follow-up and Evaluation
- Recordkeeping

Surveyor Guidance:

Review and validate the Security Management System to ensure that it addresses the respective elements as stated within SR.1 – SR.6.

PE.5 HAZARDOUS MATERIAL (HAZMAT) MANAGEMENT

- SR.1 The CAH shall have processes in place to manage hazardous materials and waste.
- SR.2 The CAH shall provide processes to manage the environment, selection, handling, storing, transporting, using, and disposing of hazardous materials and waste.
- SR.3 The CAH shall provide processes to manage reporting and investigation of all spills, exposures, and other incidents.
- SR.4 The CAH monitors staff exposure levels in hazardous environments and reports the results of the monitoring to QMS oversight.
- SR.5 A CAH may install alcohol-based hand rub dispensers in its facility if the dispensers are installed in a manner that adequately protects against inappropriate access.
- SR.6 In anesthetizing locations, which use alcohol-based skin preparations, the CAH will have implemented effective fire risk reductions measures which include:
 - SR.6a The use of unit dose skin prep solutions.
 - SR.6b Application of skin prep follows manufacture/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.
 - SR.6d Verifying that all of the above has occurred prior to initiating the surgical procedure.
- SR.7 All compressed gas cylinders in service and in storage shall be individually-secured and located to prevent mechanical shock from falling or being knocked over.

Interpretive Guidelines:

The term waste refers to common garbage, hazardous material as well as bio-hazardous wastes. The storage and disposal of trash must be in accordance with Federal, State and local laws and regulations (e.g., EPA, OSHA, CDC, 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 must be proper ventilation in at the following areas: Areas using ethylene oxide, nitrous oxide, gluteraldehydes, xylene, pentamidine, or other potentially hazardous substances;

Surveyor Guidance:

Verify that the CAH has developed and implemented policies and processes for the selection, handling, storing, transporting, using, and disposing of hazardous materials and waste in accordance with Federal, State and local laws and regulations (e.g., EPA, OSHA, CDC, State environmental, health and safety regulations).

Review and verify that processes are in place for the reporting and investigation of all spills, exposure and other incidents involving hazardous materials.

Ensure that alcohol-based hand rub dispensers are installed, located and managed in accordance with PE.5; SR.5.

Review documents to ensure employee and environmental monitoring is being conducted.

PE.6 EMERGENCY MANAGEMENT SYSTEM

The CAH must comply with all applicable Federal, State and local emergency preparedness requirements. The CAH must establish and maintain a comprehensive emergency preparedness program that meets the requirements of 42 CFR Section 485.625. The CAH must use an all-hazards approach to develop and maintain a comprehensive emergency preparedness program.

- SR.1 The CAH must have a process in place to coordinate with local authorities for emergencies in the CAH or within the community and region that may impact the CAH's ability to provide services. This may include requirements for the CAH to have appropriate measures in place to account for particular conditions, potential hazards, or other concerns with respect to the location of the CAH.
- SR.2 The CAH must provide a comprehensive Emergency Management System to respond to emergencies in the organization or within the community and region that may impact the organization's ability to provide services.
 - SR.2a The Emergency Management System and plan must be reviewed at least annually and updated as appropriate.
- SR.3 The CAH shall meet the requirements set forth in NFPA 99 (2012), Chapter 12, Emergency Management and the requirements of PE.6, SR. 4-7.
- SR.4 The CAH shall have policies, procedures, and decision criteria for the determination of protection in place or evacuation of patients in the event of a disaster.
- SR.5 The CAH must develop and implement emergency preparedness policies and procedures based on the CAH's emergency plan as required by 42 CFR Section 485.625(a), a risk assessment as required by 42CFR Section 485.625 (a)(1), and the organization's communication plan as required by 42 CFR Section 485.625(c). The policies and procedures must be reviewed and updated at least annually. At a minimum, the policies and procedures must address the following:
 - SR.5a 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, including documentation of the hospital's efforts to contact such officials and, when applicable, its participation in collaborative and cooperative planning efforts.
 - SR.5b 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 must document the specific name and location of the receiving facility or other location.
 - SR.5c A means to shelter in place for patients, staff, and volunteers who remain in the facility.
 - SR.5d Safe evacuation 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.5e A system of medical documentation that preserves patient information, protects confidentiality of patient information, and secures and maintains the availability of records.
- SR.5f The use of volunteers in an emergency and 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.
- SR.5g 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.5h The development and maintenance of an emergency preparedness communication plan that complies with Federal, State, and local laws. The communication plan must include all of the requirements of NFPA 99 (2012), Chapter 12, Emergency Management and must also include:
 - SR.5h (1) Names and contact information for the following:
 - (i) Staff,
 - (ii) Entities providing services under arrangement,
 - (iii) Patients' physicians,
 - (iv) Other hospitals,
 - (v) Volunteers,
 - (vi) Federal, State, tribal, regional, and local emergency preparedness staff, and
 - (vii) Other sources of assistance
 - SR.5h (2) Primary and alternate means for communicating with the following:
 - (i) Organization staff.
 - (ii) Federal, State, tribal, regional, and local emergency management agencies.
- SR.5i A means, in the event of an evacuation, to release patient information as permitted under 45 CFR Section 164.510(b)(1)(ii),
- SR.5j A means of providing information about the general condition and location of patients under the facility's care as permitted under 45 CFR Section 164.510(b)(4).
- SR.6 In addition to the requirements of NFPA 99 (2012), Chapter 12, Emergency Management, the CAH must comply with the conditions of participation set forth in 42 CFR Section 485.625 (d)(2) regarding exercises to test the emergency plan:
 - SR.6a Participate in a full-scale exercise that is community-based or when a community-based exercise is not accessible, an individual, facility-based. If the hospital experiences an actual natural or man-made emergency that requires activation of the emergency plan, the hospital is exempt from engaging in a community-based or individual, facility-based full-scale exercise for 1 year following the onset of the actual event.
 - SR.6b Analyze the hospital's response to and maintain documentation of all drills, table top exercises, and emergency events, and revise the hospital's emergency plan, as needed.
- SR.7 In addition to the requirements of NFPA 99 (2012), Chapter 12, Emergency Management, the CAH must comply with the conditions of participation set forth in 42 CFR Section 485.625 regarding the implementation of emergency and standby power systems based on the CAH's emergency plan:

- SR.7a The emergency generator must 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.7b The CAH must implement the emergency power system inspection, testing, and maintenance requirements found in the Health Care Facilities Code, NFPA 110, and Life Safety Code.
- SR.7c CAH's that maintain an onsite fuel source to power emergency generators must have a plan for how it will keep emergency power systems operational during the emergency, unless it evacuates.
- SR.8 If a CAH 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 CAH may choose to participate in the healthcare system's coordinated emergency preparedness program. If elected, the unified and integrated emergency preparedness program must do all of the following:
 - SR.8a Demonstrate that each separately certified facility within the system actively participated in the development of the unified and integrated emergency preparedness program.
 - SR.8b Be developed and maintained in a manner that takes into account each separately certified facility's unique circumstances, patient populations, and services offered.
 - SR.8c 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.8d Include a unified and integrated emergency plan that meets the requirements of PE.1 and 42 CFR Section 485.625(a)(2), (3), and (4). The unified and integrated emergency plan must also be based on and include the following:
 - SR.8d (i) A documented community-based risk assessment, utilizing an all-hazards approach.
 - SR.8d (ii) A documented individual facility-based risk assessment for each separately certified facility within the health system, utilizing an all-hazards approach.
 - SR.8e Include integrated policies and procedures that meet the requirements set forth in 42 CFR Section 485.625(b) and a coordinated communication plan, and training and testing programs that meet the requirements of 42 CFR Section 465.625 (c) and (d) (see PE.6 SR.1-3).
- SR.9 The CAH will coordinate with local and regional healthcare facilities and public health agencies in cases of CAH, community, or regional crisis for utilization of resources (space, personnel, and equipment). The CAH will have memorandums of understanding or provisions through other arrangements for utilization of resources as necessary.

Interpretive Guidelines:

Assuring the safety and wellbeing of patients would include developing and implementing appropriate emergency preparedness plans and capabilities in accordance with NFPA 99, 2012. The CAH must develop and implement a plan to ensure that the safety and wellbeing of patients are assured during emergency situations.

*The CAH **must** coordinate with Federal, State, regional, and local emergency preparedness and health authorities to identify likely risks for their area (e.g., natural disasters, bioterrorism threats, disruption of utilities such as water, sewer, electrical communications, fuel; nuclear accidents, industrial accidents, and other likely mass casualties, etc.) and to develop appropriate responses that will assure the safety and wellbeing of patients. In addition to or in alignment with the text in NFPA 99, 2012 Chapter 12, the following issues should be considered when developing the*

comprehensive emergency plans(s):

- The differing needs of each location where the certified CAH operates;
- The special needs of patient populations treated at the CAH (e.g., patients with psychiatric diagnosis, patients on special diets, newborns, etc.);
- Security of patients and walk-in patients;
- Security of supplies from misappropriation;
- Pharmaceuticals, food, other supplies and equipment that may be needed during emergency/disaster situations;
- Communication to external entities if telephones and computers are not operating or become overloaded (e.g., ham radio operators, community officials, other healthcare facilities if transfer of patients is necessary, etc.);
- Communication among staff within the CAH itself;
- Qualifications and training needed by personnel, including healthcare staff, security staff, and maintenance staff, to implement and carry out emergency procedures;
- Identification, availability and notification of personnel that are needed to implement and carry out the CAH emergency plans;
- Identification of community resources, including lines of communication and names and contact information for community emergency preparedness coordinators and responders;
- Transfer or discharge of patients to home, other healthcare settings, or other hospitals;
- Transfer of patients with CAH equipment to another CAH or healthcare setting;
- Methods to evaluate repairs needed and to secure various likely materials and supplies to effectuate repairs, and,
- Provisions if gas, water, electricity supply is shut off to the community.

The CAH must provide for an Emergency Management System in order to respond to emergencies in the CAH or that occur in the community that impact the CAH's ability to provide services.

The CAH must comply with the applicable provisions of the Life Safety Code®, National Fire Protection Amendments (NFPA) 101, 2012 Edition and references, such as, NFPA-99, 2012: Health Care Facilities, Chapter 12, Emergency Management, as applicable.

In order to prepare for such an emergency, the CAH must conduct a hazard vulnerability analysis to identify potential emergencies or other circumstances that may impact the CAH and the community. The CAH must maintain documentation that this analysis has been conducted and that the CAH has prioritized activities to address and prepare for these vulnerabilities.

Emergency management exercises shall be based upon the most probable emergencies or other circumstances that may impact the CAH and the community. An After-Action Report shall be created after each exercise documenting opportunities for improvement. The CAH's emergency management plan shall be revised based upon the identified opportunities for improvement.

The "community" represents local, regional, State, Federal public safety forces and/or public health agencies.

Surveyor Guidance:

Review and verify that the CAH has developed and implemented a comprehensive plan to ensure that the safety and wellbeing of patients are assured during local emergency situations. This plan must address the elements listed above

within the Interpretive Guidelines.

Review and validate that the CAH has conducted a hazard vulnerability analysis to identify potential emergencies in the CAH and the community. Determine the method used to prioritize and make preparations to address the potential hazards to the CAH and community.

Review and validate:

- That the CAH has conducted or involved in appropriate emergency management exercises
- That after-action reports identified opportunities for improvements
- That the CAH revised its emergency management plan according to the identified opportunities for improvement.

How does the CAH ensure that all personnel on its staff, including new additions to the staff, are trained to manage non-medical emergencies?

PE.7 MEDICAL EQUIPMENT MANAGEMENT

- SR.1 The CAH shall establish processes for the acquisition, safe use, and appropriate selection of equipment.
- SR.2 The CAH shall address issues related to the CAH's initial service inspection, the orientation, and the demonstration of use for rental or physician owned equipment.
- SR.3 The CAH shall address criteria for the selection of equipment.
- SR.4 The CAH shall address incidents related to serious injury or illness or death (See SMDA 1990).
- SR.5 The CAH shall have a process in place for reporting and investigating equipment management problems, failures, and user errors.
- SR.6 The CAH shall have a process in place for determining timing and complexity of medical equipment maintenance.
- SR.7 The CAH shall have a process in place for receiving and responding to recalls and alerts.

Interpretive Guidelines:

The CAH will ensure that the facilities are maintained to ensure an acceptable level of safety and quality.

There must be a regular periodic maintenance and testing program for medical devices. A qualified individual such as a clinical or biomedical engineer, or other qualified maintenance person must monitor, test, calibrate and maintain the equipment periodically in accordance with the manufacturer's recommendations, risk assessments and Federal and State laws and regulations. Equipment maintenance may be conducted using CAH staff, contracts, or through a combination of CAH staff and contracted services.

Equipment includes both facility equipment (e.g., elevators, generators, air handlers, medical gas systems, air compressors and vacuum systems, etc.) and medical equipment (e.g., biomedical equipment, radiological equipment, patient beds, stretchers, IV infusion equipment, ventilators, laboratory equipment, etc.).

The equipment to be maintained would encompass the CAH's need for medical equipment (e.g. biomedical equipment, radiological equipment, patient beds, stretchers, IV infusion equipment, ventilators, laboratory equipment) for both day-to-day operations and equipment that would be needed in likely emergency/disaster situations such as mass casualty events resulting from natural disasters, mass trauma, disease outbreaks, internal disasters, and that the CAH makes adequate provisions to ensure the availability of that equipment when needed.

The CAH will have a process in place to effectively manage medical equipment that addresses the following:

- Issues related to use of demonstration or rental equipment and how appropriate training is provided

to ensure safe operation;

- Defined criteria for the selection of equipment;
- The process of reporting and investigating incidents related to serious injury or illness or death (See SMDA 1990);
- A process for reporting and investigating equipment management problems, failures, and user errors;
- a process for determining timing and complexity of medical equipment maintenance; and,
- a process of receiving and responding to recalls and alerts

Equipment

Medical Equipment must be maintained to ensure an acceptable level of safety and quality. In order to ensure an acceptable level of safety and quality, the CAH must identify the equipment required to meet its patients' needs for both day-to-day operations and in a likely emergency/disaster situation, such as mass casualty events resulting from natural disasters, mass trauma, disease outbreaks, internal disasters, etc.

In addition, the CAH must make adequate provisions to ensure the availability and reliability of equipment needed for its operations and services. Equipment includes both facility equipment, which supports the physical environment of the CAH (e.g., elevators, generators, air handlers, medical gas systems, air compressors and vacuum systems, etc.) and medical equipment, which are devices intended to be used for diagnostic, therapeutic or monitoring care provided to a patient by the CAH (e.g., IV infusion equipment, ventilators, laboratory equipment, surgical devices, etc.).

