Center for Improvement
CIHQ
in Healthcare Quality

ACCREDITATION STANDARDS

FOR

ACUTE CARE HOSPITALS

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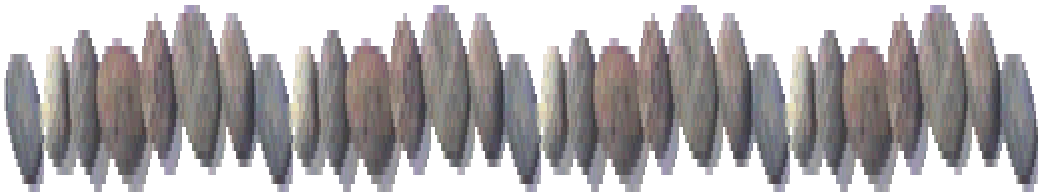

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GOVERNANCE & LEADERSHIP

42 CFR	CIHQ Standards & Requirements
482.12	GL-1: Establishment of a Governing Body The organization shall have a governing body that is legally established and responsible for the conduct of the organization as an institution. A. If the organization does not have a governing body, then it must identify the person(s) legally responsible for the conduct of the organization. This person(s) must fulfill the governance functions noted in these accreditation standards. If the organization is part of a health system in which there are multiple levels of governance, the duties and responsibilities of each level of governance must be clearly described. B. The governing body must have written bylaws that describe its organization, structure and responsibilities.
482.11	GL-2: Compliance to Law & Regulation The organization must be in compliance with applicable federal, state and local law and regulation. This includes, but is not limited to: A. Compliance with law and regulation related to the health and safety of patients B. Maintaining licensure in the State or locality where services are provided; C. Assuring that any services provided for which licensure is required are currently licensed; D. Assuring that personnel who require a State-mandated license or certification to practice their profession have a current license or certification to do so and meet other applicable standards required by State or local laws.
482.12	GL-3: Establishment of a Medical Staff The governing body shall establish a medical staff for the organization. At a minimum, the governing body must: A. Determine, in accordance with State law, which categories of practitioners are eligible candidates for appointment to the medical staff; B. Appoint members of the medical staff after considering the recommendations of the existing members of the medical staff; C. Assure that the medical staff has bylaws; D. Approve medical staff bylaws and other medical staff rules and regulations; E. Approve the privileges and/or practice prerogatives granted to individual practitioners by the medical staff; F. Ensure that the medical staff is accountable to the governing body for the quality of care provided to patients; G. Ensure the criteria for selection to the medical staff address individual character, competence, training, experience and judgment; H. Ensure that under no circumstances is the accordance of staff membership or professional privileges in the organization dependent solely upon certification, fellowship or membership in a specialty body or society. I. Consult directly with the individual assigned the responsibility for the organization and conduct of the hospital's medical staff, or his or her designee. At a minimum, this direct consultation must occur periodically throughout the fiscal or calendar year and include discussion of matters related to the quality of medical care provided to patients of the hospital. For a multi-hospital system using a single governing body, the single multi-hospital system governing body must consult directly with the individual responsible for the organized medical staff (or his or her designee) of each hospital within its system in addition to the other requirements noted under 42 CFR 482.12.

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42 CFR	CIHQ Standards & Requirements
482.12	GL-4: Leadership Responsibilities The governing body, administrative leadership and leaders of the medical staff are responsible for the following: A. Establish and implement a process to develop, review and approve policies that support the provision of patient care. The organization determines the process. B. Policies must be reviewed at least every three years and revised when necessary. C. Assure compliance to the CMS Conditions of Participation and standards of the Center for Improvement in Healthcare Quality. D. Develop and support the mission, vision, values and/or strategic objectives of the organization. E. Establish and implement structures and processes that support the delivery of safe, quality patient care. G. Assure that accurate and truthful information is provided throughout the accreditation process
482.12	GL-5: Selection of a Chief Executive Officer The governing body shall appoint a chief executive officer who is responsible for managing the organization. A. If the organization is part of a multi-structured health system, the chief executive officer is considered the individual assigned to oversee operations at the organization.
482.12	GL-6: Directing Medical Care of the Patient The governing body shall assure that the organization establishes and implements policies addressing the following: A. Patients are admitted to the hospital only on the recommendation of a licensed practitioner permitted by the State to do so; B. Every patent is under the care of one of the following providers subject to the requirements and restrictions noted under 42 CFR.482.12.(c): • A doctor of medicine or osteopathy • A doctor of dental surgery or dental medicine • A doctor of podiatric medicine • A doctor of optometry • A chiropractor • A clinical psychologist; C. A doctor of medicine or doctor of osteopathy is on duty or on call at all times to provide care to any patient who develops a medical or psychiatric problem on admission or throughout hospitalization except as permitted under 42 CFR 482.12(c).
482.12	GL-7: Financial Planning & Budgeting The organization must have a financial plan and budgeting process that addresses at least the following: A. An annual operating budget addressing anticipated income and expenses that is prepared according to generally accepted accounting principles; B. A capital expenditure plan for at least a three-year period including the year in which the operating budget has been developed; C. The plan and budget must be prepared under the direction of the governing body by a committee consisting of representatives of the governing body, the administrative staff, and the medical staff of the organization; D. The financial planning and budgetary process must meet the requirements noted under 42 CFR §482.12(d).

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482.12	GL-8: Contract Services The governing body is responsible for all services provided by the organization, including those provided by a contracted entity. A list of contract services must be maintained by the organization. For each contract service, the organization must assure at least the following: A. The nature and scope of services rendered by the contract entity is defined in writing; B. Performance expectations of the contract entity have been established to assure that services are rendered in a safe and effective manner; C. Metrics (indicators) have been established to determine whether or not performance expectations are being met; D. Data is collected, aggregated and analyzed on the metrics in a manner and frequency consistent with the organization's Quality Assessment & Performance Improvement Program; E. The results of the analysis, including issues identified and corrective actions taken are presented at least annually to the governing body.

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QUALITY ASSESSMENT & PERFORMANCE IMPROVEMENT

42 CFR	CIHQ Standards & Requirements
482.21	QA-1: Quality Assessment / Performance Improvement (QA/PI) Program The organization must establish, implement and maintain an effective program that assesses the quality and safety of its services, identifies opportunities for improvement, and works to address those opportunities. A. The organization must have a written QA/PI Program. B. The QA/PI Program must reflect the full scope and complexity of services provided by the organization. All patient care-related services, whether rendered directly by the organization or through a contracted entity, must be included in the QA/PI Program. C. The QA/PI Program must be ongoing in nature and demonstrate measurable improvement in the health outcomes of patients and a reduction in errors in care. D. The QA/PI Program must enable the organization to measure, analyze and track quality indicators, including adverse patient events, and other aspects of performance that assess processes of patient care, service, and operations. E. The governing body must approve the organization's QA/PI Program.
482.21	QA-2: Collection & Use of Data The organization shall collect, analyze and use data to monitor the effectiveness, safety, improvement in health outcomes, and quality of care and services provided. A. The organization prioritizes its efforts to focus on those processes and/or care areas that are high-volume, high-risk, or problem-prone. • The organization identifies the specific processes and/or care areas that will be monitored based on the incidence, prevalence, and severity of known or potential problems. • The organization determines the specific indicators and/or metrics that will be measured for each process or care area identified. B. Data will be collected on at least the following: • Medical errors and adverse events; • Significant medication errors and adverse drug reactions; • Use of blood and blood components; • Confirmed hemolytic blood transfusion reactions; • Significant discrepancies between pre-operative and post-operative diagnosis in pathology findings; • Adverse events involving the use of anesthesia along the continuum (i.e. moderate sedation to general anesthesia); • Adverse events related to the performance of operative and/or invasive procedures. C. The frequency and detail of data collection must be specified by the governing body. D. Data must be aggregated, analyzed and reported into the organization's QA/PI Program to: • Identify opportunities to for improvement; • Understand why those opportunities exist; • Develop and implement actions to address those opportunities; • Determine the success of those actions; • Track performance over time to assure that improvements are sustained; • Disseminate information on the results of improvement efforts to key stakeholders throughout the organization. E. The governing body receives periodic reports on indicators monitored through the QA/PI program. • The organization determines reporting frequency, however at least an annual report must be presented to the governing body.

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42 CFR	CIHQ Standards & Requirements
482.23	QA-3: Reporting of Adverse Events The organization must have a mechanism to report adverse events when they occur. A. The organization must develop and implement a policy that assures at least the following adverse events are reported to the appropriate individual(s) or entity: • Medication errors; • Adverse drug reactions; • Blood or blood-component transfusion reactions; • Actual or potential errors in care that resulted in harm to a patient or posed a risk of harm; • Any adverse event that must be reported to an external regulatory or enforcement agency in accordance with Federal or State law or regulation. B. Significant medication errors and adverse drug reactions must be reported immediately to the patient's attending physician. If the patient's attending physician is not available, a covering physician must be notified and the attending physician subsequently notified as soon as possible. C. Reporting of adverse events must be part of the organization's quality assessment and performance improvement program.
482.21	QA-4: Performance Improvement Projects As part of its QA/PI Program, the organization must conduct performance improvement projects. A. The number and scope of distinct improvement projects conducted annually must be proportional to the scope and complexity of the organization's services and operations. B. The organization must document what quality improvement projects are being conducted, the reasons for conducting these projects and the measurable progress achieved on these projects. C. An organization is not required to participate in a Quality Improvement Organization (QIO) cooperative project, but its own projects are required to be of comparable effort.
482.21	QA-5: Leadership Responsibility for Performance Improvement The organization's governing body, administrative leadership, and leadership of the medical staff are collectively responsible for ensuring the following: A. That an ongoing program for quality improvement and patient safety, including the reduction of medical errors, is defined, implemented and maintained; B. That organization-wide quality assessment and performance improvement efforts address priorities for improved quality of care and that all improvement actions are evaluated; C. That clear expectations for safety are established; D. That adequate resources are allocated for measuring, assessing, improving and sustaining the organization's performance and reducing risk to patients; E. That a determination of the number of distinct improvement projects is conducted and approved annually. (See Standard QA-4)

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MEDICAL STAFF

42 CFR	CIHQ Standards & Requirements
482.22	MS-1: The Organized Medical Staff The hospital must have an organized medical staff that operates under bylaws approved by the governing body, and which is responsible for the quality of medical care provided to patients by the hospital. A. If a hospital is part of a hospital system consisting of multiple separately certified hospitals and the system elects to have a unified and integrated medical staff for its member hospitals, after determining that such a decision is in accordance with all applicable State and local laws, each separately certified hospital must demonstrate that: • The medical staff members of each separately certified hospital in the system (that is, all medical staff members who hold specific privileges to practice at that hospital) have voted by majority, in accordance with medical staff bylaws, either to accept a unified and integrated medical staff structure or to opt out of such a structure and to maintain a separate and distinct medical staff for their respective hospital; • The unified and integrated medical staff has bylaws, rules, and requirements that describe its processes for self-governance, appointment, credentialing, privileging, and oversight, as well as its peer review policies and due process rights guarantees, and which include a process for the members of the medical staff of each separately certified hospital (that is, all medical staff members who hold specific privileges to practice at that hospital) to be advised of their rights to opt out of the unified and integrated medical staff structure after a majority vote by the members to maintain a separate and distinct medical staff for their hospital; • The unified and integrated medical staff is established in a manner that takes into account each member hospital's unique circumstances and any significant differences in patient populations and services offered in each hospital; and • The unified and integrated medical staff establishes and implements policies and procedures to ensure that the needs and concerns expressed by members of the medical staff, at each of its separately certified hospitals, regardless of practice or location, are given due consideration, and that the unified and integrated medical staff has mechanisms in place to ensure that issues localized to particular hospitals are duly considered and addressed.
482.22	MS-2: Structure of the Medical Staff The medical staff must be well organized and accountable to the governing body for the quality and safety of care and treatment rendered. A. The responsibility for the organization and conduct of the medical staff must be assigned only to one of the following: • An individual doctor of medicine or osteopathy. • A doctor of dental surgery or dental medicine, when permitted by State law of the State in which the hospital is located. • A doctor of podiatric medicine, when permitted by State law of the State in which the hospital is located. B. If the medical staff has established an executive committee, the majority of voting members of that committee must be doctors of medicine or doctors of osteopathy. C. The medical staff structure (e.g. departments, sections, committees, etc.) must be approved by the governing body.

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42 CFR	CIHQ Standards & Requirements
482.22	MS-3: Medical Staff Bylaws The medical staff shall establish, adopt and enforce bylaws, rules, regulations, and policies to carry out its responsibilities. The bylaws (including any revisions) must be approved by the governing body. At a minimum, the bylaws must address: A. A description of the duties and privileges for each category of the medical staff (active, courtesy, etc.); B. A description of how the medical staff is organized; C. The qualifications that must be met by a candidate in order for the medical staff to recommend that the candidate be appointed by the governing body; D. Include criteria for determining the privileges granted to individual practitioners and the procedure for applying the criteria to individuals who request privileges; • For distant-site physicians and practitioners requesting privileges to furnish telemedicine services under an agreement with the hospital, the criteria for determining privileges and the procedure for applying the criteria are also subject to the requirements noted under Standard MS.9. E. The criteria and process for periodic performance appraisals for members of the medical staff, including those who have not provided patient care within the organization or who has not provided care for which he/she is privileged to provide during the appropriate evaluation time frames. • In developing criteria, the medical staff should consider the following; current work practice, special training, quality of specific work, patient outcomes, education, maintenance of continuing education, adherence to medical staff rules, certifications, appropriate licensure, and currency of compliance with licensure requirements F. The performance of a medical history and physical examination as follows: • A medical history and physical examination must be completed and entered into the medical record for each patient no more than 30 days before or 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia services; • An updated examination of the patient, including any changes in the patient's condition, must be completed and documented within 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia services, when the medical history and physical examination are completed within 30 days before admission or registration; • The medical history and physical examination including any update thereto must be completed and documented by a practitioner granted privileges by the medical staff to do so. G. Except as noted herein, neither the governing body nor the medical staff may unilaterally amend the medical staff bylaws; • The governing body may, after affording an opportunity for the medical staff to do so and notifying the medical staff prior to thereof, unilaterally amend the medical staff bylaws when the medical staff refuses or is unable to make amendments necessary to comply with law, regulation, accreditation standards or situations that pose a serious and direct threat to the safety of patients. H. The medical staff enforces and complies with the medical staff bylaws.

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42 CFR	CIHQ Standards & Requirements
482.22	MS-4: Appointment or Reappointment to the Medical Staff The medical staff must be composed of doctors of medicine or osteopathy. In accordance with State law, including scope-of-practice laws, the medical staff may also include other categories of physicians (as listed at 42 CFR 482.12(c)(1)) and non-physician practitioners who are determined to be eligible for appointment by the governing body. A. The medical staff determines the criteria, process, and timeframes associated with the process, to credential and appoint / reappoint practitioners. • This may be described in the medical staff bylaws, rules and regulations, policy(s) or other written document. • The governing body approves the criteria, process and associated timeframes. B. The medical staff must examine the credentials of candidates for membership and make recommendations to the governing body on the appointment / reappointment of candidates in accordance with State law, including scope of practice laws, and the medical staff bylaws, rules, and regulations. A candidate who has been recommended by the medical staff and who has been appointed by the governing body is subject to all medical staff bylaws, rules, and regulations, in addition to the requirements contained herein. C. Appointment / reappointment to the medical staff cannot be based solely on board certification, fellowship or membership in a professional society. D. Appointment / reappointment to the medical staff must not exceed a maximum of 24 months. E. All appointments / reappointments to the medical staff must be approved by the governing body. The governing body's decision on whether or not to appoint / reappoint a practitioner to the medical staff is final. F. At the time of appointment / reappointment, the following must be confirmed for each practitioner: • Current professional licensure verified from the primary source in the State in which the organization is located; • Current Drug Enforcement Administration (DEA) number if the practitioner prescribes or furnishes medication; • Current malpractice insurance • Results of a National Practitioner Data Bank (NPDB) query; • Favorable peer reference(s); • An attestation by the practitioner that he/she is physically and mentally capable of exercising the privileges requested.
	MS-5: Granting of Clinical Privileges The medical staff develops and implements a process to assure that the granting of clinical privileges to practitioners results in the safe and effective delivery of quality patient care. A. The medical staff establishes the criteria that must be met to grant a practitioner clinical privileges. The criteria must be approved by the governing body. B. Privileges are only granted to a practitioner within the practitioner's licensure, scope of practice, education, training, experience and current competence. C. Membership on the medical staff need not be a condition for granting clinical privileges. D. Privileges, with the exception of temporary privileges, are only granted upon approval by the governing body. E. Practitioners practice within the scope of privileges granted by the medical staff and approved by the governing body.

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42 CFR	CIHQ Standards & Requirements
	MS-6: Temporary Privileges If the organization chooses to grant temporary privileges to practitioners, it must do so in a manner that assures the safety of the patient and the rendering of quality care. A. Temporary privileges may be granted for two reasons: • To fulfill an important patient care need; • To allow a practitioner to exercise his/her privileges pending formal approval by the governing body. B. Temporary privileges may only be granted to a practitioner who meets the following requirements: • Current professional licensure verified from the primary source in the State in which the organization is located; • Current Drug Enforcement Administration (DEA) number if the practitioner prescribes or furnishes medication; • Results of a National Practitioner Data Bank (NPDB) query; C. Temporary privileges may only be granted by the Chief of the Medical Staff and the Chief Executive Officer or their authorized respective designees. D. Temporary privileges may only be granted for a total of 120 days in a calendar year.

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	MS-7: Resources to Support Privileges The organization must have the infrastructure and resources necessary to support privileges granted to the medical staff. A. The organization assures that it the space, equipment, supplies, policies and personnel necessary to allow the medical staff to safely and effectively exercise their clinical privileges.
	MS-8: Fair Hearing Process The medical staff must develop and implement a fair hearing and appeal process to address any adverse decisions regarding appointment, reappointment, denial, reduction, suspension or revocation of privileges to a practitioner. *Note: The medical staff and the organization are given latitude to develop and implement this process. The standard is not prescriptive as to how the fair hearing and appeals process(es) is constructed.* A. The fair hearing and appeal process(es) must assure that the safety of patients and the quality of care rendered by the practitioner is not adversely affected. B. The fair hearing and appeal process(es) must conform to any State law and regulation. C. The fair hearing and appeal process(es) is made available to any practitioner who is a member of the medical staff or has been granted clinical privileges (with the exception of temporary privileges).
482.22	MS-9: Provision of Telemedicine Services by a Distant Site If the organization chooses to engage in telemedicine services provided by another entity, it must assure that the following requirements are met: A. The organization must have a written agreement with the entity providing the telemedicine service (distant-site) that addresses all requirements noted in this standard; • The agreement must specify that it is the responsibility of the distant site's governing body to assure that the requirements of this standard are met. • If telemedicine services are provided by an entity other than a Medicare-participating hospital, the written agreement must address all requirements for a contract service as noted under Standard GL.8. B. The privileges for all practitioners providing telemedicine services must be approved by the organization's governing body based on a recommendation by the organization's medical staff; C. The organization may rely upon the credentialing and privileging decisions made by the distant-site when making recommendations on privileges for practitioners providing telemedicine services provided all of the following are met: • If the distant site is a hospital, it must be a Medicare participating hospital (e.g. certified by Medicare or accredited through a deemed status provider); • If the distant site is other than a Medicare-participating hospital, the credentialing and privileging process used by the distant site must meet the applicable requirements noted under Standard MS.4 and Standard MS.5; • The distant site must provide a current list of privileges for each practitioner who provides telemedicine services; • Each practitioner who provides telemedicine services must hold a license issued or recognized by the State in which the organization is located; • The organization develops and implements a process to monitor the quality of care rendered by practitioners who provide telemedicine services to its patients. At a minimum, this information must include all adverse events and complaints that result from the practitioner's care.

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	MS-10: Graduate Medical Education Programs If the organization participates in graduate medical education programs (GME), it must assure, in collaboration with the medical staff, the following: A. There must be a written document describing the scope of patient care rendered by individuals enrolled in GME. This includes levels of physician supervision as appropriate; B. A policy must be developed and implemented that addresses documentation in the medical record by GME participants, including who may write patient care orders; • The policy must also address what types of entries, if any, into the medical record must be co-signed by a supervising physician. C. There must be a mechanism developed and implemented to identify and address patient safety and/or quality-of-care issues arising from care rendered by GME participants. This mechanism is determined by the organization.
	MS-11: Practitioner Health The medical staff develops and implements a process to address practitioner health issues that have the potential to adversely affect patient care. A. There is a mechanism established to report concerns about the health of a medical staff member or other practitioners granted clinical privileges. B. The medical staff investigates and acts upon potential and/or actual practitioner health issues. C. To the extent permitted by law and regulation, the confidentiality of both the practitioner and anyone who reports a practitioner health issue is protected.
482.22	MS-12: Performance of an Autopsy The medical staff shall attempt to secure autopsies in all cases of unusual deaths and of medical, legal or educational interest. A. The medical staff must develop criteria for when an autopsy should be performed. Use of coroner criteria is acceptable. B. The medical staff must attempt to secure an autopsy whenever a patient's death meets criteria. • If the death is a coroner case and the coroner declines to perform an autopsy, then no further action is required. C. Permission to perform an autopsy must be documented in a manner defined by the organization. D. The medical staff, and specifically the attending physician, must be notified when an autopsy will be performed.

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HUMAN RESOURCES

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482.23	HR-1: Verification of Licensure & Certification The organization must assure that staff are appropriately licensed and certified. A. All staff must maintain current licensure, certification and/or registration as outlined in their job description. For the purposes of this standard, these documents are collectively known as "credentials." • Credentials that are required by federal, state or local law to legally engage in a profession must be verified from the primary source at the time of hire and prior to expiration. If the primary source is unable to provide verification, then the organization may use a copy of the credential. However, the organization must document why the primary source did not provide verification. • Credentials that are required internally by the organization but are not required by federal, state or local law, must be verified at the time of hire and prior to expiration, but do not require verification from the primary source.
	HR-2: Orientation of Staff The organization must assure that staff' receive sufficient orientation to perform their job function safely. A. As appropriate to their job function, staff must receive orientation to at least the following content at the start of their employment: • Pertinent organization and/or department specific policies and procedures that govern their job function; • Emergency response procedures such as fire and disaster; • Infection control policies such as universal precautions, blood borne pathogens, hand hygiene and isolation precautions. • Training required by Federal or State law B. The organization determines the scope, content, and frequency of any further orientation.
	HR-3: Competency of Staff The organization must assure that staff' are competent in the performance of their job function. To fulfill this obligation, the organization must assure at least the following for each staff person who provides patient care, and/or directly supports the provision of patient care: A. A job description and/or other document(s) that define at least the following: • The minimum education, training, experience, health clearances and, where applicable, licensure and/or certification requirements of the job position; • The principal duties and responsibilities of the job position. B. An initial assessment of competency within a time frame required by the organization; • The scope of the competency assessment must address at least those job functions that affect the safety and quality of patient care. • Staff' does not independently perform these job functions until their competency has been established. • The method of determining competency is appropriate to the competency being assessed. C. An assessment of competency whenever any of the following occurs: • There is a new or significant modification to the staff person's job function; • New equipment, devices, supplies, medications or other processes that impact patient care are introduced into the organization; • There is data or other evidence to suggest that the competency of staff is a causative factor in untoward events and/or undesirable performance.

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482.23	HR-4: Management of Contract / Volunteer Staff The organization has a responsibility to assure that contract staff or volunteers provide care and service in a safe and competent manner. The requirements in this standard apply only to contract and volunteer staff that provide direct patient care and/or directly support the provision of patient care. A. Each person must be provided with a job description or similar document that outlines the essential duties and responsibilities they will be expected to perform. • The organization may utilize documents from the contract service if they are determined to be comparable to the organization's own. B. The organization must verify each individual's credentials. (See Standard HR-1) • The organization may perform this action directly or require the contract service to perform it on their behalf. C. The organization must assure that each individual has appropriate health clearances and immunizations as would be required of their own staff in a comparable job position. • The organization may perform this action directly or require the contract service to perform it on their behalf. D. The organization must assure that each individual is oriented to at least the following prior to or at the time of their first working shift: • Pertinent organization and/or department-specific policies and procedures that govern their job function; • Emergency response procedures such as fire and disaster; • Infection control policies such as universal precautions, blood-borne pathogens, hand hygiene and isolation precautions; • Information required by Federal or State law • The organization may provide this orientation directly or require the contract service to provide it on their behalf. E. The organization must validate the competency of each individual in performing critical aspects of their job function. At a minimum (as applicable to the job function) this includes: • The ability to perform tasks, skills or procedures that carry a high risk of safety or injury to patients; • The ability to safely operate equipment that is used on a patient. F. Contract and volunteer staff must be adequately supervised. This means assigning these individuals to work under the general supervision of a qualified employee of the organization. • For contract or volunteer nursing staff, the Chief Nurse Executive (director of nursing service) is responsible for assuring that they are adequately supervised and evaluated.

