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National Integrated Accreditation for Healthcare Organizations  
(NIAHO<sup>SM</sup>)  
Accreditation Requirements  
ISSUE 307-8.0

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Use of NIAHO<sup>SM</sup> Accreditation Requirements

Effective Date

These NIAHO<sup>SM</sup> Accreditation Requirements, Issue 307-8.0 (Revision 8.0) have an Effective Date of 09-18-09.

National Professional Organizations- Standards of Practice

Standards of practice of the national professional organizations referenced in this NIAHO<sup>SM</sup> Interpretive Guideline and Surveyor Guidance 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<sup>SM</sup> Interpretive Guideline and Surveyor Guidance document are incorporated herein by reference and constitute NIAHO<sup>SM</sup> accreditation requirements.

NIAHO standards are based upon the Center for Medicare and Medicaid (CMS) Conditions of Participation. Hospitals participating in the Medicare and Medicaid program are expected to comply with current Conditions of Participation. When new or revised requirements are published hospitals are expected to demonstrate compliance in a time frame consistent with the effective date published by CMS in the Federal Register.

Life Safety Code®

The Life Safety Code® of the National Fire Protection Association referenced in this NIAHO<sup>SM</sup> Interpretive Guideline and Surveyor Guidance document are incorporated herein by reference and constitute NIAHO<sup>SM</sup> accreditation requirements.

DEFINITIONS

AOA	American Osteopathic Association
AMA	American Medical Association
AORN	Association of periOperative Registered Nurses
APIC	Association of Professionals in Infection Control and Epidemiology
ASA	American Society of Anesthesiologists
CDC	Centers for Disease Control and Prevention
CEO	Chief Executive Officer
CFR	Code of Federal Regulations
CMS	Centers for Medicare Medicaid Services
CRNA	Certified Registered Nurse Anesthetist
DEA	Drug Enforcement Administration
FDA	Food and Drug Administration
HHA	Home Health Agency
HVAC	Heating Ventilating and Air Conditioning
ISMP	Institute for Safe Medication Practices
ISO	International Organization of Standardization
Life Safety Code	Life Safety Code® of the National Fire Protection Association
LIP	Licensed Independent Practitioner
NFPA	National Fire Protection Association
NLN	National League for Nursing
NPDB	National Practitioner Data Bank
OIG	Office of Inspector General, Department of Health and Human Services
PRN (prn)	Pro re nata, as the occasion arises, when necessary
QIO	Quality Improvement Organization
QMS	Quality Management System
Secretary	Secretary of the Department of Health and Human Services
SMDA	Safe Medical Devices Act of 1990
SNF	Skilled Nursing Facility
SR	Standard Requirement. Additional explanatory information under each major accreditation requirement in this Guide.

## QUALITY MANAGEMENT SYSTEM (QM)

### QM.1 QUALITY MANAGEMENT SYSTEM

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

In addition to any other Quality Management System standard, the organization is required to comply with QM.1 at all times as a part of its Quality Management System. Until the organization achieves ISO 9001:2008 Certification, the organization shall follow at a minimum the ISO 9001:2008 methodology specified in QM.2, SR.3 (below).

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

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

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

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

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

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

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

### QM.2 ISO 9001 QUALITY MANAGEMENT SYSTEM

SR.1 Compliance with the ISO 9001 standard must occur within three (3) years after the initial deemed NIAHO<sup>SM</sup> accreditation. The Organization shall either demonstrate compliance with the ISO 9001 Quality Management System principles through a NIAHO<sup>SM</sup> 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 organization shall maintain ISO 9001 compliance or formal Certification in order remain eligible for NIAHO<sup>SM</sup> Accreditation.

SR.1a Failure to demonstrate compliance or certification with the ISO 9001 standard within three (3) years after the NIAHO<sup>SM</sup> accreditation that first occurs after DNVHC receives deeming authority from CMS shall result in NIAHO<sup>SM</sup> Jeopardy Status.

SR.2 An Accredited Registrar recognized by the International Organization of Standardization 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 organization will initiate and continue implementation of the ISO 9001 methodology to achieve compliance or certification as stated in QM.1 SR.1. At a minimum the organization must be able to demonstrate at the time of the NIAHO<sup>SM</sup> Accreditation survey evidence of the following:

SR.3a Control of Documents: the organization's documents (i.e. policies, procedures, forms) are structured in a manner to ensure that only the proper revisions are available for use;

SR.3b Control of Records: the organization ensures that suitable records are maintained for the CoP and NIAHO<sup>SM</sup> requirements;

SR.3c Internal Surveys (Internal Audits) – the organization conducts internal reviews of its processes and resultant corrective/preventive action measures have been implemented and verified to be effective;

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

SR.3f Appropriate information has been submitted to the oversight group for quality management as required in QM.6 SR.1 as well as top management for review and analysis during a management review process.

### **QM.3 QUALITY OUTLINE**

The organization shall clearly outline its 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.

### **QM.4 MANAGEMENT REPRESENTATIVE**

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

### **QM.5 DOCUMENTATION AND MANAGEMENT REVIEWS**

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

### **QM.6 SYSTEM REQUIREMENTS**

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

SR.1 Interdisciplinary group to oversee the Quality Management System that includes at least the CEO, COO, Nurse Executive, Pharmacy, Risk Management, Safety Management, Privacy Officer, Quality Facilitator/Management Representative, and two members of the medical staff who must be doctors of medicine or osteopathy. This interdisciplinary group shall conduct Management Reviews;

SR.2 Written document defining the Quality Management System, to include all 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 based in some manner to:

SR.5a Focus on high-risk, problem-prone areas, processes or functions,

SR.5b Consider the incidence, prevalence and severity of problems in these areas, processes or functions,

SR.6c Affect health outcomes, improve patient safety and quality of care.

#### **QM.7 MEASUREMENT, MONITORING, ANALYSIS**

The organization shall evaluate all organized services and processes, both direct and supportive, including services provided by any contracted service. The monitoring shall include the use of internal reviews (audits) of each department or service at scheduled intervals, not to exceed one year and data related to these processes. Individual(s) not assigned to that department or service shall conduct the internal review (audit). Measurement, monitoring and analysis of processes throughout the organization require 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 organization must define the frequency and detail of the measurement. Those functions to be measured at a minimum must include the following:

SR.1 Threats to patient safety;

SR.2 Medication therapy/medication use; to include medication reconciliation and the use of dangerous abbreviations;

SR.3 Operative and invasive procedures; to include wrong site/wrong patient/wrong procedure surgery

SR.4 Anesthesia/moderate sedation;

SR.5 Blood and blood components

SR.6 Restraint use/seclusion;

SR.7 Effectiveness of pain management system;

SR.8 Infection control system, including nosocomial infections;

SR.9 Utilization Management System;

SR.10 Patient flow issues, to include reporting of patients held in the Emergency Department or the PACU in excess of eight hours.

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

SR.12 Discrepant pathology reports;

SR.13 Unanticipated deaths, non-sentinel event;

SR.14 Sentinel event/near miss and other medical errors;

SR.15 Other adverse events;

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

SR.17 Medical record delinquency; and,

SR.18 Physical Environment Management Systems

## **QM.8 PATIENT SAFETY SYSTEM**

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

## **GOVERNING BODY (GB)**

### **GB.1 LEGAL RESPONSIBILITY**

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

- SR.1 The governing body (or organized group or individual who assumes full legal authority and responsibility for operations of the hospital), medical staff, and administrative officials (to include the chief executive officer, chief financial officer, and nurse executive) are responsible and accountable for ensuring that the following:
- SR1a. the organization is in compliance with all applicable Federal and State laws regarding the health and safety of its patients;
  - SR1b. the organization is licensed by the appropriate State or local authority responsible for licensing hospitals;
  - SR1c. Criteria that includes aspects of individual character, competence, training, experience and judgment is established for the selection of individuals working for the organization, directly or under contract, and/or appointed through the formal medical staff appointment process; and,
  - SR1d. the personnel working in the organization are properly licensed or otherwise meet all applicable Federal, State and local laws.

### **GB.2 INSTITUTIONAL PLAN AND BUDGET**

- SR.1 The organization shall have an overall plan that includes an annual operating budget that contains all anticipated income and expenses and is prepared according to generally accepted accounting principles.
- SR.2 The plan must provide for capital expenditures for at least a 3-year period including the year identified in SR.1 (above). The plan must include and identify in detail the objective of, and the anticipated sources of financing for, each anticipated capital expenditure in excess of \$600,000 (or lesser amount established by the State in which the organization is located in accordance with Section 1122(g)(1) of the Social Security Act and is related to:
- SR2a. acquisition of land;
  - SR2b. improvement of land, buildings and equipment, or
  - SR2c. replacement, modernization or expansion of buildings or equipment.

- SR.3 The plan must be reviewed and updated annually.
- SR.4 The plan must be prepared under the direction of the governing body and by a committee consisting of representatives of the governing body, the administrative staff, and the medical staff of the institution.
- SR.5 If required, the plan must be submitted for review in accordance with Section 1122 of the Social Security Act or, as applicable, to the appropriate health planning agency in the State.

### **GB.3 CONTRACTED SERVICES**

- SR.1 The governing body shall require annual management reviews of selected indicators to ensure that all contracted services (including all joint ventures or shared services) provide services that are safe and effective and that comply with all applicable NIAHO<sup>SM</sup> requirements.
- SR.2 The governing body is responsible for services furnished in the hospital whether or not they are furnished under contract. The organization must evaluate and select contracted services (including all joint ventures or shared services) (and non-contracted services) entities/individuals based on their ability to supply products and/or services in accordance with the organization's requirements. Criteria for selection, evaluation, and re-evaluation shall be established. The criteria for selection will include the requirement that the contracted entity or individual to provide the products/services in a safe and effective manner and comply with all applicable NIAHO<sup>SM</sup> requirements, and standards required for all contracted services.
- SR.3 A documented list of contracted companies and individuals, including their scope/nature of services shall be maintained.