All equipment must be inspected and tested for performance and safety before initial use and after major repairs or upgrades.

All equipment must be inspected, tested, and maintained to ensure their safety, availability and reliability. Equipment maintenance activities may be conducted using CAH personnel, contracted services, or through a combination of CAH personnel and contracted services.

Individual(s) responsible for overseeing the development, implementation, and management of equipment maintenance programs and activities must be qualified. The CAH maintains records of CAH personnel qualifications and is able to demonstrate how it assures all personnel, including contracted personnel, are qualified.

All equipment maintenance policies, procedures and programs, as well as specific equipment maintenance inventories, activities and schedules fall under the purview of the CAH's clinical maintenance personnel, safety department personnel or other personnel who have been assigned responsibility for equipment maintenance by CAH leadership.

CAHs comply with this regulation when they follow the manufacturer-recommended maintenance activities and schedule. CAHs may choose to perform maintenance more frequently than the manufacturer recommends, but must use the manufacturer-recommended maintenance activities in such cases. When equipment is maintained in accordance with the manufacturer's recommendations, the CAH must maintain documentation of those recommendations and the CAH's associated maintenance activity for the affected equipment.

Alternate Equipment Management (AEM) Program

A CAH may, under certain conditions, use equipment maintenance activities and frequencies that differ from those recommended by the manufacturer. CAHs that choose to employ alternate maintenance activities and/or schedules must develop, implement, and maintain a documented AEM program to minimize risks to patients and others in the CAH associated with the use of facility or medical equipment. The AEM program must be based on generally accepted standards of practice for facility or medical equipment maintenance. An example of guidelines for a medical equipment maintenance program may be found in the American National Standards Institute/ Association for the Advancement of Medical Instrumentation document: ANSI/AAMI EQ 56:1999/ (R) 2013, Recommended Practice for a Medical Equipment Management Program. Likewise, an example of guidelines for physical plant equipment may be found in the American Society for Healthcare Engineering (ASHE) 2009 document: Maintenance Management for Health Care Facilities. There may be similar documents issued by other nationally

recognized organizations which CAHs might choose to reference.

Decision to Place Equipment in an AEM Program

The determination of whether it is safe to perform facility or medical equipment maintenance without following the equipment manufacturer recommendations must be made by qualified personnel, regardless of whether they are CAH employees or contractors. In the case of medical equipment, a clinical or biomedical technician or engineer would be considered qualified. Highly specialized or complex equipment may require specialized knowledge or training in order for personnel to be considered qualified to make a decision to place such equipment in an AEM program. In the case of facility equipment, a Healthcare Facility Management professional (facility manager, director of facilities, vice president of facilities) would be considered qualified.

The CAH must maintain records of the qualifications of CAH personnel who make decisions on placing equipment in an AEM program and must be able to demonstrate how they assure contracted personnel making such decisions are qualified.

In determining whether or not to include equipment in an AEM program, and which maintenance strategies to use in developing maintenance activities and frequencies for particular equipment, the CAH must take into account the typical health and safety risks associated with the equipment's use. Note that the risk may vary for the same type of equipment, depending on the patient care setting within the CAH where it is used.

A CAH is expected to identify any equipment in its AEM program which is "critical equipment," i.e., biomedical or physical plant equipment for which there is a risk of serious injury or death to a patient or staff person should the equipment fail. Surveyors must focus their review of a CAH's AEM program on critical equipment in that program and the CAH's documentation of the factors and evidence it considered in developing an AEM strategy for that equipment.

Factors for a CAH 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 CAH-wide or in a particular setting be likely to cause harm to a patient or a staff person?
- How serious is the harm likely to be? For example, a slightly miscalibrated scale in an adult internal medicine outpatient clinic might not present significant risk of harm. However, a miscalibrated scale in a neonatal intensive care unit could have very serious consequences for patient care.
- How widespread is the harm likely to be? For example, are many patients exposed to the equipment, resulting in harm due to failure impacting more patients or staff? If harm would be widespread, even if the harm to each affected individual is not serious, this would be a cause for concern.
- Information, if available, on the manufacturer's equipment maintenance recommendations, including the rationale for the manufacturer's recommendations.

Maintenance Requirements of the Equipment

- Are they simple or complex?
- Are the manufacturer's instructions and procedures available in the CAH, and if so can the CAH explain how and why it is modifying the manufacturer's instructions?
- If the manufacturer's instructions are not available in the CAH, how does the CAH assess whether the AEM uses appropriate maintenance strategies?
- How readily can the CAH validate the effectiveness of AEM methods for particular equipment? For example, can the CAH 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 CAH (or its third-party contractor), or on evidence publicly reported by credible sources outside the CAH, which:
- Provides the number, frequency and nature of previous failures and service requests?
- Indicates use of an AEM strategy does not result in degraded performance of the equipment?

Generally multiple factors must be considered, since different types of equipment present different combinations of severity of potential harm and likelihood of failure. The CAH is expected to be able to demonstrate to a surveyor the factors it considered in its risk assessment for equipment placed in its AEM program.

Equipment not Eligible for Placement in the AEM Program

Some equipment may not be eligible for placement in the AEM program, for one or more of the following reasons:

- Other Federal law (for example, regulations promulgated by another Federal agency) or State law may require that facility or medical equipment maintenance, inspection and testing be performed strictly in accordance with the manufacturer's recommendations, or may establish other, more stringent maintenance requirements.
- In these instances, the CAH must comply with these other Federal or State requirements, but State Surveyors conducting Federal surveys assess compliance only with the CAH Conditions of Participation (CoPs).
- Other CoPs require adherence to manufacturer's recommendations and/or set specific standards which preclude their inclusion in an AEM program. For example:
 - *The National Fire Protection Association Life Safety Code (LSC) requirements incorporated by reference at 42 CFR 482.41(b) has some provisions that are pertinent to equipment maintenance, and compliance with these requirements are assessed on Federal surveys. Further, §482.41(b)(9)(v) requires CAHs to adhere to the manufacturer's maintenance guidelines for alcohol-based hand-rub dispensers. Compliance with these requirements is assessed on Federal surveys.*
- Imaging/radiologic equipment, whether used for diagnostic or therapeutic purposes, is governed by 42 CFR 482.26(b)(2) and must be maintained per manufacturer's recommendations.
- The equipment is a medical laser device. It should be noted that for medical lasers the U.S. Food and Drug Administration requires manufacturers to provide a schedule of maintenance and adequate instructions for service adjustments and service procedures to purchasers and, at cost, to any other parties requesting them.
- New equipment for which sufficient maintenance history, either based on the CAH's own or its contractor's records, or available publicly from nationally recognized sources, is not available to support a risk-based determination must not be immediately included in the AEM program. New equipment must be maintained in accordance with manufacturer recommendations until a sufficient amount of maintenance history has been acquired to determine whether the alteration of maintenance activities or frequencies would be safe. If a CAH later transitions the equipment to a risk-based maintenance regimen different than the manufacturers' recommendations, the CAH must maintain evidence that it has first evaluated the maintenance track record, risks, and tested the alternate regimen.

Alternative Maintenance Frequencies or Activities

Maintenance strategies are various methodologies used for determining the most efficient and effective maintenance activities and frequencies. Manufacturers' recommendations may be based on one or more such strategies. A CAH may also use one or more maintenance strategies for its AEM program in order to determine the appropriate maintenance, inspection, and testing activities and frequencies, based upon the nature of the equipment and the level of risk it presents to patient or staff health and safety. The risk to patient health and safety that is considered in

developing alternative maintenance strategies must be explained and documented in the AEM program. In developing AEM maintenance strategies CAHs 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 CAH's (or its third-party contractor's) own experience. Maintenance strategies may be applied to groups or to individual pieces of equipment. The CAH is expected to adhere strictly to the AEM activities or strategies it has developed.

Background Information on Types of Maintenance Strategies

- **Preventive Maintenance (Time-based Maintenance)**– a maintenance strategy where maintenance activities are performed at scheduled time intervals to minimize equipment degradation and reduce instances where there is a loss of performance. Most preventive maintenance is "interval-based maintenance" performed at fixed time intervals (e.g., annual or semi-annual), but may also be "metered maintenance" performed according to metered usage of the equipment (e.g., hours of operation). In either case, the primary focus of preventive maintenance is reliability, not optimization of cost-effectiveness. Maintenance is performed systematically, regardless of whether or not it is needed at the time. Example: Replacing a battery every year, after a set number of uses or after running for a set number of hours, regardless.
- **Predictive Maintenance (Condition-based Maintenance)**– a maintenance strategy that involves periodic or continuous equipment condition monitoring to detect the onset of equipment degradation. This information is used to predict future maintenance requirements and to schedule maintenance at a time just before equipment experiences a loss of performance. Example: Replacing a battery one year after the manufacturer's recommended replacement interval, based on historical monitoring that has determined the battery capacity does not tend to fall below the required performance threshold before this extended time.
- **Reactive Maintenance (Corrective, Breakdown or Run-to-Failure Maintenance)**– a maintenance strategy based upon a "run it until it breaks" philosophy, where maintenance or replacement is performed only after equipment fails or experiences a problem. This strategy may be acceptable for equipment that is disposable or low cost and presents little or no risk to health and safety if it fails. Example: Replacing a battery after equipment failure when the equipment has little negative health and safety consequences associated with a failure and there is a replacement readily available in supply.
- **Reliability-Centered Maintenance**– a maintenance strategy that not only considers equipment condition, but also considers other factors unique to individual pieces of equipment, such as equipment function, consequences of equipment failure, and the operational environment. Maintenance is performed to optimize reliability and cost effectiveness. Example: Replacing a battery in an ambulance defibrillator more frequently than the same model used at a nursing station, since the one in the ambulance is used more frequently and is charged by an unstable power supply.

Maintenance Tools

Tools (e.g., hand tools, test equipment, software, etc.) necessary for performing equipment maintenance must be available and maintained to ensure that measurements are reliable. Tools used for maintenance are not required to be those specifically recommended by the manufacturer, but tools utilized must be capable of providing results equivalent to those required by the equipment manufacturer.

AEM Program Documentation

For each type of equipment subject to the AEM program, there must be documentation indicating:

- The pertinent types and level of risks to patient or staff health and safety;
- Alternate maintenance activities, and the maintenance strategy and any other rationale used to determine those activities; the differences from the manufacturer's recommended maintenance activities are made explicit, unless the CAH is unable to obtain the manufacturer's maintenance recommendations, due to the age of the equipment or the manufacturer's restricting the availability of its recommendations;

- Alternate maintenance frequencies to be used, if any, and the maintenance strategy and any other rationale used to determine those frequencies. For equipment identified as presenting a very low risk to patient or staff safety, it could be acceptable to not set a particular frequency but instead indicate a less specific approach. For example, an interval range, such as “every 12 – 24 months.” It could also be acceptable to employ periodic “departmental sweeps” for such very low risk equipment, where equipment functioning is sampled and operators are polled about its functionality.
- The date when AEM program maintenance activities were performed and, if applicable, further actions required/taken; and,
- Documentation of any equipment failures (not including failures due to operator error), including whether there was resulting harm to an individual.) (Note: equipment failure that is due to operator error and which results in an adverse event or near miss must be documented in accordance with the QAPI CoP, as part of the CAH’s required tracking of patient safety-related incidents. However, there is no requirement to include operator failures in equipment maintenance documentation.)

When the CAH has multiple identical equipment items, the documentation may be generic to that type of equipment, except that documentation of maintenance activities performed must be specific to each item of equipment.

Evaluating Safety and Effectiveness of the AEM Program

The CAH must have policies and procedures which address the effectiveness of its AEM program. In evaluating the effectiveness of the AEM program the CAH 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 CAH facility and medical equipment, regardless of whether it is leased or owned, and regardless of whether it is maintained according to manufacturer recommendations or is in an AEM program, is expected to be listed in an inventory which includes a record of maintenance activities. For low cost/low risk equipment, such as housekeeping cleaning equipment, it is acceptable for the inventory to indicate under one item the number of such pieces of equipment in the CAH, e.g., “15 vacuum cleaners for cleaning patient rooms and common areas.”

If the CAH is using an AEM program, the equipment managed through that program must be readily separately identifiable as subject to AEM. Critical equipment, whether in an AEM program or not, must also be readily identified as such.

To facilitate effective management, a well-designed equipment inventory contains the following information for all equipment included. However, CAHs 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 CAH believes may be useful for proper management of
- the equipment.

The CAH will develop and implement a Medical Equipment Plan that addresses the following:

- Issues related to use of demonstration or rental equipment and how appropriate training is provided to ensure safe operation;
- Defined criteria for the selection of equipment;
- The process of reporting and investigating incidents related to serious injury or illness or death (See SMDA 1990);
- A process for reporting and investigating equipment management problems, failures, and user errors;
- A process for determining timing and complexity of medical equipment maintenance; and,
- A process of receiving and responding to recalls and alerts.
- This shall apply to all locations of the CAH, all campuses, and all off-site facilities.

Surveyor Guidance:

Interview personnel in charge of equipment maintenance:

- Select a sample of equipment for which the facility uses the manufacturer’s recommendations for maintenance frequency. Sample selection should be based on:
- Risk to patient safety from equipment failure (e.g., sample high/medium/low risk).
- Critical equipment (e.g., life support devices, key resuscitation devices, critical monitoring devices, equipment used for radiologic imaging etc.) with higher risk should make up the sample majority.
- Service Requests (e.g., sample equipment with high service requests)
- Failure Records (e.g., sample high failure rates)
- Equipment Usage (e.g., sample high use)
- Type of Equipment (e.g., sample medical equipment & facility components)
- Maintenance is being performed in accordance with manufacturer’s recommendations

For the sample selected, review maintenance records to determine if:

- Maintenance, inspection, and testing records are complete and accurate;
- Maintenance records include equipment failures and down-time;
- Equipment failures are corrected (through repair or replacement) in a timely manner;
- Equipment failure patterns are investigated and addressed.
- Records contain the qualifications (e.g., training certificates, certifications, degrees, etc.) of hospital personnel responsible for performing maintenance and/or the hospital is able to demonstrate how they assure contracted personnel are qualified. In the case of medical equipment, qualified personnel would be clinical or biomedical technicians or engineers.
- Records contain documents required to support maintenance activities (e.g., manufacturer's operation and maintenance manual, standards, studies, guidance, recall information, service records, etc.)

Review the hospital's routine and preventive maintenance schedules to determine that ongoing maintenance inspections are performed and that necessary repairs are completed.

Verify that the hospital has developed and implemented a comprehensive plan to ensure that the safety and well-being of patients are assured during emergency situations.