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MANAGING THE CARE ENVIRONMENT

42 CFR	CIHQ Standards & Requirements
482.41	CE-1: Provision of Facilities The organization must maintain adequate facilities to meet its scope of services. A. Facilities are designed and maintained in accordance with Federal, State and local laws, regulations and guidelines. B. Facilities are designed and maintained to reflect the scope and complexity of the services it offers in accordance with accepted standards of practice. C. Diagnostic and therapeutic facilities are located in areas designated for that purpose. D. There must be adequate facilities to meet the scope of services provided and patient care needs.
	CE-2: Construction & Renovation The organization must assure the safe and appropriate construction or renovation of its facilities A. The organization assures that construction or renovation is performed in accordance with State or local building code and other appropriate regulation. B. Prior to commencing construction or renovation, the organization assesses the impact of such activity on patients, staff, and visitors. C. Based on the assessed impact, the organization takes appropriate action to assure that the safety of patients, staff, and visitors is maintained.
482.41	CE-3: Provision of a Safe Environment The organization must assure that the buildings and structures used to provide care are constructed, arranged and maintained to provide a safe environment for patients, staff and others. A. The organization must ensure that the condition of the physical plant and overall environment of all its care settings is developed and maintained in a manner to ensure the safety and well-being of patients. Building inspection and maintenance are to be conducted on an ongoing basis. B. A process must be developed and implemented to assure that hazards in the care environment are identified and corrected. The identification and correction of hazards is documented.
482.41	CE-4: Providing a Secure Environment The organization has a responsibility to establish and maintain a secure environment. A. The organization must identify security-sensitive areas within its facility(s). • Processes must be developed and implemented to control access to security-sensitive areas. Access must be limited only to authorized individuals. B. The organization must develop and implement a program to protect newborns and inpatient pediatric patients from abduction. • The organization determines the structural and process features of its abduction prevention program. • Staff responsible for implementing the program must be trained to their role and responsibility upon hire and at least annually thereafter. C. The organization must identify those care settings that carry a significant risk of workplace violence. • Staff' who regularly works in these settings must be provided with training on managing potentially violent situations upon hire and least annually thereafter. The organization determines the scope and content of this training. D. The organization must develop and implement a process to report and act upon security incidents and concerns.

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	CE-5: Smoking The organization develops and implements a policy that addresses smoking of tobacco or related products. A. Smoking is prohibited in any of the organization's buildings. B. If smoking is permitted outside, the organization must assure that it occurs at a sufficient distance from entrances to buildings to prevent smoke from entering the building. C. If the organization bans smoking entirely on its campus, then staff and physicians must comply with the policy.
482.41	CE-6: Management of General and Medical Waste The organization must store and dispose of general waste (garbage) and medical (bio-hazardous) waste in accordance with Federal, State and local law and regulation. A. Designated medical waste storage areas must be appropriately identified and secured against access by unauthorized individuals. B. Medical waste must be treated or removed from the organization's premises within a time frame required by law or regulation. Documentation of removal of medical waste from the premises must be maintained. C. Staff who collect, transport and dispose of general and medical waste must wear appropriate personal protective equipment. D. There must be written procedures developed and implemented to contain and clean up a medical waste spill. E. Staff responsible for cleaning up a medical waste spill must be provided with the training and protective equipment to do so.
482.41	CE-7: Management of Hazardous Materials & Waste The organization must manage hazardous materials and waste in accordance with Federal, State and local law and regulation. A. There must be written policies and procedures developed and implemented that address the procurement, storage, use, transport and disposition of hazardous materials and waste. B. Designated hazardous materials and waste storage areas must be appropriately identified and secured against access to unauthorized individuals. C. Hazardous waste must be removed from the organization's premises within a time frame required by law and regulation. Documentation of removal of hazardous waste from the premises must be maintained. D. Staff' who use, collect, transport and dispose of hazardous materials and waste must wear appropriate personal protective equipment. E. There must be written procedures developed and implemented to contain and clean up a hazardous waste spill. F. Staff responsible for cleaning up a hazardous waste spill must be provided with the training and protective equipment to do so.

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482.41	CE-8: Management of Medical Equipment The organization must assure that medical equipment used in patient care is safe. A. The organization assures that individual(s) responsible for overseeing the development, implementation, and management of equipment maintenance programs and activities are qualified by education, training, and/or experience to do so. • The organization's leadership assures that all equipment maintenance policies, procedures, programs, specific maintenance inventories, activities, and schedules are under the purview of qualified personnel. B. Medical equipment must be inspected, calibrated, tested, and maintained by qualified personnel C. Medical equipment must be tested for performance and safety before initial use and after major repairs or upgrades D. The following types of medical equipment must be maintained in accordance with manufacturer instructions: • Equipment subject to Federal or State law requiring maintenance, inspection and testing be performed strictly in accordance with the manufacturer's recommendations, or otherwise establishes, more stringent maintenance requirements. • When Medicare Conditions of Participation require adherence to manufacturer recommendations and/or set specific standards • All imaging/radiologic equipment, whether used for diagnostic or therapeutic purposes • The equipment is a medical laser device. • New equipment for which sufficient maintenance history is not available to support its inclusion in an alternative equipment management (AEM) program. E. For other medical equipment, the organization may develop, implement, and maintain a documented alternative equipment management (AEM) program. The AEM program must be based on generally accepted standards of practice. • In determining whether or not to include equipment in an AEM program, the organization shall explain and document the patient health and safety risks associated with the equipment's use. Factors for the organization to consider when evaluating the risks associated with a particular type of equipment include, but are not limited to: • How the equipment is used and the likely consequences of equipment failure or malfunction – including seriousness and prevalence of harm • Information, if available, on the manufacturer's equipment maintenance recommendations, including the rationale for the manufacturer's recommendations • Maintenance requirements of the equipment • The timely availability of alternate devices or backup systems in the event of equipment failure or malfunction • Incident history of identical or very similar equipment – is there documented evidence, based on the experience of the hospital (or its third party contractor), or on evidence publicly reported by credible sources outside the hospital, which provides the number, frequency and nature of previous failures and service requests, and indicates use of an AEM strategy does not result in degraded performance of the equipment. Note that the risk may vary for the same type of equipment, depending on the patient care setting. • The determination as to whether it is safe to perform medical equipment maintenance in an alternate manner must be made by a qualified person, regardless of whether they are hospital employees or contractors. In the case of medical equipment, a biomedical technician or engineer would be considered qualified. • The organization shall identify any equipment in its AEM program which is "critical equipment," i.e., medical equipment for which there is a risk of serious injury or death to a patient or staff person should the equipment fail.

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	• The organization shall use one or more strategies for the determination of appropriate maintenance, inspection, and testing activities and frequencies. See the glossary for the definition of acceptable maintenance strategies. The organization shall adhere strictly to the AEM activities and strategies it develops. The AEM program must not reduce the safety of equipment F. For each type of medical equipment subject to an alternative equipment management (AEM) program, there shall be documentation indicating: • The pertinent types and level of risks to patient or staff health and safety; • Alternate maintenance activities, and the maintenance strategy and any other rationale used to determine those activities; the differences from the manufacturer's recommended maintenance activities are made explicit, unless the organization is unable to obtain the manufacturer's maintenance recommendations, due to the age of the equipment or the manufacturer's restricting the availability of its recommendations; • Alternate maintenance frequencies to be used, if any, and the maintenance strategy and any other rationale used to determine those frequencies. • For equipment identified as presenting a very low risk to patient or staff safety, it is acceptable to not set a particular frequency but instead indicate a less specific approach, for example, an interval range, such as "every 12 – 24 months." It is also be acceptable to employ periodic "departmental sweeps" for such very low risk equipment, where equipment functioning is sampled and operators are polled about its functionality. • The date when AEM program maintenance activities were performed and, if applicable, further actions required/taken; and • Documentation of any equipment failures (not including failures due to operator error), including whether there was resulting harm to an individual. G. The organization shall have policies and procedures which address the effectiveness of the AEM program. In evaluating the effectiveness of the AEM program the organization shall address factors including, but not limited to: • How equipment is evaluated to ensure there is no degradation of performance, particularly for equipment where such degradation may not be readily apparent to staff using the equipment • How incidents of equipment malfunction are identified and investigated, including whether or not the malfunction could have been prevented, and what steps will be taken to prevent future malfunctions; and how a determination is made whether or not the malfunction resulted from the use of an AEM strategy; • The process for the removal from service of equipment determined to be unsafe or no longer suitable for its intended application; and • The use of performance data to determine if modifications in the AEM program procedures are required. H. If an organization elects to perform maintenance in accordance with manufacturer recommendations, it shall maintain documentation of such recommendations as well as the organization's maintenance activities. I. Medical equipment is to be used for its intended purpose(s). J. Staff must be trained on the safe operation of medical equipment before they use it. K. Medical equipment brought into the organization (e.g. rentals, vendor-owned, physician-owned, and patient-owned) for use on a patient must be inspected to assure it is operating properly before use. L. Medical equipment must be kept clean and in good working order. M. A process must be developed and implemented to identify and remove broken, malfunctioning or inoperable equipment from patient care areas. N. The organization must report any incident in which medical equipment is involved in the death or injury of a person, as required by the Safe Medical Devices Act of 1990. O. Information on the maintenance and safety of medical equipment, including equipment failure due to operator error, is incorporated into the organization's quality assessment and performance improvement program.

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	P. All medical equipment, regardless of whether it is leased or owned, and regardless of whether it is maintained according to manufacturer recommendations or is subject to alternative equipment maintenance (AEM) program, shall be listed in an inventory which includes a record of maintenance activities.
	• Equipment managed through an AEM program must be readily separately identifiable as subject to AEM.
	• Critical equipment, whether in an AEM program or not, must also be readily identified as such
	• The inventory contains the following information for all equipment included.
	  • A unique identification number;
	  • The equipment manufacturer;
	  • The equipment model number;
	  • The equipment serial number;
	  • A description of the equipment;
	  • The location of the equipment (for equipment generally kept in a fixed location);
	  • The identity of the department considered to "own" the equipment;
	  • Identification of the service provider;
	  • The acceptance date; and
	  • Any additional information that may be useful for proper management of the equipment.

482.41	CE-9: Management of Supplies The organization must assure that it has sufficient supplies available to meet patient care needs. A. The organization identifies and makes available the supplies it needs to meet its patients' needs for both day-to-day operations and those supplies that are likely to be needed in emergency situations. B. Supplies must be stored in a safe manner. • Outdated or expired supplies are removed from use in patient care areas. • Sharps, such as needles, are not stored in areas that are not frequently monitored by staff and are accessible to the general public. • Supplies are stored in a manner to prevent contamination and vector infestation.
482.41	CE-10: Management of Utilities The organization must assure that facility equipment, including essential utilities, are provided and maintained in a safe and effective manner. *Note: Facility equipment includes all devices intended to support the physical environment of care. Essential utility systems include electrical systems, water and water filtration systems, heating systems, cooling systems, medical gases, vacuum systems, air handlers, elevators and communication systems; and their components.* A. The organization assures that individual(s) responsible for overseeing the development, implementation, and management of equipment maintenance programs and activities are qualified by education, training, and/or experience to do so. • The organization's leadership assures that all equipment maintenance policies, procedures, programs, specific maintenance inventories, activities, and schedules are under the purview of qualified personnel B. Facility equipment must be inspected, calibrated, tested, and maintained by qualified personnel C. Facility equipment must be tested for performance and safety before initial use and after major repairs or upgrades D. The following types of facility equipment must be maintained in accordance with manufacturer instructions: • Equipment subject to Federal or State law requiring maintenance, inspection and testing be performed strictly in accordance with the manufacturer's recommendations, or otherwise establishes, more stringent maintenance requirements. • When Medicare Conditions of Participation require adherence to manufacturer recommendations and/or set specific standards • Equipment for which sufficient maintenance history is not available to support its inclusion in an alternative equipment management (AEM) program.

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	E. For other facility equipment, the organization may develop, implement, and maintain a documented alternative equipment management (AEM) program based upon generally accepted standards of care. • In determining whether or not to include equipment in an AEM program, the organization shall explain and document the patient health and safety risks associated with the equipment's use. Factors for the organization to consider when evaluating the risks associated with a particular type of equipment include, but are not limited to: • How the equipment is used and the likely consequences of equipment failure or malfunction – including seriousness and prevalence of harm • Information, if available, on the manufacturer's equipment maintenance recommendations, including the rationale for the manufacturer's recommendations • Maintenance requirements of the equipment • The timely availability of alternate devices or backup systems in the event of equipment failure or malfunction • Incident history of identical or very similar equipment – is there documented evidence, based on the experience of the hospital (or its third party contractor), or on evidence publicly reported by credible sources outside the hospital, which provides the number, frequency and nature of previous failures and service requests, and indicates use of an AEM strategy does not result in degraded performance of the equipment. Note that the risk may vary for the same type of equipment, depending on the patient care setting. F. The organization shall identify any equipment in its AEM program which is "critical equipment," i.e., utility systems or their components for which there is a risk of serious injury or death to a patient or staff person should the equipment fail. G. The organization shall use one or more strategies for the determination of appropriate maintenance, inspection, and testing activities and frequencies. See the glossary for the definition of acceptable maintenance strategies. The organization shall adhere strictly to the AEM activities and strategies it develops The AEM program must not reduce the safety of equipment H. For each type of facility equipment subject to an alternative equipment management (AEM) program, there shall be documentation indicating: • The pertinent types and level of risks to patient or staff health and safety; • Alternate maintenance activities, and the maintenance strategy and any other rationale used to determine those activities; the differences from the manufacturer's recommended maintenance activities are made explicit, unless the organization is unable to obtain the manufacturer's maintenance recommendations, due to the age of the equipment or the manufacturer's restricting the availability of its recommendations; • Alternate maintenance frequencies to be used, if any, and the maintenance strategy and any other rationale used to determine those frequencies. • For equipment identified as presenting a very low risk to patient or staff safety, it is acceptable to not set a particular frequency but instead indicate a less specific approach, for example, an interval range, such as "every 12 – 24 months." It is also be acceptable to employ periodic "departmental sweeps" for such very low risk equipment, where equipment functioning is sampled and operators are polled about its functionality. • The date when AEM program maintenance activities were performed and, if applicable, further actions required/taken; and • Documentation of any equipment failures (not including failures due to operator error), including whether there was resulting harm to an individual.

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	I. The organization shall have policies and procedures which address the effectiveness of its alternate equipment management (AEM). In evaluating the effectiveness of the AEM program the organization shall address factors including, but not limited to: • How equipment is evaluated to ensure there is no degradation of performance, particularly for equipment where such degradation may not be readily apparent to staff using the equipment • How incidents of equipment malfunction are identified and investigated, including whether or not the malfunction could have been prevented, and what steps will be taken to prevent future malfunctions; and how a determination is made whether or not the malfunction resulted from the use of an AEM strategy; • The process for the removal from service of equipment determined to be unsafe or no longer suitable for its intended application; and • The use of performance data to determine if modifications in the AEM program procedures are required. J. If an organization elects to perform maintenance in accordance with manufacturer recommendations, it shall maintain documentation of such recommendations as well as the organization's maintenance activities. K. The organization must have written procedures in place to address disruption and/or loss of all essential utilities. • These procedures must address both anticipated and unanticipated disruption and/or loss. L. Staff providing patient care must be trained on actions to take in the event of a disruption and/or loss of an essential utility so that patient safety is not adversely affected. • Training must be provided on hire and on at least an annual basis thereafter. • The organization determines the scope and content of this training. M. The organization must develop and implement a process to report and act upon disruptions and/or loss of essential utilities. N. Information on the maintenance and safety of essential utility systems, including equipment failure due to operator error, is incorporated into the organization's quality assessment and performance improvement program. O. All facility equipment, regardless of whether it is leased or owned, and regardless of whether it is maintained according to manufacturer recommendations or is subject to alternative equipment maintenance (AEM) program, shall be listed in an inventory which includes a record of maintenance activities. • Equipment managed through an AEM program must be readily separately identifiable as subject to AEM. • Critical equipment, whether in an AEM program or not, must also be readily identified as such • The inventory contains the following information for all equipment included. • A unique identification number; • The equipment manufacturer; • The equipment model number; • The equipment serial number; • A description of the equipment; • The location of the equipment (for equipment generally kept in a fixed location); • The identity of the department considered to "own" the equipment; • Identification of the service provider; • The acceptance date; and • Any additional information that may be useful for proper management of the equipment.

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482.41	CE-11: Ventilation, Lighting & Temperature Control The organization must assure that there is proper ventilation, lighting and/or temperature control in patient care and key support areas. A. The organization must assure that there is proper ventilation in at least the following areas: • Areas using ethylene oxide, nitrous oxide, gluteraldehydes, xylene, pentamidine or other potentially hazardous substances; • Locations where oxygen is transferred from one container to another; • Isolation rooms and reverse isolation rooms (both must be in compliance with Federal and State laws, regulations and guidelines such as OSHA, CDC, NIH, etc.); • Pharmaceutical preparation areas (hoods, cabinets, etc.); • Laboratory locations. B. The organization must assure that there is adequate lighting in all patient care areas and food and medication preparation areas. C. The organization must assure that temperature, humidity and airflow in rooms where surgeries are performed are maintained within acceptable standards to inhibit bacterial growth, prevent infection and promote patient comfort. • If the organization is unable to maintain temperature, humidity, or airflow within acceptable standards it must have a plan in place that addresses the clinical risks and safety needs of patients.
482.41	CE-12: Provision of Emergency Power & Lighting The organization must assure that emergency power is provided to critical areas. A. There must be emergency power and lighting in at least the operating and interventional procedure suites, recovery areas, intensive care units, the emergency department and stairwells. B. In all other areas not serviced by the emergency supply source, battery lamps and/or flashlights must be available. C. The organization must comply with all other applicable provisions of the Life Safety Code, National Fire Protection Amendments (NFPA) 101, 2000 Edition and applicable references, such as, NFPA-99: Health Care Facilities, for emergency lighting and emergency power.

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482.41	CE-13: Testing of Emergency Power Generators The organization must assure that emergency power is readily available to support patient care. *Note: This standard only applies if the organization has these types of emergency power systems.* A. The organization tests each emergency power generator for at least 30 continuous minutes at least monthly. • Tests must be greater than 20 days and less than 40 days apart • Tests are conducted with a dynamic load that is at least 30% of the nameplate rating of the generator or meets the manufacturer's recommended prime movers' exhaust gas temperature. • If the organization does not meet either the 30% of nameplate rating or the recommended exhaust gas temperature during any test, then it must test the emergency generator once every 12 months using supplemental (dynamic or static) loads of 25% of nameplate rating for 30 minutes, followed by 50% of nameplate rating for 30 minutes, followed by 75% of nameplate rating for 60 minutes, for a total of 2 continuous hours. B. The organization tests all automatic transfer switches for each emergency power generator at least 12 times each year. C. At least once every three years each emergency power generator is tested for a minimum of four continuous hours using a dynamic or static load that is at least 30% of the nameplate rating of the generator or meets the manufacturer's recommended prime movers' exhaust gas temperature. D. If an emergency power generator fails during a test or actual operation, the organization takes appropriate action to assure that patient care is not adversely affected. E. The organization maintains documentation to demonstrate compliance to the requirements noted in this standard.
482.41	CE-14: Emergency Battery Powered Lighting The organization must assure that emergency battery-powered lighting is in compliance with Chapter 19.2.9 of the 2000 Edition of NFPA 101. *Note: This standard only applies if the organization has these types of emergency power systems* A. Monthly, the organization tests battery-powered lights required for egress for at least 30 seconds. B. Annually, the organization either tests battery-powered lights required for egress for at least 1½ hours or replaces all the batteries. C. The organization maintains documentation to demonstrate compliance to the requirements noted in this standard.

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482.41	CE-15: Compliance to the NFPA Life Safety Code The organization must meet applicable provisions of the NFPA 101 2000 Edition of the Life Safety Code. *Note: After reviewing findings from the State Agency, 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 the patients.* *Note: The provisions of the Life Safety Code do not apply in a State where CMS finds that a fire and safety code imposed by State law adequately protects patients in hospitals.* *Note: Effective March, 2006 Chapter 19.3.6.3.2, exception number 2 of the adopted edition of the Life Safety Code does not apply to hospitals. Doors with roller latches are not permitted.* A. The organization must comply with applicable provisions – and referenced codes – of the NFPA 101 2000 Edition of the Life Safety Code for all buildings designated as healthcare occupancy, and/or ambulatory occupancy. B. For buildings designated as business occupancy, the organization must assure adequate means of egress from the building. C. The organization must implement temporary life safety measures to compensate for an identified deficiency(s) in the Life Safety Code until the deficiency(s) can be corrected. • The organization determines the temporary life safety measures required based on the nature of the deficiency. It is recognized that some deficiencies (minor) may not require temporary measures • The organization implements temporary life safety measures as required. • The implementation of temporary life safety measures is documented. D. *Effective 1/1/15:* The organization shall maintain a current set of fire and life safety drawings for each building classified as a healthcare or ambulatory occupancy. Drawings deemed to meet this requirement shall have the following minimum information displayed: • The identification of the facility and building • The type of construction of the building • The occupancy classification of the building including all use areas, floors and mixed occupancies • The areas of the building fully protected by automatic fire sprinkler systems. • The locations of all fire rated barriers • The locations of all smoke barriers • The location and limits of corridors and corridor walls • The location and boundaries of all suites including the area in square feet and identified as a sleeping or non-sleeping suite. • The location and fire rating of all vertical openings including chutes, shafts and exit enclosures. • The location of all exits and exterior exits from the building • The location of any horizontal exits • The location of all hazardous areas • The location and documentation of any approved equivalencies or waivers. Drawings shall be made available in a minimum readable format of at least 11 inches by 17 inches in size. Drawings shall display standard conventions including: • Title • Scale or graphic scale • North arrow and geographic orientation • Author or person who prepared the drawing • Date created along with any revisions • Legend
482.41	CE-16: Fire Inspections by State / Local Fire Control Agencies The organization must maintain written evidence of regular inspection and approval by State or local fire control agencies. A. The organization must maintain documentation demonstrating that deficiencies identified during inspections were corrected.

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482.41	CE-17: Fire Response Plan The organization must establish a response plan to protect patients, staff, visitors and others in the event of a fire. A. There must be a written fire response plan that addresses at least the following. The plan must be available to all supervisory personnel, employees to be kept in informed of their duties under the plan, and a copy of the plan available at all times in the telephone operator's possession or at the security center (NFPA 101 LSC 18/19.7.1): • Use of alarms and prompt reporting of a fire; • Transmission of the alarm to fire department; • Response by staff to fire alarms; • Mechanisms to isolate a fire; • Evacuation of immediate area / smoke compartment; • Preparation of floors and building for evacuation; • Extinguishing of a fire; • Cooperation with fire fighting authorities. B. Staff is trained on the fire-response plan upon hire into the organization and on an annual basis thereafter. Training addresses life safety procedures and devices. C. All fires are reported to appropriate external agencies as required by State law and/or regulation.
482.41	CE-18: Fire Drills The organization must conduct drills to assure that staff and life safety systems respond appropriately in the event of a fire. A. Drills must be conducted at least once per shift per quarter in all designated healthcare and residential occupancies. All drills must include the transmission of a fire alarm signal and simulation of an emergency fire condition. • For drills occurring between 9PM and 6AM in overnight patient care areas, signal transmission of the fire alarm system is required, but the organization may use a coded announcement instead of an audible alarm. B. Drills must be conducted at least once per quarter in all designated ambulatory occupancies. All drills must include the transmission of a fire alarm signal and simulation of an emergency fire condition. C. Drills must be conducted at least annually in designated business occupancies where patient care is provided. All drills must include the transmission of a fire alarm signal and simulation of an emergency fire condition. D. Fire drills must be unannounced. E. Each drill is documented and evaluates implementation of the organization's fire response plan.

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42 CFR	CIHQ Standards & Requirements
482.41	CE-19: Inspection & Testing of Life Safety Systems The organization must inspect/test its life safety systems. A. In accordance with NFPA 72, 1999 Edition, Table 7-3.2, the following are performed: • Every quarter, testing of supervisory signal devices (except valve tamper switches); • Every six months, testing of valve tamper switches and water-flow devices; • Every 12 months, testing of duct detectors, electromechanical releasing devices, heat detectors, manual fire alarm boxes and smoke detectors; • Every 12 months, testing of visual and audible fire alarms, including speakers; • Every quarter, testing of fire alarm equipment for notifying off-site fire responders. B. For automatic sprinkler systems, in accordance with NFPA 25, 1998 Edition, the following are performed: • Weekly, testing of fire pumps under no-flow conditions; • Every six months, testing of water-storage tank high- and low-water level alarms (Section 6-3.5); • Every month during cold weather, testing of water-storage tank temperature alarms (Section 6-3); • Every 12 months, testing of main drains at system low point or at all system risers (Section 9-2.6); • Every quarter, inspection of all fire department water supply connections (Section 9-7.1). C. In accordance with NFPA 25, 1998 Edition, the following are performed: • Every 12 months, testing fire pumps under flow; • Every five years, water-flow testing for standpipe systems; • Hydrostatic testing on standpipe occupant hoses five years after installation and every three years thereafter. D. In accordance with NFPA 96, 1998 Edition, the following are performed: • Every six months, inspection of any automatic fire-extinguishing systems in a kitchen. Discharge of the systems is not required; • Every 12 months, testing carbon dioxide and other gaseous automatic fire-extinguishing systems. Discharge of the systems is not required. E. In accordance with NFPA 10, Standard for Portable Fire Extinguishers 1998 Edition (Sections 1-6, 4-3 and 4-4), the following are performed: • Every month, inspection of portable fire extinguishers; • Every 12 months, maintenance on portable fire extinguishers. F. In accordance with NFPA 80 Standard for Fire Doors and Other Opening Protectives, 2007 Edition (Section 19.4.1.1) and NFPA 105, 2007 Edition (Section 6.5.2), the following is performed: • Newly installed fire and smoke dampers are tested one year after installation (if installed after January 1, 2008) to verify that they fully close; • Existing fire and smoke dampers are tested at least every six years to verify that they fully close; • If fire and/or smoke dampers cannot be tested because of accessibility issues, the organization notes the location of these dampers and develops a plan to gain access to them within a noted timeframe, or if/when the area undergoes construction or renovation. G. In accordance with NFPA 90A, Standard for the Installation of Air Conditioning and Ventilation Systems, 1999 Edition (Section 4-4.1), the following are performed: • Every 12 months, testing automatic smoke-detection shutdown devices for air-handling equipment. H. In accordance with NFPA 80, 1999 edition (Section 15-3.4), the following are performed: • Every 12 months, testing of sliding and rolling fire doors. I. Documentation of all tests and inspections required in this standard must include at least the following: • Name and date of the test/inspection performed; • The required frequency of the test/inspection; • Name and contact information, including affiliation, of the person who performed the test/inspection; • The NFPA standard(s) referenced for the test/inspection; • The results of the test/inspection of each item; • If an item failed its test/inspection, evidence that the item was repaired or replaced and retested/inspected.