## **CHIEF EXECUTIVE OFFICER (CE)**

### **CE.1 QUALIFICATIONS**

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

### **CE.2 RESPONSIBILITIES**

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

## **MEDICAL STAFF (MS)**

### **MS.1 ORGANIZED MEDICAL STAFF**

The organization shall have an organized medical staff that is composed of fully licensed doctors of medicine or osteopathy. In accordance with State law, the medical staff may also include other practitioners.

### **MS.2 ELIGIBILITY**

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

### **MS.3 ACCOUNTABILITY**

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

#### **MS.4 RESPONSIBILITY**

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

#### **MS.5 EXECUTIVE COMMITTEE**

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

#### **MS.6 MEDICAL STAFF PARTICIPATION**

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

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

#### **MS.7 MEDICAL STAFF BYLAWS**

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

#### **MS.8 APPOINTMENT**

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

- SR.1 Initial appointment to the medical staff:
  - SR.1a. primary source verification of licensure, education, specific training, experience, and current competence ;
  - SR.1b. current Federal Narcotics Registration Certificate (DEA) number;

SR.1c. two peer recommendations;

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

SR.1e. if available, 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.2 Reappointment to the medical staff:

SR.2a. primary source verification of licensure and current competence;

SR.2b. current DEA number;

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.

## **MS.9 PERFORMANCE DATA**

Practitioner specific performance data is required and must be rate-based with comparative peer or national data available for comparison. Areas to be measured are:

SR.1 Blood use: AABB transfusion criteria;

SR.2 Prescribing of medications: Prescribing errors and appropriateness of prescribing for Drug Use Evaluations;

SR.3 Surgical Case Review: appropriateness and outcomes for selected high-risk procedures;

SR.4 Specific department indicators that have been defined by the medical staff;

SR.5 Moderate Sedation Outcomes;

SR.6 Appropriateness of care for non-invasive specialties;

SR.7 Utilization data;

SR.8 Significant deviations from established standards of practice; and,

SR.9 Timely and legible completion of patients' medical records.

SR.10 Any variant should be analyzed for statistical significance.

## **MS.10 CONTINUING EDUCATION**

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

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

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

### **MS.11 GOVERNING BODY ROLE**

- SR.1 The governing body shall appoint members of the medical staff and approve clinical privileges after considering the recommendations of the existing members of the medical staff and ensure that the medical staff is accountable to the governing body for the quality of care provided to patients.
- SR.2 The governing body may elect to delegate the authority to render initial appointment, reappointment, and renewal or modification of clinical privileges decisions to a committee of the governing body.
- SR.3 The governing body shall ensure that under no circumstances is medical staff membership or professional privileges in the organization dependent solely upon certification, fellowship, or membership in a specialty body or society.
- SR.4. A complete application shall be acted on within a reasonable period of time, as specified in the medical staff bylaws.

### **MS.12 CLINICAL PRIVILEGES**

- SR.1 The medical staff bylaws shall include criteria for determining the privileges to be granted to individual practitioners and a procedure for applying the criteria to those individuals that request privileges.
- SR.2 Appointment or reappointments to the medical staff and the granting, renewal, or revision of clinical privileges shall be made for a period defined by State law or if permitted by State law, not to exceed three years.
- SR.3 All individuals who are permitted by the organization and by law to provide patient care services independently in the organization shall have delineated clinical privileges.
- SR.4 There shall be a provision in the medical staff bylaws for a mechanism to ensure that all individuals with clinical privileges provide services only within the scope of privileges granted.
- SR.5 The medical staff bylaws shall provide a mechanism for consideration of automatic suspension of clinical privileges in any of the following instances:
  - SR.5a. revocation/restriction of professional license;
  - SR.5b. revocation/suspension/probation of Federal Narcotics Registration Certificate (DEA);
  - SR.5c. failure to maintain the specified amount of professional liability insurance; or,
  - SR.5d. non-compliance with written medical record delinquency or deficiency requirements.
- SR.6 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.7 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.

### **MS.13 TEMPORARY CLINICAL PRIVILEGES**

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

- SR.1 On the recommendation of the medical executive committee;
- SR.2 For a period of time not to exceed thirty days. Temporary privileges may be extended for two separate 30-day intervals upon approval of the governing body.
- SR.3 Criteria for granting temporary privileges:

- SR.3a. verification of education (AMA/AOA Profile);
- SR.3b. demonstration of current competence;
- SR.3c. 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, OIG Medicare/Medicaid Exclusions.

#### **MS.14 CORRECTIVE OR REHABILITATION ACTION**

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

#### **MS.15 ADMISSION REQUIREMENTS**

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

- SR.1 The governing body shall ensure that every patient is under the care of a:
  - SR.1a. doctor of medicine or osteopathy who may delegate such care to other qualified health care professionals to the extent allowed by State law;
  - SR.1b. doctor of dental surgery or dental medicine who is legally authorized to practice dentistry by the State and who is acting within the scope of his/her license;
  - SR.1c. doctor of podiatric medicine, only with respect to functions authorized by State;
  - SR.1d. doctor of optometry who is legally authorized to practice optometry by the State;
  - SR.1e. chiropractor who is licensed by the State and legally authorized to perform the services of a chiropractor, but only with respect to treatment by means of manual manipulation of the spine to correct a subluxation demonstrated by x-ray to exist; or
  - SR.1f. clinical psychologist (doctoral degree in psychology), but only with respect to clinical psychologist services as defined in 42 CFR §410.71 and only to the extent permitted by State law.
- SR.2. The governing body shall ensure that:
  - SR.2a. a doctor of medicine or osteopathy is on duty or on call at all times; and,
  - SR.2b. a doctor of medicine or osteopathy is responsible for the care of each patient with respect to any medical or psychiatric problem that is present on admission or develops during hospitalization and is not within the scope of practice of the licensed practitioners specified in SR 1b-1f (above) as that scope of practice is defined by the medical staff and State law.

#### **MS.16 MEDICAL RECORD MAINTENANCE**

- SR.1 The medical staff bylaws shall include the requirement for the preparation and maintenance of a complete and accurate medical record for each patient and policies and procedures for dealing with medical record delinquencies.
- SR.2 The medical staff bylaws shall require that the medical staff have periodic meetings at regular intervals to review and analyze medical records of the patients for adequacy and quality of care.

## **MS.17 HISTORY AND PHYSICAL**

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

## **MS.18 CONSULTATION**

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

## **MS.19 AUTOPSY**

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

## **NURSING SERVICES (NS)**

### **NS.1 NURSING SERVICE**

- SR.1 The organization must have a well-organized nursing service with a plan of administrative authority and delineation of responsibilities for delivery of patient care.
- SR.2 There shall be 24-hour nursing services and a registered nurse must supervise and evaluate the nursing care for each patient. A registered nurse or licensed practical nurse shall be on duty at all times except in facilities that have been granted a waiver in accordance with § 488.54(c), Federal law, rules or regulations.

- SR.3 The nursing service must develop and maintain a procedure to ensure that nursing personnel for whom licensure is required have a valid and current licensure. Nursing services must be provided or supervised by a registered nurse.
- SR.4 There shall be adequate numbers of licensed registered nurses, licensed practical nurses, supervisory, and other staff to provide nursing care to all patients as needed. A registered nurse must be immediately available for the bedside care of every patient, as required by State law.
- SR.5 A registered nurse shall make any decisions regarding delegation of nursing care to other nursing staff, based on individual patient need and staff qualifications.
- SR.6 Non-employee licensed nurses who are working in the organization must adhere to the policies and procedures of the organization. The director of nursing service must provide for the adequate supervision and evaluation of the clinical activities of non-employee nursing personnel that occur within the responsibility of the nursing service.

## **NS.2 NURSE EXECUTIVE**

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

## **NS.3 PLAN OF CARE**

- SR.1 Nursing staff shall develop and maintain a plan of care for each patient within 24 hours of admission that reflects the input of other disciplines, as appropriate. Documentation of these interdisciplinary findings, including pain assessment and interventions shall be included in the plan of care, as appropriate.

## **STAFFING MANAGEMENT (SM)**

### **SM.1 LICENSURE OR CERTIFICATION**

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

### **SM.2 PROFESSIONAL SCOPE**

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

### **SM.3 DEPARTMENT SCOPE OF SERVICE**

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

- SR.1 The hours of operation;
- SR.2 Patient populations served;
- SR.3 Skill mix;
- SR.4 Core staffing and methods for determining and modifying staffing to meet patient or process needs; and,

- SR.5 Description of assessment and reassessment practices, including timeframes.
- SR.6 The organization shall consolidate these scopes of service, including these staffing requirements, into one organization-wide document.

#### **SM.4 DETERMINING AND MODIFYING STAFFING**

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

#### **SM.5 JOB DESCRIPTION**

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

#### **SM.6 ORIENTATION**

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

#### **SM.7 STAFF EVALUATIONS**

- SR.1 The performance/competency evaluation shall contain indicators that will objectively measure the ability of staff to perform all job duties as outlined in the job description. Relevant indicators shall then be selected from this complete list of indicators for measurement as outlined below.
- SR.2 The staff shall be evaluated initially and on an on-going basis against indicators that measure issues and opportunities for improvement that are identified through at least the following:
  - SR.2a variations and problem processes identified through the analysis of outcomes measurement as required by the Quality Management System;
  - SR.2b high-risk, low volume procedures;
  - SR.2c new technology/equipment/processes;
  - SR.2d customer satisfaction feedback;
  - SR.2e scheduled training session outcomes;
  - SR.2f staff learning needs assessments that include variations identified through prior staff performance measurement;
  - SR.2g staff feedback;
  - SR.2h medical staff feedback; and,
  - SR.2i requirements of Federal or State law.
- SR.3 Indicator measurement for contract staff may be modified based on organization outcomes and frequency of service of the individual. Modification of this measurement must take place no less than every calendar year and shall be justified by data analysis.
- SR.4 The organization shall aggregate the objective performance data for the individual staff and within each job classification to identify variations for further training, coaching, and mentoring.
  - SR.4a Re-measurement shall follow any intervention.
  - SR.4b The outcomes of this measurement shall be reported in the aggregate to Quality Management Oversight.