Observe the facility layout and determine if the patient's needs are met. Toilets, sinks, specialized equipment, etc. should be accessible.

Interview personnel in charge of facility, supplies and equipment maintenance to verify:

- The hospital has identified supplies and equipment that are likely to be needed in emergency situation.
- The hospital has made adequate provisions to ensure the availability of those supplies and equipment when needed.
- Interview equipment users when surveying the various units/departments of the hospital to determine if equipment failures are occurring and causing problems for patient health or safety.
- Determine if there is a complete inventory of equipment required to meet patient needs, regardless of ownership.
- Determine if the inventory is periodically reviewed and updated.
- Is critical equipment readily identified?
- If the hospital employs an AEM program, is equipment in this program readily identified?
- Determine if the hospital has documentation of the qualifications (e.g., training certificates, certifications, degrees, etc.) of hospital personnel responsible for the AEM program (if one is being used by the hospital) as well as for those performing maintenance.
- Determine if the hospital is able to demonstrate how it assures contractors use qualified personnel.

Review and validate that there is a process in place to address the repair/periodical maintenance program for equipment.

Review and validate, through a document sampling, that a clinical or biomedical engineer routinely checks medical devices and equipment.

Review and verify that the CAH maintains maintenance logs for significant medical equipment (e.g. cardiac monitors, IV infusion pumps, ventilators).

Interview the person in charge of medical equipment and determine if there is an adequate repair/periodical maintenance program.

Verify that all medical devices and equipment are routinely checked by a clinical or biomedical engineer.

Review maintenance logs for significant medical equipment (e.g., cardiac monitors, IV infusion pumps, ventilators, etc.).

Verify that supplies are maintained.

Verify that supplies are stored as recommended by the manufacturer.

Verify that supplies are stored in such a manner as to not endanger patient safety.

Verify that the CAH has identified supplies and equipment that are likely to be needed in emergency situations.

Verify that the CAH made adequate provisions to ensure the availability of supplies and equipment when needed.

Interview personnel in charge of equipment maintenance:

- Determine if the CAH has identified equipment that is essential for both regular operations and in an emergency situation.
- Determine if the CAH has made adequate provisions to ensure the availability of those and equipment when needed.

Concerning facility and medical equipment

- Interview equipment users when surveying the various units/departments of the CAH to determine if equipment failures are occurring and causing problems for patient health or safety.
- Determine if there is a complete inventory of equipment required to meet patient needs, regardless of ownership.
- Is critical equipment readily identified?
- If the CAH employs an AEM program, is equipment in this program readily identified?
- Determine if the CAH has documentation of the qualifications (e.g., training certificates, certifications, degrees, etc.) of CAH personnel responsible for the AEM program (if one is being used by the CAH) as well as for those performing maintenance.
- Determine if the CAH is able to demonstrate how it assures contractors use qualified personnel.

If the CAH is following the manufacturer-recommended equipment maintenance activities and frequencies

- In addition to reviewing maintenance records on equipment observed while inspecting various CAH locations for multiple compliance assessment purposes, select a sample of equipment from the CAH's equipment inventory to determine whether the CAH 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 CAH 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 CAH is using an AEM for some equipment

- Does the CAH's inventory include equipment which is not eligible for AEM, for example, any diagnostic imaging or therapeutic radiologic equipment?
- Determine if the CAH'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 CAH has documented maintenance activities and frequencies for all equipment included in the AEM program;
- Verify the CAH is evaluating the safety and effectiveness of the AEM program.
- If there is equipment on the inventory the CAH 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 CAH for the evidence used to make this determination. Does it seem reasonable?

Select a sample of equipment in the AEM program. The majority of the sample must include critical equipment which poses a higher risk to patient safety if it were to fail, such as ventilators, defibrillators, robotic surgery devices, etc. For the sample selected:

- Ask the responsible personnel to explain how the decision was made to place the equipment in an AEM program. Does the methodology used consider risk factors and make use of available evidence?
- Ask the responsible personnel to describe the methodology for applying maintenance strategies and determining alternative maintenance activities or frequencies for the sampled equipment. Can they readily provide an explanation and point to sources of information they relied upon?
- Determine if maintenance is being performed in accordance with the maintenance activities and frequencies defined in the AEM program.
- Verify the CAH is evaluating the safety and effectiveness of the AEM maintenance activities for this equipment and taking corrective actions when needed.
- If there is equipment on the inventory the hospital has identified as having such a very low level of risk that it has determined it can use a broad interval range or departmental "sweeps," ask the hospital for the evidence used to make this determination. Does it seem reasonable?

PE.8 UTILITY MANAGEMENT SYSTEM

- SR.1 The CAH shall ensure that processes are in place to provide for a safe and efficient environment that reduces the opportunity for CAH-acquired illnesses.
- SR.2 The CAH shall have a process in place to evaluate critical operating components.
- SR.3 The CAH shall develop maintenance, testing, and inspection processes for critical utilities.
- SR.4 The CAH shall have a process in place to address medical gas systems and HVAC systems (e.g., includes areas for negative pressure).
- SR.5 The CAH shall provide for emergency processes for utility system failures or disruptions.
- SR.6 The CAH shall provide for reliable emergency power sources with appropriate maintenance as required. [The CAH must 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 CAH shall require proper ventilation, light and temperature controls in operating rooms, sterile supply rooms, special procedures, isolation and protective isolation rooms, pharmaceutical, food preparation, and other appropriate areas.

- SR.8 There shall be emergency power and lighting in at least the operating, recovery, intensive care, emergency rooms, and in other areas where invasive procedures are conducted, stairwells, and other areas identified by the CAH (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 Life Safety Code, 101-2012, and applicable references, such as, NFPA-99, 2012: Health Care Facilities Code, for emergency lighting and emergency power.
- SR.8b NFPA 99, 2012 6.3.2.2.11 Shall apply to 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 fuel and water supply.
- SR.10 All relevant utility systems shall be maintained inspected, and, tested.

Interpretive Guidelines:

The CAH must ensure that the condition of the physical plant and overall CAH environment is developed and maintained in a manner to ensure the safety and wellbeing of patients, visitors, and staff. The CAH will ensure that routine and preventive maintenance and testing activities are performed as necessary, in accordance with Federal and State laws, regulations, and guidelines and manufacturer's recommendations, by establishing maintenance schedules and conducting ongoing maintenance inspections to identify areas in need of repair.

There should be proper ventilation, light and temperature controls in pharmaceutical, food preparation, and other appropriate areas.

There must be proper ventilation in at least the following areas:

- Areas using ethylene oxide, nitrous oxide, gluteraldehydes, xylene, pentamidine, formaldehyde, or other potentially hazardous substances;
- Locations where oxygen is transferred from one container to another;
- Isolation rooms and reverse isolation rooms (both must be in compliance with Federal and State laws, regulations, and guidelines such as OSHA, CDC, NIH);
- Pharmaceutical preparation areas (hoods, cabinets);
- Laboratory locations: and
- Anesthetizing locations:

NFPA 99, 2012 3.3.9 Anesthetizing Location. Any area of a facility that has been designated to be used for the administration of general anesthesia.*

NFPA 99, 2012 A.3.3.9 Anesthetizing Location. Areas used exclusively for sedation are not included in this definition.

(Note that this definition is applicable only for LSC purposes and does not supersede other guidance that has been given on anesthesia.)

Temperature, humidity, and airflow in the anesthetizing locations must be maintained within acceptable standards to inhibit microbial growth, reduce the risk of infection, control odor, and promote patient comfort. Each operating room should have separate temperature control. Acceptable standards such as from the Association of Operating Room Nurses (AORN) or the Facilities Guidelines Institute (FGI) should be incorporated into hospital policy.

The CAH will maintain, and regularly test and inspect, emergency power and lighting in at least the operating, recovery, in other areas where invasive procedures are conducted, intensive care, and emergency rooms, stairwells, and other areas identified by the organization (e.g. blood bank refrigerator) to comply with the applicable Life Safety

Code (101).

The CAH will maintain, and regularly test and inspect, emergency power and lighting in at least the operating, recovery, in other areas where invasive procedures are conducted, intensive care, and emergency rooms, stairwells, and other areas identified by the CAH (e.g. blood bank refrigerator) to comply with the applicable Life Safety Code (101). Where areas are not supplied with an emergency supply source, the CAH will make provisions for battery lamps and flashlights.

The CAH must have systems for emergency gas and water needs to provide care to inpatients and other persons who may come to the CAH 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 CAH 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 CAH uses in the care of patients such as oxygen, nitrogen, nitrous oxide, etc.

The CAH 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).

The CAH must meet the applicable provisions and must proceed in accordance with the 2012 National Fire Protection Association (NFPA) 101 - Life Safety Code (LSC), the 2012 edition of the NFPA 99-Health Care Facilities Code (HCFC) and Tentative Interim Amendments TIA 12-1, TIA 12-2, TIA 12-3, and TIA 12-4.) for emergency lighting and emergency power.

NFPA 99, 2012 6.3.2.2.11 (One or more battery-powered lighting units shall be provided within locations where deep sedation and general anesthesia is administered) shall apply to existing facilities.

The CAH must have a system to provide emergency gas and water as needed to provide care to inpatients and other persons who may come to the CAH in need of care. This includes making arrangements with local utility companies and others for the provision of emergency sources of water and gas. Emergency gases include fuels such as propane, natural gas, fuel oil, liquefied natural gas, as well as any gases the CAH uses in the care of patients such as oxygen, nitrogen, nitrous oxide, etc.

The CAH 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).

Guideline for periodic testing intervals:

- Daily: once a day with a period of time that is as close as possible to 24 hours between actions
- Weekly: once a week with a period of time that is as close as possible to 7 days between actions
- Monthly: once a month with a period of time that is as close as possible to 30 days between actions
- Quarterly: once every three months with a period of time that is as close as possible to 90 days between actions
- Annually: once per year with a period of time that is as close as possible to 365 days between actions

Surveyor Guidance:

Review and validate the CAH's process for managing utilities to ensure that there is a process in place to provide for a safe and efficient facility that reduces the opportunity for CAH-acquired illnesses.

Review and validate the condition of the CAH 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 CAH's routine and preventive maintenance schedules to determine that ongoing

maintenance inspections are performed and that necessary corrective/preventive action(s) are taken.

Review and verify that the facility layout is appropriate to meet patient's needs. Toilets, sinks, specialized equipment should be accessible.

The CAH 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 process for managing utilities 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 CAH staff to determine the CAH'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 CAH 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 CAH, and that they are available within a short time through additional deliveries.
- Verify that arrangements have been made with utility companies and others for the provision of emergency sources of critical utilities, such as water and gas.
- Verify that the utility systems have been tested, inspected and maintained for the safety of patient care and applicable to the services provided.

Review and verify that proper ventilation is in place in at least the following areas:

- Areas using ethylene oxide, nitrous oxide, gluteraldehydes, xylene, pentamidine, formaldehyde, or other potentially hazardous substances;
- Locations where oxygen is transferred from one container to another;
- Isolation rooms and reverse isolation rooms (both must be in compliance with Federal and State laws, regulations, and guidelines such as OSHA, CDC, NIH);
- Pharmaceutical preparation areas (hoods, cabinets); and,

Review and verify that adequate lighting is in place in all the patient care areas, and food and medication preparation areas.

Verify that each anesthetizing location has temperature control mechanisms.

Review the records for anesthetizing locations temperature and humidity to ensure levels are maintained.

Review temperature and humidity maintenance records for anesthetizing locations to ensure, if monitoring determined temperature or humidity levels were not within acceptable parameters, the corrective actions were performed in a timely manner to achieve acceptable levels.

Review and verify that each surgical suite has separate temperature control.

Review and verify that food products are stored under appropriate conditions (e.g. time, temperature, packaging, location) based on nationally accepted sources such as the United States Department of Agriculture, the Food and Drug Administration, or other nationally recognized standard.

Review and verify that pharmaceuticals are stored at temperatures recommended by the product manufacturer and according to CAH policy.

APPENDICES

SWING BEDS (SB-A)

A CAH that provides SNF-level services must conform to the additional standards specified in Appendix A of these NIAHO®-CAH Accreditation Requirements. The requirements of Appendix A are applicable to residents receiving post-CAH SNF-level services

SB.1 ELIGIBILITY

SB-A.1 The CAH must meet the following eligibility requirements:

SB-A.1a The facility has been certified as a CAH by CMS under 42 CFR Section 485.606(b); and,

SB-A.1b The facility provides not more than 25 inpatient beds. Any bed of a unit of the facility that is licensed as a distinct-part SNF at the time the facility applies to the State for designation as a CAH is not counted under SB-A.1b.

Surveyor Guidance:

Per 42 CFR 485.606(b), CMS certifies a facility as a CAH if –

- (1) The facility is designated as a CAH by the State in which it is located and has been surveyed by the State survey agency or by CMS and found to meet all conditions of participation in this part and all other applicable requirements for participation in part 489 of this chapter.*
- (2) The facility is a medical assistance facility operating in Montana or a rural primary care hospital designated by CMS before August 5, 1997 and is otherwise eligible to be designated as a CAH by the State under the rules in this subpart.*

The swing-bed concept allows a CAH 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.

A 3-day qualifying stay for the same spell of illness in any hospital or CAH is required prior to admission to swing-bed status. The 3-day qualifying stay does not need to be from the same facility as the swing-bed admission.

Swing-bed patients receive a SNF level of care, and the CAH is reimbursed for providing a SNF level of care, however swing-bed patients are not SNF patients. Swing-bed patients in CAHs are considered to be patients of the CAH.

ADMISSION, TRANSFER AND DISCHARGE (TD)

TD.1 TRANSFER AND DISCHARGE REQUIREMENTS

Transfer and discharge includes movement of a resident to a bed outside of the certified facility whether that bed is in the same physical plant or not. Transfer and discharge does not refer to movement of a resident to a bed within the same certified facility.

The CAH must permit each resident to remain in the CAH, and not transfer or discharge the resident from the CAH unless:

- SR.1 The transfer or discharge is necessary for the resident's welfare and the resident's needs cannot be met in the CAH;
- 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 CAH;
- SR.3 The safety of individuals in the CAH is endangered [due to the clinical or behavioral status of the resident](#);
- SR.4 The health of individuals in the CAH would otherwise be endangered;
- 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 CAH. [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 CAH, the CAH may charge a resident only allowable charges under Medicaid; or
- SR.6 The CAH ceases operations.
- SR.7 [The CAH may not transfer or discharge a resident while an appeal is pending, pursuant to 42 CFR Section 431.230 when a resident exercises his or her right to appeal a transfer or discharge notice from the CAH pursuant to 42 CFR Section 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 CAH. The CAH must 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 does not refer to movement of a resident to a bed within the same certified facility.