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482.41	CE-20: Use of Alcohol-Based Hand-Rub Dispensers Notwithstanding any provisions of the 2000 Edition of the Life Safety Code to the contrary, if the organization chooses to install alcohol-based hand-rub dispensers in its facility(s), it must assure the following: A. 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 healthcare facilities. B. The dispensers are installed in a manner that minimizes leaks and spills that could lead to falls. C. The dispensers are installed in a manner that adequately protects against inappropriate access. D. If dispensers are stored in corridors, the corridor must be a minimum of 72 inches. E. The maximum individual dispenser fluid capacity shall be 1.2 liters (0.3 gallons) for dispensers in rooms, corridors and areas open to corridors and 2.0 liters (0.5 gallons) for dispensers in suites of rooms. F. The dispensers shall have a minimum horizontal spacing of four feet (1.2m) from each other. G. 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. H. Storage of quantities greater than 18.9 liters (five gallons) in a single smoke compartment shall meet the requirements of NFPA 30, Flammable and Combustible Liquids Code. I. The dispensers shall not be installed over or directly adjacent to an ignition source. J. In locations with carpeted floor coverings, dispensers installed directly over carpeted surfaces shall be permitted only in sprinklered smoke compartments. K. Where minimum corridor width is 72 inches (1830 mm), projections of maximum six inches (152 mm) from the corridor wall above the handrail shall be permitted for the installation of hand-rub dispensing units. L. The dispensers are maintained in accordance with dispenser manufacturer instructions.

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INFECTION PREVENTION & CONTROL

42 CFR	CIHQ Standards & Requirements
482.42	IC-1: Establishment of an Infection Prevention & Control Program The organization must develop, implement and maintain an active hospital-wide program for the prevention, control and investigation of infections and communicable diseases. A. The organization must designate in writing, the individual(s) responsible for directing the program. • This individual(s) must be qualified by virtue of education, training and experience to competently direct the program. • This individual(s) must demonstrate evidence of ongoing education and training in the area of infection prevention and control. B. The organization must assure that there are adequate resources to support the program. • The organization must consider patient census, characteristics of the patient population and complexity of the healthcare services it offers in determining the size and scope of the resources it commits to infection prevention and control. C. The organization must assure that the program addresses all patient care (both inpatient and outpatient) settings, as well as departments and services that support the provision of patient care. D. The organization is responsible for assuring the following: • The activities of the program must be integrated into the organization's quality assessment and performance improvement program; • Corrective action must be undertaken to address identified issues arising from surveillance and monitoring activities; • Staff must be provided with sufficient training appropriate to their job function, in the principles and practices of infection prevention and control. E. The organization periodically evaluates the infection control and prevention program to assure that it continues to meet its needs. • The organization determines the scope and content of the evaluation. • The evaluation must be performed at least every three years.
482.42	IC-2: Surveillance Program The organization must establish, implement and maintain an active infection control and prevention surveillance program. *Note: Surveillance includes infection detection, data collection and analysis, monitoring and evaluation of preventive interventions.* A. The surveillance program must be organization-wide in scope. There must be mechanisms in place to identify and monitor infections and communicable diseases occurring in various locations, departments and/or care settings. *Note: This does not imply or require that the organization conduct total house-wide surveillance.* B. Surveillance activities must be conducted in accordance with recognized infection control and prevention practices. C. Surveillance activities must be documented and reported through the organization's quality assessment and performance improvement program. This includes at least the following: • Identification of the specific patient populations, processes of care and environmental and support activities that will be part of the surveillance program; • The type of data collected and the frequency of data collection; • Analysis of collected data to identify issues, concerns or opportunities for improvement; • Actions taken to address any issues, concerns or identified opportunities for improvement.

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42 CFR	CIHQ Standards & Requirements
482.42	IC-3: Infection Prevention & Control Policies The organization must establish and implement policies that address at least the following: A. Maintenance of a sanitary environment; B. Prevention of healthcare-acquired infections; C. Infection-prevention and control-measure-associated with air-handling systems and ventilation; D. Food sanitation; E. Cleaning of environmental surfaces such as carpeting and furniture; F. Pest and vector control; G. Infection prevention-and-control measures for potable water and cooling towers (if any); H. Measures to prevent the following in accordance with accepted standards of care: • Surgical site infections, including prophylactic antibiotics; • Ventilator-associated pneumonias; • Central-line-associated bloodstream infections; • Urinary-catheter-associated infections; • Aspiration of tube feedings; I. Measures to prevent infection for the following: • Immune-compromised patient; • Patients with a tracheostomy; • Patients receiving respiratory therapy; J. Use, maintenance and testing of negative and positive pressure rooms (if any); K. Use and maintenance of portable air filtration units (HEPA filters) and/or other equipment designed to prevent the spread of infection; L. Preparedness, response and coordination with public-health agencies in the event of bioterrorism; M. Authority and indications for obtaining microbial cultures of the environment and patients; N. Reporting infections to the local public health authorities.
482.42	IC-4: Management of Multi-Drug-Resistant Organisms The organization must establish, implement and maintain processes to effectively manage the presence of multi-drug-resistant organisms (MDRO). A. The organization determines those MDRO that it considers significant in their community and patient population. B. The organization determines the specific patient populations and/or care settings that implement a mechanism(s) to identify patients who may have an MDRO upon admission and/or presentation for care. C. The organization implements timely and appropriate precautions on patients with a confirmed MDRO to prevent the spread of infection.

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482.42	IC-5: Management of Communicable Disease Outbreaks The organization must develop, implement and maintain processes to appropriately and effectively manage outbreaks of communicable diseases within its care settings. A. The organization has a process in place to notify and work with public health authorities when an outbreak occurs. B. The organization must have procedures developed to prevent transmission of disease(s) among patients, healthcare personnel and visitors during an outbreak. At a minimum these procedures must address: • Identification and notification of persons who may be infected and/or exposed; • Provision of treatment and/or prophylaxis to affected or potentially affected persons. C. The organization must have a plan in place to manage the presence of a large number of infected or potentially infectious patients. At a minimum, this plan must address the following logistical and patient care issues: • Patient placement within the facility(s) and the need for isolation or quarantine; • Availability and replenishment of necessary equipment and supplies, including protective equipment for healthcare personnel; • Communication and coordination with public health authorities.
482.42	IC-6: Hand Hygiene The organization must develop, implement and maintain a program to promote effective hand-hygiene practices by healthcare personnel. A. The organization follows either the Center for Disease Control (CDC) or World Health Organization (WHO) recommendations for hand hygiene. B. The organization must demonstrate that it has an active program in place that encourages healthcare personnel to engage in effective hand hygiene practices. At a minimum, the organization must: • Educate healthcare personnel on appropriate hand hygiene practices. The organization determines the manner and frequency of this education; • Make available alcohol-based – or other effective – hand gel or foam for use by healthcare personnel.
482.42	IC-7: Disinfection & Sterilization Practices The organization must assure that equipment, supplies, instrumentation and surfaces are disinfected or sterilized appropriately. A. Low-level disinfection must be performed in accordance with the manufacturer's instructions for the disinfection agent used. B. Intermediate and high-level disinfection must be performed in accordance with *the CDC Guidelines for Sterilization and Disinfection in Healthcare Facilities*, and manufacturer's instructions for the disinfection agent, instrumentation and equipment used. C. Sterilization must be performed in accordance with the *CDC Guidelines for Sterilization and Disinfection in Healthcare Facilities*, and manufacturer's instructions for the instrumentation and equipment used. • If immediate use steam sterilization (IUSS) is being performed due to lack of sufficient instrumentation, the organization must have a plan in place to obtain sufficient instrumentation over time. The use of IUSS must not be for the convenience of the organization or practitioners. IUSS is not acceptable in the following situations: • For implant devices, except in a documented emergency situation when no other option is available. • For post-procedure decontamination of instruments used on patients who may have Creutzfeldt-Jakob disease (CJD) or other prion-associated diseases; • On devices or loads that have not been validated with the specific cycle used; or • On devices that are sold by the manufacturer already processed and packaged as sterile and intended for single-use only.

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482.42	IC-8: Infection Prevention & Control Education The organization must assure that staff and patients are educated, as necessary, on appropriate infection control and prevention strategies. A. As appropriate to their job function, staff' are educated on key infection control prevention and control requirements upon hire and on an annual basis thereafter. This education is documented. B. Patients placed in isolation or other precautions due to a communicable disease are educated on their role in assuring that said precautions are appropriately implemented. This education is documented in the patient's medical record.
482.24	IC-9: Leadership Responsibilities for Infection Control The chief executive officer, the medical staff, and the director of nursing services must; A. Ensure that the hospital-wide quality assessment and performance improvement (QAPI) program and training programs address problems identified by the infection control officer or officers; and B. Be responsible for the implementation of successful corrective action plans in affected problem areas.

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EMERGENCY PREPAREDNESS

42 CFR	CIHQ Standards & Requirements
482.41	EP-1: Emergency Preparedness Planning The organization must develop and implement a comprehensive plan to ensure the safety and well being of patients, staff and visitors during emergency situations. At a minimum, the organization must develop and implement processes that demonstrate at least the following: A. Coordination with Federal, State and local emergency preparedness and health authorities to identify likely risks for their area (e.g., natural disasters, bioterrorism threats, disruption of utilities such as water, sewer, electrical communications and fuel, nuclear accidents, industrial accidents and other likely mass casualties, etc. • The risk assessment must be reviewed at least once every three years or more frequently if necessary; • The risk assessment must be revised as necessary to reflect the identification of any new risks or significant changes in existing risk. B. Specific response procedures to identified risks. • The organization determines those identified risks for which it wishes to develop specific response procedures. C. Integration of the organization's emergency management command structure with that of its community. D. If the organization intends to provide medical treatment to the victims of disaster, the plan must also address requirements noted under NFPA 99 (1999 edition) Chapter 11
482.41	EP-2: Emergency Preparedness Plan The organization must develop a written emergency preparedness plan appropriate to its scope of services that addresses at least the following: A. Establishment of an "all hazards" response to emergency situations that is flexible and can be tailored to the needs of the organization and the emergency it faces. Use of the Hospital Incident Command Structure (HICS) is one method of meeting this requirement; B. The needs of each location where the organization provides patient care; C. The needs of special patient populations treated by the organization (e.g., patients with psychiatric diagnosis, patients on special diets, newborns, etc.); D. Security of patients, staff and visitors during the emergency; E. Availability and security of pharmaceuticals, food, potable water, supplies and equipment that may be needed during emergency/disaster situations; F. Communication with external entities such as State and/or local emergency services and other healthcare facilities. This includes a back-up plan in case normal methods of communication are not available; G. Communication among staff and physicians within the organization itself; H. Qualifications and training needed by personnel, including healthcare staff, security staff and maintenance staff, to implement and carry out emergency procedures; I. Identification, availability and notification of personnel that are needed to implement and carry out the organization's emergency plans; J. Identification of community resources, including lines of communication, and names and contact information for community emergency preparedness coordinators and responders; K. Provisions if gas, water, electricity supply is not available to the organization; L. Transfer or discharge of patients to home or other healthcare settings; M. Transfer of patients with equipment to another healthcare setting; N. Methods to evaluate repairs needed and to secure various likely materials and supplies to effectuate repairs. O. If the organization intends to provide medical treatment to the victims of disaster, the plan must also address requirements noted under NFPA 99 (1999 edition) Chapter 11

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42 CFR	CIHQ Standards & Requirements
482.41	EP-3: Provision of Emergency Gas & Water The organization must have a system to provide emergency gas and water as needed to provide care to inpatients and other persons who may come to the organization's inpatient care site(s). *Note: Emergency gas includes fuels such as propane, natural gas, fuel oil, liquefied natural gas, as well as any gases the hospital uses in the care of patients such as oxygen, nitrogen, nitrous oxide, etc.* A. The organization must have arrangements with local utility companies and others for the provision of emergency sources of water and gas. B. The organization must have a plan to protect emergency gas and water supplies and have a plan for prioritizing their use until replenishment occurs. • The plan must address the event of a disruption in supply (e.g., disruption to the entire surrounding community).
482.41	EP-4: Testing of the Emergency Preparedness Plan The organization must test its emergency preparedness plan at least once a year. In testing its plan, the organization must be able to demonstrate the following: *Note: A table-top exercise is not sufficient to meet this standard* *Note: Actual implementation of the emergency preparedness plan may be used in place of a test to meet this standard provided the requirements below were met.* A. The test scenario was designed to address one of the organization's identified risks; B. The test required establishment of the organization's emergency management command structure; C. The scope of the test was sufficient to assess the ability of the organization to implement its emergency preparedness plan; • The organization determines those sites, settings and services that are required to participate in the test and their degree of participation; D. There is a documented critique of the test that identifies opportunities, if any, to improve the organization's emergency preparedness; E. There is documentation of actions taken to address opportunities for improvement identified by the critique. F. If the organization intends to provide medical treatment to victims of a disaster. the plan must also address requirements noted under NFPA 99 (1999 edition) Chapter 11

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UTILIZATION REVIEW

42 CFR	CIHQ Standards & Requirements
482.30	UR-1: Utilization Review Plan The organization must have in effect a utilization review (UR) plan that provides for review of services furnished by the institution and by members of the medical staff to patients entitled to benefits under the Medicare and Medicaid programs. *Note: This standard does not apply to organizations where:* • *A Quality Improvement Organization (QIO) has assumed binding utilization review, or* • *CMS had determined that UR procedures developed and required by the State exceed the requirements under 42 CFR 456.50 through 42 CFR 456.245.* A. The organization's UR plan must include a delineation of the responsibilities and authority for those involved in the performance of UR activities. B. The plan must also establish procedures for the review of the medical necessity of admissions, the appropriateness of the setting, the medical necessity of extended stays and the medical necessity of professional services.
482.30	UR-2: Utilization Review Committee The organization must establish a Utilization Review (UR) Committee to oversee the utilization review function. *Note: This standard does not apply to organizations where:* • *A Quality Improvement Organization (QIO) has assumed binding utilization review, or* • *CMS had determined that UR procedures developed and required by the State exceed the requirements under 42 CFR 456.50 through 42 CFR 456.245.* A. The governing body delegates oversight of the utilization review function to the UR Committee. B. At least two members of the UR Committee must be doctors of medicine or osteopathy. C. The UR Committee must be internal to the organization, or if external to the organization, established in a manner approved by CMS. • If, because of the small size of an organization it is impractical to have a properly functioning internal committee, then the committee must be externally established. D. Individual(s) on the UR Committee may not engage in review functions when: • The individual(s) has a direct financial interest in the organization; • The individual(s) was professionally involved in the care of the patient being reviewed.

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42 CFR	CIHQ Standards & Requirements
482.30	UR-3: Scope & Frequency of Utilization Review The organization must assure that the minimum scope of utilization review addresses the medical necessity of admissions, duration of stay and professional services rendered. *Note: This standard does not apply to organizations where:* • *A Quality Improvement Organization (QIO) has assumed binding utilization review, or* • *CMS had determined that UR procedures developed and required by the State exceed the requirements under 42 CFR 456.50 through 42 CFR 456.245.* A. The organization must establish and use criteria to determine both the appropriateness of a patient's admission, as well as the patient's required level of care. • Review for appropriateness of admission and level of care may be performed prior to, at the time of, or after admission. B. The organization must establish and use criteria to determine whether or not a patient's continued inpatient stay is both medically necessary and at an appropriate level of care. • Review may occur either on all patients or on a sampling of patients as defined by the organization. C. If the organization is reimbursed for its inpatient services under CMS' prospective payment system (IPPS) per 42 CFR 412, then the following must occur: • All cases where the extended length of a patient's stay is reasonably assumed to be an outlier as described in 42 CFR 412.80(a)(1)(i), must be reviewed; • All cases that are reasonably assumed to be outlier cases based on extraordinarily high costs, as described in 42 CFR 412.80(a)(1)(ii) must be reviewed. D. If the organization is not reimbursed under the IPPS per 42 CFR 412, the UR committee must make a periodic review, as specified in the UR Plan, of each current inpatient receiving inpatient services during a continuous period of extended duration. • The organization must define what is considered an extended duration of stay in the UR Plan. If the organization uses a different number of days for different diagnosis or functional categories for the period of extended stay, there must be a written list with lengths of stay designated for each diagnosis of functional category. • The scheduling of reviews may be the same for all cases or differ for different classes of cases. The reviews must be within 7 days after the time specified in the UR Plan.

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42 CFR	CIHQ Standards & Requirements
482.30	UR-4: Determination of Medical Necessity When the organization determines that as a result of utilization review activities, a patient's admission or continued inpatient stay is not medically necessary, it assures the following: *Note: This standard does not apply to organizations where:* • *A Quality Improvement Organization (QIO) has assumed binding utilization review, or* • *CMS had determined that UR procedures developed and required by the State exceed the requirements under 42 CFR 456.50 through 42 CFR 456.245.* A. When other than a doctor of medicine or osteopathy makes an initial finding that the written criteria for medical necessity are not met, the case must be referred to the UR committee or subgroup thereof which contains at least one physician. B. If the committee or subgroup agrees after reviewing the case that admission or continued stay is not medically necessary or appropriate, the attending physician must be notified and allowed an opportunity to present his/her views and any additional information relating to the patient's needs for admissions or extended stay. C. When a physician member of the committee performs the initial review instead of a non-physician reviewer and he/she finds that admissions or extended stay is not necessary, no referral to the committee or subgroup is necessary and he/she may notify the attending physician directly. D. If the attending physician does not respond or does not contest the findings of the committee or subgroup or those of the physician who performed the initial review, then the findings are final. E. If the attending physician contests the committee or subgroup findings or if he presents additional information relating to the patient's need for extended stay, at least one additional physician member of the committee must review the case. • If the two physician members determine that the patient's stay is not medically necessary or appropriate after considering all the evidence, their determination becomes final. • Written notification of this decision must be sent to the attending physician, patient (or next of kin), facility administrator and the single State agency (in the case of Medicaid) no later than 2 days after such final decision and in no event later than 3 working days after the end of the assigned extended stay period.
482.30	UR-5: Review of Professional Services The UR Committee must review professional services provided to determine medical necessity and to promote the most efficient use of available health facilities and services. *Note: This standard does not apply to organizations where:* • *A Quality Improvement Organization (QIO) has assumed binding utilization review, or* • *CMS had determined that UR procedures developed and required by the State exceed the requirements under 42 CFR 456.50 through 42 CFR 456.245.* *Note: "Professional" services include the aspects of care rendered by laboratory personnel, physical therapists, nurses and others, as well as services provided by the medical staff.* A. The review of professional services must include medical necessity and efficient use of available health facilities and services. Areas of focus should include, but are not necessarily limited to: • Availability and use of necessary services, i.e., under-use, overuse, appropriate use; • Timeliness of scheduling of services; • Appropriateness of therapeutic procedures.

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PATIENT RIGHTS

42 CFR	CIHQ Standards & Requirements
482.13	PR-1: Recognition of Patient Rights The organization must recognize, protect and promote the rights of each patient consistent with federal, state and local law and regulation.
482.13	PR-2: Informing Patients of Their Rights The organization must inform each patient in writing of his or her rights. Whenever possible, this information must be provided before providing or stopping care. A. For inpatient settings, written information shall be provided to each patient, whenever possible, within 24 hours of admission. B. For outpatient settings, written information shall at least be posted in each registration area in a manner where it can be easily seen. C. Written information and/or posting shall be provided or explained in a language and manner that the patient can understand. D. In accordance with 42 CFR 489.27(b), each Medicare beneficiary is to receive the "An Important Message from Medicare Notice" (IM) within two days of admission E. In addition, the IM is to also be given to each Medicare beneficiary within two days of their anticipated discharge. • If the initial delivery of the IM occurs within two days of the patient's discharge, the second delivery of the IM is not required. F. When a patient who is not incapacitated has designated, either orally to staff or in writing, another individual to be his/her representative, the organization must provide the designated individual with the required notice of patients' rights in addition to the patient. • In the case of a patient who is incapacitated, when an individual presents with an advance directive, medical power of attorney or similar document executed by the patient and designating an individual to make medical decisions for the patient when incapacitated, then the hospital must, when presented with the document, provide the required notice of its policies to the designated representative. • The explicit designation of a representative takes precedence over any non-designated relationship and continues throughout the patient's inpatient stay or outpatient visit, unless expressly withdrawn, either orally or in writing, by the patient.
482.13	PR-3: Notification of Hospitalization The patient has the right to have a family member or representative of his or her choice and his or her own physician notified promptly of his or her admission to the hospital. A. For every inpatient admission, the organization must ask the patient whether the hospital should notify a family member or representative about the admission. If the patient requests such notice and identifies the family member or representative to be notified, the organization must provide such notice promptly to the designated individual. • When a patient is incapacitated or otherwise unable to communicate the organization must make reasonable efforts to identify and promptly notify a family member or patient's representative. • The organization must document that the patient, unless incapacitated, was asked no later than the time of admission whether he or she wanted a family member/representative notified, the date, time and method of notification when the patient requested such, or whether the patient declined to have notice provided. If the patient was incapacitated at the time of admission, the medical record must indicate what steps were taken to identify and provide notice to a family member/representative. B. For every inpatient admission, the organization must ask the patient whether the hospital should notify his/her own physician. If the patient requests notice to and identifies the physician, the organization must provide such notice promptly to the designated physician, regardless of whether the admission was scheduled in advance or emergent.

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482.13	PR-4: Patient Grievances The organization must establish a process to receive, recognize and respond to a grievance filed by a patient. A. The governing body must approve the organization's grievance process. B. The governing body is responsible for managing the grievance process unless it formally delegates this responsibility in writing to a committee. The delegation cannot be made to an individual person. C. If a patient wishes to file a grievance, the organization must: • Inform the patient of the internal grievance process, including whom to contact to file a grievance; • Provide the patient a phone number and address for lodging a grievance with the State agency (the agency that has licensure survey responsibility for the organization), and inform the patient that he/she may lodge a grievance with the State agency directly. D. Unless there are extenuating circumstances, grievances must be resolved within seven days following receipt of the grievance. • If the grievance cannot be resolved within seven days, the patient must be notified and apprised of when anticipated resolution of the grievance will occur. E. Written notification(s) to the patient must contain the name of the organization contact person, the steps taken on behalf of the patient to investigate the grievance, the results of the investigation and the date of completion. The mechanism for prompt resolution of patient concerns regarding quality-of-care issues or premature discharge to the appropriate Utilization and/or Quality Improvement Organization. F. Data collected regarding patient grievances, as well as other complaints that are not defined as grievances (as determined by the organization), must be incorporated in the organization's Quality Assessment and Performance Improvement Program.
482.13	PR-5: Right to Make Informed Decisions The patient or his or her representative (as allowed under State law) has the right to make informed decisions regarding his/her care. To assure this right, the organization must do the following: A. Assure that each patient / representative is given information on his/her health status, diagnosis and prognosis. B. Inform patients / representatives about any significant errors or adverse events involving their care. • The organization determines who will inform the patient / representative and how the information will be provided. C. Establish and implement policies that assure a patient's / representative's right to request or refuse treatment. Such policies should indicate how the patient's request will be addressed. • The organization is under no obligation to fulfill a patient's / representative's request for a treatment or service that the responsible practitioner has deemed medically unnecessary or inappropriate. D. Inform the patient / representative of any disclosures as required under 42 CFR 482.13(b)(2). E. Assure that the patient / representative receives the above information in a manner that the patient can understand.

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482.13	PR-6: Advance Directives The patient (both inpatient and outpatient) has the right to formulate an advance directive. To assure this right, the organization must do at least the following: A. Provide written information to patients at the time of admission concerning their rights under State law (whether statutory or recognized by the courts of the State) to make decisions concerning their medical care including their right to accept or refuse medical care and their right to formulate an advance directive; • Both inpatients and outpatients have the same rights. The written information must be provided at least to outpatients (or their representative) who are in the emergency department, in observation status, or who are undergoing same day surgery. The information must be provided at the time of registration. Provision of information to outpatients in other care settings is determined by the organization. • If an individual is incapacitated or otherwise unable to communicate, the organization may provide the advance directive information required to the individual's family or surrogate in the same manner that it issues other materials about policies and procedures to the family of the incapacitated individual or to a surrogate or other concerned persons in accordance with State law. B. For inpatients, assess and document in the medical record whether or not the patient has executed an advance directive; C. For outpatients, the organization may determine whether or not to assess for, and/or document the presence of, an advance directive; D. Not condition the provision of care or otherwise discriminate against an individual based on whether or not the individual has executed an advance directive; E. Ensure compliance with requirements of State law concerning advance directives and inform individuals that complaints concerning advance directive requirements may be filed with the State survey and certification agency; F. Provide for the education of staff concerning its policies and procedures on advance directives; G. Provide and document community education provided by the organization regarding advanced directives; H. Provide a clear and precise statement of limitation to the patient if the organization cannot implement an advance directive on the basis of conscience. At a minimum, this statement of limitation should: • Clarify any differences between institution-wide conscience objections and those that may be raised by individuals in the organization; • Identify the legal authority permitting such an objection; • Describe the range of medical conditions or procedures affected by the objection. I. When a patient who is incapacitated has executed an advance directive designating a particular individual to make medical decisions for him/her when incapacitated, the organization must, when presented with the document, provide the designated individual the information required to make informed decisions about the patient's care. • The organization must also seek the consent of the patient's representative when informed consent is required for a care decision. The explicit designation of a representative in the patient's advance directive takes precedence over any non-designated relationship and continues throughout the patient's inpatient stay or, as applicable, outpatient visit, unless the patient ceases to be incapacitated and expressly withdraws the designation, either orally or in writing.