- SR.5 The organization shall define a timeframe, not to exceed one calendar year, and a policy and practice for sharing the indicators measurement of individual staff members with those staff members that allows for staff feedback.
- SR.6 The organization shall require each staff member, including contract staff, to participate in continuing education as required by individual licensure/certification, professional association, law or regulation, or organization policy. Compliance with this standard shall be reported to Quality Management Oversight.

## **MEDICATION MANAGEMENT (MM)**

### **MM.1 MANAGEMENT PRACTICES**

- SR.1 The organization shall have a pharmacy service that meets the needs of the patients. Medications will be administered in accordance with accepted professional principles. The pharmacy service will be directed by a full time, part time, or consulting registered pharmacist responsible for developing, supervising, and coordinating all the activities of the pharmacy services. The pharmacy service must have an adequate number of qualified personnel to ensure effective medication management services, including emergency services.
- SR.2 All medications shall be administered by or under the supervision of nursing or other qualified personnel in accordance with applicable Federal and State laws. All drugs and biologicals 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.3 All compounding, packaging, and dispensing of medication shall be under the supervision of a pharmacist.
- SR.4 All drugs and biologicals must be controlled, secured and distributed in accordance with applicable standards of practice and consistent with Federal and State law at all times.
  - SR.4a Drugs listed as Schedule II, III, IV, and V of the Comprehensive Drug Abuse Prevention and Control Act of 1970 must be kept locked within a secure area.
  - SR.4b. Only personnel authorized by the pharmacy service shall have access to locked areas.
- SR.5 Outdated, mislabeled, or otherwise unusable medications shall not be available for patient use.
- SR.6 Medications prescribed without specific duration or number of doses shall automatically be stopped after a reasonable time that has been predetermined by the medical staff.
- SR.7 Staff other than doctors of medicine or osteopathy who administer blood transfusions and intravenous medications shall have special training.

### **MM.2 FORMULARY**

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

### **MM.3 SCHEDULED DRUGS**

- SR.1 Current and accurate records must be kept of the receipt and disposition of all scheduled drugs, and in compliance with all Federal and State documentation requirements.
- SR.2 Abuses and losses of controlled substances must be reported, in accordance with applicable Federal and State laws, to the individual responsible for the pharmaceutical service, and to the chief executive officer, as appropriate.

#### **MM.4 MEDICATION ORDERS**

All medication orders shall:

- SR.1 Include the name of the drug, the dosage and frequency of administration and the route of administration.
- SR.2 Be in writing and signed, including date and time, by the practitioner or practitioners responsible for the care of the patient as specified under 42 CFR§482.12(c) and authorized to write such orders by hospital policy and in accordance with State law.
  - SR.2a. Influenza and polysaccharide vaccines may be administered in accordance with a policy approved by the medical staff after an individual assessment for contraindications.
- SR.3 Telephone or verbal orders are to be used infrequently and when used must be accepted only by personnel authorized by the medical staff and in accordance with Federal and State law.
- SR.4 Verbal orders must be signed or initialed by the prescribing practitioner must be authenticated in accordance with Federal and State law. If there is not State law that designates a specific timeframe for the authentication of verbal orders, the orders must be authenticated within 48 hours.

#### **MM.5 REVIEW OF MEDICATION ORDERS**

A licensed pharmacist must review all medication orders prior to administration of the first dose to a patient. If 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.
- 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.6 This licensed individual shall leave a duplicate dose with a copy of the order or comparable method for verification by a licensed pharmacist upon arrival in the organization.
- SR.7 The removal of the medication must be documented, tracked and trended and the results analyzed to determine need for additional pharmacy staff or medication storage resources and appropriateness of any pharmacy after-hour practices, as appropriate.

#### **MM.6 OVERSIGHT GROUP**

- SR.1 The medical staff is responsible for developing policies and procedures that minimize drug errors. The medical staff may delegate this responsibility to an organized pharmacy oversight group.

- SR.2 There shall be procedures for reporting transfusion reactions, adverse drug reactions, and errors in prescribing, preparing, and administering of drugs, in the aggregate, for trending and analysis.
- SR.3 Drug preparation, administration, and prescribing errors, adverse drug reactions, and incompatibilities shall be immediately reported to the attending physician and to the organization-wide quality management program.

#### **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.

### **SURGICAL SERVICES (SS)**

#### **SS.1 ORGANIZATION**

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

#### **SS.2 STAFFING AND SUPERVISION**

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

#### **SS.3 PRACTITIONER PRIVILEGES**

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

#### **SS.4 HISTORY AND PHYSICAL**

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

#### **SS.5 AVAILABLE EQUIPMENT**

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

- SR.1 Call-in system;
- SR.2 Cardiac monitor;
- SR.3 Resuscitator;
- SR.4 Defibrillator;
- SR.5 Suction equipment; and,
- SR.6 Provisions for emergency airway intervention.

#### **SS.6 OPERATING ROOM REGISTER**

The operating room register shall be complete and current.

#### **SS.7 POST-OPERATIVE CARE**

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

#### **SS.8 OPERATIVE REPORT**

- SR.1 An operative report describing techniques, findings, and tissues removed or altered shall be written or dictated and signed by the surgeon immediately following surgery.
- SR.2 The operative report shall be dictated or written 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).

## **SS.9 IMMEDIATE POST-OPERATIVE NOTE**

- SR.1 An immediate postoperative note is required to be written if there is a dictation turn around delay. This shall include identification or description of:
- SR.1a the surgeon and assistants;
  - SR.1b pre-op and post-op diagnosis;
  - SR.1c procedures performed;
  - SR.1d specimens removed;
  - SR.1e blood administered; and,
  - SR.1f any complications.
  - SR.1g type of anesthesia administered
  - SR.1h grafts or implants
- SR.2 If information identified in the post-operative note is available in nursing documentation; it is acceptable if authenticated as accurate by the attending surgeon.

## **ANESTHESIA SERVICES (AS)**

### **AS.1 ORGANIZATION**

- SR 1 Anesthesia services shall be provided in an organized manner, and function under the direction of a qualified doctor of medicine or osteopathy. The service is responsible for all anesthesia administered in the organization.
- SR 2 Anesthesia services shall be appropriate to the scope of the services offered.

### **AS.2 ADMINISTRATION**

Anesthesia shall only be administered by the following:

- SR.1 A qualified anesthesiologist or a doctor of medicine or osteopathy (other than an anesthesiologist);
- SR.2 A dentist, oral surgeon, or podiatrist who is qualified to administer anesthesia under State law;
- SR.3 A certified registered nurse anesthetist (CRNA) as defined in 42 CFR §410.69(b), who is under the supervision of the operating practitioner or of an anesthesiologist who is immediately available if needed;
- SR.4 For CRNAs to operate as licensed independent practitioners, the governor of the State must have received an exemption from CMS for that particular State; or
- SR.5 An anesthesiologist's assistant as defined in 42 CFR §410.69(b), if approved by State law, who is under the supervision of an anesthesiologist who is immediately available if needed.

### **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, to include a documented airway assessment, anesthesia risk assessment, and anesthesia drug and allergy history, by an individual qualified and privileged to administer anesthesia/sedation, performed no more than 48 hours prior to surgery or procedure requiring anesthesia services;
  - SR.2b an intra-operative anesthesia/sedation record;

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

SR.2c(1) A post-anesthesia evaluation for anesthesia recovery is required and must be completed In accordance with State law and hospital policies and procedures approved by the medical staff and reflect current standards of care anytime general, regional, or monitored (this would include deep sedation/analgesia has been administered to the patient.

SR.2c(2) 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 for outpatient surgery, a follow-up report as defined by the medical staff.

## **LABORATORY SERVICES (LS)**

### **LS.1 ORGANIZATION**

SR.1 The organization shall maintain, or have available, adequate laboratory services, either directly or through contractual services, to meet the needs of its patients.

SR.2 The organization shall ensure that all laboratory services provided to its patients are performed in a laboratory certified in accordance with 42 CFR §493.

SR.3 The organization shall have the capability to perform necessary laboratory studies, including blood gas analysis and electrolyte determination 24 hours a day.

SR.4 A documented scope of laboratory services shall be available to the medical staff.

SR.5 The laboratory shall have policies and practices for proper receipt and reporting of tissue specimens.

SR.6 The medical staff and a pathologist shall determine which tissue specimens require a macroscopic (gross) examination and which require both macroscopic and microscopic examinations.

### **LS.2 INFECTIOUS BLOOD AND PRODUCTS**

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

SR.1 If an organization regularly uses the services of an outside blood bank, it shall have an agreement with the blood bank that governs the procurement, transfer, and availability of blood and blood products.

SR.2 The agreement shall require that the blood bank promptly notify the organization of the following:

SR.2a Within 3 calendar days if the blood bank supplied blood and blood products collected from a donor who tested negative at the time of donation but tests repeatedly reactive for the antibody to HIV or HCV on a later donation; and

SR.2b the results of the FDA licensed, more specific test or other follow-up testing recommended or required by the FDA completed within forty five (45) calendar days after the donor's repeatedly reactive screening test for HIV or HCV.

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

### **LS.3 PATIENT NOTIFICATION**

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

- SR.1 Promptly make at least three attempts to notify the patient, and/or patient's attending physician (the physician of record) or the physician who ordered the blood or blood product. (See LS.3 SR.7 regarding notification of legal representative when applicable)
- SR.2 Request that the physician immediately notify the patient, or other individual of the need for HIV testing and counseling.
- SR.3 If the physician is unavailable, declines to make the notification, or later informs the organization that he or she was unable to notify the patient, promptly make at least three attempts to notify the patient, legal representative or relative of the need for HIV or HCV testing and counseling.
- SR.4 Document in the patient's medical record the notification or attempts to give the required notification.
- SR.5 Timeframe for notification:

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

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

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

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

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

SR.5c The notification effort begins when the blood bank notifies the organization that it received potentially HIV or HCV infectious blood and blood products. The organization shall make reasonable attempts to give notification and must complete the actions within one (1) year of the date on which the organization received notification from the blood bank.