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 must conduct the appropriate assessment, prior to any transfer or discharge to determine if a new care plan would allow the facility to meet the resident's needs. If the significant change in the resident's condition is an emergency, immediate transfer should be arranged.

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 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 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 CAH transfers or discharges a resident under any of the circumstances specified in TD.1, the CAH must 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 must include:

SR.1a The basis for the transfer per TD.1.

SR.1b In the case of TD.1, SR.1, the specific resident need(s) that cannot be met, CAH attempts to meet the resident needs, and the service available at the receiving facility to meet the need(s).

The documentation must 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 CAH or the [resident's health has improved sufficiently so the resident](#) no longer needs the services provided by the CAH.

SR.3 A physician when transfer or discharge is necessary as the health of individuals in the CAH would otherwise be endangered [or the safety of the individuals in the CAH 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 must be provided prior to transferring or discharging a resident. The CAH must:

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 CAH must 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 must 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 must be made by the CAH:
- SR.4a As soon as practicable before transfer or discharge when:
 - SR.4a (1) The safety of individuals in the CAH would be endangered (See TD.1, SR.3);
 - SR.4a (2) The health of individuals in the CAH 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 CAH for 30 days.
 - SR.4b All other reasons require at least 30 days notice before transfer or discharge.

TD.4 ORIENTATION FOR TRANSFER OR DISCHARGE

- SR.1 The CAH must provide and document sufficient preparation and orientation to residents to ensure safe and orderly transfer or discharge from the facility. This orientation must be provided in a form and manner that the resident can understand.
- SR.2 In the case of facility closure, the individual who is the administrator of the CAH must provide written notification prior to the impending closure to the State Survey Agency, the State LTC ombudsman, residents of the facility, and the legal representatives of the residents or other responsible parties, as well as the plan for the transfer and adequate relocation of the residents, as required at 42 CFR Section 483.70(l).

Interpretive Guidelines:

"Sufficient preparation" means the facility informs the resident where he or she is going and assures safe transportation. 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.

Surveyor Guidance:

Review the social service notes to determine if appropriate referrals have been made and, if necessary, if resident counseling has occurred.

TD.5 CHANGE OF ROOM IN COMPOSITE DISTINCT PART

Room changes in a CAH that is a composite distinct part (as defined in 42 CFR Section 483.5), are subject to the requirements of 42 CFR Section 483.10(e)(7) and must be limited to moves within the particular building in which the resident resides. If the resident is to be moved to another building of the distinct part location, unless the resident voluntarily agrees to this move within the CAH.

TD.6 DISCHARGE SUMMARY

When the CAH anticipates discharge, a resident must have a discharge summary that includes:

- SR.1 A recapitulation of the resident's stay;
- SR.2 A final summary of the resident's status at the time of the discharge that is available for release to authorized individuals and agencies, with the consent of the resident or their legal representative
- SR.3 A post-discharge plan of care that is developed with the participation of the resident and his or her family, which will assist the resident to adjust to his or her new living environment.

Interpretive Guidelines:

"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/care giver education needs to ensure the resident/care giver is able to meet care needs after discharge.

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 a pertinent to 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 CAH must conduct initially and periodically a comprehensive, accurate, standardized, reproducible assessment of each resident's functional capacity.

- SR.1 The assessment must 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 potential.
 - 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 Within 14 calendar days after admission, excluding readmissions in which there is no significant change in the resident's physical or mental condition, the CAH must 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.3 A comprehensive assessment of the resident will be completed not less often than once every 12 months.
- SR.4 A facility must coordinate assessments with the preadmission screening and resident review (PASARR) program under Medicaid as noted in 42 CFR Section 483.20(c) to the maximum extent practicable to avoid duplicative testing and effort. Coordination includes:
 - SR.4a Incorporating the recommendations from the PASARR level II determination and the

PASARR evaluation report into a resident's assessment, care planning, and transitions of care.

- SR.4b Referring all level II residents and all residents with newly evident or possible serious mental disorder, intellectual disability, or a related condition for level II resident review upon a significant change in status assessment.

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.

The CAH is not required to use the resident assessment instrument (RAI) specified by the State that is required under §483.20(b), or to comply with the requirements for frequency, scope, and number of assessments prescribed in §413.343(b). §485.645(d)(6)

"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.

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; or done on an annual review. These assessments need to be in the final discharge summary.

PC.2 CARE PLAN

- SR.1 The CAH must develop a comprehensive care plan for each resident:
 - SR.1a To meet a resident's medical, nursing, mental and psychosocial needs;
 - SR.1b That have been identified in the comprehensive assessment;
 - SR.1c Includes measurable objectives goals; and,
 - SR.1d Be developed within 7 days after the completion of the comprehensive assessment.
 - SR.1e Prepared by an interdisciplinary team, that includes:
 - SR.1e (1) The attending physician;
 - SR.1e (2) A registered nurse with responsibility for the resident; and
 - SR.1e (3) Other appropriate staff in disciplines as determined by the resident's needs, and, to the extent practicable;
 - SR.1e (4) The participation of the resident, the resident's family or the resident's legal representative; and,
 - SR.1e (5) Be periodically reviewed and revised by a team of qualified persons after each assessment.
- SR.2 The care plan must 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;
- SR.2b Any services that would otherwise be required under 42 CFR Section 483.25 but are not provided due to the resident's exercise of rights 42 CFR Section 483.10, including the right to refuse treatment; and,
- SR.2c Any specialized services or specialized rehabilitative services the nursing facility will provide as a result of PASARR recommendations.
 - SR.2c (1) If a facility disagrees with the findings of the PASARR, it must indicate its rationale in the resident's medical record.
- SR.2d Documented consultation with the resident and the resident's legal representative(s) that specifies:
 - SR.2d (1) The resident's goals for admission and desired outcomes, and,
 - SR.2d (2) The resident's preference and potential for future discharge.
- SR.2e The CAH must 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.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 CAH must
 - SR.4a Meet professional standards of quality; and
 - SR.4b Be provided by qualified persons in accordance with each resident's written plan of care.

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 must 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 must 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 must 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 CAH, licensing board, accreditation body or other regulatory agency. Recommended practices to achieve desired resident outcomes might also be found in clinical literature.

Surveyor Guidance:

In sampling of resident records, verify:

- That the care plan address the needs, strengths and preferences identified in the comprehensive assessment
- Interdisciplinary expertise utilized to develop a plan to improve the resident's functional abilities
- The care plan oriented toward preventing avoidable declines in functioning or functional levels
- The care plan evaluated and revised as the resident's status changes
- If there is resident has refused treatment, does the care plan reflect the facility's efforts to find alternative means to address the problem

Validate that schedule care plan meetings are 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
- they had concerns or questions about your 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 resident 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 CAH. A CAH must 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 CAH 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 CAH 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.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 CAH must 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 CAH.
 - SR.1a The CAH must also provide the resident with the notice (if any) of the State developed under section 1919(e)(6) of the Act. Such notification must be made prior to or upon admission and during the resident's stay. Receipt of such information, and any amendments to it, must 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 CAH.
- 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 must 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 must be presented in language that the resident can understand.

Communicating with the resident in language that the resident can understand includes minimizing the use of technical words, providing interpreters for non-English speaking residents, using sign language when needed, or other interventions, as appropriate.

"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 must be fully informed of the nature of the experiment and understand the possible consequences of participating. The opportunity to refuse to participate in experimental research must occur prior to the start of the research. Aggregated resident statistics that do not identify individual residents may be used for studies without obtaining resident permission.

"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 a personal attending physician
- 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 must 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 must 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 CAH must allow the patient to formulate advance directives and to have CAH staff and practitioners comply with the advance directives in accordance with Federal and State law, rules and regulations.

The CAH 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 CAH is not relieved of its obligation to provide this information to the individual once he or she is no longer incapacitated or unable to receive such information. Follow-up procedures must be in place to provide the information to the individual directly at the appropriate time.

- SR.1 The CAH shall document in the patient's medical record whether or not the patient has executed an advance directive.
- SR.2 The CAH shall not condition the provision of care or otherwise discriminate based on the execution of the advance directive.
- SR.3 The CAH shall ensure compliance with State law regarding the provision of an advance directive.

- SR.4 The CAH 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.2-ADVANCE DIRECTIVES

Surveyor Guidance:

Refer to PATIENT RIGHTS – PR.2-ADVANCE DIRECTIVES

RR. 5 MEDICAID BENEFITS

Each resident who is entitled to Medicaid benefits, must be informed in writing, at the time of admission to the CAH or, when the resident becomes eligible for Medicaid of:

- SR.1 The items and services that are included through CAH services under the State plan and for which the resident may not be charged;
- SR.2 Those other items and services that the CAH 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 \(42 CFR Section 483.10\(g\)\(17\)\(i\)\(A\) and \(B\)\)](#).
- SR.3 The CAH must inform each resident before, or at the time of admission, and periodically during the resident's stay, of services available in the CAH and of charges for those services, including any charges for services not covered under Medicare or by the CAH's per diem rate.

Interpretive Guidelines:

If Medicare or Medicaid does not make payment for services, the provider must fully inform the resident of any related charges both at the time of admission and prior to the time that changes will occur in their bills.

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 CAH must 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 must 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 must 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 42 CFR Section 483.70(i)(2):

The facility must 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 Section 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 Section 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 must examine and treat residents in a manner that maintains the privacy of their bodies. A resident must be granted privacy when going to the bathroom and in other activities of personal hygiene. If an individual requires assistance, authorized staff should respect the individual's need for privacy. 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 must establish alternate areas in the facility for visiting. These areas could include the chapel, a suitable office area, a dining room, or a porch or patio area.

When a room is available for a married couple to share, the facility must permit them to share it if they choose.

All residents' possessions must 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.6 - Restraints and Seclusion;

PR.7 - Restraints and Seclusion: Staff Training Requirements; and,

PR.8 - Restraints and Seclusion: Report of Death

RR.8 FREEDOM FROM ABUSE, NEGLIGENCE, 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 CAH must:
- SR.1a Not use verbal, mental, sexual, or physical abuse, corporal punishment, or involuntary seclusion;
- 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 CAH must use the least restrictive alternative for the least amount of time and document ongoing re-evaluation of the need for restraints.
- SR.2 The CAH must 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 Establish policies and procedures to investigate any such allegations.
- SR.3 The CAH must 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 CAH must 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 CAH staff.
- SR.5 In response to allegations of abuse, neglect, exploitation, or mistreatment, the CAH must:
- 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 CAH 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 must be taken.

Interpretive Guidelines:

The facility must assure that each resident is free from abuse, corporal punishment, and involuntary seclusion. The facility is responsible for preventing abuse, but also for those practices and omissions, neglect and misappropriation of property, which if left unchecked, lead to abuse. Residents must not be subjected to abuse by anyone, including, but not limited to, facility staff, other residents, consultants or volunteers, staff of other agencies serving the individual, family members or legal guardians, friends, or other individuals.

CMS 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.
- **Exploitation:** 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.
- **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 she will never be able to see her family again.
- **Sexual abuse:** includes, but is not limited to, sexual harassment, sexual coercion, or sexual assault.
- **Physical abuse:** includes hitting, slapping, pinching, 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 nolo contendere.

- **"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 must 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)?

RR.9 WORK

SR.1 [The resident has a right to choose to or refuse to perform services for the facility and the facility must not require a resident to perform services for the facility. The resident may perform services for the facility, if he or she chooses, when:](#)

SR.1a The facility has documented the need or desire for work in the plan of care;

SR.1b The plan specifies the nature of the services performed and whether the services are voluntary or paid;

SR.1c Compensation for paid services is at or above prevailing rates; and

SR.1d The resident agrees to the work arrangement described in the plan of care.

Interpretive Guidelines:

All resident work, whether of a voluntary or paid nature, must be part of the plan of care.

A resident's desire for work is subject to medical appropriateness. As part of the plan of care, the resident must agree to a therapeutic work assignment. The resident also has the right to refuse such treatment at any time that he or she wishes. At the time of development or review of the plan, voluntary or paid work can be negotiated.

The "prevailing rate" is the wage paid to workers in the community surrounding the facility for the same type,

quality, and quantity of work requiring comparable skills.

Surveyor Guidance:

Determine if any residents engaged in work (e.g., doing housekeeping, doing laundry, preparing meals) and verify if the plan of care has been updated to reflect this.

FACILITY SERVICES (FS)

FS.1 ACTIVITIES

- SR.1 The CAH must provide, based on the comprehensive assessment and care plan and the preferences of each resident, an ongoing program to support residents in their choice of activities, both facility-sponsored group and individual activities and independent activities, designed to meet the interests of and support the physical, mental, and psychosocial well-being of each resident, encouraging both independence and interaction in the community.
- SR.2 The activities program may be directed by a qualified professional who is a qualified therapeutic recreation specialist or an activities professional who:
- SR.2a Is licensed or registered, if applicable, by the State in which practicing; and,
 - SR.2b Is eligible for certification as a therapeutic recreation specialist or as an activities professional by a recognized accrediting body on or after October 1, 1990; or has 2 years of experience in a social or recreational program within the last 5 years, 1 of which was full-time in a therapeutic activities program or;
 - SR.2c Is a qualified occupational therapist or occupational therapy assistant; or
 - SR.2d Has completed a training course approved by the State.
 - SR.2e Absent the professional qualifications described above, at a minimum, patient activities must be directed by an individual on the CAH staff who is designated as the activities director and who serves in consultation with a therapeutic recreation specialist, occupational therapist, or other professional with experience or education in recreational therapy.

Interpretive Guidelines:

In a Critical Access CAH, the services may be directed either by a qualified professional meeting the requirements of FS.1, or by an individual on the facility staff who is designated as the activities director and who serves in consultation with a therapeutic recreation specialist, occupational therapist, or other professional with experience or education in recreational therapy.

A "recognized accrediting body" refers to those CAHs or associations recognized as such by certified therapeutic recreation specialists or certified activity professionals or registered occupational therapists.

The activities program should be multi-faceted and reflect individual resident's needs on their care plan. Activities can occur at any time and are not limited to formal activities being provided by activity staff. Others involved may be any facility staff, volunteers, and visitors.

Surveyor Guidance:

Observe individual, group and bedside activities.

Verify that residents who are confined or choose to remain in their rooms provided with suitable in-room activities,

Determine if facility staff members assist the resident with activities.

Ascertain that if a resident sit for long periods of time with no apparently meaningful activities what the cause is.