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482.13	PR-7: Personal Privacy The patient has the right to privacy and safety. To assure this right, the organization must have a policy(s) and process(es) in place that address at least the following: A. The right to privacy during personal hygiene activities (e.g., toileting, bathing, dressing), during medical/nursing treatments and when requested as appropriate; B. The right to limiting the release or disclosure of patient information such as the patient's presence in the facility or location in the hospital, or personal information such as name, age, address, income, health information without prior consent from the patient; • The organization should have procedures in place in accordance with State law to provide appropriate information to patient families or significant others in those situations where the patient is unable to make their wishes known; C. That people not involved in the care of the patient should not be present without his/her consent while he/she is being examined or treated, nor should video or other electronic monitoring/recording methods be used while he/she is being examined without his/her consent; D. A patient's right to privacy may be limited in situations where a person must be continuously observed, such as when restrained or in seclusion when immediate and serious risk to harm self (such as when the patient is under suicide precautions or special observation status) or others exists.
482.13	PR-8: Right to Receive Care in a Safe Setting Patients have the right to receive care in an environment that is safe. A. The organization must address any safety needs presented to them by the patient or identified through patient-specific assessment activities. B. The organization must develop and implement a process(s) to protect patients who may be at risk of physical or psychological harm from family, visitors or other individuals while under the organization's care.
482.13	PR-9: Abuse, Neglect or Harassment Patients have the right to be free of abuse and harassment. To assure this right, the organization must do the following: A. Screen staff upon hire to determine if they have a prior record (conviction) of abuse or neglect; B. Provide staff with information on recognizing patient abuse, neglect and harassment during initial orientation and on at least an annual basis thereafter; C. Protect patients from abuse, neglect or harassment, including when any allegation of same is being investigated; D. Investigate and respond to any allegation of abuse, neglect or harassment while under the organization's care; E. Report any incidence of abuse, neglect or harassment while under the organization's care to the appropriate legal authority(s).
482.13	PR-10: Confidentiality of Information Patients have the right to confidentiality of their health information. To assure this right, the organization must do the following: A. Assure that individuals accessing patient health information are designated by law, regulation or organization policy as having a need to know; B. Assure that patient health information is secure and accessed only by authorized individuals; C. Assure that access to patient health information is limited to individuals necessary to provide care, treatment or service to the patient.

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482.13	PR-11: Access to Personal Health Information The patient has the right to access their health information within a reasonable timeframe. To assure this right, the organization must do the following: A. A. Assure that patients are allowed to inspect and obtain a copy of health information about them and that the organization may not withhold information except as permitted by law and regulation • The organization must assure that it meets patient requests for information as quickly as its record keeping system permits. B. Assure that the cost of providing a copy of the patient's health information not create a barrier to the individual's ability to receive it. • The organization may impose reasonable cost-based fees for copying or duplicating medical records or other patient health information.
482.13	PR-12: Right to Visitation Patients have the right to receive visitors during their hospitalization. To assure this right, the organization must do following: A. Inform each patient (or support person where appropriate) of their right to visitation, and develop and implement written policies and procedures that recognize the right of patients to receive visitors, including any clinically necessary or reasonable restrictions that need to be placed on visitation. Visitors may be restricted for any of the following reasons: • The patient requests that visitors be restricted; • Restriction is necessary to assure the safety of the patient; • During periods when medical care and treatment is being delivered as warranted; • If visitors are being disruptive to the therapeutic milieu. B. Inform each patient (or support person, where appropriate) of the right, subject to his or her consent, to receive the visitors whom he or she designates, including, but not limited to, a spouse, a domestic partner (including a same-sex domestic partner), another family member or a friend, and his or her right to withdraw or deny such consent at any time; C. Not restrict, limit or otherwise deny visitation privileges on the basis of race, color, national origin, religion, sex, gender identity, sexual orientation or disability; D. Ensure that all visitors enjoy full and equal visitation privileges consistent with patient preferences.
482.13	PR-13: Participation in Care Planning The patient has the right to participate in the planning of his/her care. At a minimum, the patient's medical record must include documentation that the patient was involved in at least the following: A. Development and implementation of his/her inpatient treatment/care plan, outpatient treatment/care plan; B. Development and implementation of his/her discharge plan; C. Development and implementation of his/her pain management plan if the patient is being treated for pain. D. When a patient who is not incapacitated has designated, either orally or in writing, another individual to be his/her representative, the organization must involve the designated representative in the development and implementation of the patient's plan of care. . • In the case of a patient who is incapacitated, when an individual presents the hospital with an advance directive, medical power of attorney or similar document executed by the patient and designating an individual to make medical decisions for the patient when incapacitated, the hospital, when presented with the document, must involve the designated representative in the development and implementation of the patient's plan of care.

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MEDICATION MANAGEMENT

42 CFR	CIHQ Standards & Requirements
482.25	MM-1: Establishment of a Pharmacy Service The organization must meet the medication needs of the patient. To meet this requirement, the organization must establish a pharmacy service. In doing so, the organization must assure that: A. All pharmacy services are under the direction of a registered pharmacist (Pharmacy Director); B. The main pharmacy, as well as all medication storage areas, is under the jurisdiction of the pharmacy service; and must be administered in accordance with accepted practice principles. C. The scope of pharmacy services must include the procuring, manufacturing, compounding, packaging, dispensing, ordering, distributing, disposition, use and administering of all medications, biologicals, pharmaceutical chemicals, the use of medication related devices and the provision of pharmaceutical care; D. The medical staff is responsible for establishing a multidisciplinary committee composed of representatives from nursing, pharmacy, administration and the medical staff that develop medication related policies and procedures. The focus of policies and procedures addressing medications is to reduce or minimize errors. E. The pharmacy service is integrated into the organization's quality assessment and performance improvement program.
482.25	MM-2: Management & Staffing of Pharmacy Services The organization must assure that pharmacy services are adequately managed and staffed. A. A single pharmacist (Pharmacy Director) must be responsible for the overall administration of the pharmacy service and must be responsible for developing, supervising and coordinating all the activities of the pharmacy service. • The job description or the written agreement for the responsibilities of the pharmacist must be clearly defined and include development, supervision and coordination of all the activities of pharmacy services. B. The Pharmacy Director or designee must be actively involved in those committees responsible for establishing medication-related policies and procedures. C. Pharmacy services must be staffed with sufficient personnel in types, numbers, and training to provide quality services, including 24 hour, 7-day emergency coverage, or there is an arrangement for emergency services as determined by the needs of the patients and as specified by the medical staff. D. There must be sufficient numbers and types of personnel to provide accurate and timely medication delivery, ensure accurate and safe medication administration and to provide appropriate clinical services, as well as the participation in continuous quality improvement programs that meet the needs of the patient population being served.
482.25	MM-3: Availability of Pharmacist Expertise The organization must assure that a pharmacist is continuously available to respond to patient care needs. A. If pharmacy services are not provided on-site 24/7, then the organization assures that a pharmacist is on-call and can respond to patient care needs (in person if necessary) in a timely manner. B. The organization has immediately available sufficient texts and other resources on drug therapy. A pharmacist also should be readily available by telephone or other means to discuss drug therapy, interactions, side effects, dosage, etc., with practitioners to assist in drug selection and with personnel to assist in the identification of drug-induced problems.

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482.25	MM-4: Management of the Medication Formulary The organization must establish and effectively maintain an inventory (formulary) of medications that will be used for patient care. A. The formulary and any changes to it must be approved by the medical staff. B. The formulary must list the medications for dispensing or administration that the organization maintains or that are readily available. C. In accordance with accepted standards of practice, the medical staff, in consultation with the pharmacy service, must develop written criteria for determining what medications are available for dispensing or administration. • At a minimum, the criteria include the indication for use, effectiveness, risks (including propensity for medication errors, abuse potential and sentinel events) and costs. • Medications on the formulary are reviewed periodically based on emerging safety and efficacy information. D. Processes and mechanisms must be established to monitor patient responses to a newly added medication before the medication is made available for dispensing or administration. E. There must be a process to approve and procure medications that are not on the formulary. F. There must be a process to address medication shortages and outages, including the following: • Communicating with appropriate prescribers and staff; • Developing approved substitution protocols; • Educating appropriate licensed independent practitioners, health care professionals and staff about these protocols; • Obtaining medications in the event of a disaster.
482.25	MM-5: Storage of Medications The organization must develop and implement processes to assure that medications are appropriately and safely stored. A. Medications must be stored in accordance with manufacturer's instructions, as well as law and regulation. • If there are no manufacturer instructions, law or regulation, then medications will be stored as instructed by the Director of Pharmacy. B. The temperature of refrigerators and warmers must be maintained within the parameters of the medication stored therein. • The organization must be able to demonstrate that temperatures of medication refrigerators and warmers were monitored at least daily or more frequently if necessary. • If a medication refrigerator or warmer is not within acceptable temperature parameters, there must be documentation of action taken by the organization to correct the issue. C. Expired, mislabeled or otherwise unusable medications must be removed from storage areas and returned to the pharmacy for disposal. D. Medication storage areas will be inspected at least monthly or more frequently if required by law, regulation or organization policy.
482.25	MM-6: Control & Distribution of Medications Drugs and biologicals must be controlled and distributed in accordance with applicable Federal and State laws and regulations and in accordance with applicable standards of practice. A. Applicable standards of practice include compliance with all Federal and State laws, regulations, and guidelines, as well as, standards and recommendations promoted by nationally recognized professional organizations that apply to pharmaceutical care and the control and distribution of drugs and biologicals.

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482.25	MM-7: Tracking of Controlled Medications The organization is required to develop, implement and maintain a system to accurately record and track the receipt and disposition of all controlled medications (Schedule II, III, IV and V medications as classified by law and regulation). This system must assure at least the following: A. Accountability procedures to ensure control of the distribution, use and disposition of all controlled medication; B. Records of the receipt and disposition of all controlled medications must be current and must be accurate; C. Records trace the movement of controlled medications throughout the service; D. All medication records are in order and an account of all controlled medications is maintained and any discrepancies in count are reconciled promptly; E. Any wastage of a controlled medication is witnessed; • The identity of the individual who wasted the controlled medication and the witness are documented; F. Loss or diversion of all controlled medications are managed in such a manner as to minimize the timeframe between the actual loss or diversion to the time of detection and determination of the extent of loss or diversion; G. The Chief Executive Officer and the Pharmacy Director are notified of any diversion or significant loss of inventory of a controlled medication.
482.25	MM-8: Security of Medications Medications must be secured so that they are not accessible to unauthorized personnel. A. Medications listed in Schedules II, III, IV, and V by federal law must be placed behind a locked room or cabinet or under the continuous visual observation of authorized staff at all times. Use of a plastic lock to secure controlled substances is not permitted because such locks do not prevent unauthorized access. • Only individuals who are permitted by law, regulation and scope of practice to access these medications are able to do so. B. All other medications must be stored in a secure area or placed behind a locked room or cabinet. A secure area means that drugs and biologicals are stored in a manner to prevent unmonitored access by unauthorized individuals. The following are considered - by definition - secure areas: • Areas where patients and visitors are not allowed without the supervision or presence of health care personnel; • Areas in which staff is present and actively providing care to patients or preparing to receive patients (e.g., setting up for procedures before the arrival of a patient); • Labor and delivery suites and critical care units, provided access to these units is controlled and restricted to appropriate staff, patients and visitors; • Operative suites, provided the suite is staffed and in active use. The suite is not considered in active use when it is closed. In addition, if an individual operating room is closed, then that room is not considered in active use; • Patients who are permitted to self-administer medications may have these medications left at their bedside (with the exception of controlled substances) and be considered secured. C. The organization must develop and implement a policy assuring only authorized personnel access medications. • The policy must describe the categories of personnel who have authorized access to storage areas, as well as levels of access for different personnel. Drugs and biologicals may be removed from the pharmacy and storage areas only by personnel designated in the policies of the medical staff and pharmacy service in accordance with Federal and State law. • Non-licensed staff may access medication storage areas if permitted by policy, and access is required as part of their job function. These individuals may not access medication.

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482.25	MM-9: After-Hour Access to the Pharmacy For organizations that do not provide 24/7 on-site pharmacy services, there must be a process to provide medications to meet patient care needs when the pharmacy is closed. A. After-hour access to the pharmacy by non-pharmacy personnel is forbidden except in clearly emergent situations. The Director of Pharmacy or the pharmacist on call must be immediately notified should any after-hour access occur. B. If medications are needed when the pharmacy is closed, the organization must assure the following: • Access is limited to a set of medications that has been approved by the hospital. These medications can be stored in a night cabinet, automated storage and distribution device or a limited section of the pharmacy; • Only trained, designated prescribers and nurses are permitted access to medications; • Quality control procedures (such as an independent second check by another individual or a secondary verification built into the system, such as bar coding) are in place to prevent medication retrieval errors; • The organization arranges for a qualified pharmacist to be available either on call or at another location (for example, at another organization that has 24-hour pharmacy service) to answer questions or provide medications beyond those accessible to non-pharmacy staff; • Access is evaluated on an on-going basis, and changes are implemented as appropriate to reduce the amount of times non-pharmacist healthcare professionals are obtaining medications after the pharmacy is closed.
482.25	MM-10: Management of High-Risk Medications The organization shall establish and implement processes to safely manage medications that carry a high risk of harm to patients. A. The organization must identify those medications from its inventory that will be designated as high-risk. In developing the list, the organization should consider: • Medications that pose risk due to look-alike / sound-alike issues; • Medications with a narrow therapeutic window; • Medications shown in the literature to place patients at risk of harm or injury due to errors. B. For each medication designated as high-risk, the organization must develop and implement processes that reduce the risk of harm to the patient. C. The organization determines the specific risk reduction strategies to be taken.
482.25	MM-11: Emergency Medications The organization must assure that medications are readily and immediately available to meet the emergent care needs of the patient. A. The organization defines those medications that are designated for emergency use. • The Director of Pharmacy (or designee) is involved in this process. B. The organization assures that emergency medications are available in age-appropriate concentration/dosage and in the most ready-to-administer form possible. C. The organization assures that emergency medications are stored throughout the facility and can be accessed in a timely manner (within five minutes of identified need). D. The organization periodically reviews (at least every three years) its designation of emergency medications to assure that it continues to meet patient care needs.

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482.25	MM-12: Investigational Medications The organization must assure that patients on investigational medications are appropriately cared for. A. There is a process and policy to ensure that investigational medications are safely controlled and administered. B. There is a written process for reviewing, approving, supervising and monitoring investigational medications, specifying that when pharmacy services are provided, the pharmacy controls the storage, dispensing, labeling and distribution of the investigational medication.
482.25	MM-13: Standardized Concentrations The concentration of medications available for use should be standardized whenever possible. A. The organization identifies those medications whose concentrations have been standardized. B. Where possible, the concentration of medication designated by the organization to be "high-risk" is standardized.
482.25	MM-14: Concentrated Electrolytes The organization must assure that concentrated electrolytes are safely and appropriately managed. A. Concentrated potassium may only be stored in the pharmacy. • If concentrated potassium is required for cardiac surgery, it is dispensed directly to the perfusionist in the operating room on a case by case basis. B. Other concentrated electrolytes may be stored outside of the pharmacy provided the following safety precautions are taken: • There is a clinical need for the concentrated electrolyte to be stored in the area; • Only the amount needed for necessary patient care is stored in the area; • Specific precautions have been taken to prevent an inadvertent misadministration of the electrolyte.
482.25	MM-15: Management of Hazardous Medications The organization must assure that hazardous medications are safely managed. A. The organization identifies those medications in its inventory that it considers hazardous. B. Processes are developed and implemented to safely procure, store, prepare, dispense and administer hazardous medications.
482.25	MM-16: Management of Recalled Medications The organization must develop and implement a process to assure that recalled medications are safely managed. A. The organization receives information about a medication recall in a timely manner. B. The organization determines if a recalled medication is in its inventory and the specific storage locations. C. Recalled medications are removed from inventory in a timely manner. D. Depending on the nature of the recall, practitioners who order/dispense the medication are notified, as well as patients who were dispensed and/or administered the medication, and informed of any necessary actions. • The organization determines who will be responsible for notifying the practitioners and patients.

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482.25	MM-17: Medication from Outside Sources The organization must assure that medications administered to a patient that were not procured by the organization's pharmacy are appropriately managed. A. The organization defines by policy, whether or not patients may use their own medication(s). • If patients are permitted to use their own medication(s), the organization has a process implemented to assure that the medication(s) is appropriately identified, managed and administered. B. The organization defines by policy, whether or not practitioners may bring in medication from outside the organization to be administered to patients. • If practitioners are permitted to bring medication(s) from an outside source, the organization has a process implemented to assure that the medication(s) is appropriately identified, managed and administered. C. The organization defines by policy, whether or not sample medications may be dispensed to patients. • If the organization permits sample medications, the organization has a process implemented to inventory, secure, and track the dispensing of sample medications and management of recall notifications.
482.25	MM-18: Unused Medication The organization must develop and implement a process to safely manage medications that are not used. A. The pharmacy must have a system to reconcile medications that are not administered that remain in the patient's medication drawer, slot, etc., when the pharmacy inventories patient medications or restocks patient medications. The pharmacy should determine the reason the medications were not used. B. Unused medications are returned to the pharmacy.
	MM-19: Availability of Patient-Specific Information The organization must assure that sufficient information about a patient is readily available to personnel involved in the ordering, preparing, dispensing, administering and monitoring of medication. A. The organization defines by policy, the minimum amount of demographic information that is necessary. • At a minimum, the diagnosis and allergy status must be known on all patients receiving medication. • When necessary, the patient's height, weight, pregnancy, and/or lactation status must also be obtained. B. For inpatient settings, the organization obtains an accurate list of medications that a patient is currently taking upon admission. The list is to include, when available, at least the name, dose, and frequency of the medication. For PRN medications, the indication for use should also be determined. • If a list of current medications cannot be obtained (or is only partially obtained), the medical record must reflect why the information (or remaining information) could not be obtained. C. For outpatient settings, the organization obtains an accurate list of medications that the patient is currently taking. The list is to include at least the name of the medication. This requirement does not apply to outpatient settings that do not prescribe, administer, or manage a patient's medications • For recurrent care settings, the list is to be obtained on the initial visit and updated whenever changes occur. • For diagnostic and/or procedural-based outpatient settings, the list need only include those medications pertinent and relevant to the safe rendering of care to the patient. • If a list of current medications cannot be obtained (or is only partially obtained), the medical record must reflect why the information (or remaining information) could not be obtained. D. The organization develops and implements a process to assure that information is readily available to clinicians involved in the patient's care.

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482.25	MM-20: Use of Unsafe Abbreviations The organization must assure that abbreviations known to increase the risk of a medication error are not used. A. The organization identifies by policy, those abbreviations that it considers to be unsafe. B. The organization assures that these abbreviations are not used for medication-related documentation in the patient's medical record or in other medication processes. • An organization will be considered to have met this requirement if an unsafe abbreviation was used but was recognized and corrected before the medication was administered to the patient.
482.25	MM-21: Use of Protocols and Standing Orders The organization must assure that protocols and standing orders involving medications are appropriately developed, implemented and maintained. A. The standing order / protocol must clearly identify the specific clinical situations, patient conditions, or diagnoses in which the order/protocol would be appropriate B. The standing order / protocol must be consistent with accepted standards of care and evidence-based care practices C. The standing order / protocol must be approved by the medical staff D. Practitioners and staff responsible for using the standing order / protocol must be oriented to the conditions, criteria, initiation, and execution requirements thereof E. The standing order / protocol must be added to the patient's medical record at the time of initiation. F. The physician or other practitioner responsible for the care of the patient authenticates the initiation of all standing orders either prior to or after the fact G. Appropriate use of standing orders / protocols must be monitored as part of the organization's Quality Assessment & Performance Improvement Program. H. Standing orders / protocols must be reviewed / revised as necessary, but at least reviewed every three years.

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482.23	MM-22: Medication Orders The organization must assure that medication orders are written in a manner that supports safe patient care. The organization must develop and implement policies that address at least the following: A. Who may order medications B. In accordance with standard practice, practitioner orders for the administration of drugs and biological must include at least the following: • Name of the patient; • Age and weight of the patients, or other dose calculation requirements, where applicable; • Date and time of the order, and the name of the prescriber; • Drug name. dose, frequency, and route; • Exact strength or concentration, when applicable; • Quantity and/or duration, when applicable; • Specific instructions for use, when applicable; and C. The minimum elements of what constitutes a complete medication order for at least the following: • Range orders; • Titration orders; • Taper orders; D. That PRN orders for medication must include the clinical indication for use unless there is only one clinical indication for use; E. That "resume all medication" orders are prohibited; F. Automatic stop orders for medications and biologicals within a time frame specified by the medical staff when the discontinuation date or number of doses of a medication is not specified in the order; G. When weight-based dosing is required for pediatric medication orders; H. In instances of duplicate therapy (two or more PRN medications ordered for the same clinical indication), the orders must provide sufficient direction to personnel in determining which PRN medication to administer; I. With the exception of influenza and pneumococcal vaccines, which may be administered per physician-approved hospital policy after an assessment of contraindications, orders for drugs and biologicals must be documented and signed by a practitioner who is authorized to write orders by hospital policy and in accordance with State law, and who is responsible for the care of the patient; • If a medical staff-approved protocol containing medication is designed to address an urgent or emergent need, or the timely and necessary delivery of care, the protocol may be initiated by appropriately qualified and competent staff prior to obtaining an order. In these cases, however, an order must be obtained as soon as possible afterwards; J. Actions that must be taken when an order is unclear or incomplete.

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482.25	MM-23: Pharmacy Review of Medication Orders The organization must develop and implement a process to assure that ordered medications are appropriate for the patient. A. When pharmacy services are available, all medication orders must be reviewed for appropriateness by a pharmacist before the first dose is administered. • This requirement does not apply to situations where the medication is administered under the direct supervision of a physician or when the medication is needed to treat an urgent or emergent patient care need. • When pharmacy services are not available, a designee(s) deemed competent by the pharmacist to do so, performs the review. The pharmacist then reviews the orders at the earliest available opportunity. B. Review of medication orders should address: • Therapeutic appropriateness of a patient's medication regimen; • Therapeutic duplication in the patient's medication regimen; • Appropriateness of the drug, dose, frequency, route and method of administration; • Real or potential interactions; • Real or potential allergies or sensitivities; • Variation from organizational criteria for use; • Other contraindications.
482.25	MM-24: Preparation of Medications The organization must assure that medications are safely prepared. All compounding, admixing and dispensing of drugs and biologicals must be conducted by a registered pharmacist or under the supervision of a registered pharmacist and performed consistent with State and Federal laws. A. Only the pharmacy compounds or admixes all sterile medications, intravenous admixtures or other drugs except in emergencies or when not feasible (for example, when the product's stability is short). • All staff that compound and/or admix intravenous medications have been trained and deemed competent to do so. B. A laminar airflow hood or other appropriate environment is used while preparing any intravenous (IV) admixture in the pharmacy, any sterile product made from non-sterile ingredients or any sterile product that will not be used with 24 hours. C. Whenever medications are prepared, the organization assures the following: • Staff uses safety materials and equipment while preparing hazardous medications; • Staff uses techniques to assure accuracy in medication preparation; • Staff uses appropriate techniques to avoid contamination during medication preparation, which include but are not limited to the following: • Using clean or sterile technique as appropriate; • Maintaining clean, uncluttered and functionally separate areas for product preparation to minimize the possibility of contamination; • Visually inspecting the integrity of the medications.

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482.25	MM-25: Dispensing of Medications Medications must be dispensed in a manner that is safe and meets the needs of the patient. A. Only individuals permitted by law, regulation, scope of practice, and organization policy may dispense medication. B. Quantities of medications are dispensed to minimize diversion and potential adverse events while meeting the needs of the patient. C. Medications are dispensed in a timely manner. The organization must have a system that ensures that medication orders get to the pharmacy and medications get back to patients promptly. D. Whenever possible, medications are dispensed in the most ready-to-administer form available from the manufacturer or, if feasible, in unit dose that have been repackaged by the pharmacy. • The pharmacy must use the same dose packaging system whenever possible. E. Any concerns, issues or questions are clarified with the prescriber before the medication is dispensed.
	MM-26: Labeling of Medications The organization assures that medication labeling practices are safe. A. Information on medication labels (name of medication, dose, expiration date, etc.) must be displayed in accordance with law, regulation and accepted standards of practice. B. In addition, any medication that is prepared but not immediately administered must be labeled with the following information: *Note: "Immediately administered" means that there was no interruption (however minor) in the process from the time the medication was prepared to the time it was administered.* • Date the medication was prepared; • Time the medication was prepared; • Identity of the person who prepared the medication; • The type of diluent or other substance(s) used in the preparation (if any); • As necessary, any directions for use and accessory or cautionary instructions; • The name of the patient and if necessary, the patient's location, if the medication will be administered by someone other than the person who prepared it.
482.25	MM-27: Medication Delivery Devices The organization must assure that devices used to deliver medication are operated in a safe and appropriate manner. A. The variety and type of medication delivery devices must be standardized whenever possible. B. Staff using medication delivery devices must be deemed competent to do so prior to use. C. Medication delivery devices must be operated and maintained in accordance with manufacturer instructions. D. The pharmacy must be involved in the evaluation, use and monitoring of medication delivery systems, administration devices and automated medication-dispensing machines. • The evaluation and monitoring should include the potential for medication errors.