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

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

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

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

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

SR.7 Policies and Procedures: The organization shall establish policies and procedures for notification and documentation that conform to Federal, State, and local laws, including requirements for confidentiality and medical records. A notification to legal representative or relative shall address the following:

SR.7a if the patient has been adjudged incompetent by a State court, the physician or organization shall notify a legal representative designated in accordance with State law;

SR.7b if the patient is competent, but State law permits a legal representative or relative to receive the information on the patient's behalf, the physician or organization shall notify the patient or his/her legal representative or relative; and,

SR.7c if the patient is deceased, the physician or organization shall continue the notification process and inform the deceased patient's legal representative or relative.

SR.7d If the patient is a minor, the physician or organization must notify the patient's parents or legal guardian.

#### LS.4 GENERAL BLOOD SAFETY

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

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

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

## **RESPIRATORY CARE SERVICES (RC)**

### **RC.1 ORGANIZATION**

- SR.1 The organization of the respiratory care services shall be appropriate to the scope and complexity of the services offered.
- SR.2 Respiratory care services provided at the organization shall be delivered in accordance with medical staff directives.
- SR.3 There shall be a director of respiratory care services who is a doctor of medicine or osteopathy with the knowledge, experience, and capabilities to supervise and administer the service properly.
- SR.4 There shall be appropriate numbers of respiratory therapists, respiratory therapy technicians and other qualified personnel whose training meets the qualifications specified by the medical staff and State law.

### **RC.2 PHYSICIAN ORDER**

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

### **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

### **RC.4 TESTS OUTSIDE THE LABORATORY**

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

## **MEDICAL IMAGING (MI)**

### **MI.1 ORGANIZATION**

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

### **MI.2 RADIATION PROTECTION**

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

**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.

**MI.4 ORDER**

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

**MI.5 SUPERVISION**

- SR.1 A qualified full-time, part-time, or consulting radiologist shall supervise the ionizing medical imaging services and shall interpret those radiology tests that are determined by the medical staff to require a radiologist's specialized knowledge.
- SR.2 For purposes of this standard, a radiologist is a doctor of medicine or osteopathy who is qualified by education and experience in radiology.

**MI.6 STAFF**

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

**MI.7 RECORDS**

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

**MI.8 INTERPRETATION AND RECORDS**

- SR.1 The radiologist or other practitioner who interprets radiology images and outcomes must sign the written reports of his/her interpretations.
- SR.2 The organization must maintain the following for at least 5 years:
  - SR.2a copies of reports and printouts; and,
  - SR.2b films, scans, and other image records.

## **NUCLEAR MEDICINE SERVICES (NM)**

### **NM.1 ORGANIZATION**

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

### **NM.2 RADIOACTIVE MATERIALS**

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

### **NM.3 EQUIPMENT AND SUPPLIES**

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

### **NM.4 INTERPRETATION**

- SR.1 The practitioner approved by the medical staff to interpret diagnostic procedures must sign the interpretation of these tests.
- SR.2 The organization must maintain signed and dated reports of nuclear medicine interpretations, consultations, and procedures.
- SR.3 The organization must maintain copies of nuclear medicine reports for at least five (5) years.

## **REHABILITATION SERVICES (RS)**

### **RS.1 ORGANIZATION**

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

### **RS.2 MANAGEMENT AND SUPPORT**

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

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

SR.1b the director/manager shall have the qualifications, experience and/or training defined by the organization and appropriate for this position;

SR.1c staff who meet the qualifications as defined by the medical staff and organization and consistent with State law shall be performed by qualified physical therapists, physical therapists assistants, occupational therapists, occupational therapist assistants, speech-language pathologists, or audiologists. (as defined in § 484.4 Personnel qualifications.)

### **RS.3 TREATMENT PLAN**

The organization 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. 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 § 409.17.

## **OBSTETRIC SERVICES (OB)**

### **OB.1 COMPLIANCE**

Obstetrical services will comply with recommendations of the American College of Obstetrics and Gynecology.

### **OB.2 ANESTHESIA SERVICES**

SR.1 If anesthesia services are provided for labor and delivery, the same standard of coverage as that of operating room anesthesia will be provided and comply with the recommendations of the American Society of Anesthesiology.

SR.2 If a patient has received epidural analgesia, there will be a practitioner immediately available to manage any complication for the analgesia or the specific obstetrical condition.

## **EMERGENCY DEPARTMENT (ED)**

### **ED.1 ORGANIZATION**

- SR. 1 The organization must meet the emergency needs of its patients in accordance with acceptable standards of practice.
- SR.2 Emergency Services shall be organized and integrated with other departments under the direction and supervision of a qualified member of the medical staff.
- SR.3 The medical staff shall be responsible for developing and maintaining policies and procedures governing the medical care delivered.

### **ED.2 STAFFING**

- SR.1 Adequate medical and nursing staff qualified in emergency care, as outlined in the written scope of service, must be present to meet the written emergency procedures and needs determined by the organization.
- SR.2 A qualified registered nurse shall perform patient triage upon presentation to the emergency department.

### **ED.3 EMERGENCY SERVICES NOT PROVIDED**

If emergency services are not provided at the organization, the governing body must assure that the medical staff has written policies and procedures for appraisal of emergencies, initial treatment, and referral when appropriate.

### **ED.4 OFF-CAMPUS DEPARTMENTS**

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

## **OUTPATIENT SERVICES (OS)**

### **OS.1 ORGANIZATION**

If the organization provides outpatient services, the services shall be appropriately organized and integrated with inpatient services.

### **OS.2 STAFFING**

The organization shall assign an individual to be responsible for outpatient services and have appropriate professional and nonprofessional staff available.

### **OS.3 SCOPE OF SERVICE**

A documented scope of service shall be available for each patient care site that includes core staffing for each site with associated staff responsibilities.

## **DIETARY SERVICES (DS)**

### **DS.1 ORGANIZATION**

- SR.1 Dietary Services are organized processes that shall be carried out internally or through a contract with a nutrition management company that interacts on a regular basis with the medical staff on dietetic policies affecting patient care.

- SR.2 The organization shall ensure that there is the appropriate management and support for this core process. These requirements shall include a full-time person responsible for the management, direction and accountability for ensuring food and dietetic services are carried out daily throughout the organization. This full-time person shall have the qualifications, experience and training defined by the organization and appropriate for the position;
- SR.3 The full-time person responsible for the management of Food and Dietetic Services shall ensure that the appropriate administrative and technical personnel are competent and adequate to carry out this process for the organization.
- SR.4 The organization shall have a qualified dietitian in the organization who is available to address issues, concerns and patient care planning. This dietitian shall be employed by the organization on a full-time or part-time basis or contracted as a consultant for the organization and available as needed.

## **DS.2 SERVICES AND DIETS**

Dietary Services shall be provided and menus/diets offered that meet the needs of the patients. The following criteria shall be applied:

- SR.1 All menus/diets offered must meet the needs of the patients
- SR.2 All therapeutic diets shall be prescribed by a practitioner or practitioners responsible for the care of the patient; and,
- SR.3 All nutritional needs of patients shall be met in accordance with recognized dietary practices that are consistent with the orders of the practitioner or practitioners responsive for the care of the patients.

## **DS.3 DIET MANUAL**

- SR.1 The organization shall maintain a written dietary manual that defines the current therapeutic diets used by the organization.
- SR.2 The dietary manual shall be approved by a dietitian (full-time, part-time or contracted) and the medical staff.
- SR.3 The dietary manual shall be a document that is communicated, controlled and available to all staff and practitioners who are directly or indirectly responsible for ensuring that appropriate nutritional services are implemented.

## **PATIENT RIGHTS (PR)**

### **PR.1 SPECIFIC RIGHTS**

The organization shall protect and promote each patient's rights. The organization shall inform, whenever possible, each patient and/or legal representative (as allowed under State law) of the patient's rights in advance of providing or discontinuing care and allow the patient to exercise his or her rights accordingly. The written listing of these rights shall be provided to the patient and /or family and shall include policies and procedures that address the following:

- SR.1 Beneficiary Notice of non-coverage and right to appeal premature discharge;
- SR.2 Patient participation and means for making informed decisions regarding his/her plan of care;
- SR.3 Information to the patient or family of patient care and to involve the patient and family to make informed decisions regarding their care planning and treatment, including the requesting and/or refusing treatment, their health status, not to be construed as a demand for the provision of treatment or services deemed medically unnecessary or inappropriate;

- SR.4 Prompt notification of the patient and his/her representative of patient choice and to promptly notify the patient's physician of admission;
- SR.5 Personal privacy;
- SR.6 Provision of care in a safe setting;
- SR.7 Freedom from all forms of abuse or harassment;
- SR.8 Confidentiality of clinical records;
- SR.9 Access information contained in his or her clinical records within a reasonable timeframe; and,
  - SR.9(a) The hospital must not impede the legitimate efforts of individuals to gain access to their own clinical records and must actively seek to meet these requests as quickly as the record keeping system permits.
- SR.10 Procedure for submission of a written or verbal grievance. (See PR.5 Grievance Procedure)
- SR.11 Pain Management
- SR.12 Other rights defined within the Patient Rights requirements (PR.1 – PR.8)

## **PR.2 ADVANCE DIRECTIVE**

The organization must allow the patient to formulate advance directives and to have organization staff and practitioners comply with the advance directives in accordance with Federal and State law, rules and regulations.

- SR.1 The organization shall document in the patient's medical record whether or not the patient has executed an advance directive.
- SR.2 The organization shall not condition the provision of care or otherwise discriminate based on the execution of the advance directive.
- SR.3 The organization shall ensure compliance with State law regarding the provision of an advance directive.
- SR.4 The organization shall provide education for staff 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.

## **PR.3 LANGUAGE AND COMMUNICATION**

The organization shall inform the patient and/or legal representative of their rights in language or format that the patient and/or legal representative understand.

- SR.1 Organization policy and practice provides for competent individuals to interpret the patient's language for individuals who do not speak English or provide alternative communication aids for those who are deaf, blind, or otherwise impaired.

## **PR.4 INFORMED CONSENT**

The organization shall obtain an informed written consent from each patient or authorized representative for the provision of medical and/or surgical care except in medical emergencies. The consent shall include an explanation of risks, benefits, and alternatives for high-risk procedures, sedation, and participation in research projects, as defined by the medical staff and State law.