For example:

- The resident's choice;
- Failure of any staff or volunteers either to inform residents when activities are occurring or to encourage resident involvement in activities;

- Lack of assistance with ambulation;
- Lack of sufficient supplies and/or staff to facilitate attendance and participation in the activity programs; or
- Program design that fails to reflect the interests or ability levels of residents, such as activities that are too complex?

Interview residents to determine what interests they have, if any of these activities are offered, if not, what other types of activities are offered that they participate in, if they are encouraged to participate,

Review the activity calendar for the month prior to the survey to determine if the formal activity program:

- Reflects the schedules, choices and rights of the residents;
- Offers activities at hours convenient to the residents (e.g., morning, afternoon, some evenings and weekends);
- Reflects the cultural and religious interests of the resident population; and
- Would appeal to both men and women and all age groups living in the facility.

Review clinical records and activity attendance records of residents to determine if:

- Activities reflect individual resident history indicated by the comprehensive assessment;
- Care plans address activities that are appropriate for each resident based on the comprehensive assessment;
- Activities occur as planned; and
- Outcomes/responses to activities interventions are identified in the progress notes of each resident.
- If there are problems with provision of activities, determine if qualified staff provide these service.

FS.2 SOCIAL SERVICES

- SR.1 The CAH must provide medically-related social services to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident.
- SR.2 A CAH have a qualified social worker available on a full-time, part-time, or through contractual agreement to serve the needs of patients.
- SR.3 A qualified social worker is an individual with
- SR.3a A **minimum of a** bachelor's degree in social work or a bachelor's degree in a human services field including but not limited to sociology, **gerontology**, special education, rehabilitation counseling, and psychology; and,
- SR.3b One year of supervised social work experience in a health care setting working directly with individuals.

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:

- 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 staff to inform 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;
- Finding options that meet the physical and emotional needs of each resident;
- Meeting the needs of residents who are grieving; and
- Assisting residents with dental/denture care, podiatric care; eye care; hearing services, and obtaining equipment for mobility or assistive eating devices.
- Where the Medicaid State Plan does not cover needed services, facilities are still required to attempt to obtain these services.

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
- Access services for Medicaid recipients when a Medicaid State Plan does not cover those services?

FS.3 DENTAL SERVICES

SR.1 The CAH must assist residents in obtaining routine and 24-hour emergency dental care.

SR.1a The CAH **must** provide or obtain from an outside resource, in accordance with 42 CFR Section 483.70(g), routine (to the extent covered under the State plan) and emergency dental services to meet the needs of each resident.

- SR.2 The CAH must 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 CAH must 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 must 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 CAH must assist the resident if necessary or if requested:
- SR4a In making appointments; and,
 - SR.4b By arranging for transportation to and from the dental services location.
- SR.5 The CAH may charge a Medicare resident an additional amount for routine and emergency dental services;
- SR.6 The CAH must 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 must 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 must see the dentist at that time, but does mean that an appointment (referral) is made, or that the facility is aggressively working at replacing the dentures.

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)

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 CAH must:

- 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 must 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 must 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 must 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 must 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 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 must 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 that professional staff are licensed, certified or registered to provide specialized therapy/rehabilitative services in accordance with applicable State laws. Health rehabilitative services for MI and MR must be implemented consistently by all staff unless the nature of the services is such that they are designated or required to be implemented only by licensed or credentialed personnel.

Surveyor Guidance:

Verify that the facility employ 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 CAH must 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.

Interpretive Guidelines:

Refer to DIETARY SERVICES (DS)

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 life style 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;

Slow eating pace resulting in food becoming unpalatable, or in staff removing the tray before resident has finished eating; and Cancer. 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, diarrhea not relieved by treatment given according to accepted standards of practice.

"Therapeutic diet" means a diet ordered by a MD/DO 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

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?

APPENDICES

DISTINCT PART UNIT - REHABILITATION UNIT (RU-B)

These standards are applicable to the rehabilitation unit and services provided as a distinct part unit of the CAH. The CAH may have only one unit of each type (psychiatric or rehabilitation) excluded from the prospective payment systems.

GENERAL REQUIREMENTS (GR)

GR-R.1 COMPLIANCE WITH DNV GL- HEALTHCARE NIAHO® Accreditation Requirements for Hospitals STANDARDS FOR REQUIRED SERVICES

The rehabilitation unit must be in compliance with all of the following DNV GL- Healthcare NIAHO® Accreditation Requirements for Hospitals to the extent such requirements are not addressed, modified by or in conflict with the CAH requirements:

- SR.1 Quality Management System (QM);
- SR.2 Governing Body (GB);
- SR.3 Chief Executive Officer (individual who assumes full legal authority and responsibility for operations of the CAH) (CE);
- SR.4 Medical Staff (MS);
- SR.5 Nursing Services (NS);
- SR.6 Staffing Management (SM);
- SR.7 Medication Management (MM);
- SR.8 Laboratory Services (LS);
- SR.9 Medical Imaging (MI);
- SR.10 Dietary Services (DS);
- SR.11 Patient Rights (PR);
- SR.12 Infection Control (IC);
- SR.13 Medical Records Service (MR);
- SR.14 Discharge Planning (DC);
- SR.15 Utilization Review (UR);
- SR.16 Physical Environment (PE); and,
- SR.17 Organ, Eye and Tissue Procurement (TO)

GR-R.2 COMPLIANCE WITH DNV GL- HEALTHCARE NIAHO® Accreditation Requirements for Hospitals STANDARDS FOR OPTIONAL SERVICES

The rehabilitation unit must be in compliance with the following DNV GL- Healthcare NIAHO® Accreditation Requirements for Hospitals if such service is offered:

- SR.1 Surgical Services (SS);
- SR.2 Anesthesia Services (AS);

- SR.3 Respiratory Care Services (RC);
- SR.4 Nuclear Medicine Services (NM);
- SR.5 Rehabilitation Services (RS);
- SR.6 Obstetric Services (OB);
- SR.7 Emergency Department (ED);
- SR.8 Outpatient Services (OS)

GR-R.3 TRANSFER OF CLINICAL INFORMATION

The rehabilitation unit shall have policies in place that assure the prompt transfer of clinical information when a patient is transferred between the CAH and the rehabilitation unit.

Surveyor Guidance:

The clinical records are to be easily retrievable and available to all professional staff members of the organization and other authorized individuals when patients are transferred between the CAH and the distinct part unit.

Review the policy and procedure in place to reflect the manner in which clinical information is shared between the CAH and the distinct part unit.

Review the process in place to ensure clinical information and records is shared in accordance with the CAH policy and how this information is managed. As a part of the open medical record review trace the information to the CAH to ensure the effectiveness of the process when a patient is transferred from the CAH to the distinct part unit.

GR-R.4 COMPLIANCE WITH LAWS

The rehabilitation unit shall be in compliance with all federal, state and local laws.

Surveyor Guidance:

Where applicable State or Local law or regulation is applicable, verify the objective evidence in place to reflect the CAH and distinct part unit is operating in compliance with such law or regulation

Document any nonconformity where the facility is not currently in compliance with applicable Federal laws and regulations related to the health and safety of patients

GR-R.5 PHYSICAL LOCATION

The rehabilitation unit must be physically separate from other CAH beds. The CAH may only have one distinct part unit (rehabilitation) designated.

- SR.1 The rehabilitation unit must be physically separate from other CAH inpatient units.
- SR.2 The rehabilitation unit beds in a Satellite Facility must be physically separate from the beds of the hospital in which it is located. When the rehabilitation unit beds are located in a Satellite Facility, the facility must independently comply with the accreditation requirements under Appendix RU-B for rehabilitation units.
 - SR.2a The unit will be under the control of the governing body (or individual who assumes full legal authority and responsibility for operations of the CAH) of the CAH.
 - SR.2b Patient care services are provided under the under the control and meet the requirements for the medical staff (or Medical Director) of the CAH.
 - SR.2c The Satellite Facility will maintain separate patient records and shall be readily available.

SR.2d The location of the beds in the Satellite Facility will be separate from the other beds in the facility.

SR.2d (1) Off-campus and co-location requirements for CAHs. A CAH may continue to meet the location requirement of GR-R.5; SR.2 based only if the CAH meets the following:

(A) If a CAH or a necessary provider CAH operates an off-campus provider-based location, excluding an RHC as defined in §405.2401(b), but including a department or remote location, as defined in §413.65(a)(2), or an off-campus distinct part rehabilitation unit, as defined in §485.647, that was created or acquired by the CAH on or after January 1, 2008, the CAH can continue to meet the location requirement of only if the off-campus provider-based location or off-campus distinct part unit is located more than a 35 mile drive (or, in the case of mountainous terrain or in areas with only secondary roads available, a 15 mile drive) from a hospital or another CAH.

(B) If either a CAH or a CAH that has been designated as a necessary provider by the State does not meet the requirements by co-locating with another hospital or CAH on or after January 1, 2008, or creates or acquires an off-campus provider-based location or off-campus distinct part unit on or after January 1, 2008, that does not meet the requirements of 412.23(b)(2), the CAH's provider agreement will be subject to termination in accordance with the provisions of §489.53(a)(3), unless the CAH terminates the off-campus arrangement or the co-location arrangement, or both.

Interpretive Guidelines:

As a part of the confirming the accuracy of the information provided in the application for accreditation, the location of the beds for the distinct part unit will be verified if the beds are located at a Satellite Facility. These distinct part unit beds will be separate from those of the CAH and also separate in the case where the beds are located at a Satellite Facility.

485.610(e)(2) requires that if a CAH operates an off-campus provider-based facility as defined in §413.65(a)(2) (except for a rural health clinic (RHC)) or off-campus rehabilitation or psychiatric distinct part unit as defined at §485.647, that was created or acquired on or after January 1, 2008, then the off-campus facility must meet the requirement at 42 CFR 485.610(c) to be more than a 35-mile drive (or 15 miles in the case of mountainous terrain or an area with only secondary roads) from another hospital or CAH. Off-campus CAH facilities that were in existence prior to January 1, 2008, are not subject to this requirement.

The drive to another hospital or CAH is to be calculated from the provider-based facility's location to the main campus of the other hospital or CAH.

The distance to another hospital or CAH requirement does not apply to the following types of facilities/services, because such facilities or services are not eligible for provider-based status in accordance with §413.65(a)(1)(ii):

- Ambulatory surgical centers (ASCs);
- Comprehensive outpatient rehabilitation facilities (CORFs);
- Home Health Agencies (HHAs);
- Skilled nursing facilities (SNFs);
- Hospices;
- Independent diagnostic testing facilities furnishing only services paid under a fee schedule, such as facilities that furnish only screening mammography services, facilities that furnish only clinical diagnostic laboratory tests, or facilities that furnish only some combination of these services;

- ESRD facilities;
- Departments of providers that perform functions necessary for the successful operation of the CAH, but for which separate CAH payment may not be claimed under Medicare or Medicaid, e.g., laundry, or medical records department; and,
- Ambulances.

If the CAH is identified as having a provider-based off-campus facility that appears not to comply with the provider-based location requirements, the Team Leader is to notify the DNV GL- Healthcare Central Office. The DNV GL- Healthcare Central Office will notify the RO. The RO will utilize the guidance in §2254H of the SOM to determine if the CAH satisfies the provider-based location requirements at §485.610(e)(2). The RO will notify the CAH, State Agency, and DNV GL- Healthcare of its determination.

Surveyor Guidance:

Verify that the distinct part unit beds are separate from the CAH.

Verify that the distinct part unit is controlled under the governing body (or individual who assumes full legal authority and responsibility for operations of the CAH) of the CAH.

Verify that the medical staff, providing patient care services to patients within the distinct part unit, are meeting the requirements of under the medical staff of the CAH.

GR-R.6 SERVICES

The rehabilitation unit shall provide the following services through qualified personnel who meet the qualifications as defined by the medical staff and CAH and consistent with State law shall be performed by:

- SR.1 Rehabilitation nursing;
- SR.2 Physical therapy;
- SR.3 Occupational therapy and, as needed,
- SR.4 Speech therapy, social services or psychological services (including neurological services), and orthotic and prosthetic services.

Surveyor Guidance:

Verify that staff providing rehabilitative services meet the qualifications as defined by the medical staff and organization and consistent with State law shall be performed by qualified physical therapists, physical therapists assistants, occupational therapists, occupational therapist assistants, speech-language pathologists, or audiologists. (as defined in § 484.4 Personnel qualifications.)

If services are provided under a contractual arrangement, determine that the agreement requires the staff to be appropriately qualified (as listed above) and scope of services provided.

Sample personnel files to verify that current licensure, certifications and ongoing training, are consistent with applicable State laws.

GR-R.7 UTILIZATION REVIEW STANDARDS

The rehabilitation unit must also meet all Utilization Review (UR) requirements of the DNV GL- Healthcare NIAHO® Accreditation Requirements for Hospitals.

The rehabilitation unit shall have in place an active utilization review program applicable to the type and level of care provided.

Interpretive Guidelines:

The distinct part unit of the CAH shall have a UR plan to include a delineation of the responsibilities and authority for those involved in the performance of UR activities, define the requirement for all review findings to be reported to the Quality Management Oversight group, and ensure that there is no conflict of interest (financial or otherwise) by those individuals participating in the review.

Surveyor Guidance:

Compliance with the DNV GL- Healthcare NIAHO® Accreditation Requirements for Hospitals Standards will apply for the psychiatric unit and services provided as a distinct part unit. Cite the hospital Standard Requirement number for any nonconformities identified for the distinct part unit of the CAH under the hospital NIAHO® Accreditation Requirements for Hospitals.

Verify that the distinct part unit of the CAH has a utilization review plan for those services provided and its medical staff to patients.

Sample records and reports, and supporting documentation that UR activities are being performed as described in the UR plan.

Verify the composition of the UR committee.

Review for any conflicts of interest regarding individuals involved in the UR activities, when applicable, are not included as a part of the UR process when there may be a potential conflict of interest.

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 appropriateness of admissions, utilization of professional services and extended stay reviews with approval or disapproval noted in a status report of any actions taken.

Note: Do not apply these UR requirements if any of the following situations apply:

- A Quality Improvement Organization (QIO) has assumed binding review for the hospital;
- The State has entered into a contract with a QIO that is deemed under 42 CFR §431.630, or
- Compliance with the DNV GL-Healthcare NIAHO® Accreditation Requirements for Hospitals Standards will apply for the psychiatric unit and services provided as a distinct part unit of the CAH. Cite the hospital Standard Requirement number for any nonconformities identified for the distinct part unit of the CAH under the hospital NIAHO® Accreditation Requirements for Hospitals as applicable regarding UR activities.

MEDICAL RECORDS SERVICES (MR)

The rehabilitation unit must also meet all Medical Record Services (MR) requirements of the DNV GL- Healthcare NIAHO® Accreditation Requirements for Hospitals.