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42 CFR	CIHQ Standards & Requirements
482.23	MM-28: Administration of Medication The organization must assure that medications and biologicals are prepared and administered in accordance with Federal and State law, upon orders from an authorized practitioner responsible for the patient's care and within accepted standards of care. A. The organization must develop a policy(s) that outlines who may administer medications. This policy must be approved by the medical staff. B. Only individuals authorized by scope of practice and organization policy may administer medications. C. Staff administering medications shall receive sufficient training and education to safely do so. At a minimum, such training shall address medication preparation and administration topics such as: • Safe handling and preparation of authorized medications; • Knowledge of the indications, side effects, drug interactions, compatibility, and dose limits of administered medications; • Equipment, devices, special procedures, and/or techniques required for medication administration; • Basic safe medication administration practices • Required time frames for medication administration D. Staff shall confirm the following prior to each administration of medication • The patient's identity. Acceptable patient identifiers include but are not limited to: the patient's full name; an identification number assigned by the hospital; or date of birth. Identifiers must be confirmed by patient wrist band, patient identification card, patient statement (when possible) or other means outlined in the hospital's policy. The patient's identification must be confirmed to be in agreement with the medication administration record and medication labeling prior to medication administration to ensure that the medication is being given to the correct patient. • The correct medication, to ensure that the medication being given to the patient matches that prescribed for the patient • The correct dose, to ensure that the dosage of the medication matches the prescribed dose, and that the prescription itself does not reflect an unsafe dosage level (i.e., a dose that is too high or too low); • The correct route, to ensure that the method of administration – orally, intramuscular, intravenous, etc., is the appropriate one for that particular medication and patient; and • The appropriate time, to ensure adherence to the prescribed frequency and time of administration. E. The organization shall identify those medications that do not have scheduled administration times F. The organization shall identify those medications that are critical to be administered at scheduled times • Critically timed medication must be administered within thirty minutes before or after their scheduled dosing time, for a total window of 1 hour. G. For those medications that are not critical to be administered at scheduled times: • Medications prescribed for daily, weekly or monthly administration may be within 2 hours before or after the scheduled dosing time, for a total window that does not exceed 4 hours. • Medications prescribed more frequently than daily but no more frequently than every 4 hours may be administered within 1 hour before or after the scheduled dosing time, for a total window that does not exceed 2 hours. H. Staff must remain with the patient until the patient takes the medication. • For intravenous fluids / medications and breathing treatments, this means at least until the infusion / treatment has been initiated. I. If the patient is being administered a medication for the first time, staff must educate the patient on the following: • The purpose of the medication; • The intended response to the medication; • Any significant concerns or precautions that must be taken. J. Drugs and biologicals may be prepared and administered on the orders contained within pre-printed and electronic standing orders, order sets, and protocols for patient orders only if such orders meet the requirements of 42 CFR 482.24(c)(3) K. Intravenous medications must be administered only by individuals who have the requisite licensure, scope of practice allowance, and training to do so, and in accordance with medical staff approved policies and procedures.

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42 CFR	CIHQ Standards & Requirements
	MM-29: Patient Self-Administration of Medication The organization must assure that patient self-administration of medication is safely and appropriately performed. A. The organization determines by policy whether or not patients are permitted to self-administer medications B. If patients are permitted to self-administer organization-issued medications, then the following must occur: • A practitioner responsible for the care of the patient must issue an order permitting self-administration, and the specific medications that are to be self-administered; • The capacity of the patient (or the patient's caregiver/support person where appropriate) to self-administer the specified medication(s) must be assessed; • The patient (or the patient's caregiver/support person where appropriate) must be instructed in the safe and accurate administration of the specified medication(s); • The security of the medication(s) must be assured • The administration of each medication must be documented in the patient's medical record C. If patients are permitted to self-administer their own medications, then the following must occur: • A practitioner responsible for the care of the patient must issue an order permitting self-administration, use of the patient's own medications, and the specific medications that are to be self-administered; • The capacity of the patient (or the patient's caregiver/support person where appropriate) to self-administer the specified medication(s) must be assessed; • The patient (or the patient's caregiver/support person where appropriate) must be instructed in the safe and accurate administration of the specified medication(s); • The medication must be in its original packaging from the manufacturer and/or compounding/issuing pharmacy. The medication must be labeled with at least the following information: o The patient's name o The name and dose of the drug o A "use by" or expiration date. • The integrity of the medication must be visually evaluated • The security of the medication(s) must be assured • The administration of each medication must be documented in the patient's medical record
482.25	MM-30: Monitoring the Effect of Medications The effects of medication(s) on patients must be monitored to assure medication therapy is appropriate and minimizes the occurrence of adverse events. A. The organization must demonstrate that it has a process in place to monitor the effects of medications administered to the patient. The patient's overall medical record must support that this monitoring has occurred. This may be evidenced by: • Use of clinical and laboratory data to evaluate the efficacy of medication therapy to anticipate or evaluate toxicity and adverse effects; • Assessing physical signs and clinical symptoms relevant to the patient's medication therapy; • Assessing the patient's own perceptions about side effects, and, when appropriate, perceived efficacy.

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42 CFR	CIHQ Standards & Requirements
482.25	MM-31: Reporting of Adverse Medication Events The organization must develop and implement a process to identify and report adverse medication events. A. The organization defines what is considered a reportable adverse medication event. • Medication errors, incompatibilities and adverse drug reactions are included in the definition. B. Adverse medication events are identified and reported in accordance with the process established by the organization. • Serious adverse drug reactions are reported to the federal MedWatch program. • Significant medication error and adverse drug reactions are immediately reported to the patient's attending physician. If the attending physician is not available, the report may be to a covering physician and the attending physician notified as soon as possible. C. The organization incorporates reporting of adverse medication events into its quality assessment and performance improvement (QA/PI) program.

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MANAGEMENT OF THE MEDICAL RECORD

42 CFR	CIHQ Standards & Requirements
482.24	MR-1: Organization of the Medical Record Service The medical records service must be organized, equipped and staffed in accordance with the scope and complexity of the organization's services and in such a manner as to comply with the requirements of this regulation and other Federal and State laws and regulations. A. There must be an established medical record system that is organized and employs adequate personnel to ensure prompt: • Completion of medical records; • Coding and filing of medical records; • Retrieval of medical records. B. There must be adequate numbers of qualified personnel to administer the medical record service. • Personnel must be employees of the organization. This does not mean that the organization is prohibited from using contract staff to supplement need, but the medical record service itself may not be outsourced.
482.24	MR-2: Establishment of a Unified Patient Medical Record The organization must have one unified medical record service that has administrative responsibility for all medical records, both inpatient and outpatient records. A. The organization must have a mechanism to know the location of all components of a patient's medical record. B. The organization must have a mechanism to assemble components of a medical record in a timely manner (within 24 hours) when necessary. C. Components must be integrated into a single patient medical record once the patient no longer receives care or service.

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42 CFR	CIHQ Standards & Requirements
484.24	MR-3: Management of Medical Records The organization must maintain a medical record for each inpatient and outpatient evaluated or treated in any part or location of the organization. The organization must establish policy(s) and processes that address the following: A. The medical record must be properly filed and retained. The organization must have a medical record system that ensures the prompt retrieval of any medical record of any patient evaluated or treated at any location of the organization within the past five years. B. The medical record must be accessible. The organization must have a medical record system that allows the medical record of any patient, inpatient or outpatient evaluated and/or treated at any location of the organization within the past five years to be accessible by appropriate staff, 24 hours a day, seven days a week, whenever that medical record may be needed. C. The organization must have a system of coding and indexing medical records. The system must allow for timely retrieval by diagnosis and procedure in order to support medical care evaluation studies. D. Medical records must be properly stored in secure locations where they are protected from fire, water damage and other threats. E. The medical record system must ensure that medical record entries are not lost, stolen, destroyed, altered or reproduced in an unauthorized manner. F. The organization must ensure that unauthorized individuals cannot gain access to patient records and that individuals cannot alter patient records. Patient records must be secure at all times and in all locations. G. The organization must have sufficient safeguards to ensure that access to all information regarding patients is limited to those individuals designated by law, regulation and policy, or duly authorized as having a need to know. No unauthorized access or dissemination of clinical records is permitted. H. Original medical records must be released by the organization only in accordance with Federal or State laws, court orders or subpoenas.
482.24	MR-4: Entries into the Medical Record The organization must assure that entries into the medical record are complete, legible and authenticated in accordance with law, regulation and the organization's policy(s). A. The organization defines by policy, what is considered a timely entry into the medical record. B. The organization, by policy, identifies those types of individuals who are permitted to make entries into the medical record. • If scribes are used to make entries into the medical record, the entry must reflect the name of the scribe as well as the name and title of who the person for whom the scribe was used. C. The organization defines by policy, what is considered a legible entry, has a process to identify those practitioners whose entries into the medical record are illegible and works to improve the legibility of entries by these individuals. D. Each individual entry into the medical record must contain sufficient information on the matter that is the subject of the entry to permit the medical record to be considered complete. E. The organization must have a process to identify the author of each entry into the medical record. F. Entries into the medical record must be dated, timed and signed by the individual who made the entry. • When rubber stamps or electronic authorizations are used for authentication, the organization must have policies and procedures to ensure that such stamps or authorizations are used only by the individuals whose signature they represent. There shall be no delegation of stamps or authentication codes to another individual. • The organization must demonstrate how it prevents alterations of record entries after they have been authenticated. • The date and time of an entry must reflect when the entry was actually made into the medical record. G. The organization assures that there is no intentional and willful falsification of a patient's medical record.

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42 CFR	CIHQ Standards & Requirements
482.24	MR-5: Minimum Content of the Medical Record The medical record must contain information to justify admission and continued hospitalization, support the diagnosis and describe the patient's progress and response to medications and services. Each patient's medical record must document, as appropriate, the following specific information: A. A medical history and physical examination (H&P) completed and documented no more than 30 days before or 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia services. The medical history and physical examination must be placed in the patient's medical record within 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia services. • The medical staff may define the minimum content of a medical history and physical. The specific content may vary by patient population and care setting. • An H&P is not required for a procedure that is not surgical or does not require anesthesia services, which includes the use of moderate sedation / analgesia. B. An updated examination of the patient, including any changes in the patient's condition, when the medical history and physical examination are completed within 30 days before admission or registration. • Documentation of the updated examination must be placed in the patient's medical record within 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia services. C. Admitting diagnosis. D. Results of all consultative evaluations of the patient and appropriate findings by clinical and other staff involved in the care of the patient. E. Documentation of complications, hospital acquired infections and unfavorable reactions to drugs and anesthesia. F. Properly executed informed consent forms (patient consent) for procedures and treatments specified by the medical staff, or by Federal or State law if applicable, to require written patient consent. G. 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. H. Discharge summary with outcome of hospitalization, disposition of case and provisions for follow-up care. • A final progress note may be used in lieu of a discharge summary for patients whose length of stay was less than 48 hours. I. Final diagnosis with completion of medical records within 30 days following discharge.

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USE OF RESTRAINT & SECLUSION

42 CFR	CIHQ Standards & Requirements
482.13	RS-1: Freedom from Restraint or Seclusion Patients have the right to be free from physical or mental abuse, corporal punishment or restraint / seclusion imposed as a means of coercion, discipline, convenience or retaliation by staff. Restraint or seclusion may only be imposed to ensure the immediate physical safety of the patient, a staff member or others and must be discontinued at the earliest possible time.
482.13	RS-2: Definition of Restraint The organization's policy recognizes that the definition of restraint is: A. Any manual method, physical or mechanical device, material or equipment that immobilizes or reduces the ability of a patient to move his or her arms, legs, body or head freely; or B. A drug or medication when it is used as a restriction to manage the patient's behavior or restrict the patient's freedom of movement and is not a standard treatment or dosage for the patient's condition. C. A restraint does not include devices, such as orthopedically-prescribed devices, surgical dressings or bandages, protective helmets or other methods that involve the physical holding of a patient for the purpose of conducting routine physical examinations or tests or to protect the patient from falling out of bed or to permit the patient to participate in activities without the risk of physical harm (this does not include a physical escort).
482.13	RS-3: Definition of Seclusion The organization's policy recognizes that the definition of seclusion is: A. The involuntary confinement of a patient alone in a room or area from which the patient is physically prevented from leaving. Seclusion may only be used for the management of violent or self-destructive behavior.
482.13	RS-4: Use of Restraint / Seclusion Restraint or seclusion may only be used when less restrictive interventions have been determined to be ineffective to protect the patient, a staff member or others from harm.
482.13	RS-5: Type or Technique of Restraint / Seclusion The type or technique of restraint or seclusion used must be the least restrictive intervention that will be effective to protect the patient, a staff member or others from harm.
482.13	RS-6: Planning & Implementing Restraint / Seclusion The use of restraint / seclusion must be in accordance with a written modification to the patient's plan of care and implemented in a safe and appropriate manner consistent with organization policy and in accordance with State law.
482.13	RS-7: Initial Order for Restraint / Seclusion The use of restraint or seclusion must be in accordance with the order of a physician or other licensed independent practitioner responsible for the care of the patient as specified under 42 CFR §482.12(c) and as permitted by State law and hospital policy as having the authority to independently order restraints or seclusion for patients. A. Orders must be obtained prior to the initiation of restraint and/or seclusion. B. In emergency application situations, the order must be obtained either during the emergency application of the restraint or seclusion or immediately (within a few minutes) after the restraint or seclusion has been applied. C. The attending physician must be consulted as soon as possible if the attending physician did not order the restraint or seclusion.

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42 CFR	CIHQ Standards & Requirements
482.13	RS-8: PRN Orders for Restraint / Seclusion Orders for the use of restraint or seclusion must never be written as a standing order or on an as-needed basis (PRN). A. A trial release from restraint / seclusion is considered a PRN use thereof and is not permitted. If the patient is released for this purpose and subsequently requires placement back into restraint or seclusion, then a new order must be obtained. The temporary release of restraint / seclusion for the purposes of providing necessary treatment or care is not considered a trial release.
482.13	RS-9: Renewal of Orders for Restraint / Seclusion Unless superseded by State law that is more restrictive, orders for restraint and/or seclusion must be renewed as follows: A. Each order for restraint or seclusion used for the management of violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member or others may only be renewed in accordance with the following limits for up to a total of 24 hours: • Four hours for adults 18 years of age or older; • Two hours for children and adolescents 9 to 17 years of age; • One hour for children under 9 years of age. B. After 24 hours, before writing a new order for the use of restraint or seclusion for the management of violent or self-destructive behavior, a physician or other licensed independent practitioner who is responsible for the care of the patient as specified under 42 CFR 482.12(c) and authorized to order restraint or seclusion by organization policy in accordance with State law must see and assess the patient. C. Each order for restraint used to ensure the physical safety of the non-violent or non-self-destructive patient may be renewed as authorized by hospital policy.
482.13	RS-10: Discontinuation of Restraint / Seclusion Restraint or seclusion must be discontinued at the earliest possible time, regardless of the length of time identified in the order.
482.13	RS-11: Monitoring the Patient in Restraint / Seclusion The condition of the patient who is restrained or secluded must be monitored by a physician, other licensed independent practitioner or trained staff that have completed the training criteria specified in Standard RS-17 at an interval determined by organization policy.
482.13	RS-12: Training of Practitioners Who Order Restraint / Seclusion Physicians and other licensed independent practitioners authorized to order restraint or seclusion by hospital policy in accordance with State law must have a working knowledge of the organization's policy regarding the use of restraint or seclusion. The training requirements must be specified in hospital policy.

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42 CFR	CIHQ Standards & Requirements
482.13	RS-13: Evaluation of a Patient in Restraint / Seclusion for Violent / Self-Destructive Behavior When a patient is placed into restraint or seclusion for violent or self-destructive behavior, the following must occur: A. The patient must be seen face-to-face within one hour after the initiation of the intervention by a physician or other licensed independent practitioner or registered nurse or physician assistant trained in accordance with Standard RS-17. • If the face-to-face evaluation is conducted by a trained registered nurse or physician assistant, the trained registered nurse or physician assistant must consult the attending physician or other licensed independent practitioner who is responsible for the care of the patient as specified as soon as possible after the completion of the one- hour, face-to-face evaluation. B. The face-to-face evaluation must address at least the following: • The patient's immediate situation; • The patient's reaction to the intervention; • The patient's medical and behavioral condition; • The need to continue or terminate the restraint or seclusion. C. If State law or regulation is more restrictive than this standard, the organization must abide by the State law or regulation.
482.13	RS-14: Simultaneous Use of Restraint / Seclusion Simultaneous restraint and seclusion use is only permitted if the patient is continually monitored face-to-face by an assigned, trained staff member or by trained staff using both video and audio equipment. This monitoring must be in close proximity to the patient.
482.13	RS-15: Documentation of Restraint / Seclusion in the Medical Record When restraint or seclusion is used, there must be documentation in the patient's medical record of at least the following: A. The one-hour, face-to-face medical and behavioral evaluation if restraint or seclusion is used to manage violent or self-destructive behavior; B. A description of the patient's behavior and the intervention used; C. Alternatives or other less restrictive interventions attempted (as applicable); D. The patient's condition or symptom(s) that warranted the use of the restraint or seclusion; E. The patient's response to the intervention(s) used, including the rationale for continued use of the intervention.
482.13	RS-16: Scope of Staff Training in Restraint / Seclusion The patient has the right to the safe use of restraint and seclusion by a trained and qualified staff. To assure this right, the organization must: *Note: See Standard RS-17 for the minimum content and documentation requirements for staff training and competency.* A. Identify those staff who, by their job function, will be involved in the care of a patient placed in restraint and/or seclusion. B. As appropriate to the staff person's responsibility and job function, assure that he/she has been trained and are able to demonstrate competency in the following: • Safe application of restraint; • Implementation of seclusion; • Monitoring, assessing and providing care for a patient in restraint or seclusion. C. Training and competency assessment must occur as follows: • Prior to caring for a patient in restraint and/or seclusion; • On a periodic basis thereafter as defined by organization policy.

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42 CFR	CIHQ Standards & Requirements
482.13	RS-17: Content of Staff Training in Restraint / Seclusion Staff must have the education, training and demonstrated knowledge to care for patients placed in restraint and/or seclusion. A. As appropriate to their responsibility and job function, staff caring for a patient placed in restraint and/or seclusion must be trained and deemed competent in at least the following: • Techniques to identify staff and patient behaviors, events and environmental factors that may trigger circumstances that require the use of a restraint or seclusion; • The use of non-physical intervention skills; • Choosing the least restrictive intervention based on an individualized assessment of the patient's medical or behavioral status or condition; • 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); • Clinical identification of specific behavioral changes that indicate that restraint or seclusion is no longer necessary; • 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 one-hour face-to-face evaluation; • The use of first-aid techniques and certification in the use of cardiopulmonary resuscitation, including required periodic recertification. B. Individuals who train and deem staff competent must themselves be qualified as evidenced by their education, training and experience. C. The organization must document in the staff personnel records that the training and demonstration of competency were successfully completed.
482.13	RS-18: Reporting of Death Associated with Restraint / Seclusion Except as noted below, the organization must report deaths associated with the use of seclusion or restraint. A. The organization must report the following information to CMS: • Each death that occurs while a patient is in restraint or seclusion; • Each death that occurs within 24 hours after the patient has been removed from restraint or seclusion; • Each death known to the organization that occurs within one week after restraint or seclusion where it is reasonable to assume that use of restraint or placement in seclusion contributed directly or indirectly to a patient's death. "Reasonable to assume" in this context includes, but is not limited to, deaths related to restrictions of movement for prolonged periods of time, or death related to chest compression, restriction of breathing or asphyxiation. B. Each death must be reported to CMS by facsimile, or electronically as determined by CMS no later than the close of business the next business day following knowledge of the patient's death. The patient's medical record must contain documentation of the date and time the death was reported to CMS. C. When no seclusion has been used and when the only restraints used on the patient are those applied exclusively to the patient's wrist(s), and which are composed solely of soft, non-rigid, cloth-like materials, the hospital staff must, in lieu of reporting the death to CMS, record in an internal log or other system, the following information. The patient's medical record must contain documentation of the date and time the death was entered into the log: • Any death that occurs while a patient is in such restraints. • Any death that occurs within 24 hours after a patient has been removed from such restraints. • Each entry must be made not later than seven days after the date of death of the patient. • Each entry must document the following: o Patient's name, date of birth, and date of death, o Name of attending physician or other licensed independent practitioner who is responsible for the care of the patient. o Medical record number, and primary diagnosis • The information must be made available in either written or electronic form immediately upon request.

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TARGETED PATIENT QUALITY & SAFETY PRACTICES

42 CFR	CIHQ Standards & Requirements
	QS-1: Fall Management Program The organization must develop and implement a program to reduce the incidence of patient falls that result in injury. At a minimum, the organization must do the following: A. Conduct a patient-specific fall risk assessment on all patients admitted to inpatient status. • The organization determines the scope and content of this assessment. • The assessment must be completed within 24 hours of the patient's admission. The frequency of any further assessment is defined by the organization. • Note: This assessment is not required for neonatal, infant, and toddler patients. These patients developmental age inherently places them at risk for drop or fall. B. For outpatient care areas the organization must at least perform an environmental assessment to identify and correct hazards that could contribute to a fall. • In addition, there must be a general plan in place to assist patients who inherently or obviously present as a fall risk (e.g. provide protective and/or assistive devices, assist with ambulation, etc.). C. When a patient is identified as a fall risk, the organization must take steps to protect the patient. • The organization determines the interventions that will be employed for the patient. These interventions are then consistently implemented. D. Should a patient fall, the organization must assess the patient for any injury and take action as necessary.
	QS-2: Pain Management The organization must have a written policy developed, approved by the medical staff and implemented that addresses at least the following: A. For inpatient care settings: • There is an assessment performed within 24 hours of admission to identify if patients have pain. The organization determines the content of this assessment. • Patients are reassessed at regular intervals as determined by the organization. The organization determines frequency and the content of this reassessment. B. For outpatient settings: • If a patient complains of pain and/or care is rendered that is likely to produce pain, then the patient is assessed for pain. The organization determines the content of this assessment. • The organization determines the frequency of reassessment (if any). The organization determines the content of this reassessment. C. The organization uses patient age and patient-condition appropriate tools to assess pain. D. If a patient complains of pain, the organization does the following: • Determines the patient's level of pain • Treats the patient's pain or refers to the patient to an appropriate care setting for treatment • If the patient's pain is treated, the effectiveness of treatment is determined. E. Assessments, reassessments, treatments, and effectiveness of treatments are documented in the patient's medical record.

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42 CFR	CIHQ Standards & Requirements
	QS-3: Provision of Interpretive / Translation Services The organization must assure the adequate availability of interpretive and translation services. *Note: This standard applies only to the provision of medically necessary interpretation and/or translation.* A. Interpretation services by qualified personnel are available to patients. • Individuals who provide interpretive services must be fluent in both English and the targeted language, have knowledge of basic medical terminology, and know how to interpret appropriately. • If family is used, they must meet the above noted requirements and the patient must consent to the use of family to provide this service. B. Translation services must be provided to patients. • The organization determines the medically necessary information that must be available in a translated language to patients. This information is provided when indicated.
482.23	QS-4: Verbal / Telephone Orders Verbal (in-person) / telephone orders pose an increased risk of miscommunication that could contribute to a medication or other error, resulting in a patient adverse event. A. Verbal / telephone orders must be used only to meet the care needs of the patient when it is impossible or impractical for the ordering practitioner to write the order or enter it into a computer (in the case of an organization with an electronic prescribing system) without delaying treatment. • Verbal orders are limited to emergency situations and/or when issued during procedures or actual care delivery. B. Verbal / telephone orders are not to be used for the convenience of the ordering practitioner. C. The organization must have a policy that addresses at least the following: • Describe limitations or prohibitions on the use of verbal / telephone orders; • Provide a mechanism to ensure validity/authenticity of the practitioner issuing a verbal / telephone order; • List the elements required for inclusion in the verbal / telephone order process; • Describe situations in which verbal / telephone orders may be used; • Define the types of personnel who may issue and receive verbal / telephone orders; • Defines a process for clear and effective communication, verification and authentication of verbal / telephone orders. D. Staff receiving a verbal / telephone order must read the order back to the practitioner to assure that the order was understood correctly. E. All verbal / telephone orders must be authenticated by the ordering or covering practitioner within a time frame established by law or regulation. • In the absence of law or regulation, verbal / telephone orders must be authenticated within a time frame established by organization policy.
	QS-5: Resuscitative Services The organization must assure that resuscitative services are provided in a timely and appropriate manner. A. The organization must identify the level of resuscitative services (e.g. basic life support, advanced life support, etc) that it will provide in its various settings and care sites. B. The organization must assure that there is sufficient, and readily available, age-appropriate equipment, supplies and medications to meet the level of resuscitative services provided. C. The organization must assure that a sufficient number of staff is readily available to provide the appropriate level of resuscitative services. D. The organization must assure that staff providing resuscitative services are competent to do so. E. The organization evaluates the effectiveness of its resuscitation services and takes action to address identified opportunities for improvement.

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42 CFR	CIHQ Standards & Requirements
	QS-6: Patient / Family Education Patients receive the education necessary to effectively participate in their care. *Note: When appropriate, this standard applies to the patient's family and/or significant others* A. The organization identifies the educational needs of the patient necessary to safely and effectively participate in his or her care B. Education is provided to the patient that addresses identified needs in a timely manner. C. Education is provided in a manner that enables the patient to understand the information. D. The effectiveness of the education provided to the patient is determined E. The provision of education is documented in the patient's medical record.
	QS-7: Accuracy in Patient Identification – *Effective 1/1/15* Patients are accurately identified prior to administering medications, performing laboratory and diagnostic tests, performing procedures, administering blood and blood products, and obtaining specimens A. Patients are identified using two distinct identifiers (e.g. name and birthdate, name and medical record number, etc.). If bar code technology is employed, then only one additional identifier is required. B. The organization determines the identifiers to be used. However, the patient's room number may not be used as an identifier.
	QS-8: Critical Test Results – *Effective 1/1/15* Critical results of laboratory and other diagnostic tests are acted upon in a timely manner A. The organization identifies those test results that are considered critical. A critical result is a result that is - or potentially is - life threatening. B. The organization identifies the acceptable length of time it should take for a critical result to be reported to the responsible care provider. For the purposes of this standard, the responsible care provider is the individual who has the authority and ability to act on the result. C. Critical test results are reported to the responsible care provider within the time frame defined by the organization
	QS-9: Safe Management of Clinical Alarms – *Effective 1/1/15* The organization assures that alarms on equipment and devices designed to alert staff of a life threatening – or potentially life threatening – patient condition are safely managed A. Alarms are maintained in the on or active position at all times. Alarms may be temporarily suspended while staff are in direct attendance of the patient and performing care, but must be returned to the on or active position when care is completed B. The volume of alarms is loud enough so that it can be heard and responded to by staff.