## **PR.5 GRIEVANCE PROCEDURE**

The organization shall develop and implement a formal grievance procedure for submission of a patient's written or verbal grievance to the hospital, approved by the governing body, that provides for the following:

- SR.1 A list of whom to contact;
- SR.2 The governing body responsibility for effective operation of the grievance process. The governing body must review and resolution of grievances or the written delegation of this function to an appropriate person or committee ;
- SR.3 A process for timely referral of quality of care issues or premature discharge to the Utilization Review, Quality Management or Peer Review functions and Utilization and Quality Improvement Organizations (QIO), 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 organization contact person;
  - SR.5b steps taken to investigate;
  - SR.5c results of the grievance process; and,
  - SR.5d date of completion.

## **PR.6 RESTRAINT OR SECLUSION**

All patients have the right to be free from physical or mental abuse, and corporal punishment.

All patients have the right to be free from restraint or seclusion, of any form, that is not medically necessary, or that is imposed by staff as a means of coercion, discipline, convenience, or retaliation. Each patient should be treated with respect and dignity.

- SR.1 The patient has the right to be free from restraints of any form that are not medically necessary or are used as a means of coercion, discipline, convenience, or retaliation by staff.
  - SR.1a A restraint is any manual method, physical or mechanical device, material, or equipment that immobilizes or reduces the ability of a patient to move his or her arms, legs, body, or head freely; or a drug or medication when it is used as a restriction to manage the patient's behavior or restrict the patient's freedom of movement and is not a standard treatment or dosage for the patient's condition.

A restraint does not include devices, such as orthopedically prescribed devices, surgical dressings or bandages, protective helmets, or other methods that involve the physical holding of a patient for the purpose of conducting routine physical examinations or tests, or to protect the patient from falling out of bed, or to permit the patient to participate in activities without the risk of physical harm (this does not include a physical escort).
  - SR.1b A restraint includes a drug or medication used as a restriction to manage the patient's behavior or restrict the patient's freedom of movement and is not a standard treatment or dosage for the patient's condition.
  - SR.1c Seclusion is the involuntary confinement of a patient alone in a room or area from which the patient is physically prevented from leaving. A situation where a patient is restricted to a room or area alone and staff are physically intervening to prevent the patient from leaving the room or area is also considered seclusion

Seclusion may only be used for the management of violent or self- destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others.

- SR.2 The hospital will keep the patient safe and protect their rights when restraint or seclusion are applied.
- SR.2a. The hospital will have policies and procedures designed to protect patient rights and dignity with regards to the use of restraint and seclusion, and ensure safety of the patient, staff and others. These policies and procedures guide staff in the safe use of restraint or seclusion, and incorporate all elements of the Federal and State regulations.
  - SR.2b. Restraint or seclusion may only be imposed to ensure the immediate physical safety of the patient, staff or others and must be discontinued at the earliest possible time.
  - SR.2c. Restraint or seclusion may only be used when less restrictive interventions have been determined to be ineffective to protect the patient or others from harm.
  - SR.2d. The type or technique of restraint or seclusion used must be the least restrictive intervention that will be effective to protect the patient or others from harm.
  - SR.2e. The use of restraint or seclusion must be in accordance with a written modification to the patient's plan of care, and implemented in accordance with safe and appropriate restraint and seclusion techniques as determined by hospital policy in accordance with State law.
  - SR.2f. Restraint and seclusion may not be used simultaneously, unless the patient is continually monitored, face-to-face, by an assigned, trained staff member; or continually monitored by trained staff using both video and audio equipment.
    - SR.2f(1) This monitoring must be in close proximity to the patient.
    - SR.2f(2) For the purposes of this provision, "continually" means ongoing without interruption

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 licensed independent practitioner (LIP) who is responsible for the care of the patient as specified under § 482.12(c) and is authorized to order restraint or seclusion by hospital policy in accordance with State law.
- SR.3b. An order for restraint or seclusion must be obtained prior to the application of restraints, except in emergency situations when the need for intervention may occur quickly;
- SR.3c. An order for restraint or seclusion is never to be written as a standing order or on an as needed basis (PRN).
- SR.3d. The attending physician must be consulted as soon as possible if restraint or seclusion is not ordered by the patient's attending physician.
- SR.3e. Each order for restraint or seclusion used to manage violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others based on the age of the patient.
  - SR.3e(1) Orders are limited to 4 hours for adults 18 years of age or older; 2 hours for children and adolescents 9 to 17 years of age; and 1- hour for children under 9 years of age.
  - SR.3e(2) The restraint or seclusion order may only be renewed in accordance with these limits for up to a total of 24 hours unless superseded by State law that is more restrictive.
  - SR.3e(3) After 24 hours, and before writing a new order for the use of restraint or seclusion for the management of violent or self-destructive behavior a physician or other LIP (if allowed by State law) must see and assess the patient.

SR.3e(4) If the restraint or seclusion is discontinued prior to the expiration of the order, a new order must be obtained prior to re-initiation of the restraint or seclusion.

SR.3f. Each order for restraint used to ensure the physical safety of the non-violent or non-self-destructive patient may be renewed as authorized by hospital policy, at least each calendar day.

#### 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 LIP, 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 LIP responsible for the care of the patient must be consulted as soon as possible after completion of the evaluation.

#### SR.5 Assessment, Monitoring, and Evaluation of the Restrained or Secluded Patient

SR.5a. The condition of patients in restraint or seclusion is monitored and assessed by a physician, other licensed independent practitioner or trained staff at an interval determined by hospital policy, at least every 24 hours.

SR.5a(1) Hospital policies address the frequency of assessment and the assessment parameters (for example, vital signs, circulation checks, hydration needs, elimination needs, level of distress and agitation, mental status, cognitive functioning, skin integrity).

SR.5a(2) Hospital policies guide staff in how to determine an appropriate interval for assessment and monitoring based on the individual needs of the patient, the patient's condition, and the type of restraint used. (for example, every 15 minutes)

SR.5b. Restraint or seclusion must be discontinued at the earliest possible time, regardless of the length of time identified in the order.

SR.5c. The LIP must evaluate the patient even if the patient is removed from restraint prior to the expiration of the order within 24 hours of the order initiation.

SR.5d. 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.5d(1) This monitoring must be in close proximity to the patient.

SR.5d(2) For the purposes of this provision, "continually" means ongoing without interruption

#### SR.6. Documentation in the Medical Record

SR.6a When restraint or seclusion is used, there must be documentation in the patient's medical record of the following:

- SR.6a(1) A description of the patient's behavior and the intervention used;

- SR.6a(2) Alternatives or other less restrictive interventions attempted (as applicable);
  - SR.6a(3) The patient's condition or symptom(s) that warranted the use of the restraint or seclusion; and,
  - SR.6a(4) The patient's response to the intervention(s) used, including the rationale for continued use of the intervention
  - SR.6a(5) The 1-hour face- to-face medical and behavioral evaluation and assessment findings if restraint or seclusion is used to manage violent or self- destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others;
  - SR.6a(6) Monitoring and assessment activities
  - SR.6a(7) Written modification to the patient's plan of care or treatment plan based on an assessment and evaluation of the patient.
  - SR.6a(8) The plan of care or treatment plan should be reviewed and updated in writing within a timeframe specified by hospital policy.
  - SR.6a(9) Additional elements of documentation, such as name, title, and credentials of staff members involved in the procedure, should be specified in hospital policy.
- SR.6b. In addition, staff must document in the patient's medical record the date and time any death associated with restraint or seclusion use was reported to CMS. (see section on Report of Death)

#### SR.7 Quality Monitoring

- SR.7a. The use of restraint and seclusion is to be monitored and evaluated on a continual basis as part of the organization's Quality Management System. (See also QM.7.SR.6)
- SR.7b Evidence of prolonged restraint, as defined by the organization, and, if possible, actions taken to reduce or eliminate the use of restraints must be analyzed by the treatment team.
- SR.7c Aggregate data regarding the use of restraint must be collected and analyzed for the identification of patterns and trends. Intensive analysis must be implemented in the event a patient is injured through the use of restraint or a staff member is injured through the application of a restraint.

#### **PR.7 RESTRAINT OR SECLUSION: STAFF TRAINING REQUIREMENTS**

The patient has the right to safe implementation of restraint or seclusion by trained staff.

- SR.1 Staff must be trained and able to demonstrate competency in the application of restraints, implementation of seclusion, monitoring, assessment, and providing care for a patient in restraint or seclusion
  - SR.1a. Training must occur before performing any of these actions, as part of orientation, and subsequently on a periodic basis consistent with hospital policy.
- SR.2 The hospital must require appropriate staff to have education, training, and demonstrated knowledge based on the specific needs of the patient population in at least the following:
  - SR.2a. Techniques to identify staff and patient behaviors, events, and environmental factors that may trigger circumstances that require restraint or seclusion;
  - SR.2b. The use of non-physical intervention skills, including de-escalation and dealing with aggressive behavior;
  - SR.2c. Choosing the least restrictive intervention based on an individualized assessment of the patient's medical or behavioral status or condition;

- SR.2d. The safe application and use of all types of restraint or seclusion used in the hospital, including training in how to recognize and respond to signs of physical and psychological distress (for example, positional asphyxia);
  - SR.2e. Clinical identification of specific behavioral changes that indicate that restraint or seclusion is no longer necessary;
  - SR.2f. Monitoring the physical and psychological well-being of the patient who is restrained or secluded, including but not limited to, respiratory and circulatory status, skin integrity, vital signs, and any special requirements specified by hospital policy associated with the 1-hour face-to-face evaluation; and;
  - SR.2g. The use of first aid techniques and certification in the use of cardiopulmonary resuscitation, including recertification requirements.
- SR.3 At a minimum, physicians and other LIP's authorized to order restraint or seclusion by hospital policy in accordance with State law must have a working knowledge of the hospital policy regarding the use of restraint or seclusion.
- SR.3a. Physician and other LIP training requirements must be specified in hospital policy
- SR.4 Individuals providing staff training must be qualified as evidenced by education, training, and experience in techniques used to address patients' behaviors.
- SR.5 The hospital must document in the staff personnel records that the training and demonstration of competency were successfully completed

#### **PR.8 RESTRAINT OR SECLUSION: REPORT OF DEATH**

- SR.1 Hospitals must report deaths associated with the use of restraint or seclusion directly to CMS in accordance with 42 CFR 482.13(g), the Conditions of Participation, and the State Operations Manual.
- SR.2 Staff must document in the patient's medical record the date and time the death was reported to CMS.