MR-R.1 MEDICAL RECORD

A medical record shall be maintained for each patient admitted to the rehabilitation unit.

- SR.1 Admission and discharge records shall be separate from those of the hospital where the rehabilitation unit is located and shall be readily available.

Interpretive Guidelines:

The distinct part unit of the CAH must maintain a medical record for each patient treated and this will be separate from the CAH.

The distinct part unit of the CAH must ensure that all medical records accurate and completely document all orders, evaluations, treatment plans, treatments, interventions, care provided and the patient's response to those treatments, interventions and care.

The distinct part unit of the CAH 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 distinct part unit or off-premises through a contractual arrangement, the hospital must ensure there is a process in place to protect and retrieve these records in a timely manner.

The distinct part unit of the CAH will maintain a compliance program as required under the Health Insurance Portability and Accountability Act (HIPAA).

Surveyor Guidance:

Review the area(s) where medical records are maintained by the distinct part unit. Verify that a medical record is maintained for each person treated or receiving care.

Verify that medical records are stored and maintained in area(s) that ensure the records are secure, protected from damage by flood, fire, and other casualties, and access is limited to authorized staff.

Verify that the hospital has a process to ensure that records are accurate, completed promptly, easily retrieved and readily accessible in all area(s) where medical records are maintained.

Validate the hospital's current practices in place for protecting and securing the confidentiality of patient records.

TREATMENT PLAN (TP)

TP-R.1 PREADMISSION SCREENING

Each patient shall be screened prior to admission to determine to determine if the patient is likely to significantly benefit from an inpatient assessment or rehabilitation program.

- SR.1 The patient's current physical condition and medical history will be utilized in the preadmission screening criteria. This procedure must ensure that the preadmission screening for each Medicare Part A Fee-for-Service patient is reviewed and approved by a rehabilitation physician prior to the patient's admission to the IRF. This preadmission screening will include, but not limited to:
 - SR.1a Current physical conditions and medical history;
 - SR.1b Contraindications, if any;
 - SR.1c The extent to which the patient is aware of the diagnosis(es) and prognosis; and,
 - SR.1d If appropriate, the summary of treatment furnished and results achieved during previous periods of rehabilitation service.
- SR.2 There shall be written criteria for admission that are uniformly applied to both Medicare and non-Medicare patients.
 - SR.2a The patient is admitted for inpatient rehabilitation for a condition that is not one of the conditions specified in SR.2c (1-13).
 - SR.2b The patient has a comorbidity that falls in one of the conditions specified in SR.2c (1-13).
 - SR.2c The comorbidity has caused significant decline in functional ability in the individual that, even in the absence of the admitting condition, the individual would require the intensive rehabilitation treatment that is unique to inpatient rehabilitation facilities and that cannot be appropriately performed in another care setting covered under this distinct part unit. The list of conditions includes:
 - SR.2c (1) Stroke
 - SR.2c (2) Spinal cord injury SR.2c (3) Congenital deformity
 - SR.2c (4) Amputation.
 - SR.2c (5) Major multiple trauma
 - SR.2c (6) Fracture of femur (hip fracture)
 - SR.2c (7) Brain injury.
 - SR.2c (8) Neurological disorders, including multiple sclerosis, motor neuron diseases, polyneuropathy, muscular dystrophy, and Parkinson's disease.
 - SR.2c (9) Burns
 - SR.2c (10) Active, polyarticular rheumatoid arthritis, psoriatic arthritis, and seronegative arthropathies resulting in significant functional impairment of ambulation and other activities of daily living that have not improved after an appropriate, aggressive, and sustained course of outpatient therapy services or services in other less intensive rehabilitation settings immediately preceding the inpatient rehabilitation admission or that result from a systemic disease activation immediately before admission, but have the potential to improve with more intensive rehabilitation.

- SR.2c (11) Systemic vasculidities with joint inflammation, resulting in significant functional impairment of ambulation and other activities of daily living that have not improved after an appropriate, aggressive, and sustained course of outpatient therapy services or services in other less intensive rehabilitation settings immediately preceding the inpatient rehabilitation admission or that result from a systemic disease activation immediately before admission, but have the potential to improve with more intensive rehabilitation.
- SR.2c (12) Severe or advanced osteoarthritis (osteoarthrosis or degenerative joint disease) involving two or more major weight bearing joints (elbow, shoulders, hips, or knees, but not counting a joint with a prosthesis) with joint deformity and substantial loss of range of motion, atrophy of muscles surrounding the joint, significant functional impairment of ambulation and other activities of daily living that have not improved after the patient has participated in an appropriate, aggressive, and sustained course of outpatient therapy services or services in other less intensive rehabilitation settings immediately preceding the inpatient rehabilitation admission but have the potential to improve with more intensive rehabilitation. (A joint replaced by a prosthesis no longer is considered to have osteoarthritis, or other arthritis, even though this condition was the reason for the joint replacement.)
- SR.2c (13) Knee or hip joint replacement, or both, during an acute hospitalization immediately preceding the inpatient rehabilitation stay and also meet one or more of the following specific criteria:
- SR.2c (13)(i) The patient underwent bilateral knee or bilateral hip joint replacement surgery during the acute hospital admission immediately preceding the rehabilitation admission.
 - SR.2c (13)(ii) The patient is extremely obese with a Body Mass Index of at least 50 at the time of admission to the Rehabilitation unit/facility.
 - SR.2c (13)(iii) The patient is age 85 or older at the time of admission to the Rehabilitation unit/facility.
- SR.3 In the case of new inpatient rehabilitation unit/facility or new inpatient rehabilitation beds, the rehabilitation unit/facility must provide a written certification that the inpatient population it intends to serve meets the requirements of this section. This written certification will apply until the end of the rehabilitation unit/facility first full 12-month cost reporting period or, in the case of new rehabilitation unit beds, until the end of the cost reporting period during which the new beds are added to the inpatient rehabilitation unit/facility.

Definition:

- **New Inpatient Rehabilitation Facility (IRF) beds:** Any inpatient rehabilitation facility beds that are added to an existing IRF must meet all applicable State Certificate of Need and State licensure laws. New IRF beds may be added one time at any point during a cost reporting period and will be considered new for the rest of that cost reporting period. A full 12-month cost reporting period must elapse between the delicensing or decertification of IRF beds in an IRF hospital or IRF unit and the addition of new IRF beds to that IRF hospital or IRF unit. Before an IRF can add new beds, it must receive written approval from the appropriate CMS Regional Office (RO), so that the CMS RO can verify that a full 12-month cost reporting period has elapsed since the IRF has had beds delicensed or decertified. New IRF beds are included in the compliance review calculations per CMS from the time that they are added to the IRF.
- **Change of ownership or leasing:** An IRF hospital or IRF unit that undergoes a change of ownership or leasing, as defined in §489.18 of this chapter, retains its excluded status and will continue to be paid under the prospective payment system specified in §412.1(a)(3) before and after the change of ownership or leasing if the new owner(s) of the IRF accept assignment of the previous owners' Medicare provider agreement and the IRF continues to meet all of the

requirements for payment under the IRF prospective payment system. If the new owner(s) do not accept assignment of the previous owners' Medicare provider agreement, the IRF is considered to be voluntarily terminated and the new owner(s) may re-apply to participate in the Medicare program. If the IRF does not continue to meet all of the requirements for payment under the IRF prospective payment system, then the IRF loses its excluded status and is paid according to the prospective payment systems described in §412.1(a)(1).

- **Mergers:** If an IRF hospital (or a hospital with an IRF unit) merges with another hospital and the owner(s) of the merged hospital accept assignment of the IRF hospital's provider agreement (or the provider agreement of the hospital with the IRF unit), then the IRF hospital or IRF unit retains its excluded status and will continue to be paid under the prospective payment system specified in §412.1(a)(3) before and after the merger, as long as the IRF hospital or IRF unit continues to meet all of the requirements for payment under the IRF prospective payment system. If the owner(s) of the merged hospital do not accept assignment of the IRF hospital's provider agreement (or the provider agreement of the hospital with the IRF unit), then the IRF hospital or IRF unit is considered voluntarily terminated and the owner(s) of the merged hospital may reapply to the Medicare program to operate a new IRF.

Interpretive Guidelines:

The distinct part unit is to provide a screening of the patient to obtain the following information at, or prior to, the time of admission: current physical condition, past medical history, diagnosis(es), rehabilitation goals and contraindications, and any previous therapy or hospitalization related to the current medical condition.

Surveyor Guidance:

Review a sample of medical records during the survey to determine the practices in place to appropriately screen patients prior to admission to the distinct part unit and documentation of the elements of the screening of patients.

TP-R.2 PLAN ELEMENTS

The plan shall be in accordance with the practitioner's orders who are authorized by the medical staff to order the services include the following:

- SR.1 Physician review of the plan including any revisions;
- SR.2 Involvement of professional personnel including consultation with the patient's Physician;
- SR.3 Anticipated goals and specifies for those services to be provided.
- SR.4 Patients receive close medical supervision, as evidenced by at least 3 face-to-face visits per week by a licensed physician with specialized training and experience in inpatient rehabilitation to assess the patient both medically and functionally, as well as to modify the course of treatment as needed to maximize the patient's capacity to benefit from the rehabilitation process.
- SR.5 Involved a coordinated interdisciplinary team approach in the rehabilitation of each inpatient, as documented by the periodic clinical entries made in the patient's medical record to note the patient's status in relationship to goal attainment and discharge plans, and that team conferences are held at least once per week to determine the appropriateness of treatment.
- SR.6 The plan will be established, reviewed and revised as needed.

Interpretive Guidelines:

The distinct part unit shall have an individualized plan of treatment, 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. At a minimum, this treatment plan will include:

- The order from the practitioner for the service(s) with involvement of individuals qualified to provide the service(s);

- Measurable short-term and long-term goals, services to be provided; and,
- Reviews and revisions, as necessary, to account for changes in the patient's response to therapeutic intervention.

Surveyor Guidance:

- Sample patient records to verify that rehabilitation services are provided only in accordance with practitioner orders who are authorized by the medical staff to order these services and that those orders are documented in the medical record.
- In the review of patient records, verify that there is a plan of treatment established in writing prior to the beginning of treatment and there are stated short-term and long-term goals for the patient.
- Verify that changes in the treatment plan are documented in the patient's medical record to include the evaluation, test results, or orders, and practitioner approvals of changes.

TP-R.3 TEAM ASSESSMENT

The treatment plan will include the active involvement of a multidisciplinary team to assess patient progress with the treatment plan and make recommendations as appropriate to the patient's Physician.

- SR.1 Team conferences will be documented in the patient's medical record at least once per week to determine the appropriateness of treatment.

Surveyor Guidance:

Interview the distinct part unit staff and verify that the involvement of a multidisciplinary approach for assessment and progress of patients in accordance with the treatment plan and treatment provided is appropriate to the needs of the patient.

Verify through sampling a review of medical records to ensure that there are at least weekly conferences of the multidisciplinary teams and this is documented accordingly within the medical record.

STAFFING MANAGEMENT (SM-C)

The rehabilitation unit must also meet all Staffing Management (SM) requirements of the DNV GL- Healthcare NIAHO® Accreditation Requirements for Hospitals.

SM-R.1 CLINICAL DIRECTOR

The rehabilitation unit must be under the clinical direction of a licensed doctor of medicine or osteopathy who is qualified by background, training and after completing a [one year hospital internship](#) with at least two (2) years of experience in the medical management of inpatient rehabilitation patients.

- SR.1 The clinical director shall provide services to patients in the unit for at least twenty (20) hours per week.

Interpretive Guidelines:

The services provided within the distinct part unit must be under the direction of a licensed doctor of medicine or osteopathy who is qualified by background, training and at least two (2) years of experience in the medical management of inpatient rehabilitation patients that will have the accountability, qualifications, and experience appropriate as the clinical director.

Surveyor Guidance:

Review the hospital's policies and procedures and scope of responsibilities of the clinical director to verify that these services are under the direction of a qualified individual.

Review the personnel or medical staff file of the clinical director to verify these individuals has the appropriate background, training and experience.

SM-R.2 STAFFING

The rehabilitation unit must have an adequate number of properly trained, professional and qualified staff to perform the following services:

- SR.1 Rehabilitation nursing;
- SR.2 Physical therapy;
- SR.3 Occupational therapy; and, as needed,
- SR.4 Speech therapy, social services or psychological services (including neuropsychological services), and orthotic and prosthetic services.

Surveyor Guidance:

Review and verify the method(s) used by the distinct part unit for determining and modifying staffing needs with qualified professional staff.

Verify that staff providing rehabilitative services meet the qualifications as defined by the medical staff and organization and consistent with State law shall be performed by qualified nurses, physical therapists, physical therapist's assistants, occupational therapists, occupational therapist assistants, speech-language pathologists, or audiologists. (as defined in § 484.4 Personnel qualifications.)

If services are provided under a contractual arrangement, determine that the agreement requires the staff to be appropriately qualified (as listed above) and scope of services provided.

Sample personnel files to verify that current licensure, certifications and ongoing training, are consistent with applicable State laws.

APPENDICES

DISTINCT PART UNIT - PSYCHIATRIC UNIT (PU-B)

These standards are applicable to the psychiatric unit and services provided as a distinct part unit of the CAH. The CAH may have only one unit of each type (psychiatric or rehabilitation) excluded from the prospective payment systems.

GENERAL REQUIREMENTS (GR-P)

GR-P.1 COMPLIANCE WITH DNV GL- HEALTHCARE NIAHO® ACCREDITATION REQUIREMENTS FOR HOSPITALS STANDARDS FOR REQUIRED SERVICES

The psychiatric unit must be in compliance with all of the following DNV GL- Healthcare NIAHO® Accreditation Requirements for Hospitals to the extent such requirements are not addressed, modified by or in conflict with the CAH requirements:

- SR.1 *Quality Management System (QM);*
- SR.2 *Governing Body (GB);*
- SR.3 *Chief Executive Officer (individual who assumes full legal authority and responsibility for operations of the CAH) (CE);*
- SR.4 *Medical Staff (MS);*
- SR.5 *Nursing Services (NS);*
- SR.6 *Staffing Management (SM);*
- SR.7 *Medication Management (MM);*
- SR.8 *Laboratory Services (LS);*
- SR.9 *Medical Imaging (MI);*
- SR.10 *Dietary Services (DS);*
- SR.11 *Patient Rights (PR);*
- SR.12 *Infection Control (IC);*
- SR.13 *Medical Records Service (MR);*
- SR.14 *Discharge Planning (DC);*
- SR.15 *Utilization Review (UR);*
- SR.16 *Physical Environment (PE); and,*
- SR.17 *Organ, Eye and Tissue Procurement (TO)*

Surveyor Guidance:

Compliance with the DNV GL- Healthcare NIAHO® Accreditation Requirements for Hospitals Standards will apply for the psychiatric unit and services provided as a distinct part unit of the CAH. Cite the hospital Standard Requirement number for any nonconformities identified for the distinct part unit of the CAH under the hospital NIAHO® Accreditation Requirements for Hospitals.