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ANESTHESIA SERVICES

42 CFR	CIHQ Standards & Requirements
482.52	AN-1: Organization of Anesthesia Services The organization must assure that there is effective oversight and direction of anesthesia services. *Note: This standard applies to the continuum of anesthesia from moderate sedation/analgesia to general anesthesia* A. Anesthesia services must be under the direction of one individual (director of anesthesia services) who is a qualified doctor of medicine (MD) or doctor of osteopathy (DO). B. The governing body approves the criteria and qualifications for the director of anesthesia services. • Such criteria must be consistent with State laws and acceptable standards of practice. C. The director of anesthesia services provides direction and oversight for all anesthesia-related activities, including the following: • Establishing the minimum qualifications, criteria and supervision requirements for each category of practitioner who is permitted to provide anesthesia services; • Policies and procedures that guide the safe management of patients undergoing anesthesia, including pre/post anesthesia responsibilities; • Establishing and implementing processes to monitor the safety of anesthesia services, including analysis of adverse events, medication errors and other pertinent safety indicators; • Evaluating the quality and appropriateness of anesthesia services. D. The organization must provide adequate resources to support the provision of anesthesia services. This includes, but is not necessarily limited to, the following: • Appropriate numbers of trained and qualified staff during all phases of anesthesia care; • Sufficient supplies and equipment; • Availability of age-appropriate resuscitative services. E. The organization must assure that the provision of anesthesia services is incorporated into the organization's quality assessment and performance improvement program.

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42 CFR	CIHQ Standards & Requirements
482.52	AN-2: Provision of Anesthesia The organization must assure that anesthesia is provided safely. *Note: For the purposes of this standard, the term "anesthesia" means deep sedation, monitored anesthesia care, regional anesthesia and general anesthesia. This standard does not apply to a patient who is already intubated, placed on a ventilator and is being cared for in a monitored setting.* A. Anesthesia must only be administered by a qualified anesthesia provider. Please see the glossary for the definition of a qualified anesthesia provider including State exemption requirements for CRNA's as permitted under 42 CFR 482.52(c) B. The organization must ensure that procedures are in place to rescue patients whose level of anesthesia (e.g. deep sedation to general anesthesia) becomes deeper than initially intended. • At least one qualified individual must be in direct attendance with the patient during the administration of moderate sedation/analgesia with expertise in airway management and advanced life support. C. A pre-anesthesia evaluation must be performed by a qualified anesthesia provider on any patient receiving anesthesia. • The evaluation must be completed and documented within 48 hours prior to the start of anesthesia. • Some of the individual elements contributing to the pre-anesthesia evaluation may be performed prior to the 48-hour timeframe. However, under no circumstances may these elements be performed more than 30 days prior to surgery or a procedure requiring anesthesia services. Review of these elements must be conducted and any appropriate updates documented, within the 48-hour timeframe. D. The pre-anesthesia evaluation must address at least the following: • Review of the patient's medical history, including anesthesia, drug and allergy history; • A physical examination of the patient that addresses at least the patient's cardio-respiratory status and airway; • Notation of anesthesia risk according to established standards of practice (e.g., ASA classification of risk); • Identification of potential anesthesia problems; • Additional information as required in accordance with standard practice; • Development of the plan for the patient's anesthesia care; • Discussion with the patient (or patient's representative) of the risks and benefits of the delivery of anesthesia. E. The intra-procedure anesthesia record must reflect that the patient was appropriately monitored and cared for. At a minimum, the record must include: • Name and hospital identification number of the patient; • Name of practitioner who administered anesthesia and as applicable, the name and profession of the supervising anesthesiologist or operating practitioner; • Name, dosage, route and time of administration of drugs and anesthesia agents; IV fluids; • Blood or blood products, if applicable; • Oxygen flow rate; • Continuous recordings of patient status noting blood pressure, heart and respiration rate; • Any complications or problems occurring during anesthesia, including time and description of symptoms, vital signs, treatments rendered and patient's response to treatment. F. A post-anesthesia evaluation must be completed on each patient receiving anesthesia within 48 hours following anesthesia by a qualified anesthesia provider. • The evaluation may not be performed until the patient has left the operative/procedural suite. • The evaluation may not begin until the patient has sufficiently recovered from the acute effects of anesthesia. • The evaluation must be performed regardless of the patient's condition no later than the 48-hour mark. G. The post-anesthesia evaluation must address at least the following: • Respiratory function, including respiratory rate, airway patency and oxygen saturation; • Cardiovascular function, including pulse rate and blood pressure; • Mental status, temperature, pain; • Nausea and vomiting; • Postoperative hydration. H. The organization must assure that the patient is appropriately monitored and cared for during the post-anesthesia recovery period in accordance with accepted standards of care. I. Patients must be discharged from post-anesthesia recovery only upon the assessment of a qualified anesthesia provider or by a trained registered nurse utilizing discharge criteria approved by the director of anesthesia services.

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42 CFR	CIHQ Standards & Requirements
482.52	AN-3: Provision of Moderate Sedation/Analgesia The organization must assure that moderate sedation/analgesia is provided safely. *Note: Moderate sedation/analgesia is part of the continuum of anesthesia, but its use is subjected to the requirements of this standard.* *Note: This standard does not apply to the use of medications for the purpose of treating a patient's pain.* *Note: This standard does not apply to a patient who is already intubated, placed on a ventilator and is being cared for in a monitored setting.* A. The organization must establish and implement policies and procedures based on nationally recognized guidelines, that address those care settings and procedures in which moderate sedation/analgesia will be provided. • In establishing such policies, the organization must take into account the characteristics of the patients served, the skill set of the clinical staff in providing the services, as well as the characteristics of the sedation medications used in the various clinical settings. • The organization must document the specific nationally recognized guideline(s) that it has used in developing its policies and procedures. B. Only individuals qualified by education, training, law and regulation, scopeof practice and organization policy may administer moderate sedation/analgesia. C. The organization must ensure that procedures are in place to rescue patients whose level of sedation becomes deeper than initially intended. • At least one qualified individual must be in direct attendance with the patient during the administration of moderate sedation/analgesia with expertise in airway management and advanced life support. D. Any patient receiving moderate sedation/analgesia must have a pre-sedation evaluation performed by a qualified individual. • While the organization may determine the specific content of the evaluation – in accordance with nationally recognized guidelines – it must at least include a cardiopulmonary and airway assessment. E. Patients receiving moderate sedation/analgesia must be appropriately monitored during the procedure. • While the organization may determine the frequency and scope of monitoring – in accordance with nationally recognized guidelines – it must at least include vital signs, oxygenation, level of consciousness and airway status. F. The organization must assure that the patient is appropriately monitored and cared for during the post-sedation recovery period in accordance with accepted standards of care. G. Patients must be discharged from post-sedation recovery only upon the assessment of a qualified physician or by a trained registered nurse utilizing discharge criteria approved by the director of anesthesia services.

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DIETARY (NUTRITION) SERVICES

42 CFR	CIHQ Standards & Requirements
482.28	NU-1: Provision of Dietary Services The organization must provide dietary services to meet the clinical and nutritional needs of its patients. A. There must be an individual full-time employee who has been granted the authority and delegated responsibility by the organization's governing body and medical staff for the operation of dietary services. • This individual must demonstrate through education, experience and/or specialized training, the qualifications necessary to manage the service, appropriate to the scope and complexity of the food-service operations. B. The organization must develop and implement policies and procedures that address at least the following: • Availability of a diet manual and therapeutic diet menus to meet patients' nutritional needs; • Frequency of meals served; • System for diet ordering and patient trays delivery; • Accommodation of non-routine occurrences (e.g., parenteral nutrition (tube feeding), total parenteral nutrition, peripheral parenteral nutrition, change in diet orders, early/late trays, nutritional supplements, etc.); • Integration of the food and dietetic service into the hospital-wide quality assessment and performance improvement and infection control programs; • Guidelines for acceptable hygiene practices of food service personnel; • Guidelines for kitchen sanitation; • Safety practices for food handling; • Emergency food supplies; • Orientation, work assignments, supervision of work and personnel performance; • Menu planning, purchasing of foods and supplies and retention of essential records. C. The organization must be in compliance with Federal and State licensure requirements for food and dietary personnel, as well as food service standards, laws and regulations.

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42 CFR	CIHQ Standards & Requirements
482.28	NU-2: Staffing for Dietary Services The organization must assure that dietary services are adequately staffed. A. A qualified dietitian must supervise the nutritional aspects of patient care. • Qualification is determined on the basis of education, experience, specialized training, State licensure or registration when applicable, and maintaining professional standards of practice. B. If a dietitian does not work full time, and/or when the dietitian is not available, the organization must make adequate provisions for dietary consultation that meets the needs of the patients. • The frequency of consultation depends on the total number of patients, their nutritional needs and the number of patients requiring therapeutic diets or other nutritional supplementation. C. Responsibilities of the dietitian include, but are not limited to: • Approving patient menus and nutritional supplements; • Patient, family and caretaker dietary counseling; • Performing and documenting nutritional assessments and evaluating patient tolerance to therapeutic diets when appropriate; • Collaborating with other departments and services to plan and implement patient care as necessary in meeting the nutritional needs of the patients; • Maintaining pertinent patient data necessary to recommend therapeutic diets as needed to meet the nutritional needs of the patients. D. There must be a sufficient number of administrative and technical personnel who are competent in the performance of their respective job functions.
482.28	NU-3: Food Preparation & Storage The organization must assure that food is prepared and stored in a safe manner. A. Food must be prepared and stored in a manner consistent with State law and regulation, as well as accepted standards regarding appropriate sanitation, temperature regulation and, when necessary, moisture, light and ventilation control. B. The temperature of patient food refrigerators and freezers must be monitored. • The organization must have a mechanism to demonstrate that appropriate temperature control is maintained. • If appropriate temperature control is not maintained, there is documentation of corrective action taken. C. Food products that have been damaged or expired are removed from inventory and either discarded or returned to the supplier. D. Any open food containers placed into storage must be labeled with the date the container was opened. E. If food brought in by the patient's family is stored, it must be labeled with the patient's name and date it was placed into storage. F. The organization must develop and implement a policy that addresses when open food containers and/or food brought in by the patient's family is to be discarded.

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42 CFR	CIHQ Standards & Requirements
482.28	NU-4: Menus & Meals Menus and meals provided by the organization must be nutritionally balanced and meet the special needs of the patients. A. Menus are based on current national standards for recommended dietary allowances such as the current Recommended Dietary Allowances (RDA) or the Dietary Reference Intake (DRI) of the Food and Nutrition Board of the National Research Council. B. Current menus must be posted in the hospital kitchen. C. Meals are designed to meet the nutritional needs of the patient in accordance with recognized dietary practices and in accordance with orders of the practitioner or practitioners responsible for the care of the patients, or by a qualified dietitian or qualified nutrition professional as authorized by the medical staff and in accordance with State law governing dietitians and nutrition professionals. D. Patients who refuse food served should be offered substitutes that are of equal nutritional value in order to meet their basic nutritional needs. E. If food is brought in by family for the patient, a good-faith effort is made to assure that any dietary restrictions are adhered to.
482.28	NU-5: Nutrition Assessments & Care Plans The organization must plan a patient's nutritional care based on the patient's assessed needs. A. Specific screening criteria must be developed to identify patients at potential nutritional risk. The criteria must be appropriate to the patient population served. B. Each inpatient must be screened within 24 hours of admission using the criteria to determine if a nutritional assessment is warranted. • The organization determines who performs the screening, as long as the individual is qualified to do so. C. For outpatients, routine screening for potential nutritional risk is not required. However, practitioners are expected to be knowledgeable of the criteria used to identify patients at nutritional risk and have a plan to refer these patient's for a nutritional assessment by a qualified individual if needed. D. Once a patient is identified potentially as being at risk, a nutritional assessment must be performed on the patient within a timeframe defined by the organization. • The nutritional assessment must be performed by a clinical dietitian or other qualified individual. E. The following types of patients must receive a nutritional assessment by a clinical dietitian within timeframes defined by the organization: • All patients requiring artificial nutrition by any means; • Patient's whose diagnosis, medical condition, surgical intervention or physical status significantly interferes with their ability to ingest, digest or absorb nutrients. F. Patients identified as being at nutritional risk must be reevaluated as necessary to ensure their ongoing nutritional needs are met. • The organization defines the timeframe(s) for the nutritional reassessment. • Nutritional re-assessments must be performed by a clinical dietitian or other qualified individual. G. A plan of care is developed and implemented for any patient identified as being at nutritional risk.

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42 CFR	CIHQ Standards & Requirements
482.28	NU-6: Ordering of Therapeutic Diets Individual patient nutritional needs must be met in accordance with recognized dietary practices. A. All patient diets, including therapeutic diets, must be ordered by a practitioner responsible for the care of the patient, or by a qualified dietitian or qualified nutrition professional as authorized by the medical staff and in accordance with State law governing dietitians and nutrition professionals. • Clinical dietitians may alter the texture of a diet without requiring an order from the practitioner responsible for the patient's care. However, should the texture of a diet be altered, the practitioner must be notified.
482.28	NU-7: Diet Manual A current therapeutic diet manual approved by the dietitian and medical staff must be readily available to all medical, nursing and food service personnel. A. The publication or revision date of the approved therapeutic diet manual must not be more than five years old. B. The therapeutic diet manual must be available in each patient care area where nutrition services are provided. • If the manual is provided in an electronic format, there must be at least one paper copy available for use during prolonged periods of power disruption or when computer systems are not functional.

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DISCHARGE PLANNING SERVICES

42 CFR	CIHQ Standards & Requirements

482.43	DC-1: Discharge Planning Evaluation
	The organization must develop, implement and maintain written policies and processes applying to all inpatients that result in effective discharge planning. At a minimum, the organization must:
	A. Identify patients who require an evaluation to determine the need for a discharge plan. The patient or physician has the right to request a discharge planning evaluation regardless of identified need.
	B. For patients who require a discharge planning evaluation:
	• Assure that the evaluation is performed at an early stage in the patient's hospitalization
	• Assure that the evaluation is performed or overseen by qualified personnel such as a registered nurse or social worker. Responsible personnel should have experience in discharge planning, knowledge of social and physical factors that affect functional status at discharge and knowledge of community resources to meet post-discharge clinical and social needs.
	• The evaluation must address, as appropriate, at least the following:
	  • The likelihood of the patient needing post-hospitalization services and the availability of those services;
	  • The patient's capacity for self-care or return to his/her prior care environment.
	• The evaluation must be completed in a timely manner so that appropriate arrangements for post-hospital care are in place prior to discharge.
	• The result of the discharge planning evaluation is discussed with the patient or individual(s) acting on the patient's behalf. This discussion is documented in the patient's medical record.
	• The result of the discharge planning evaluation forms the basis for the patient's written discharge plan.

482.43	DC-2: Discharge Plan The organization must develop a written discharge plan for any patient for whom discharge planning services are needed. *Note: In the absence of a finding by the organization that a patient needs a discharge plan, the patient's physician may request a discharge plan. In such a case, the organization must develop a discharge plan for the patient.* A. The discharge plan must be developed or overseen by qualified personnel such as registered nurse or social worker. Responsible personnel should have experience in discharge planning, knowledge of social and physical factors that affect functional status at discharge and knowledge of community resources to meet post-discharge clinical and social needs. B. The discharge plan must be discussed with the patient or individual(s) acting on the patient's behalf. C. The discharge plan must be documented in the patient's medical record. D. The organization must arrange for the initial implementation of the discharge plan. This includes arranging for necessary post-hospital services and care. E. If factors present themselves that may affect the appropriateness of the discharge plan, the patient's discharge planning needs are reevaluated and the discharge plan modified as necessary. F. The patient and, when necessary, other key individuals are educated on the discharge plan. G. The organization must assure that patients receive proper post-hospital care within the constraints of its authority under State law and within the limits of a patient's right to refuse discharge-planning services. • If a patient exercises the right to refuse discharge planning or to comply with a discharge plan, this refusal must be documented in the patient's medical record.

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42 CFR	CIHQ Standards & Requirements
482.43	DC-3: Discharge Plans Involving Home Health Services or Skilled Nursing Facility Placement If the discharge plan for a patient involves the provision of home health services or placement into a skilled nursing facility, the organization must do the following: A. Provide a list of home health agencies (HHAs) or skilled nursing facilities (SNFs) that are available to the patient that are participating in the Medicare program and that serve the geographic area (as defined by the HHA) in which the patient resides, or in the case of a SNF, in the geographic area requested by the patient. HHAs must request to be listed by the organization as available. • This list must only be presented to patients for whom home healthcare or post-hospital extended care services are indicated and appropriate as determined by the discharge planning evaluation. • For patients enrolled in managed care organizations, the organization must indicate the availability of home health and post-hospital extended care services through individuals and entities that have a contract with the managed care organizations. • The organization must document in the patient's medical record that the list was presented to the patient or to the individual acting on the patient's behalf. B. The organization must inform the patient or the patient's family of their freedom to choose among participating Medicare providers of post-hospital care services and must, when possible, respect patient and family preferences when they are expressed. C. The organization must not specify or otherwise limit the qualified providers that are available to the patient. D. The discharge plan must identify any HHA or SNF to which the patient is referred in which the organization has a financial interest, and any HHA or SNF that has a financial interest in the organization under Medicare.
482.43	DC-4: Transfer & Referral The organization must transfer or refer patients, along with necessary medical information, to appropriate facilities, agencies or outpatient services, as needed, for follow-up or ancillary care. A. When a patient is referred or transferred, the organization assures that it provides at least the following information to the receiving entity: • The reason for referral or transfer; • A summary of the patient's current physical and psychosocial condition; • A summary of care that has been provided to the patient; • The patient's current care needs; • The patient's current orders for care and treatment.
482.43	DC-5: Evaluating the Effectiveness of the Discharge Planning Process The organization must assure that its discharge planning process is effective and meets patient care needs. A. The organization's discharge planning process must be integrated into its quality assessment and performance improvement program. There must be a review of discharge plans to ensure that they are responsive to discharge needs. B. The organization must develop and evaluate performance measures that address the effectiveness of its discharge planning process. • At a minimum, the organization must track readmission rates and identify potentially preventable readmissions. The organization takes action to address issues identified.

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EMERGENCY SERVICES

42 CFR	CIHQ Standards & Requirements
482.55	ED-1: Emergency Department Services The organization must assure that emergency department services are available to meet patient care needs in a safe, effective manner and within established standards of care. *Note: This standard applies to organizations that have a designated Emergency Department and/or Urgent Care Clinic that is subject to the requirements of an Emergency Department.* A. The organization's emergency department services must be under the direction of a qualified member of the medical staff. • A single emergency services director must be responsible for all emergency services. B. Emergency department services must be integrated with other departments and services. At a minimum, the organization must have processes in place that support at least the following: • Coordination and communication between services/departments; • Physical access for emergency patients to the services, equipment, personnel and resources of other departments/services; • The immediate availability of services, equipment, personnel and resources of other hospital departments/services to emergency patients within timeframes that protect the health and safety of patients and is within acceptable standards of practice. C. The organization's medical staff must establish policies and procedures governing the medical care provided in the emergency service or emergency department. D. A qualified member of the medical staff must supervise the provision of emergency services. • The medical staff must establish criteria in accordance with State law, regulations and guidelines, delineating the qualifications a medical staff member must possess in order to be granted privileges for the supervision of the provision of emergency care services. E. The organization must staff the emergency department with the appropriate numbers and types of professionals and other staff who possess the skills, education, certifications, specialized training and experience in emergency care to meet the written emergency procedures and needs anticipated by the facility. • The medical staff must establish criteria in accordance with State law and regulations and acceptable standards of practice, delineating the qualifications required for each category of emergency services staff.

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42 CFR	CIHQ Standards & Requirements
482.12	ED-2: Provision of Emergency Services at Non-Emergency Department Locations The governing body must assure that adequate provisions are made for the availability of emergency services. *Note: This standard applies to organizations that do not provide designated emergency services either at their main campus or in any off-site location.* A. If emergency services are not provided at all by 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. These policies must assure at least the following: • Assuring that there is a trained and qualified registered nurse (RN) immediately available to determine if a patient has an emergency medical condition; • Provide necessary stabilizing medical treatment within the capabilities of the location. There must be RN(s) who are qualified through a combination of education, licensure and training, to provide initial treatment to a person experiencing a medical emergency; • Refer or transfer the patient to a facility with the appropriate capabilities to manage the patient's condition; • Meet all other requirements noted under CFR 482.12(f). B. If emergency services are provided at the organization's main campus but are not provided at one or more off-campus departments, the governing body must assure that the medical staff has written policies and procedures in effect with respect to the off campus department(s) for appraisal of emergencies and referral when appropriate. • Assuring that there are trained and qualified personnel immediately available to determine if a patient has an emergency medical condition. • Provide necessary stabilizing medical treatment within the capabilities of the location. • Refer or transfer the patient to a facility with the appropriate capabilities to manage the patient's condition. • Meet all other requirements noted under 42 CFR 482.12(f).

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LABORATORY SERVICES

42 CFR	CIHQ Standards & Requirements
482.27	LB-1: Provision of Laboratory Services The organization must maintain or have available laboratory services whenever its patients need those services. A. The organization must maintain, or have available, adequate laboratory services to meet the needs of its patients at each campus or off-campus location. • The organization may make laboratory services available directly, through contractual agreements or through a combination of direct and contractual services. B. A written description of laboratory services provided (both routine and emergent) must be available to the medical staff. C. All laboratory services, whether direct or contractual, whether conducted in a lab or in another location, must be provided in accordance with Clinical Laboratory Improvement Act (CLIA) requirements. • Every laboratory service must operate under a current CLIA certificate appropriate to the level of services performed. The CLIA certification may be accomplished by having one certificate for the entire organization's laboratory services, by having one certificate for each laboratory or by a combination thereof. D. The organization's laboratory services, including any contracted services, must be integrated into its quality assessment and performance improvement program. E. Patient laboratory results and all other laboratory clinical patient records are considered patient medical records and must be treated as such.
482.27	LB-2: Provision of Emergency Laboratory Services The organization must provide emergency laboratory services 24 hours a day, seven days a week. Emergency lab services include collection, processing and provision of results to meet a patient's emergency laboratory needs. A. In an organization with multiple inpatient campuses, emergency laboratory services must be available onsite 24/7 at each campus. B. The medical staff must determine which laboratory services are to be immediately available to meet the emergency laboratory needs of patients who may be currently hospitalized or those patients who may present in an emergent condition. • The emergency laboratory services (procedures, tests, personnel) available should reflect the scopeand complexity of the hospital's operation and be provided in accordance with Federal and State law, regulations and guidelines and acceptable standards of practice. C. For each off-campus location, the medical staff must determine which, if any, laboratory services must be immediately available to meet the emergency laboratory needs of the patients. • The emergency laboratory services available must reflect the scope and complexity of the hospital's operations at the location and be provided in accordance with Federal and State law, regulations and guidelines and acceptable standards of practice. • The services must be available during the hours of operation of that location.
482.27	LB-3: Management of Tissue Specimens The organization must safely and effectively manage tissue specimens. A. The organization must have written instructions for the collection, preservation, transportation, receipt and reporting of tissue specimen results. B. Policy(s) must state which tissue specimens require a macroscopic examination and which tissue specimens require both macroscopic and microscopic examination. • The policy(s) must be approved by a pathologist and the medical staff.

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42 CFR	CIHQ Standards & Requirements
482.27	LB-4: Management of Potentially Infectious Blood & Blood Components The organization must develop and implement policies and processes to assure that infected blood products are managed appropriately. A. The organization must comply with all requirements noted under 42 CFR 482.27(b) and 42 CFR 482.27(c).
	LB-5: Waived Testing The organization assures that any waived laboratory testing is performed in a safe and appropriate manner. A. All waived testing performed in a patient care setting must be under the direction of the individual whose name appears on the Clinical Laboratory Improvement Amendments of 1988 (CLIA certificate) for that setting. B. Waived tests must only be performed at the level permitted by the CLIA certificate for that setting. C. Policy(s) must be developed and implemented, consistent with law and regulation, for each waived test performed that address at least the following: • Identification of which care settings may perform the test; • Whether or not the test is to be used for screening or definitive treatment. If a test is for screening purposes, the policy must also state what confirmatory test(s) must be performed; • Collection, processing, preservation, labeling and storage of specimens being tested; • Performance of the test, including use of materials such as reagents and control solutions, cleaning, maintenance, storage and calibration of instrumentation (if applicable) and quality-control requirements. D. Staff performing waived testing must be qualified and competent to do so. • Competency must be determined prior to the first time staff perform the test and on at least an annual basis thereafter. • Competency must be assessed using at least two of the following methods: - Performance of a test on a blind specimen; - Observation of routine work by a qualified person; - Monitoring of quality-control performance; - Use of a written exam. • Physicians or other licensed independent practitioners may be deemed competent for non-instrument-based waived tests provided performances of such tests are included in their clinical privileges. E. The results of a waived test must be documented in the patient's medical record. If the test is quantitative in nature, the normal reference values must also be documented in the medical record. F. Quality control for waived tests must be performed in accordance with manufacturer instructions and the results documented.

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42 CFR	CIHQ Standards & Requirements
	LB-6: Tissue Management The organization must assure that tissue implanted into a patient is managed in a safe and effective manner. *Note: This standard applies to any article or material classified by the FDA as tissue.* A. Tissue must only be obtained from outside sources that have a current tissue registration with the FDA, and current licensure, if required, by the State. • This does not apply to autologous tissue- or cellular-based products classified as medical devices by the FDA. B. There must be a system to document and track each article of tissue. The organization determines the specific method for doing so. At least the following must be documented: • Date and time the tissue was received into the organization; • Identify of the person who received the tissue; • Type of tissue, lot number and expiration date; • Whether packaging was intact and any temperature requirements maintained when the tissue was received; • Date and time the tissue was removed from storage for implantation; • Identity of the person who removed the tissue from storage for implantation; • The identity of the patient in whom that tissue was implanted; • The name, lot number and expiration date of any materials used to reconstitute or prepare the tissue. C. Refrigerators, freezers and nitrogen tanks that store tissue must be maintained at appropriate temperature, as well as the following: • Plugged into emergency power; • Have an alarm that is audible to staff 24/7 to notify the organization when temperature is not maintained; • Have the temperature continuously monitored and documented at least daily. D. Tissue requiring room temperature storage must have the temperature of the storage area maintained and the temperature documented daily. E. The organization develops and implements a policy to address adverse events involving tissue. F. The organization maintains records of tissue implantation as required by law and regulation.
	LB-7: Management of Blood & Blood Products The organization must assure that blood is managed in a safe manner. A. The organization receives, stores, dispenses, transports, and administers blood and/or blood products in accordance with law, regulation, and accepted standards of care. B. The matching of the correct blood or blood component to the correct patient must be verified by two practitioners at the time of administration. One of the practitioners must be the individual who will be administering the blood. • If it is not possible to have a second individual present to verify the blood at the time of administration, then matching of the blood to the patient must be accomplished by bar code technology. C. Blood and blood products must be administered only by individuals who have the requisite licensure, scope of practice allowance, and training to do so, and in accordance with medical staff approved policies and procedures.