### **INFECTION CONTROL (IC)**

#### **IC.1 INFECTION CONTROL SYSTEM**

- SR.1 The organization shall have a process in place, as required and/or recommended by the Centers for Disease Control (CDC) and related professional organizations, to maintain a sanitary environment for organization patients, staff, and others. This process shall provide the means for avoiding and transmitting infections and communicable diseases.
- SR.2 The organization shall have a documented process, policies and procedures to define how infections and communicable diseases are prevented, controlled and investigated throughout the organization.
- SR.3 The Infection Control System shall be evaluated at least annually. This evaluation shall be forwarded to Quality Management oversight.
- SR.4 The documented process shall define the following:
  - SR.4a there shall be a designated Infection Control Officer that has the appropriate qualifications and experience as defined by the organization and shall govern the policies for controlling infections and communicable diseases;
  - SR.4b any designated practitioner shall have completed a course in basic surveillance by a recognized body. If in the role five (5) years or longer there must be evidence of pertinent continuing education related to infection control, minimally every two (2) years;
  - SR.4c the process for identifying, reporting, investigating and controlling infections and communicable diseases; and,
  - SR.4d the maintaining and control of records to account for incidents related to infections and communicable diseases.

- SR.5 Infections and communicable diseases shall be measured and analyzed to identify any patterns or trends.
- SR.6 The organization, through its chief executive officer, medical staff and nurse executive shall ensure that the Infection Control System and associated activities adequately address issues identified throughout the organization and there are prevention, correction, improvement and training programs to address these issues and provide adequate resources to accomplish the associated activities of the infection control program,
- SR.7 Significant infection control data/information shall be disseminated no less than quarterly to the organization oversight group responsible for the infection control function.
- SR.8 Surveillance methodology shall be appropriate for the population(s) served and approved no less than annually by the Infection Control oversight. The inpatient and outpatient populations shall be reported to this oversight group as an annual summary of reported illnesses

## **MEDICAL RECORDS SERVICE (MR)**

### **MR.1 ORGANIZATION**

- SR.1 Administrative responsibility for medical records shall rest with the medical record service of the organization.
- SR.2 The organization shall provide these services in accordance with the scope and complexities of services offered and allocate the appropriate resources to ensure efficient functioning.

### **MR.2 COMPLETE MEDICAL RECORD**

- SR.1 The organization shall maintain an accurately written, promptly completed medical record for each inpatient and outpatient.
- SR.2 The organization shall have a process for providing services for the completion, filing, and retrieval of the medical record. The process for completion of the medical record must address timeframes.
- SR.3 Authenticity and security of all record entries shall be safeguarded.

### **MR.3 RETENTION**

- SR.1 Medical records (original or legally reproduced form) shall be retained for a period of at least five (5) years.
- 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.

### **MR.4 CONFIDENTIALITY**

- SR.1 Confidentiality of patient records shall be assured.
- SR.2 Individuals who are authorized by the patient to receive information from or copies of records shall follow processes designed to protect improper or inadvertent release of private information to unauthorized individuals.
- SR.3 The organization shall also ensure that the medical record cannot be altered or accessed by unauthorized individuals.
- SR.4 Original medical records shall be released by the organization only in accordance with Federal or State laws, court orders, or subpoenas.

## **MR.5 RECORD CONTENT**

SR.1 The medical record shall contain information to:

- SR.1a justify admission and continued hospitalization;
- SR.1b support the diagnosis; and,
- SR.1c describe the patient's progress and response to medications and services

SR.2 All entries shall be:

- SR.2a legible, complete, dated and timed; and,
- SR.2b authenticated by the person responsible for providing or evaluating the services provided consistent with hospital policy.

SR.3 Authentication may include written signatures or initials. Electronic authentication is permissible.

SR.4 All orders must be dated, timed and authenticated promptly by the prescribing practitioner.

SR.5 Verbal orders must be in accordance with Federal and State law and authenticated within forty (48) hours or earlier if required by State law.

SR.5(1) 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.5(2) Verbal orders must be authenticated in accordance with Federal and State law by the ordering practitioner or a practitioner responsible for the care of the patient. If there is not State law that designates a specific timeframe for the authentication of verbal orders, the orders must be authenticated within 48 hours.

SR.5(3) For the limited time period defined in 42 CFR §482.24(c)(1)(ii), all such orders may be dated, timed and authenticated by another practitioner who is responsible for the patient's care as specified in 42 CFR §482.12(c) and who is authorized to write orders in accordance with hospital policy and State law.

## **MR.6 IDENTIFICATION OF AUTHORS**

The organization shall have a system to identify the author of each entry into the medical record.

## **MR.7 REQUIRED DOCUMENTATION**

All records must document the following, as appropriate:

SR.1 Evidence of a physical examination, including a health history, must be performed no more than thirty (30) days prior to admission or within twenty four (24) hours after admission or registration, but prior to surgery or procedure requiring anesthesia services:

SR.1a the history and physical completed and documented no more than thirty (30) days before or twenty four (24) hours after admission or registration, but prior to surgery or procedure requiring anesthesia services; and placed in the patient's medical record within twenty four (24) hours after admission or registration, but prior to surgery or procedure requiring anesthesia services.

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, but prior to surgery or procedure requiring anesthesia services.

SR.2 Admitting diagnosis,

- SR.3 Results of all consultative evaluations of the patient and appropriate finding by clinical and other staff involved in the care of the patient,
- SR.4 Documentation of complications, organization acquired infections, and unfavorable reactions to drugs and anesthesia,
- SR.5 Properly executed informed written consent forms for procedures and treatments specified by the medical staff, or by Federal or State law if applicable, signed by the patient or his/her authorized representative,
- SR.6 All practitioners' orders, nursing notes, reports of treatment, medication records, radiology, and laboratory reports, and vital signs and other information necessary to monitor the patient's condition,
- SR.7 Discharge summary with outcome of hospitalization, disposition of case, and provisions for follow up care,
- SR.8 Final diagnosis with completion of medical records within thirty, (30) days following discharge

## **DISCHARGE PLANNING (DC)**

### **DC.1 WRITTEN POLICIES**

- SR.1 Written policies shall be in place to establish a system for discharge planning that applies to all patients.
- SR.2 At an early stage of hospitalization, all patients who are at risk for negative outcomes without adequate discharge planning shall be identified and a plan developed to account for the patient's needs.
- SR.3 A registered nurse, social worker, or other appropriately qualified personnel shall develop, or supervise the development of, a discharge planning evaluation for or upon the request of:
  - SR.3a the patients identified in the above paragraph;
  - SR.3b any patients upon their request;
  - SR.3c a person acting on the patient's behalf; or,
  - SR.3d the patient's physician.

### **DC.2 DISCHARGE PLANNING EVALUATION**

- SR.1 The discharge planning evaluation shall include:
  - SR.1a an evaluation of the likelihood of a patient needing post-hospital services and of the availability of the services; and,
  - SR.1b an evaluation of the likelihood of a patient's capacity for self-care or of the possibility of the patient being cared for in the environment from which he or she entered the organization.
  - SR.1c A means to inform the patient or the patient's family of their freedom to choose among participating Medicare providers of post-hospital care services, and must, when possible, respect patient and family preferences when they are expressed.
- SR.2 The discharge planning evaluation shall be completed on a timely basis so that appropriate arrangements are made before discharge, and unnecessary delays in discharge are avoided.
- SR.3 The discharge planning evaluation shall be a part of the patient's medical record and be used when forming the discharge plan with the patient or individual acting on his or her behalf.
- SR.4 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.

### **DC.3 PLAN IMPLEMENTATION**

- SR.1 The initial implementation of the patient's discharge plan shall be performed by the organization.
- SR.2 Patients shall be transferred or referred with necessary medical information, to appropriate facilities, agencies, or outpatient services, as needed.
- SR.3 When the discharge planning evaluation determines a referral is medically appropriate, the organization shall give the patient a list of Medicare-participating providers (including those qualified to receive the patient from the patient's managed care organization where applicable) that are available and serve the geographical area where the patient resides. The organization shall document in the medical record that the patient (or authorized representative) received a copy of the list and was advised of his/her freedom of choice.
- SR.3a The organization must respect the choice of the patient or authorized representative except in unusual circumstances. The organization may not lead, direct, specify or otherwise limit the selection of qualified Medicare-participating providers.
- SR.3b The organization must identify in writing any Medicare-participating providers to which the patient is referred in which the organization has a disclosable financial interest and any Medicare-participating providers that has a disclosable financial interest in the organization. Disclosable financial interests are defined by 42 CFR §420, Subpart C.
- SR.4 When the organization must transfer or refer patients, the necessary medical information and other supporting documentation must be provided to appropriate facilities, agencies or outpatient services as needed, for follow-up or ancillary care.

### **DC.4 EVALUATION**

- SR.1 The discharge plan shall be periodically reevaluated on an on-going basis to provide for changes in the patient's condition or circumstances. The reassessment must include a review of the discharge plans to ensure that they are responsive to discharge needs.
- SR.2 As needed, the patient and family members or interested persons shall be educated to prepare them for post-hospital care.

## **UTILIZATION REVIEW (UR)**

### **UR.1 DOCUMENTED PLAN**

The organization shall maintain a documented utilization review plan that provides for review of organizational and medical staff services to patients, particularly those patients entitled to benefits under both Medicare and Medicaid. The plan shall include:

- SR.1 Responsibilities and authority for those involved in utilization review activities in a Utilization Review (UR) Committee. A UR committee consisting of two or more practitioners must carry out the UR function. At least two of the members of the committee must be doctors of medicine or osteopathy. The other members may be any of the other types of practitioners as defined in MS.15 (SR.1)
- SR.1(a) A staff committee of the institution; or
- SR.1(b) A group outside the institution established by the local medical society and some or all of the hospitals in the locality; or
- SR.1(c) Established in a manner approved by CMS.
- SR.2 Requirement for all review findings in the aggregate to be reported to Quality Management Oversight.