GR-P.2 COMPLIANCE WITH DNV GL- HEALTHCARE NIAHO® Accreditation Requirements for Hospitals STANDARDS FOR OPTIONAL SERVICES

The psychiatric unit must be in compliance with the following DNV GL- Healthcare NIAHO® Accreditation Requirements for Hospitals if such service is offered:

- SR.1 *Surgical Services (SS);*
- SR.2 *Anesthesia Services (AS);*
- SR.3 *Respiratory Care Services (RC);*
- SR.4 *Nuclear Medicine Services (NM);*
- SR.5 *Rehabilitation Services (RS);*
- SR.6 *Obstetric Services (OB);*
- SR.7 *Emergency Department (ED); (See ED.1 SR.1 above for CAH)*
- SR.8 *Outpatient Services (OS)*

Surveyor Guidance:

Compliance with the DNV GL- Healthcare NIAHO® Accreditation Requirements for Hospitals Standards will apply for the psychiatric unit and services provided as a distinct part unit of the CAH. Cite the hospital Standard Requirement number for any nonconformities identified for the distinct part unit of the CAH under the hospital NIAHO® Accreditation Requirements for Hospitals.

GR-P.3 TRANSFER OF CLINICAL INFORMATION

The psychiatric unit shall have policies in place that assure the prompt transfer of clinical information when a patient is transferred between the CAH and the psychiatric unit.

Surveyor Guidance:

The clinical records are to be easily retrievable and available to all professional staff members of the organization and other authorized individuals when patients are transferred between the CAH and the distinct part unit.

Review the policy and procedure in place to reflect the manner in which clinical information is shared between the CAH and the distinct part unit.

Review the process in place to ensure clinical information and records is shared in accordance with the CAH policy and how this information is managed. As a part of the open medical record review trace the information to the CAH to ensure the effectiveness of the process when a patient is transferred from the CAH to the distinct part unit.

GR-P.4 COMPLIANCE WITH LAWS

The psychiatric unit shall be in compliance with all federal, state and local laws.

Surveyor Guidance:

Where applicable State or Local law or regulation is applicable, verify the objective evidence in place to reflect the CAH and distinct part unit is operating in compliance with such law or regulation

Document any nonconformity where the facility is not currently in compliance with applicable Federal laws and regulations related to the health and safety of patients

GR-P.5 PHYSICAL LOCATION

The psychiatric unit must have no more than ten (10) beds that are physically separate from other CAH beds. The CAH may only have one distinct part unit (psychiatric) designated.

- SR.1 The psychiatric unit must be physically separate from other CAH inpatient units.
- SR.2 The psychiatric unit beds in a Satellite Facility must be physically separate from the beds of the hospital in which it is located. When the psychiatric unit beds are located in a Satellite Facility, the facility must independently comply with the accreditation requirements under Appendix PU- B for psychiatric units.
- SR.2a The unit will be under the control of the governing body (or individual who assumes full legal authority and responsibility for operations of the CAH) of the CAH.
- SR.2b Patient care services are provided under the under the control and meet the requirements for the medical staff (or Medical Director) of the CAH.
- SR.2c The Satellite Facility will maintain separate patient records and shall be readily available.
- SR.2d The location of the beds in the Satellite Facility will be separate from the other beds in the facility.
- SR.2d (1) Off-campus and co-location requirements for CAHs. A CAH may continue to meet the location requirement of GR-P.5; SR.2 based only if the CAH meets the following:
- (A) If a CAH or a necessary provider CAH operates an off-campus provider-based location, excluding an RHC as defined in §405.2401(b), but including a department or remote location, as defined in §413.65(a)(2), or an off-campus distinct part psychiatric unit, as defined in §485.647, that was created or acquired by the CAH on or after January 1, 2008, the CAH can continue to meet the location requirement of only if the off- campus provider-based location or off-campus distinct part unit is located more than a 35 mile drive (or, in the case of mountainous terrain or in areas with only secondary roads available, a 15 mile drive) from a hospital or another CAH.
- (B) If either a CAH or a CAH that has been designated as a necessary provider by the State does not meet the requirements by co-locating with another hospital or CAH on or after January 1, 2008, or creates or acquires an off-campus provider-based location or off-campus distinct part unit on or after January 1, 2008, that does not meet the requirements of 412.27(a) , the CAH's provider agreement will be subject to termination in accordance with the provisions of §489.53(a)(3), unless the CAH terminates the off-campus arrangement or the co-location arrangement, or both

Interpretive Guidelines:

As a part of the confirming the accuracy of the information provided in the application for accreditation, the location of the beds for the distinct part unit will be verified if the beds are located at a Satellite Facility. These distinct part unit beds will be separate from those of the CAH and also separate in the case where the beds are located at a Satellite Facility.

Surveyor Guidance:

Verify that the distinct part unit beds are separate from the CAH.

Verify that the distinct part unit of the CAH is controlled under the governing body (or individual who assumes full legal authority and responsibility for operations of the CAH) of the CAH.

Verify that the medical staff, providing patient care services to patients within the distinct part unit of the CAH, are meeting the requirements of under the medical staff of the CAH.

GR-P.6 SERVICES

The psychiatric unit must provide the following services through qualified personnel:

- SR.1 Psychological services;
- SR.2 Social work services;
- SR.3 Psychiatric nursing;
- SR.4 Occupational therapy; and,
- SR.5 Recreational therapy

Interpretive Guidelines:

The distinct part unit of the CAH must be adequately staffed with qualified health professionals and other support staff to carry out services provided to ensure 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 treatment of patients.

Surveyor Guidance:

Review and validate the policy and practice of the CAH and distinct part unit for verifying the current licensure and/or certification of all staff members as required by the organization, and Federal and State law.

GR-P.7 UTILIZATION REVIEW STANDARDS

The psychiatric unit must also meet all Utilization Review (UR) requirements of the DNV GL- Healthcare NIAHO® Accreditation Requirements for Hospitals.

The psychiatric unit shall have in place an active utilization review program applicable to the type and level of care provided.

Interpretive Guidelines:

The distinct part unit of the CAH shall have a UR plan to include a delineation of the responsibilities and authority for those involved in the performance of UR activities, define the requirement for all review findings to be reported to the Quality Management Oversight group, and ensure that there is no conflict of interest (financial or otherwise) by those individuals participating in the review.

Surveyor Guidance:

Compliance with the DNV GL- Healthcare NIAHO® Accreditation Requirements for Hospitals Standards will apply for the psychiatric unit services provided as a distinct part unit of the CAH. Cite the hospital Standard Requirement number for any nonconformities identified for the distinct part unit of the CAH under the hospital NIAHO® Accreditation Requirements for Hospitals.

Surveyor Guidance:

Verify that the distinct part unit of the CAH has a utilization review plan for those services provided and its medical staff to patients.

Sample records and reports and supporting documentation that UR activities are being performed as described in the UR plan.

Verify the composition of the UR committee.

Review for any conflicts of interest regarding individuals involved in the UR activities, when applicable, are not included as a part of the UR process when there may be a potential conflict of interest.

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 appropriateness of admissions, utilization of professional services and extended stay reviews with approval or disapproval noted in a status report of any actions taken.

Note: Do not apply these UR requirements if any of the following situations apply:

- A Quality Improvement Organization (QIO) has assumed binding review for the CAH
- The State has entered into a contract with a QIO that is deemed under 42 CFR 431.630

PSYCHIATRIC ADMISSIONS (PA-P)

PA-P.1 ADMITTING DIAGNOSIS

An admitting diagnosis must be made on all patients admitted to the psychiatric unit.

- SR.1 All psychiatric patients must be admitted with a principal psychiatric diagnosis.
 - SR.1a The principal psychiatric diagnosis must be one that is listed in the Fourth Edition of the American Psychiatric Association's Diagnostic and Statistical Manual or in Chapter Five ("Mental Disorders") of the International Classification of Diseases, Ninth Revision, Clinical Modification **OR- the most current editions approved by CMS.**
- SR.2 The admitting diagnosis must include the medical diagnosis, other disease diagnoses, if any, and the psychiatric diagnoses.
- SR.3 The reasons for admission must be clearly documented as identified by the patient or others significantly involved with the admission, or both.
- SR.4 There shall be written criteria for admission that are uniformly applied to both Medicare and non-Medicare patients.

Interpretive Guidelines:

There is an admission diagnosis written in the Fourth Edition of the American Psychiatric Association's Diagnostic and Statistical Manual (DSM) or the approved International Classification of Diseases (ICD) Ninth Revision nomenclature. This diagnosis is made and entered into the patient's record at the time of the admission.

Other diagnoses (other than psychiatric) must be documented when they are made. Attention should be given to physical examination notes, including known medical conditions, allergies and recent exposure to infections, illness, or substance abuse, and to available laboratory or test reports which identify abnormal findings to see that these are reflected by appropriate diagnosis.

These diagnoses may be found in a variety of locations in the medical record, e.g., the identification/face sheet, the finding of admission physical examination, the psychiatric evaluation the "admission work up "or the physician's progress notes. Diagnostic categories should include physical illness when present.

Surveyor Guidance:

Please be aware that, since the CMS publication of the requirements of PA-P.1, SR.1, a 5th edition of the American Psychiatric Association's Diagnostic and Statistical Manual (DSM-5) was published (2013) and the American Medical Association has published a 10th revision of the International Classification of Diseases (ICD- 10) in 2017.

PA-P.2 NEUROLOGICAL EXAMINATION

A complete neurological examination neurological examination, if indicated, must be documented at the time of admission to the psychiatric unit.

Interpretive Guidelines:

At the time of admission, the patient should receive a thorough history and physical examination with all indicated laboratory examinations. This examination must be sufficient to identify 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 practitioner responsible for the care of the patient to determine the presence of continuing pathology or possible sequelae any of which may be determined to be pertinent to the present mental illness. Equally important is a thorough physical examination to identify signs of any current illness since psychotic symptoms may be due to a general medical condition or substance related disorder.

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 a complete neurological examination, all the systems are examined, but the practitioner responsible for the care of the patient will emphasize even more the areas pertinent to the problem for which the examination was requested.

Surveyor Guidance:

Verify through sampling a review of medical records to ensure there is evidence that a neurological examination was completed and documented within the patient's record at the time of admission to the distinct part unit of the CAH.

Verify through sampling a review of medical records to ensure there is documentation to indicate the neurological examination and history of the patient identified possible involvement (tremors, paralysis, motor weakness or muscle atrophy, severe headaches, seizures, head trauma).

PA-P.3 PSYCHIATRIC EVALUATION

Each patient must receive a psychiatric evaluation within sixty (60) hours of admission to the psychiatric unit. The psychiatric evaluation must include the following:

- SR.1 Medical history;
- SR.2 Assessment of mental status;
- SR.3 Description of the onset of illness and circumstances resulting in admission;
- SR.4 Description of the patient's attitudes and behavior;
- SR.5 Assessment of intellectual and memory functioning and orientation; and,
- SR.6 Description of the patient's assets in descriptive, not interpretative language

Interpretive Guidelines:

The psychiatric evaluation is to determine the patient's diagnosis and treatment and, therefore, it must contain the necessary information to justify the diagnosis and planned treatment.

The psychiatric evaluation is a total appraisal or assessment of the patient's illness. It is the practitioner'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. Through the psychiatric evaluation, the practitioner is to secure a biographical- historical perspective of the patient's personality, with a clear psychological picture of the patient his/ her individual problems. While conducting the psychiatric evaluation, the practitioner will have an understanding of the patient's basic personality structure, the patient's developmental period, of his/ her value systems, of his or her past medical history including surgical procedures and other treatments, his or her past psychological traumatic experiences, his/ her defense mechanisms, his/ her support systems, any precipitating factors and how these may have impacted the patient to result in the present illness.

The psychiatric evaluation includes all the requirements described in this standard and the information necessary to justify the diagnosis and treatment. In those cases, where the mental status portion of the psychiatric evaluation is performed by a non-physician, there should be evidence that the person is credentialed by the distinct part unit of the CAH, legally authorized by the State to perform that function, and a physician review and countersignature is present, where required by hospital policy or State law.

Assets of the patient would include strengths by way of personal attributes e.g., knowledge, interests, skills, aptitudes, personal experiences, education, talents and employment status

Surveyor Guidance:

Verify through sampling a review of medical records to ensure there is documentation to indicate the psychiatric evaluation of the patient and this include review of the patient's history of any psychiatric problems and treatment, including prior precipitating factors, diagnosis, course and treatment.

Verify that the psychiatric evaluation has determined for the patient the onset of illness, attitudes and behavior, Assessment of intellectual and memory functioning and orientation, other specific signs and symptoms, and other factors involved with the patient to justify the diagnosis of the patient.

Verify that the psychiatric evaluation was completed within 60 hours of the patient's admission to the distinct part psychiatric unit.

Verify that there is documentation to reflect an accurate and clear description of the patient's personal attributes that have been considered for preparing a treatment plan for the patient.

MEDICAL RECORDS SERVICES (MR-P)

The psychiatric unit must also meet all Medical Record Services (MR) requirements of the DNV GL- Healthcare NIAHO® Accreditation Requirements for Hospitals.

MR-P.1 MEDICAL RECORD

A medical record shall be maintained for each patient admitted to the psychiatric unit.

- SR.1 Each medical record shall contain sufficient information that identifies the degree and intensity of the psychiatric treatment.
- SR.2 Each medical record shall include elements that identify the development of assessment or diagnostic information.
- SR.3 Each medical record shall contain information regarding the history of findings and treatment for the specific psychiatric condition(s) for which the patient is being treated in the psychiatric unit.
- SR.4 Admission and discharge records for satellite facilities shall be separate from those of the hospital where the psychiatric unit is located and shall be readily available.

Interpretive Guidelines:

The distinct part unit of the CAH must maintain a medical record for each patient treated and this will be separate from the CAH.

The distinct part unit of the CAH must ensure that all medical records accurate and completely document all orders, evaluations, treatment plans, treatments, interventions, care provided and the patient's response to those treatments, interventions and care.

The distinct part unit of the CAH 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 distinct part unit or off-premises through a contractual arrangement, the hospital must ensure there is a process in place to protect and retrieve these records in a timely manner.

The distinct part unit of the CAH will maintain a compliance program as required under the Health Insurance Portability and Accountability Act (HIPAA).