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ORGAN, TISSUE & EYE PROCUREMENT

42 CFR	CIHQ Standards & Requirements
482.45	OP-1: Organ, Tissue & Eye Procurement The organization must develop, implement and maintain a policy(s) and process(s) to assure that organ, tissue and/or eye procurement is effectively managed. A. The organization must have a written agreement with a designated organ procurement organization (OPO). B. The organization must notify in a timely manner, the OPO or a third party designated by the OPO of individuals whose death is imminent or who have died in the hospital. C. The OPO determines 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. D. Incorporate an agreement with at least one tissue bank and at least one eye bank to cooperate in the retrieval, processing, preservation, storage and distribution of tissues and eyes, as may be appropriate to assure that all usable tissues and eyes are obtained from potential donors, insofar as such an agreement does not interfere with organ procurement. E. Ensure, in collaboration with the designated OPO, that the family of each potential donor is informed of its options to donate organs, tissues or eyes, or to decline to donate. • The individual designated by the organization to initiate the request to the family must be an organ procurement representative or a designated requestor. A designated requestor is an individual who has completed a course offered or approved by the OPO and designed in conjunction with the tissue and eye bank community in the methodology for approaching potential donor families and requesting organ or tissue donation. F. Encourage discretion and sensitivity with respect to the circumstances, views and beliefs of the families of potential donors. G. Ensure that the organization works cooperatively with the designated OPO, tissue bank and eye bank in educating staff on donation issues, reviewing death records to improve identification of potential donors and maintaining potential donors while necessary testing and placement of potential donated organs, tissues and eyes take place.

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42 CFR	CIHQ Standards & Requirements
482.45	OP-2: Organ Transplantation The organization shall assure that any organ transplantation is performed in accordance with law and regulation. *Note: This standard only applies to organizations that perform organ transplantation.* *Note: For the purpose of this standard, the term "organ" means a human kidney, liver, heart, lung or pancreas.* A. The organization must be a member of the Organ Procurement and Transplantation Network (OPTN) established and operated in accordance with section 372 of the Public Health Service (PHS) Act (42 U.S.C. 274) and abide by its rules. • The term "rules of the OPTN" means those rules provided for in regulations issued by the Secretary of Health & Human Services in accordance with section 372 of the PHS Act which are enforceable under 42 CFR 121.10. • No organization is considered to be out of compliance with section 1138(a)(1)(B) of the Social Security Act or with the requirements of this standard unless the Secretary of Health & Human Services has given the OPTN formal notice that he or she approves the decision to exclude the organization from the OPTN and has notified the organization in writing. B. The organization must provide organ transplant related data as requested by the OPTN, the Scientific Registry and the OPO's. • The organization must also provide such data directly to the Department of Health & Human Services when requested.

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NUCLEAR MEDICINE SERVICES

42 CFR	CIHQ Standards & Requirements
482.53	NM-1: Organization of Nuclear Medicine Services If the organization provides nuclear medicine services, it must do so in a safe, effective manner and in accordance with law, regulations and established standards of care. A. The scope of nuclear medicine services offered by the organization must be defined in writing and approved by the medical staff. B. The nuclear medicine service director must be a doctor of medicine or osteopathy and must demonstrate through education, experience and specialized training that he/she is qualified in nuclear medicine, appropriate to the scope and complexity of services offered. C. The organization must have written policies, developed and approved by the nuclear medicine service director and medical staff, who specify the qualifications, training, functions and experience of personnel responsible for performing each type of nuclear medicine procedure. Qualifications include at a minimum, job title, education, experience, specialized training and licensure/certification, consistent with Federal and State law. D. Equipment and supplies must be appropriate for the types of nuclear medicine services offered and must be maintained for safe and efficient performance. • Equipment must be maintained in safe operating condition and inspected, tested and calibrated at least annually by qualified personnel. E. The organization must assure that the nuclear medicine services are integrated into the organization's quality assessment and performance improvement program.
482.53	NM-2: Provision of Nuclear Medicine Services The organization must assure the following are developed and implemented: A. Written safety standards for radioactive materials that address, at a minimum: • Handling of equipment and radioactive materials; • Protection of patients and personnel from radiation hazards; • Labeling of radioactive materials, waste and hazardous areas; • Transportation of radioactive materials between locations within the hospital; • Security of radioactive materials, including determining who may have access to radioactive materials and controlling access to radioactive materials; • Testing of equipment for radiation hazards; • Maintenance of personal radiation monitoring devices; • Storage of radio nuclides and radio pharmaceuticals as well as radioactive waste; • Disposal of radio nuclides, unused radio pharmaceuticals and radioactive waste. B. Nuclear medicine services must be ordered only by practitioners whose scope of Federal or State licensure and whose defined staff privileges allow such referrals. C. All in-vitro tests and all in-vivo procedures classified under radio bioassay must be performed in accordance with the requirements of 42 CFR §482.27. D. In-house preparation of radiopharmaceuticals is by, or under the supervision of, an appropriately trained registered pharmacist or a doctor of medicine or osteopathy. E. The organization must maintain signed and dated reports of nuclear medicine interpretations, consultations and procedures. • The practitioner approved by the medical staff to interpret diagnostic procedures must sign and date the interpretation of tests performed. F. The organization must maintain copies of nuclear medicine reports for at least five years. G. The organization must maintain records of the receipt and distribution of radio pharmaceuticals.

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NURSING SERVICES

42 CFR	CIHQ Standards & Requirements
482.23	NS-1: Chief Nurse Executive The organization shall have a single licensed registered nurse qualified by education, training and experience to direct all nursing services provided. This individual shall be responsible for: A. Establishment of a single organized nursing service with administrative structure and chain of command; B. Assuring that all nursing services ultimately reports to him or her; C. Assuring that all nursing services are provided or supervised by a registered nurse, and that there is at least one registered nurse on duty at all times; D. Determining the types and numbers of nursing personnel and staff necessary to provide nursing care for all areas of the hospitals; E. Representing nursing services (directly or through designee) through attendance and voice on all decision-making bodies, including the governing body, when nursing services is being discussed; F. Approval (directly or through designee) of all nursing-service policies; G. Integration of nursing services into the organization's quality assessment and performance improvement program.
482.23	NS-2: Staffing of Nursing Services Except as permitted by law, the organization must provide 24-hour inpatient nursing services that are furnished or supervised by a registered nurse (RN). A. Every inpatient unit/department/location within the organization-wide nursing service must have adequate numbers of RN's physically present at each location to ensure the immediate availability of an RN for the bedside care of any patient. • There must be at least one RN physically present at each inpatient campus location and on duty at all times. B. There must be sufficient numbers, types and qualifications of supervisory and staff nursing personnel to respond to the appropriate nursing needs and care of the patient population of each department or nursing unit. C. The organization must maintain, review and revise as necessary, nurse staffing schedules to meet the patient care needs and to make adjustments for nursing staff absenteeism.

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42 CFR	CIHQ Standards & Requirements
482.23	NS-3: Delivery of Nursing Care The organization must assure that nursing care is rendered to patients in a safe and appropriate manner. A. A registered nurse (RN) must evaluate and supervise the care for each patient The initial evaluation must be completed within 24 hours of the patient's admission. • Evaluation would include assessing the patient's care needs, patient's health status/conditioning, as well as the patient's response to interventions. B. An RN must assign the nursing care of each patient to other nursing personnel in accordance with the patient's needs and the specialized qualifications and competence of the nursing staff available. C. Each patient that receives nursing care must have a nursing care plan. • The nursing care plan must be initiated on admission or establishment of care. • The nursing care plan must address each patient's current nursing care needs, including care goals, as well as planning for discharge to meet post-hospitalization needs. • The nursing care plan must be based the patient's nursing care needs (not solely those needs related to the admitting diagnosis) and developing appropriate nursing interventions in response to those needs. • The nursing care plan must be updated or revised in response to ongoing assessment findings. • The nursing care plan must part of the patient's medical record.

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OPERATIVE & INVASIVE SERVICES

42 CFR	CIHQ Standards & Requirements
482.51	OI-1: Provision of Operative & Invasive Services If the organization provides operative or invasive services, it must do so in a safe manner and within accepted standards of care. A. The organization must assure that both inpatient and outpatient operative and invasive services are designed and maintained to a comparable level of care in accordance with the complexity of services offered.. B. The organization must assure acceptable standards of practice include maintaining compliance with applicable Federal and State laws, regulations and guidelines governing surgical services or surgical service locations, as well as any standards and recommendations promoted by or established by nationally recognized professional organizations (e.g., the American Medical Association, American College of Surgeons, Association of Operating Room Nurses, Association for Professionals in Infection Control and Epidemiology, etc.). C. The organization must develop and implement processes to assure the following: • Access to operative, invasive and recovery areas is limited to authorized personnel and that the traffic flow pattern adheres to accepted standards of practice; • The conformance to aseptic and sterile technique by all individuals involved in operative and invasive procedures; • Appropriate cleaning between cases and appropriate terminal cleaning applied; • Donning of attire appropriate for the kind of operative or invasive procedure performed; • That equipment is available for rapid and routine sterilization of equipment, supplies and instrumentation; • That sterilized materials are packaged, handled, labeled and stored in a manner that ensures sterility; • That temperature and humidity of operative suites are monitored and maintained within accepted standards of practice. D. The organization's operative and invasive services must be integrated into its organization-wide quality assessment and performance improvement program.

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42 CFR	CIHQ Standards & Requirements
482.51	OI-2: Staffing for Operative & Invasive Procedures The organization must provide adequate staffing for the performance of operative and invasive procedures. A. There must be an adequate number of trained and qualified staff to assure the provision of safe patient care when operative and invasive procedures are performed. B. When surgical procedures are performed, the organization must assure the following: • Surgical services must be supervised by an experienced and appropriately qualified registered nurse (RN) or physician; • Licensed practical nurses (LPN) and/or surgical technologists may serve as "scrub nurses" provided they are under the supervision of an RN; • Qualified RN's may perform circulating duties in the operating room. In accordance with applicable State laws and approved medical staff policies and procedures, LPNs and surgical technologists may assist in circulatory duties under the supervision of a qualified RN who is immediately available to respond to emergencies; • Surgical privileges must be delineated for all practitioners performing surgery in accordance with the competencies of each practitioner. The surgical service must maintain a roster of practitioners specifying the surgical privileges of each practitioner; • If the organization utilizes RN First Assistants, Physician Assistants or other non-MD/DO surgical assistants, the organization must establish criteria, qualifications and a credentialing process to grant specific privileges to individual practitioners in accordance with Federal and State laws and regulations; • When a practitioner may perform certain surgical procedures under supervision, the specific tasks/procedures and the degree of supervision must be delineated in that practitioner's surgical privileges and included on the surgical roster.

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42 CFR	CIHQ Standards & Requirements
482.51	OI-3: Policies Governing the Performance of Operative and Invasive Procedures The organization must establish, implement and enforce policies – consistent with accepted standards of care – when operative or invasive procedures are performed that address at least the following: A. Scheduling of patients for procedures; B. The minimum amount of information that must be available in the patient's medical record prior to the start of a procedure; C. Identification and management of patients with an infection; D. Management of treatment limitation orders such as "do not resuscitate" during intra-procedure and immediate post-procedure care; E. Duties of staff that perform scrub and circulating functions; F. Procedure-specific or general lists of equipment, materials and supplies necessary to properly perform procedures; G. Reduce the associated risk of fire when using alcohol-based skin preparations in anesthetizing locations. This includes document the implementation of these precautions in the patient's medical record; H. Safe and accurate labeling and processing of specimens; I. Aseptic and sterile surveillance and practice, including scrub techniques; J. Timely provision of age-appropriate resuscitation services during pre/intra/post-procedure care, including necessary equipment, supplies and the availability of adequate numbers of qualified staff; K. Timely provision of services to treat instances of malignant hyperthermia; L. Assuring that at least the following equipment is available: • Call system; • Cardiac monitor; • Resuscitator; • Defibrillator; • Suction equipment; • Tracheotomy set (a cricothyroidotomy set is not a substitute).
	OI-4: Preventing Wrong Patient / Wrong Site Procedures The organization must establish, implement and enforce processes to prevent the performance of a procedure on the wrong patient and/or a procedure on the wrong side/site of a patient. *Note: This standard applies to surgical and complex invasive procedures. The organization may choose to apply this standard to other procedures if it so wishes.* A. The organization establishes a process to assure that pertinent and relevant information necessary to assure the correct procedure is performed on the correct patient is verified prior to the procedure. The organization defines the information and verification process. B. The side and/or site of the procedure is marked and verified prior to the start of the procedure. • The organization determines those procedures for which marking of the procedural side/site is required, as well as the method of marking and who will perform the marking. C. Immediately prior to the start of a procedure, all practitioners involved at the start of the procedure verify and agree on the following: • The identity of the patient; • The procedure to be performed; • The side and/or site of the procedure if applicable.

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42 CFR	CIHQ Standards & Requirements
482.51	OI-5: Informed Consent The organization must assure that the patient provides informed consent prior to the performance of any operative or invasive procedure. *Note: This standard does not apply to procedures that are considered simple and low-risk in nature and are permitted under the general consent for care and treatment.* *Note: For the purposes of complying with this standard, evidence that informed consent has been provided to the patient means that the patient has signed the consent form.* A. The organization must establish, implement and enforce an informed consent policy that addresses at least the following: • Who may obtain the patient's informed consent; • Which procedures require informed consent; • The circumstances under which a procedure is considered an emergency and may be undertaken without an informed consent; • The circumstances when a patient's representative, rather than the patient, may give informed consent; • The content of the consent form and instructions for completing it; • The process used to obtain informed consent, including how informed consent is to be documented in the medical record; • Mechanisms that ensure the consent form is properly executed and is in the patient's medical record prior to the procedure (except in the case of emergency); • If the informed consent process and consent form are obtained outside the organization, how the properly executed informed consent form is incorporated into the patient's medical record prior to the procedure. B. Informed consent must be obtained, and the consent form must be placed in the patient's medical record prior to the procedure except in the case of emergency. C. The practitioner(s) responsible for the procedure provides informed consent to the patient in a manner consistent with the organization's policies governing the informed consent process. D. If there are additional requirements under State law for informed consent, the organization must comply with those requirements.
482.51	OI-6: Immediate Post-Operative / Invasive Procedure Care The organization must make adequate provisions for immediate post-procedure care needs of the patient. A. Care must be provided in accordance with acceptable standards of practice. B. There must be a sufficient number of qualified staff to provide immediate post-procedure care. C. There must be sufficient equipment, medication and supplies to meet the immediate post-procedure care needs of the patient. D. The immediate post-procedure (recovery) care area must be physically distinct and separate from the operative/invasive suite. Access is limited to authorized personnel. E. If immediate post-procedure care is provided outside of the designated post-procedure (recovery) care area, the organization must assure that the patient receives the same level of care as would have occurred in the immediate post-procedure (recovery) care area.

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42 CFR	CIHQ Standards & Requirements
482.51	OI-7: Post-Operative / Invasive Procedure Report The organization must assure that a post-operative / invasive procedure report is dictated or handwritten immediately following any surgical or high-risk invasive procedure and entered into the patient's medical record and signed by the surgeon/ practitioner. A. The post-operative / invasive procedure report must include at least: • Name and hospital identification number of the patient; • Date and times of the surgery / procedure; • Name(s) of the surgeon(s) and assistants or other practitioners who performed surgical / invasive tasks (even when performing those tasks under supervision); • Pre-operative / procedure and post-operative/ procedure diagnosis; • Name of the specific procedure(s) performed; • Type of anesthesia administered; • Complications, if any; • A description of techniques, findings and tissues removed or altered; • Surgeons or practitioners name(s) and a description of the specific significant surgical tasks that were conducted by practitioners other than the primary surgeon/practitioner (significant surgical procedures include opening and closing, harvesting grafts, dissecting tissue, removing tissue, implanting devices, altering tissues); • Prosthetic devices, grafts, tissues, transplants or devices implanted, if any.
482.51	OI-8: Record of Surgical Procedures Performed The organization must maintain a complete and up-to-date record (log or equivalent) of all surgical procedures performed. A. The record must include at least the following information: • Patient's name; • Age of patient; • Patient's hospital identification number; • Date of the operation; • Inclusive or total time of the operation; • Name of the surgeon and any assistant(s); • Name of nursing personnel (scrub and circulating); • Type of anesthesia used and name of person administering it; • Operation performed; • Pre- and post-op diagnosis.

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OUTPATIENT SERVICES

42 CFR	CIHQ Standards & Requirements
482.54	OS-1: Outpatient Services If the organization provides outpatient services, it must do so in a safe, effective manner and within established standards of care. A. All outpatient services provided by the organization must meet the needs of the patients in accordance with acceptable standards of practice. B. The organization must ensure that equipment, staff and facilities are adequate to provide the outpatient services offered. C. Outpatient services at all locations must be integrated with inpatient services (e.g., medical records, radiology, laboratory, surgical services, anesthesia [including pain management] services, other diagnostic services, etc.), as appropriate to the services offered. • The organization must have written policies in place to assure the integration of outpatient services, including an established method of communication between outpatient service departments to corresponding inpatient services. D. Outpatient services must be accountable to an individual(s) who directs the overall operation of the organization's entire outpatient services (all locations, all services). • The organization must define in writing the qualifications and competencies necessary to direct the outpatient services. E. Adequate types and numbers of qualified professional and nonprofessional personnel must be available to provide patients with the appropriate level of care and services offered by each outpatient location. • The types and numbers of qualified personnel are based on the scope and complexity of outpatient services offered and the number and types of patients treated as outpatients. E. The organization's outpatient services must be integrated into its organization-wide quality assessment and performance improvement program. F. Outpatient services must be ordered by a practitioner who meets the following conditions: • Is responsible for the care of the patient. • Is licensed in the State where he or she provides care to the patient. • Is acting within his or her scope of practice under State law. • Is authorized in accordance with State law and policies adopted by the medical staff, and approved by the governing body, to order the applicable outpatient services. This applies to the following: • All practitioners who are appointed to the hospital's medical staff and who have been granted privileges to order the applicable outpatient services. • All practitioners not appointed to the medical staff, but who satisfy the above criteria for authorization by the medical staff and the hospital for ordering the applicable outpatient services for their patients.

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RADIOLOGY SERVICES

42 CFR	CIHQ Standards & Requirements
482.26	RD-1: Provision of Radiology Services The hospital must maintain or have available diagnostic radiologic services to meet patient's needs. All radiology services provided by the organization, including diagnostic and therapeutic services, must be provided in accordance with acceptable standards of practice and must meet professionally approved standards for safety and personnel qualifications. A. The scope and complexity of radiology services offered must be specified in writing and approved by the medical staff and governing body. B. All radiology services, including those provided by contract, must be integrated into the organization's quality assessment and performance improvement program.
482.26	RD-2: Oversight of Radiology Services The organization must assure that the provision of radiology services is overseen by qualified medical personnel. A. The head of radiology services must be a doctor of medicine or doctor of osteopathy who is qualified by education and experience in radiology. B. The medical staff must establish the qualifications necessary for radiologist appointment to the medical staff. C. There must be written policies developed and approved by the medical staff to designate which radiology tests require interpretation by a radiologist. D. When telemedicine is provided, the radiologist interpreting the test must meet the requirements noted under Standard MS-9. E. The organization must assure that processes are developed and implemented that address at least the following: • Ensuring that radiology reports are signed by the practitioner who interpreted them; • Assigning duties to radiology personnel appropriate to their level of training, experience and licensure if applicable; • Enforcing infection-control standards; • Ensuring that emergency care is provided to patients who experience an adverse reaction to diagnostic agents; • Ensuring that files, scans and other image records are kept in a secure area and are readily retrievable; • Ensuring that the medical staff determines which personnel are qualified to use the radiology equipment and administer procedures; • Training radiology staff' on how to operate equipment safely, perform tests, and manage emergency radiation hazards and accidents.
482.26	RD-3: Availability of Radiology Services to Meet Patient Care Needs The scope and complexity of radiology services provided must meet the needs of the patients. A. The hospital must maintain or have available diagnostic radiologic services to meet patient's needs. Radiology services may be provided by the organization directly or through a contractual arrangement. • Diagnostic radiology services provided under contract may be provided either on the organization's premises or in an adjacent or other nearby, readily accessible facility. B. Radiology services must be provided in accordance with acceptable standards of practice and applicable Federal and State laws, regulations and professional guidelines.

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42 CFR	CIHQ Standards & Requirements
482.26	RD-4: Safety of Radiology Services The provision of radiology services, particularly ionizing procedures, must be free from hazards for patients and staff. A. The organization must develop and implement policies and procedures related to: • Adequate shielding for patients, personnel and facilities; • Labeling of radioactive materials, waste and hazardous areas; • Transportation of radioactive materials between locations within the hospital; • Security of radioactive materials, including determining who may have access to radioactive materials and controlling access to radioactive materials; • Testing of equipment for radiation hazards; • Maintenance of personal radiation monitoring devices (badges), including testing staff for radiation exposure; • Proper storage of radiation monitoring badges when not in use; • Storage of radio nuclides and radio pharmaceuticals as well as radioactive waste; • Disposal of radio nuclides, unused radio pharmaceuticals and radioactive waste; • Methods of identifying pregnant patients. B. The organization must have policies and procedures in place to ensure that periodic inspections of radiology equipment are conducted and that problems identified are corrected in a timely manner. • The organization must ensure that equipment is inspected in accordance with manufacturer's instructions, Federal and State laws, regulations and guidelines and organization policy.
482.26	RD-5: Ordering of Radiology Services Radiology services must be provided only on the order of practitioners with clinical privileges or consistent with State law, of other practitioners authorized by the medical staff and the governing body to order the services.
482.26	RD-6: Maintenance of Radiology Records The organization must maintain records for all radiology procedures performed. A. The organization must have written policies and procedures that ensure the integrity of authentication and protect the privacy of radiology records. • At a minimum, these records include copies of reports and printouts and any films, scans or other image records as appropriate. • The radiologist or other practitioner who performs radiology services must sign reports of his or her interpretations. B. Radiology films, image records, scans, reports and printouts must be secure, properly stored, be accessible and promptly retrievable for any care, procedure, treatment or test provided or conducted within the past five years.

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REHABILITATION SERVICES

42 CFR	CIHQ Standards & Requirements
482.56	RB-1: Rehabilitation Services If the organization provides rehabilitation services, it must do so in a safe, effective manner and in accordance with established standards of care and as defined in 42 CFR 484. A. If rehabilitative services are provided, they must be organized and staffed in such a manner to ensure the health and safety of patients. • Acceptable standards of practice include compliance with any applicable Federal or State laws, regulations or guidelines, as well as standards and recommendations promoted by nationally recognized professional organizations (e.g., American Physical Therapy Association, American Speech and Hearing Association, American Occupational Therapy Association, American College of Physicians, American Medical Association, etc.). B. The scope of rehabilitation services offered by the organization must be defined in written policies and procedures and approved by the Medical staff. C. There must be an adequate number of qualified staff available when needed to evaluate each patient, initiate the plan of treatment and supervise supportive personnel when they furnish rehabilitation services. • The number of qualified staff is based on the type of patients treated and the frequency, duration and complexity of the treatment required. D. The rehabilitative service director must demonstrate through education, experience and/or specialized training that he/she has the necessary knowledge, experience and capabilities to properly supervise and administer the service(s). E. Physical therapy, occupational therapy or speech-language pathology or audiology services, if provided, must be provided by qualified physical therapists, physical therapist assistants, occupational therapists, occupational therapy assistants, speech-language pathologists or audiologists. F. Services must be given in accordance with orders of practitioners who are authorized by the medical staff to order the services, and the orders must be incorporated in the patient's record. G. The organization's rehabilitation services must be integrated into the quality assessment and performance improvement program.