SR.3 Provision for avoidance of conflict by prohibiting any individual with any financial or professional involvement in the case from participating in the review. This shall be strictly enforced.

SR.4 Review of:

SR.4a. medical necessity of admissions and extended stays;

SR.4b. appropriateness of setting; and,

SR.4c. medical necessity of professional services.

## **UR.2 SAMPLING**

The review may be done before, at or after admission and may be conducted by sampling. The review shall include medical necessity for the following:

SR.1 Admissions;

SR.2 Length of stay; and,

SR.3 Professional services furnished, including medications.

## **UR.3 MEDICAL NECESSITY DETERMINATION**

SR.1 The committee must review professional services, to determine medical necessity and to promote the most efficient use of available health facilities and services.

SR.2 The determination that an admission or continued stay is not medically necessary may be made by two members of the Quality Management Oversight group after the practitioner(s) caring for the patient has (have) been notified and given an opportunity to present his/her views.

SR.2a Practitioner(s), the organization and the patient must receive written notification of a decision that admission or continued stay is determined to be not medically necessary.

SR.2b The notification must be given no later than two (2) days after such decision is made.

## **UR.4 EXTENDED STAY REVIEW**

The utilization review plan must include a process to periodically review all patients who receive services during a continuous period of extended duration.

SR.1 For organizations paid under the prospective payment system, all patients whose length of stay is considered an outlier must be reviewed.

SR.2 All reviews must be conducted no later than seven (7) days after the day required in the utilization review plan.

## **PHYSICAL ENVIRONMENT (PE)**

### **PE.1 FACILITY**

The facility shall be constructed, arranged, and maintained to ensure patient safety, and to provide areas for diagnosis and treatment and for special organization services appropriate to the needs of the community.

SR.1 The condition of the physical plant and the overall hospital environment must be developed and maintained in such a manner that the safety and well-being of patients, visitors, and staff are assured.

SR.,2 The hospital must maintain adequate facilities for its services.

SR.2 (a) Diagnostic and therapeutic facilities must be located for the safety of patients.

SR.2. (b) Facilities, supplies, and equipment must be maintained to ensure an acceptable level of safety and quality.

SR.2 (c) The extent and complexity of facilities must be determined by the services offered.

- SR.3 The organization 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 organization's patients, staff, and others.
- SR.4 The organization shall have a documented process, policies and procedures to define how unfavorable occurrences, incidents, or impairments in the facility's infrastructure, Life Safety, Safety, Security, Hazardous Material/Waste, Emergency, Medical Equipment, and Utilities Management Systems are prevented, controlled investigated, and reported throughout the organization.
- SR.5 The organization shall evaluate the facility's physical environment management systems at least annually. This evaluation shall be forwarded to Quality Management oversight.
- SR.6 Occurrences, incidents, or impairments shall be measured and analyzed to identify any patterns or trends.
- SR.7 The organization, through its senior leadership shall ensure that the physical environment and associated management systems adequately address issues identified throughout the organization and there are prevention, correction, improvement and training programs to address these issues.
- SR.8 Significant physical environment data/information shall be disseminated regularly to Quality Management oversight.

## **PE.2 LIFE SAFETY MANAGEMENT SYSTEM**

- SR.1 The organization shall meet the applicable provisions of the 2000 edition of the Life Safety Code® of the National Fire Protection Association.
- SR.1a Effective March 13, 2006 a hospital may no longer continue to keep in service existing roller latches even when those roller latches are demonstrating the ability to keep the door closed against 5 lbf, Chapter 19.3.6.3.2, exception number 2.
- SR.1b. A hospital has until March 31, 2006, to replace 1 hour batteries with 1 ½ hour batteries in emergency lighting systems that use batteries as power sources, Chapter 19.2.9, Emergency Lighting.
- SR.2 Any hospital that on November 26,1982, complied, with or without waivers, with the requirements of the 1967 edition of the Life Safety Code®, is considered to be in compliance with this standard as long as the facility continues to remain in compliance with that edition of the Life Safety Code®.
- SR.3 After consideration of the State survey agency findings, CMS may waive specific provisions of the Life Safety Code®, which, if rigidly applied, would result in unreasonable hardship upon the facility, but only if the waiver does not adversely affect the health and safety of patients.
- SR.3a The provisions of the Life Safety Code® do not apply in a State where CMS finds that a fire and safety code imposed by State law adequately protect patients.
- SR.4 The organization must have written fire control plans that contain provisions for prompt reporting of fires; extinguishing fires; protection of patients, personnel and guests; evacuation; and cooperation with fire fighting authorities.
- The fire control plan shall provide for the following (NFPA 101-2000, 18.7.2.2 & 19.7.2.2):
- The organization shall establish a Life Safety Management System that provides for written fire control processes that contain provisions for:
- SR.4a. Use of alarms

- SR.4b. Transmission of alarm to fire department
  - SR.4c. Response to alarms
  - SR.4d. Isolation of fire
  - SR.4e. Evacuation of immediate area
  - SR.4f. Evacuation of smoke compartment
  - SR.4g. Preparation of floors and building for evacuation
  - SR.4h. Extinguishment of fire
- SR.5 The organization shall maintain written evidence of regular inspection and approval by State or local fire control agencies.
- SR.6 Health care occupancies shall conduct unannounced fire drills regularly, but not less than one (1) drill per shift per building each calendar quarter that transmits a fire alarm signal and simulates an emergency fire condition. When fire drills are conducted between 9:00 p.m. (2100 hours) and 6:00 a.m. (0600 hours), a coded announcement shall be permitted to be used instead of audible alarms. (NFPA 101-2000, 18.7.1.2. & 19.7.1.2). False alarms may be used (up to 50% of total drills) if all elements of the fire plan are exercised. Business occupancies shall conduct at least one unannounced fire drill annually per shift.
- SR.6a. Fire drills must be thoroughly documented and evaluate the organization's knowledge to the items listed in PE.2, SR.4
- SR.6a.(i) At least annually, the organization shall evaluate the effectiveness of the fire drills, The report of effectiveness shall be forwarded to Quality Management oversight.
- SR.7 The Life Safety Management System shall address applicable Interim Alternative Life Safety Measures (ALSM) that shall be implemented whenever life safety features, systems, or processes are impaired , or deficiencies deficient are created or occur. Thorough documentation is required.
- SR.7a. All alternative life safe measures must be approved by the authority having local jurisdiction
- SR.8 Life Safety Management System shall require that Life Safety systems (e.g., fire alarm suppression, notification, and detection equipment) shall be is tested and inspected (including portable systems).
- SR.9 The Life Safety Management System shall require a process for reviewing the acquisition of bedding, draperies, furnishings and decorations for fire safety.
- SR.10 The Life Safety Management System shall require that a tobacco-free policy be developed and enforced campus-wide. Substantial progress toward complete conformity shall be demonstrated over time.
- SR.11 Construction, Repair, and Improvement operations shall involve the following activities:
- SR.12.a During construction, repairs, or improvement operations, or otherwise affecting the space, *the Guidelines for Design and Construction of Hospitals and Health Care Facilities*, 2006 edition, published by the American Institute of Architects shall be consulted for designing purposes.
  - SR.12. b The organization shall assess, document, and minimize the impact of construction, repairs, or improvement operations upon occupied area(s). The assessment shall include, but not be limited to, provisions for infection control, utility requirements, noise, vibration, and alternative life safety measures (ALSM).
  - SR.12. c In occupied areas where construction, repairs, or improvement operations occur, all required means of egress and required fire protection features shall be in place and continuously maintained or where alternative life safety measures acceptable to the authority having local jurisdiction are in place.

NFPA 241-1996, *Standard for Safeguarding Construction, Alteration, and Demolition Operations* shall be referenced in identifying and implementing alternative life safety measures.

- SR.12. d All construction, repairs, or improvement operations, shall be in accordance with applicable NFPA 101-2000 standards, and State and local building and fire codes. Should standards and codes conflict, the most stringent standard or code shall prevail.

### **PE.3 SAFETY MANAGEMENT SYSTEM**

- SR.1 The organization shall provide a Safety Management System that shall maintain safe and adequate facilities for its services. Diagnostic and therapeutic facilities must be located for the safety of patients.
- SR.2 The Safety Management System shall require that facilities, supplies, and equipment be maintained and ensure an acceptable level of safety and quality. The extent and complexity of facilities shall be determined by the services offered.
- SR.3 The Safety Management System shall require proper ventilation, light and temperature controls in pharmaceutical, food preparation, and other appropriate areas.
- SR.4 The Safety Management System shall require that the organization maintain an environment free of hazards and manages staff activities to reduce the risk of occupational related illnesses or injuries.
- SR.5 The Safety Management System shall require periodic surveillance of the hospital grounds to observe and correct safety issues that may be identified.
- SR.6 The Safety Management System shall address safety recalls and alerts.

### **PE.4 SECURITY MANAGEMENT SYSTEM**

- SR.1 The organization shall develop a Security Management System that provides for a secure environment.
- SR.2 The Security Management System shall provide for identification of patients, employees and others.
- SR.3 The Security Management System shall address issues related to abduction, elopement, visitors, workplace violence, and investigation of property losses.
- SR.4 The Security Management System shall establish emergency security procedures to include all hazard events
- SR.5 The Security Management System shall require vehicular access to emergency service areas.
- SR.6 The Security Management System shall require a process for reporting and investigating security related issues.