Surveyor Guidance:

Review the area(s) where medical records are maintained by the distinct part unit of the CAH.

Verify that a medical record is maintained for each person treated or receiving care and includes sufficient information that identifies the degree and intensity of the psychiatric treatment, identifies the development of assessment and diagnostic information, and history of the patient including previous treatment of psychiatric conditions.

Verify that medical records are stored and maintained in area(s) that ensure the records are secure, protected from damage by flood, fire, and other casualties, and access is limited to authorized staff.

Verify that the hospital has a process to ensure that records are accurate, completed promptly, easily retrieved and readily accessible in all area(s) where medical records are maintained.

Validate the hospital's current practices in place for protecting and securing the confidentiality of patient records.

MR-P.2 PROGRESS NOTES

Each medical record shall contain adequate progress notes.

- SR.1 Each medical record shall contain progress notes from the:

SR.1a Doctor of medicine or osteopathy responsible for the care of the patient;

SR.1b Nurse;

SR.1c Social worker; and,

SR.1d Others involved in active treatment modalities.

SR.2 Progress notes shall be made no less than weekly for the first two (2) months and at least monthly thereafter.

SR.3 Progress notes must contain a progress assessment in accordance with the original or revised treatment plan and recommendations for revisions.

MR-P.3 LEGAL STATUS

Patient identification data must include the patient's legal status.

Surveyor Guidance:

Definition: 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.

Determine through interview with distinct part unit staff the terminology used to define "legal status." If evaluation and recertification is required by the State, determine that legal documentation supporting this status is present. Changes in legal status should also be recorded with the date of change.

MR-P.4 SOCIAL SERVICES RECORDS

The medical records shall contain social service records that include a social history and assessment of home plans and family attitudes. These records shall include interviews with the patient, family and other involved parties.

TREATMENT PLAN (TP-P)

TP-P.1 PLAN REQUIREMENT

Each patient shall have a written comprehensive treatment plan that is based on the patient's strengths and disabilities.

TP-P.2 PLAN ELEMENTS

The comprehensive treatment plan shall include the following:

- SR.1 A substantiated diagnosis;
- SR.2 Identification of short and long-term goals;
- SR.3 Identification of treatment modalities;
- SR.4 Responsibilities of each member of the treatment team;
- SR.5 Documentation to justify the diagnosis, treatment and rehabilitation activities; and,
- SR.6 Documentation that treatment included all active therapeutic efforts.

Interpretive Guidelines:

The patient and treatment team collaboratively develop the patient's treatment plan. The treatment plan directs the staff of the distinct part unit for treatment of the patient based on an assessment of the patient's needs. The distinct part will have a defined process in place for preparing the treatment plans and updating the treatment plan as needed.

The treatment plan will include the documentation to justify the diagnosis, identification of goals to evaluate the patient's progress, treatment modalities, rehabilitative activities and other treatment therapies to be applied.

Surveyor Guidance:

Verify through sampling a review of medical records, to ensure that the assessment and evaluation of the patient has been utilized to develop the treatment plan to meet the needs of the patient and includes the elements as described in under this standard.

Verify that Short-term and long-range goals identify specific dates for expected achievement and the treatment plan is revised accordingly based on attainment or regression in relation to these goals.

Verify that treatment modalities are specifically described in order to ensure consistency for treatment of the patient. Determine if the treatment methods, approaches and interventions from all disciplines are included in the treatment plan

THERAPEUTIC ACTIVITY (TA-P)

TA-P.1 PLAN REQUIREMENT

The psychiatric unit must provide a therapeutic activities program tailored to the needs and interests of its patients.

- SR.1 The program shall be designed to restoring and maintaining optimal levels of physical and mental functioning.

Interpretive Guidelines:

A variety of therapeutic and rehabilitative activities may be used as therapeutic tools in providing active treatment of patients. 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

Use of individualized therapeutic and rehabilitative staff modalities should be based on patient need and goals set in the patient's treatment plan. Rehabilitative services may include educational, occupational, recreational, physical, art, dance, music, and speech therapies and vocational rehabilitation evaluation and counseling. There may also be other disciplines that also serve the needs of patients.

Surveyor Guidance:

Verify that there is a therapeutic activities program in place and tailored to meet the needs and supports the interest of patients.

TA-P.2 STAFFING

The therapeutic activities program shall be adequately staffed with qualified therapists, consultants, support staff and others to provide a comprehensive program tailored to each patient's active treatment plan.

Interpretive Guidelines:

The distinct part unit of the CAH may include consultants involved to provide in the treatment of the patient which may include appropriately qualified; occupational therapists/ occupational therapy assistants, therapeutic recreation specialist, therapeutic recreation assistants, speech-language pathologist music therapist, art therapist, and physical therapists. The distinct part unit of the CAH may also consult as qualified vocational specialist to perform duties of a rehabilitation counselor, vocational evaluator, or the work adjustment specialist when determined to be beneficial for treatment of patients.

Surveyor Guidance:

Determine if the distinct part unit of the CAH involves other qualified professionals in the treatment of the patient and the means for involving these professionals in the treatment of the patient.

DISCHARGE PLANNING (DC-P)

The psychiatric unit must also meet all Discharge Planning (DC) requirements of the DNV GL- Healthcare NIAHO® Accreditation Requirements for Hospitals.

DC-P.1 DISCHARGE PLAN

The record of each discharged patient shall include a concise summary of the patient's psychiatric hospitalization, condition on discharge and recommendations for follow-up care or post-discharge care from appropriate services.

- SR.1 The psychiatric unit must provide for adequate qualified professional and support staff to evaluate patients.
- SR.2 The written discharge plan will be comprehensive and individualized for the patient to reflect the treatment plan and current treatment measures.

Interpretive Guidelines:

The discharge planning process will identify the following factors when patients are leaving the hospital setting: functional status; cognitive ability of the patient; and, family support.

The distinct part unit of the CAH should have a process in place to identify patients who are at risk of requiring post-discharge services. The distinct part unit of the CAH needs to ensure the availability of services that the patient may need and determine the patient's ability for self-care or care to be provided by another party when necessary.

The discharge planning process will be initiated in a timely manner in order for arrangements to be made for the patient prior to discharge.

The documentation associated with the discharge planning process will be included as a part of the patient's medical record as a means of coordinating communication with other providers involved in the patient's care throughout the hospital. The patient's practitioner, a registered nurse, social worker, and/or other qualified staff member will be responsible for the development of information and materials to implement the discharge plan for the patient.

Surveyor Guidance:

Verify that the discharge planning is effective and an inherent part of the patient care delivery system through the following means:

- Interview staff to determine how patients are identified and require discharge planning;
- Review the hospital's policy and procedures to verify that at-risk patients are provided discharge planning; and,
- Sample records to see when the discharge planning process is initiated, the roles of individuals involved in the process, reassessments as needed and the implementation of the discharge plan.

STAFFING MANAGEMENT (SM-P)

The psychiatric unit must also meet all Staffing Management (SM) requirements of the DNV GL- Healthcare NIAHO® Accreditation Requirements for Hospitals.

SM-P.1 STAFFING

The psychiatric unit must have an adequate number of properly trained, professional staff to perform the following duties:

- SR.1 Evaluate psychiatric inpatients;
- SR.2 Develop written comprehensive treatment plans individualized to each patient;
- SR.3 Provide appropriate treatment according to the treatment plan; and,
- SR.4 Participate in discharge planning individualized to each patient.

Interpretive Guidelines:

The distinct part unit of the CAH shall provide for sufficient number of appropriately qualified professional staff to provide for the evaluation of patients, development of comprehensive treatment plans, provide appropriate treatment in accordance with the treatment plan and participate in the discharge planning process for patients.

Surveyor Guidance:

Verify that there is an adequate number of properly trained professional staff for evaluation of patients.

Review a sampling of personnel records to ensure that professional staff have the appropriate education, experience and/or training in psychiatric care.

Interview professional staff to determine their role in the evaluation of patients, development of treatment plans, providing treatment for patients and how they participate in the discharge planning process.

SM-P.2 PSYCHOLOGICAL SERVICES

Psychological services shall be provided in a manner to meet patient needs in accordance with acceptable standards of practice, service objectives and written policies and procedures.

Interpretive Guidelines:

Written policies and procedures will be in place to describe psychological services provided in accordance with acceptable standards of practice and may include diagnostic testing and diagnostic formulations on request from practitioners; provision of individual, group and family therapies; participation in multi-disciplinary treatment conferences; and program development and evaluation.

Surveyor Guidance:

Determine the types of psychological services offered by the distinct part unit of the CAH (e.g., assessments, therapy).

Review written policies and procedures in place describing psychological services provided.

MEDICAL STAFF (MS-P)

The psychiatric unit must also meet all Medical Staff (MS) requirements of the DNV GL- Healthcare NIAHO® Accreditation Requirements for Hospitals.

MS-P.1 CLINICAL DIRECTOR

The psychiatric unit must be under the direction of a doctor of medicine or osteopathy who is qualified by background, training and experience to be board certified or board eligible by the American Board of Psychiatry and Neurology or the American Osteopathic Board of Neurology and Psychiatry.

- SR.1 The Clinical Director shall be responsible for supervising, monitoring and evaluating the quality and appropriateness of psychiatric services.

Interpretive Guidelines:

The distinct part unit of the CAH shall have a clinical director responsible for the supervision, monitoring and evaluation of the appropriateness of psychiatric service provided. The clinical director will be a doctor of medicine or osteopathy who is qualified by background, training and experience. The clinical director shall be qualified through board certification or determined to be board eligible upon successful completion of a psychiatric residency program approved by the American Board of Psychiatry and Neurology and/or the American Osteopathic Board of Psychiatry and Neurology.

Surveyor Guidance:

Review the personnel record and job description/scope of responsibilities of the clinical director and/or interview the clinical director to determine if he/she has:

- A doctor of medicine or osteopathy
- Maintains certification of the American Board of Psychiatry and Neurology and/or certification of the American Osteopathic Board of Neurology and Psychiatry
- Training and equivalency to be board eligible

MS-P.2 STAFFING

The psychiatric unit shall have an adequate number of qualified doctors of medicine or osteopathy to meet patient needs for psychiatric services.

Interpretive Guidelines:

The number of full-time, part-time and consulting qualified psychiatric doctors of medicine or osteopathy must be adequate to provide necessary services to patients. Arrangements with outside resources must assure that necessary patient services will be provided.

Surveyor Guidance:

Verify that the distinct part unit of the CAH has a means in place and provides for an adequate number of qualified psychiatric doctors of medicine or osteopathy to meet patient needs.

Determine the process in place for making arrangements with outside resources when necessary to carry out the services provided.

NURSING SERVICES (NS-P)

The psychiatric unit must also meet all Nursing Services (NS) requirements of the DNV GL Healthcare NIAHO® Accreditation Requirements for Hospitals.

NS-P.1 NURSING DIRECTOR

The psychiatric unit shall have a nursing director who is a registered nurse and qualified by background, training and experience in psychiatric nursing.

- SR.1 The nursing director shall possess a master's degree in psychiatric or mental health nursing (or equivalent degree) from a National League of Nursing (NLN) accredited school of nursing or be otherwise qualified by education, training and experience in the care of psychiatric patients.
- SR.2 The nursing director must be competent to participate in the formulation of the patient's comprehensive treatment plan, provide skilled nursing care and therapy, and to direct, monitor and evaluate nursing care provided.

Surveyor Guidance:

Interview the Nursing Director for the distinct part unit of the CAH and review the job description and personnel file to verify his/her educational background and psychiatric nursing and leadership skills.

Determine if the Nursing Director has a Master's Degree in Psychiatric Nursing or equivalent degree, evidence of experience and on-going training in psychiatric nursing.

Interview the Nursing Director to determine how he/she participates in the formulation of the patient's comprehensive treatment plan, ensures that skilled nursing care and therapy are provided, and directs, monitor and evaluates nursing care provided to patients of the distinct part unit of the CAH.

NS-P.2 STAFFING

There shall be an appropriate number nursing staff (registered nurses, licensed practical nurses and nursing assistants, and mental health staff) to provide the proper level of nursing care and to document the nursing care given each patient according to each patient's comprehensive treatment plan.

- SR.1 There shall be a registered nurse available twenty-four (24) hours a day.
- SR.2 There will be a method in place for determining and modifying staffing to meet the needs of patients within the psychiatric unit.

Interpretive Guidelines:

The distinct part unit of the CAH shall provide for sufficient number of staff RNs, LPNs and mental health staff to provide the proper level of nursing care and to document the nursing care given each patient according to each patient's comprehensive treatment plan.

Patient care assignments should be appropriate to the skills and qualifications of the nursing personnel providing patient care.

Nursing personnel and mental health staff should be appropriately qualified through education, experience and/or training in psychiatric care.

Surveyor Guidance:

Verify that there is a registered nurse available in the distinct part unit of the CAH twenty-four (24) hours a day.

Review a sampling of personnel records to ensure that nursing personnel have education, experience and/or training in psychiatric care.

Determine the method in place for determining and modifying staffing and patient care assignments by qualified staff are made to meet the needs of patients within the distinct part unit of the CAH.

SOCIAL SERVICES (SS-P)

SS-P.1 STAFFING

There shall be a director of social services who is responsible for monitoring and evaluating the quality and appropriateness of social services.

SS-P.2 SERVICES

Social services will be provided according to accepted standards of practice and written policies and procedures. Social services will include at least the following:

- SR.1 Discharge planning;
- SR.2 Assisting in the arrangement for post-hospital care; and,
- SR.3 Establishing mechanisms for the exchange of appropriate information with outside sources.

Interpretive Guidelines:

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 significant others of the patient. Such functions may include patient and family education, support, and advocacy; providing coordination/liaison with community-based social and mental health agency(ies); 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.

Social Services will be described in written policies and procedures regarding contact with the patient, family, and significant others should occur during, or as soon as possible, after the admission.

Involvement of Social Services shall be in place for early integration into the treatment plan and subsequent planning and actions to be taken to plan for the discharge of the patient, assisting with making arrangements for post-hospital care and establishing the means to exchange information with outside sources.

The distinct part unit of the CAH will have an appropriately qualified Social Services director responsible for monitoring and evaluating the quality and appropriateness of services provided.

Surveyor Guidance:

Verify that an appropriately qualified director of social services has been identified and the defined scope of responsibilities for monitoring and evaluating the quality and appropriateness of social services provided.

Determine if the distinct part unit of the CAH involves Social Services professionals in the discharge planning process, planning of post-hospital treatment of the patient and providing the appropriate contact with outside sources to make arrangements that may be required to facilitate the continued treatment of the patient.