### **PE.5 HAZARDOUS MATERIAL (HAZMAT) MANAGEMENT SYSTEM**

- SR.1 The organization shall provide a Hazmat Management System to manage hazardous materials and waste.
- SR.2 The HAZMAT Management System shall provide processes to manage the environment, selection, handling, storing, transporting, using, and disposing of hazardous materials and waste.
- SR.3 The HAZMAT Management System shall provide processes to manage reporting and investigation of all spills, exposures, and other incidents.
- SR.4 The organization monitors staff exposure levels in hazardous environments and report the results of the monitoring to the Quality Management System.
- SR.5 Notwithstanding any provisions of the 2000 edition of the Life Safety Code to the contrary, a hospital may install alcohol-based hand rub dispensers in its facility if:

- SR.5a. Use of alcohol-based hand rub dispensers does not conflict with any State or local codes that prohibit or otherwise restrict the placement of alcohol-based hand rub dispensers in health care facilities;
  - SR.5b. The dispensers are installed in a manner that minimizes leaks and spills that could lead to falls;
  - SR.5c. The dispensers are installed in a manner that adequately protects against inappropriate access
  - SR.5d. The dispensers are maintained in accordance with dispenser manufacturer guidelines.
  - SR.5e. If dispensers are stored in corridors, the corridor must be a minimum of 72 inches.
  - SR.5f. The maximum individual dispenser fluid capacity shall be:
    - 1.2 liters (0.3 gallons) for dispensers in rooms, corridors, and areas open to corridors.
    - 2.0 liters (0.5 gallons) for dispensers in suites of rooms.
  - SR.5g. The dispensers shall have a minimum horizontal spacing of 4 ft (1.2m) from each other.
  - SR.5h. Not more than an aggregate 37.8 liters (10 gallons) of ABHR solution shall be in use in a single smoke compartment outside of a storage cabinet.
  - SR.5i. Storage of quantities greater than 18.9 liters (5 gallons) in a single smoke compartment shall meet the requirements of NFPA 30, *Flammable and Combustible Liquids Code*.
  - SR.5j. The dispensers shall not be installed over or directly adjacent to an ignition source.
  - SR.5k. In locations with carpeted floor coverings, dispensers installed directly over carpeted surfaces shall be permitted only in sprinklered smoke compartments.
  - SR.5l. Where minimum corridor width is 72 inches (1830 mm), projections of maximum 6 inches (152 mm) from the corridor wall, above the handrail, shall be permitted for the installation of hand-rub dispensing units.
- SR.6 In anesthetizing locations, which use alcohol-based skin preparations, 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 Verify that nonflammable medical gas located outside of an enclosure, in use for patients, does not exceed 300 cubic feet per smoke compartment.

## **PE.6 EMERGENCY MANAGEMENT SYSTEM**

- SR.1 The organization must provide a comprehensive Emergency Management System to respond to emergencies in the organization or within the community and region that may impact the organization's ability to provide services.
- SR.2 The organization shall meet the requirements set forth in NFPA 99, Chapter 12, Emergency Management.
- SR.3 The Emergency Management System shall require that the organization conduct a hazard vulnerability analysis to identify potential emergencies in the organization and the community.
- SR.4 The Emergency Management System shall establish an emergency process to address the potential hazards to the organization and the community. The hospital shall conduct an organization-wide emergency management exercise, including the triage and disposition of patients. The organization-wide emergency management exercises, including the triage and disposition of patients, shall be conducted no less frequently than twice per year

SR.4a. Emergency management exercises shall test the most threatening hazard(s) identified in the HVA and tax the resources of the organization.

SR.4b. At least every other emergency management exercise shall be conducted with the community to evaluate surge capacity, the integration of Incident Command and intraoperability of communications.

SR.4c The organization shall formulate an After Action Report of all emergency management exercises to identifying opportunities for improvements and revise its emergency management plan according to the identified opportunities for improvement.

SR.5 The Emergency Management System processes shall address alternative means to support essential building functions such as electricity, water, ventilation, fuel, medical gas and vacuum systems, and other identified utilities.

SR.6 The Emergency Management System shall include memorandums of understanding for utilization of resources (space, personnel, and equipment) with local and regional healthcare facilities and public health agencies in cases of organizational, community, or regional crisis.

SR.7 The organization shall have policies, procedures, and decision criteria for the determination of protection in place or evacuation of patients in the event of a disaster.

#### **PE.7 MEDICAL EQUIPMENT MANAGEMENT SYSTEM**

SR.1 The organization shall establish a Medical Equipment Management System that provides processes for the acquisition, safe use, and the appropriate selection of equipment.

SR.2 The Medical Equipment Management System shall address issues related to the organization's initial service inspection, the orientation, and the demonstration of use for of demonstration or rental or physician owned equipment.

SR.3. The Medical Equipment Management System shall address criteria for the selection of equipment.

SR.4 The Medical Equipment Management System shall address incidents related to serious injury or illness or death (See SMDA 1990).

SR.5 The Medical Equipment Management System shall have a process for reporting and investigating equipment management problems, failures, and user errors.

SR.6 The Medical Equipment Management System shall address a process for determining timing and complexity of medical equipment maintenance.

SR.7 The Medical Equipment Management System shall address the process of receiving and responding to recalls and alerts.

#### **PE.8 UTILITY MANAGEMENT SYSTEM**

SR.1 The organization shall require a Utility Management System that provides for a safe and efficient facility that reduces the opportunity for organization-acquired illnesses.

SR.2 The Utility Management System shall provide for a process to evaluate critical operating components.

SR.3 The Utility Management System shall develop maintenance, testing, and inspection processes for critical utilities.

SR.4 The Utility Management System shall contain a process to address medical gas systems and HVAC systems (e.g., includes areas for negative pressure).

- SR.5 The Utility Management System shall provide for emergency processes for utility system failures or disruptions.
- SR.6 The Utility Management System shall provide for reliable emergency power sources with appropriate maintenance as required.
- SR.7 The Utility Management System shall require proper ventilation, light and temperature controls in operating rooms, sterile supply rooms, special procedures, isolation and protective isolation rooms, pharmaceutical, food preparation, and other appropriate areas.
- SR.8 There shall be emergency power and lighting in at least the operating, recovery, intensive care, emergency rooms, and in other areas where invasive procedures are conducted, stairwells, and other areas identified by the organization (e.g., blood bank refrigerator, etc.). In all other areas not serviced by the emergency supply source, battery lamps and flashlights shall be available.
- Emergency lighting standards shall comply with Section 7.9 of Life Safety Code, 101-2000, and applicable references, such as, NFPA-99: Health Care Facilities, for emergency lighting and emergency power.
- SR.9 There shall be facilities for emergency gas and water supply.
- SR.10 All relevant utility systems shall be maintained inspected, and, tested,

## **ORGAN, TISSUE AND EYE PROCUREMENT (TO)**

### **TO.1 PROCESS**

- SR.1 The organization shall have a process in place for the procurement of organs, tissue, and eyes. The organization shall have an agreement with at least one tissue bank and one eye bank.

### **TO.2 ORGAN PROCUREMENT ORGANIZATION (OPO) WRITTEN AGREEMENT**

The organization shall have a written agreement an OPO designated under 42 CFR §486. Per SR.1 through SR.5 (below), this agreement shall:

- SR.1 Contain procurement protocols that have been approved by the organization's governing body and medical staff,
- SR.2 Ensure that timely notification is provided to the OPO or a third party designated by the OPO for all individuals whose death is imminent or who have died in the hospital,
- SR.3 Ensure communication of the policy for organ, tissue and eye procurement to all appropriate area of the organization, in addition to any revisions or modifications under a controlled document,
- SR.4 Acknowledge that it is the OPO's responsibility for the determination of medical suitability for organ donation, and, in the absence of alternative arrangements by the organization, the OPO determines medical suitability for tissue and eye donation, using the definition of potential tissue and eye donor and the notification protocol developed in consultation with the tissue and eye banks identified by the organization for this purpose.
- SR.5 Ensure, in collaboration with the designated OPO, that the family 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 hospital to initiate the request to the family must be an organ procurement representative or a designated requestor. If a designated requestor is responsible for initiating this request, this individual must have completed a course offered or approved by the OPO that has been designed in conjunction with the tissue and eye bank community in the methodology for approaching potential donor families and requesting organ or tissue donation.
- SR.6 Ensure that it works cooperatively with the designated OPO, tissue bank and eye bank in educating staff on donation issues, reviewing death records to improve identification of potential donors, and maintaining

potential donors while necessary testing and placement of potential donated organs, tissues, and eyes takes place.

### **TO.3 ALTERNATIVE AGREEMENT**

In the event the organization has an alternative agreement with a tissue and/or eye bank, this agreement shall:

- SR.1 Specify the criteria for referral of all individuals who have died in the organization, and,
- SR.2 Acknowledge the OPO's responsibility for the determination of medical suitability in lieu of any alternative arrangement with a different tissue and/or eye bank

### **TO.4 RESPECT FOR PATIENT RIGHTS**

The organ, tissue and eye procurement policies, procedures and practices shall demonstrate the respect for individual patient and family rights that reflect their views, religious beliefs and other special circumstances that have been communicated by the patient and/or family to the organization personnel.

### **TO.5 DOCUMENTATION**

Documents and records of organ procurement will be maintained in the manner directed by the OPO.

### **TO.6 ORGAN TRANSPLANTATION**

If the organization performs organ transplantation, the organization shall:

- SR.1 Be a member in the Organ Procurement and Transplantation Network (OPTN), which is established and operated in accordance with section 372 of the Public Service Act (42. U.S.C 274) and abide by its rules,
- SR.2 Define the term "organ" as to what transplantation is done. The consistency in terms shall apply to a kidney, liver, heart, lung or pancreas, and,
- SR.3 Provide data related to the performance of organ transplantation as requested by the OPTN, the Scientific Registry of Transplant Recipients and the OPO. The organization shall be required to provide this data to CMS as requested by the Secretary.

### **TO.7 TRANSPLANT CANDIDATES**

- SR.1 The organization shall ensure the appropriate candidates for receipt of transplanted organs have been screened, matched and medically cleared prior to receipt of any organs.
- SR.2 Candidate information shall be documented, accurate and available at the time of the organ transplantation.
- SR.3 Authority for transplantation shall be co-signed by the patient or designated representative of the patient and the practitioner(s) performing the transplantation.