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RESPIRATORY SERVICES

42 CFR	CIHQ Standards & Requirements
482.57	RT-1: Respiratory Services If the organization provides respiratory services, it must assure that respiratory services are provided in a safe, effective manner and in accordance with established standards of care. A. The organization must provide the appropriate equipment and types and numbers of qualified personnel necessary to furnish the services offered in accordance with acceptable standards of practice. B. The scope of diagnostic and/or therapeutic respiratory services offered by the organization must be defined in writing and approved by the Medical staff. C. The respiratory service director must be a doctor of medicine or osteopathy and must demonstrate through education, experience and specialized training that he/she has the qualifications necessary to supervise and administer the service properly, appropriate to the scope and complexity of services offered. D. There should be written policies for the delivery of respiratory care services that are developed and approved by the medical staff. Appropriate to the scope of services provided, the written policies must address at least the following: • Equipment assembly, operation and preventive maintenance; • Safety practices, including infection control measures for equipment, sterile supplies, biohazardous waste, posting of signs and gas-line identification; • Handling, storage and dispensing of therapeutic gases to both inpatients and outpatients; • Cardiopulmonary resuscitation; • Procedures to follow in the advent of adverse reactions to treatments or interventions; • Pulmonary function testing; • Therapeutic percussion and vibration; • Bronchopulmonary drainage; • Mechanical ventilatory and oxygenation support; • Aerosol, humidification and therapeutic gas administration; • Storage, access, control, administration of medications and medication errors; • Procedures for obtaining and analyzing blood samples (e.g., arterial blood gases); • Each type of respiratory care service provided by the hospital; • The qualifications, including job title, licensure consistent with State law, education, training and experience of personnel authorized to perform each type of respiratory care service and whether they may perform it without supervision; • The type of personnel qualified to provide the direct supervision. E. If blood gases or other clinical laboratory tests are performed in the respiratory care unit, the unit must meet the applicable requirements for laboratory services specified in 42 CFR 482.27. F. Services must be provided only on, and in accordance with, the orders of a qualified and licensed practitioner G. The organization's respiratory services must be integrated into its quality assessment and performance improvement program. H. All respiratory services must be documented in the patient's medical record in accordance with the requirements at 42 CFR 482.24

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PYSCHIATRIC HOSPITALS

42 CFR	CIHQ Standards & Requirements
482.60	PY-1: Admission to the Psychiatric Hospital The psychiatric hospital must meet the following requirements: *Note: This standard applies only to psychiatric hospitals. It does not apply to psychiatric units in general acute care hospitals* A. Admit only patients whose admission to the hospital is required for active treatment, of an intensity that can be provided appropriately only in an inpatient hospital setting, of a psychiatric principal diagnosis. B. Maintain clinical records on all patients as specified in Standard PY-2 C. Furnish, through the use of qualified personnel, psychological services, social work services, psychiatric nursing, and therapeutic activities as specified in Standard PY-3.
482.61	PY-2: Content of the Medical Record The medical record of a patient treated in the psychiatric hospital must meet the following requirements: *Note: This standard applies only to psychiatric hospitals. It does not apply to psychiatric units in general acute care hospitals* A. Medical records must stress the psychiatric components of the record, including history of findings and treatment provided for the psychiatric condition for which the inpatient is treated in the unit. B. The identification data must include the inpatient's legal status. C. A provisional or admitting diagnosis must be made on every inpatient at the time of admission, and must include the diagnoses of diseases as well as the psychiatric diagnoses. D. The reasons for admission must be clearly documented as stated by the inpatient or others significantly involved, or both. E. The social service records, including reports of interviews with inpatients, family members, and others must provide an assessment of home plans and family attitudes, and community resource contacts as well as a social history. F. When indicated, a complete neurological examination must be recorded at the time of the admission physical examination. G. Each inpatient must receive a psychiatric evaluation that must: • Be completed within 60 hours of admission; • Include a medical history; • Contain a record of mental status; • Note the onset of illness and the circumstances leading to admission; • Describe attitudes and behavior; • Estimate intellectual functioning, memory functioning, and orientation; and • Include an inventory of the inpatient's assets in descriptive, not interpretative fashion. H. Each inpatient must have an individual comprehensive treatment plan that must be based on an inventory of the inpatient's strengths and disabilities. The written plan must include a substantiated diagnosis; short-term and long-term goals; the specific treatment modalities utilized; the responsibilities of each member of the treatment team; and adequate documentation to justify the diagnosis and the treatment and rehabilitation activities carried out. I. Progress notes must be recorded by the doctor of medicine or osteopathy responsible for the care of the inpatient, a nurse, social worker and, when appropriate, others significantly involved in active treatment modalities. The frequency of progress notes is determined by the condition of the inpatient but must be recorded at least weekly. J. The record of each patient who has been discharged must have a discharge summary that includes a recapitulation of the inpatient's hospitalization in the unit and recommendations from appropriate services concerning follow-up or aftercare as well as a brief summary of the patient's condition on discharge.

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42 CFR	CIHQ Standards & Requirements
482.62	PY-3: Staffing of the Psychiatric Hospital The psychiatric hospital must have adequate numbers of qualified professional and supportive staff to evaluate inpatients, formulate written, individualized, comprehensive treatment plans, provide active treatment measures and engage in discharge planning *Note: This standard applies only to psychiatric hospitals. It does not apply to psychiatric units in general acute care hospitals* A. The hospital must employ or undertake to provide adequate numbers of qualified professional, technical, and consultative personnel to • Evaluate inpatients; • Formulate written, individualized, comprehensive treatment plans; • Provide active treatment measures; and • Engage in discharge planning. B. Inpatient psychiatric services must be under the supervision of a clinical director, service chief, or equivalent that is qualified to provide the leadership required for an intensive treatment program. The number and qualifications of doctors of medicine and osteopathy must be adequate to provide essential psychiatric services. • The clinical director, service chief, or equivalent must meet the training and experience requirements for examination by the American Board of Psychiatry and Neurology or the American Osteopathic Board of Neurology and Psychiatry. • The director must monitor and evaluate the quality and appropriateness of services and treatment provided by the medical staff. • If medical and surgical diagnostic services and treatment are not available within the institution, the institution must have an agreement with an outside source of these services to ensure that they are immediately available or a satisfactory agreement must be established for transferring patients to a general hospital that participates in the Medicare program. C. The hospital must have a qualified director of psychiatric nursing services. In addition to the director of nursing, there must be adequate numbers of registered nurses, licensed practical nurses, and mental health workers to provide nursing care necessary under each inpatient's active treatment program and to maintain progress notes on each inpatient. • The director of psychiatric nursing services must be a registered nurse who has a master's degree in psychiatric or mental health nursing, or its equivalent, from a school of nursing accredited by the National League for Nursing, or be qualified by education and experience in the care of the mentally ill. The director must demonstrate competence to participate in interdisciplinary formulation of individual treatment plans; to give skilled nursing care and therapy; and to direct, monitor, and evaluate the nursing care furnished. • The staffing pattern must ensure the availability of a registered nurse 24 hours each day. There must be adequate numbers of registered nurses, licensed practical nurses, and mental health workers to provide the nursing care necessary under each inpatient's active treatment program. D. The hospital must provide or have available psychological services to meet the needs of the inpatients. The services must be furnished in accordance with acceptable standards of practice, service objectives, and established policies and procedures. E. There must be a director of social services who monitors and evaluates the quality and appropriateness of social services furnished. The services must be furnished in accordance with accepted standards of practice and established policies and procedures. Social service staff responsibilities must include, but are not limited to, participating in discharge planning, arranging for follow-up care, and developing mechanisms for exchange of appropriate information with sources outside the hospital. F. The hospital must provide a therapeutic activities program. • The program must be appropriate to the needs and interests of inpatients and be directed toward restoring and maintaining optimal levels of physical and psychosocial functioning. • The number of qualified therapists, support personnel, and consultants must be adequate to provide comprehensive therapeutic activities consistent with each inpatient's active treatment program.

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42 CFR	CIHQ Standards & Requirements
482.58	LT.1: Requirements for Hospital Providers of Long Term Care Services *Note: This standard applies to a hospital that has a Medicare provider agreement granted an approval from CMS to provide post-hospital extended care services, as specified in § 409.30 of the 42 Code of Federal Regulations (CFR), and be reimbursed as a swing-bed hospital, as specified in § 413.114* A. The hospital must meet the following eligibility requirements: • The facility has fewer than 100 hospital beds, excluding beds for newborns and beds in intensive care type inpatient units (for eligibility of hospitals with distinct parts electing the optional reimbursement method, see § 413.24(d)(5) of the 42 CFR). • The hospital is located in a rural area. This includes all areas not delineated as "urbanized" areas by the Census Bureau, based on the most recent census. • The hospital does not have in effect a 24-hour nursing waiver granted under § 488.54(c) of the 42 CFR. • The hospital has not had a swing-bed approval terminated within the two years previous to application. B. The facility is substantially in compliance with the following skilled nursing facility requirements contained in the 42 CFR. • Resident rights (§ 483.10 (b)(3), (b)(4), (b)(5), (b)(6), (d),(e), (h), (i), (j)(1)(vii), (j)(1)(viii), (l),(m)) • Admission, transfer, and discharge rights (§ 483.12 (a)(1), (a)(2), (a)(3), (a)(4), (a)(5), (a)(6), and (a)(7)). • Resident behavior and facility practices (§ 483.13). • Patient activities (§ 483.15(f)). • Social services (§ 483.15(g)). • Discharge planning (§ 483.20(e)). • Specialized rehabilitative services (§ 483.45). • Dental services (§ 483.55).

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GLOSSARY

Advance Directive
A document or documentation allowing a person to give direction about future healthcare or to designate another individual to make healthcare decisions on his/her behalf.

Adverse Event
An occurrence that results in temporary or permanent harm to a patient.

Adverse Drug Event
A medication error, adverse drug reaction, medication incompatibility, or other drug-related occurrence that results in temporary or permanent harm to a patient.

Adverse Drug Reaction
A response to a medication that is noxious and unintended and that occurs at doses normally used in humans for the prophylaxis, diagnosis, or treatment of disease or for the restoration, correction, or modification of physiological or psychological function.

Alternate Equipment Maintenance Strategies
- Preventive Maintenance (Time-based Maintenance) – a maintenance strategy where maintenance activities are performed at scheduled time intervals to minimize equipment degradation and reduce instances where there is a loss of performance.

- Predictive Maintenance (Condition-based Maintenance) – a maintenance strategy that involves periodic or continuous equipment condition monitoring to detect the onset of equipment degradation. This information is used to predict future maintenance requirements and to schedule maintenance at a time just before equipment experiences a loss of performance.

- Reactive Maintenance (Corrective, Breakdown or Run-to-Failure Maintenance) – a maintenance strategy based upon a "run it until it breaks" philosophy, where maintenance or replacement is performed only after equipment fails or experiences a problem. This strategy may be acceptable for equipment that is disposable or low cost, and presents little or no risk to health and safety if it fails

- Reliability-Centered Maintenance – a maintenance strategy that not only considers equipment condition, but also considers other factors unique to individual pieces of equipment, such as equipment function, consequences of equipment failure, and the operational environment. Maintenance is performed to optimize reliability and cost effectiveness.

Anesthesia
"Anesthesia" involves the administration of a medication to produce a blunting or loss of: pain perception (analgesia); voluntary and involuntary movements; autonomic function; and memory and/or consciousness.
- General Anesthesia
  A drug-induced loss of consciousness during which patients are not arousable, even by painful stimulation. The ability to independently maintain ventilatory support is often impaired. Patients often require assistance in maintaining a patent airway, and positive pressure ventilation may be required because of depressed spontaneous ventilation or drug-induced depression of neuromuscular function. Cardiovascular function may be impaired.

- Regional Anesthesia
  The delivery of anesthetic medication at a specific level of the spinal cord and/or to peripheral nerves, including epidurals and spinals and other central neuraxial nerve blocks, is used when loss of consciousness is not desired but sufficient analgesia and loss of voluntary and involuntary movement is required.

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- Monitored Anesthesia Care (MAC) / Deep Sedation/Analgesia
  Anesthesia care that includes the monitoring of the patient by a practitioner who is qualified to administer anesthesia as defined by the regulations at §482.52(a). Indications for MAC depend on the nature of the procedure, the patient's clinical condition, and/or the potential need to convert to a general or regional anesthetic. Deep sedation/analgesia is included in MAC.
  Deep sedation/analgesia: a drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully following repeated or painful stimulation. The ability to independently maintain ventilatory function may be impaired. Patients may require assistance in maintaining a patent airway, and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained.

- Moderate Sedation / Analgesia
  A drug-induced depression of consciousness during which patients respond purposefully to verbal commands, either alone or accompanied by light tactile stimulation. No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is usually maintained.

Qualified Anesthesia Provider
- A qualified anesthesiologist;
- A qualified doctor of medicine or osteopathy (other than an anesthesiologist);
- A dentist, oral surgeon, or podiatrist who is qualified to administer anesthesia under State law;
- A certified registered nurse anesthetist (CRNA), who, unless the State in which he/she practices has been exempted by CMS, is under the supervision of the operating practitioner or of an anesthesiologist who is immediately available if needed;
- An anesthesiologist's assistant who is under the supervision of an anesthesiologist who is immediately available if needed.

Biologicals
Medicines made from living organisms and their products, including serums, vaccines, antigens, and antitoxins.

Bylaws
A written document that establishes the roles and responsibilities of the governing body of an organization and/or the organized medical staff.

Clinical Laboratory Improvement Act (CLIA)
Federal legislation that created uniform standards for regulating laboratory testing.

Contract Service
Service(s) provided through a written agreement with another entity, agency, or individual on behalf of the organization. Contract services reviewed for compliance to accreditation requirements are those that directly provide patient care, or provide services that directly impact patient care.

Competency
The ability to safely and effectively perform the essential functions, tasks, skills, duties, and responsibilities of a job position to an accepted level or standard of care.

CMS Certification Number (CCN)
The identification number that is linked to an organization's Medicare provider agreement. The CCN used to be called the "provider number." The CCN identifies the boundaries of an organization in terms of what locations it has identified on its Form CMS 855A application (including all subsequent 855A's submitted with location updates); all of these locations are covered under the same CCN. All sites and services rendered under the same CCN must be surveyed as part of the accreditation process.

Credentialing
Obtaining, verifying, and determining the qualifications of an individual to provide care or service

Credentials
Evidence of licensure, education, training, experience, or other necessary qualifications of an individual.

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Disinfection
A process that eliminates many or all pathogenic microorganisms, except bacterial spores, on inanimate objects. In health-care settings, objects usually are disinfected by liquid chemicals or wet pasteurization.

Formulary
A list of medications available for use in the organization when providing patient care.

Falsification of the Medical Record
Falsification of the medical record includes, but it not necessarily limited to:
1. Dating and timing the authentication of an entry to make it appear as though the entry was made into the medical record other than the date and time when the entry actually occurred.
2. Entering information into the medical record that does not or could not accurately reflect the clinical condition of the patient or information available about the patient at the time the entry was made.
3. Having the author of an entry into the medical record appear to be someone other than the person who actually made the entry

Graduate Medical Education
The period of didactic and clinical education in a medical specialty which follows the completion of a recognized undergraduate medical education and which prepares physicians for the independent practice of medicine in that specialty, also referred to as residency education. The term "graduate medical education' also applies to the period of didactic and clinical education in a medical subspecialty which follows the completion of education in a recognized medical specialty and which prepares physicians for the independent practice of medicine in that subspecialty.

Grievance
A complaint made by a patient or surrogate decision maker that cannot be resolved immediately. Any complaint made in writing is considered a grievance.

Informed Consent
A document signed by the patient or surrogate decision maker indicating that he/she has been made aware of the nature, benefits, risks, and alternatives of a treatment or procedure.

Interpretation
Rendition of a spoken message in which the interpreter comprehends the source language and can speak comprehensively in the target language to convey the meaning intended in the source language.

Licensed Independent Practitioner
Any practitioner permitted by law and by the organization to provide care and services, without direction or supervision, within the scope of the practitioner license and consistent with individually assigned clinical responsibilities. This language is not to be construed to limit the authority of a licensed independent practitioner to delegate tasks to other qualified health care personnel (for example, physician assistants and advance practice registered nurses) to the extent authorized by state law or a state's regulatory mechanism or federal guidelines, and organizational policy.

Life Safety Code®
Set of standards for the construction and operation of buildings intended to provide a reasonable degree of safety during fires. These standards are prepared, published, and periodically revised by the National Fire Protection Association (NFPA).

- Temporary Life Safety Measures
  Actions taken to compensate for a deficiency in compliance to the Life Safety Code ® until the deficiency can be corrected. Such actions include:
  - Notify the fire department (or other emergency response group) and initiate a fire watch when a fire alarm or sprinkler system is out of service more than 4 hours in a 24-hour period in an occupied building.
  - Post signage identifying the location of alternative exits to everyone affected.
  - Inspect exits in affected areas on a daily basis.
  - Provide temporary but equivalent fire alarm and detection systems for use when a fire system is impaired.
  - Provide additional firefighting equipment.

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- Use temporary construction partitions that are smoke-tight or made of noncombustible or limited-combustible material that will not contribute to the development or spread of fire.
- Increase surveillance of buildings, grounds and equipment, giving special attention to construction areas and storage, excavation and field offices.
- Enforce storage, housekeeping and debris-removal practices that reduce the building's flammable and combustible fire load to the lowest feasible level.
- Provide additional training to those who work in the hospital on the use of firefighting equipment.
- Conduct one additional fire drill per shift per quarter.
- Inspects and tests temporary systems monthly.
- Conduct education to promote awareness of building deficiencies, construction hazards and temporary measures implemented to maintain fire safety.
- Train those who work in the hospital to compensate for impaired structural or compartmental fire safety features.

Medical Equipment
Devices intended to be used for diagnostic, therapeutic, or monitoring care provided to a patient in a hospital

Medical Record
The recording of the care and treatment rendered to a patient. This includes but is not limited to; written documents, computerized electronic information, radiology film and scans, laboratory reports and pathology slides, videos, audio recordings, and other forms of information regarding the condition of a patient.

Medical Staff – Organized
Self-governing entity accountable to the governing body that operates under a set of bylaws, rules and regulations, and policies developed and adopted by the voting members of the organized medical staff and approved by the governing body. The organized medical staff is comprised of doctors of medicine and osteopathy, and, in accordance with the medical staff bylaws, may include other practitioners.

Medication
Any prescription medications, sample medications, herbal remedies, vitamins, nutraceuticals, vaccines, or over-the-counter drugs; diagnostic and contrast agents used on or administered to persons to diagnose, treat, or prevent disease or other abnormal conditions; radioactive medications, respiratory therapy treatments, parenteral nutrition, blood derivatives, and intravenous solutions (plain, with electrolytes and/or drugs); and any product designated by the Food and Drug Administration (FDA) as a drug. This definition of medication does not include enteral nutrition solutions (which are considered food products), oxygen, and other medical gases.

Medication Error
Any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. Such events may be related to professional practice, health care products, procedures, and systems, including prescribing; order communication; product labeling, packaging, and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use. - National Coordinating Council Medication Error Reporting and Prevention.

- Significant Medication Error
  A medication error that resulted in harm to the patient or where there is a known potential for harm to occur. Additionally, if the outcome of the error is unknown the error is considered significant. Harm means a temporary or permanent untoward effect that required intervention, extended duration of care, or transfer to a higher level of care.

Medication Orders
A directive given by an authorized individual to prepare, dispense, and administer a medication to the patient.

- Range Orders
  Orders that have a range of dose and/or frequency when being administered

- Titration Orders
  Orders that allow for the adjustment of the dose of a medication to achieve a desired effect

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- Taper Orders
  Orders that allow for the gradual reduction of a dose and/or frequency of medication to a defined end-point

- Automatic Stop Orders
  Orders that will automatically be discontinued after a defined period of time or number of doses administered

- Weight-Based Orders
  Orders for which the dose is calculated based on the patient's weight. The calculation (e.g. mg/kg) may be written as part of the order, or be required when determining the total dose of a medication

Nurse Executive – Chief
A masters-prepared or equivalently qualified registered professional nurse responsible for the full-time, direct supervision of nursing services and who is currently licensed by the state in which he or she practices.

Nursing
The health profession dealing with nursing care and services as (1) defined by the Code of Ethics for Nurses with Interpretive Statements, Nursing's Social Policy Statement, Nurses' Bill of Rights, Scope and Standards of Nursing Practice of the American Nurses Association and specialty nursing organizations; and (2) defined by relevant state, commonwealth, or territory nurse practice acts and other applicable laws and regulations.

Occupancy
The purpose for which a building or portion thereof is used or intended to be used. Depending on the organization, occupancies may include ambulatory health care occupancy, business occupancy, and healthcare occupancy.

- Ambulatory Healthcare Occupancy
  An ambulatory healthcare occupancy is classified as a building that:
  - Does not provide sleeping accommodations;
  - Does not provide medical treatment or services on a 24-hour basis;
  - Provides anesthesia services; and
  - Renders patients incapable of self-preservation.

- Business Occupancy
  A business occupancy is classified as a building that:
  - Does not provide sleeping accommodations;
  - Does not provide medical treatment or services on a 24-hour basis;
  - Does not provide anesthesia; and
  - Does not render patients incapable of self-preservation.

- Healthcare Occupancy
  A healthcare occupancy is classified as a building that:
  - Provides sleeping accommodations;
  - Provides medical treatment or services on a 24-hour basis; and
  - Patients are incapable of self-preservation.

Orders
A directive or series of directives issued by an authorized individual for the purposes of care and treatment.

- Standing Orders
  Orders that have been written for a specific patient and may be used repeatedly throughout the patient's care experience. The order, once written, "stands" for the duration of the patient's care.

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- Pre-Printed Orders
  Orders or order sets that have been typed, printed, and/or computer generated and electronically stored. Basically, orders that are not hand-written. These orders or order sets must be authorized each time they are used.

- Protocol
  An order or series of orders and other directives that have been approved by the medical staff for use in patient care. Depending on its nature and/or content, a protocol may or may not be implemented for use without requiring prior authorization each time they are used.

- Verbal Orders
  Orders that are communicated face-to-face by the authorized individual to the person receiving the order

- Telephone Orders
  Orders that are communicated via telephone or other communication device (such as text message) by the authorized individual to the person receiving the order

Patient
An individual who receives medical and/or other healthcare related treatment or service. Depending on the context, the term "patient" can also mean a surrogate decision maker or person authorized to make healthcare decisions on the patient's behalf.

Physician
As defined by the Centers for Medicare & Medicaid Services in Sec. 1861.[42 U.S.C.1395x] of the Social Security Act:
The term "physician," when used in connection with the performance of any function or action, means
(1) A doctor of medicine or osteopathy legally authorized to practice medicine and surgery by the State in which he performs such function or action (including a physician within the meaning of section 1101(a)(7)),
(2) A doctor of dental surgery or of dental medicine who is legally authorized to practice dentistry by the State in which he performs such function and who is acting within the scopeof his license when he performs such functions,
(3) A doctor of podiatric medicine for the purposes of subsections (k), (m), (p)(1), and (s) of this section and sections 1814(a), 1832(a)(2)(F)(ii), and 1835 but only with respect to functions which he is legally authorized to perform as such by the State in which he performs them,
(4) A doctor of optometry, but only for purposes of subsection (p)(1) with respect to the provision of items or services described in subsection (s) which he is legally authorized to perform as a doctor of optometry by the State in which he performs them, or
(5) A chiropractor who is licensed as such by the State (or in a State which does not license chiropractors as such, is legally authorized to perform the services of a chiropractor in the jurisdiction in which he performs such services), and who meets uniform minimum standards promulgated by the Secretary, but only for the purpose of sections 1861(s)(1) and 1861(s)(2)(A) and only with respect to treatment by means of manual manipulation of the spine (to correct a subluxation) which he is legally authorized to perform by the State or jurisdiction in which such treatment is provided. For the purposes of section 1862(a)(4) and subject to the limitations and conditions provided in the previous sentence, such term includes a doctor of one of the arts, specified in such previous sentence, legally authorized to practice such art in the country in which the inpatient hospital services (referred to in such section 1862(a)(4)) are furnished.

Privilege(s)
Authorization granted by the appropriate authority (for example, the governing body) to a practitioner to provide specific care, treatment, or services in the organization within well-defined limits

Primary Source Verification
Verification of an individual practitioner's reported qualifications by the original source or an approved agent of that source. Methods for conducting primary source verification of credentials include direct correspondence, documented telephone verification, secure electronic verification from the original qualification source.

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Quality Improvement Organization (QIO)
CMS contracts with one organization in each state, as well as the District of Columbia, Puerto Rico, and the U.S. Virgin Islands to serve as that state/jurisdiction's Quality Improvement Organization (QIO) contractor. QIOs are private, mostly not-for-profit organizations, which are staffed by professionals, mostly doctors and other health care professionals, who are trained to review medical care and help beneficiaries with complaints about the quality of care and to implement improvements in the quality of care available throughout the spectrum of care.

Restraint
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).

Scope of Services
A written document that outlines the range of clinical and patient care support services provided by the organization either directly or through the establishment of contractual agreements. This document is sometimes called the “plan for patient care”.

Seclusion
The involuntary confinement of a patient alone in a room or area from which the patient is physically prevented from leaving. Seclusion may only be used for the management of violent or self-destructive behavior.

Staff
As appropriate to their roles and responsibilities, all people who provide care, treatment, or services in the organization, including those receiving pay (for example, permanent, temporary, part-time personnel, as well as contract employees), volunteers and health profession students. The definition of staff does not include licensed independent practitioners who are not paid staff or who are not contract employees.

Sterilization
A process that destroys or eliminates all forms of microbial life and is carried out in health-care facilities by physical or chemical methods. Steam under pressure, dry heat, ethylene oxide gas, hydrogen peroxide gas plasma, and liquid chemicals are the principal sterilizing agents used in health-care facilities.

- Immediate Use Steam Sterilization (IUSS)
  The process for steam sterilizing an instrument that is needed immediately, not intended to be stored for later use, and which allows for minimal or no drying after the sterilization cycle.
  “Immediate use” is broadly defined as the shortest possible time between a sterilized item’s removal from the sterilizer and its aseptic transfer to the sterile field. Immediacy implies that a sterilized item is used during the procedure for which it was sterilized and in a manner that minimizes its exposure to air and other environmental contaminants. A sterilized item intended for immediate use is not stored for future use, nor held from one case to another.

Stored Emergency Power Supply Systems (SEPSS)
Systems that automatically supply illumination or power to critical areas and equipment essential for safety to human life. Included are systems that supply emergency power for such functions as illumination for safe exiting, ventilation where it is essential to maintain life, fire detection and alarm systems, public safety communications systems, and processes where the current interruption would produce serious life safety or health hazards to patients, residents, individuals served, the public, or staff.

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Supervision
Overseeing the care, treatment, or service provided by a healthcare practitioner by another healthcare practitioner

- Direct Supervision
  Care and/or treatment rendered while the supervising practitioner is at the patient's bedside or within the department and immediately available to respond to the patient's bedside.

- General Supervision
  Care and/or treatment rendered while the supervising practitioner is within the facility and immediately available to respond to the patient's bedside.

Surgery
Structurally altering the human body by the incision or destruction of tissues and is part of the practice of medicine. Surgery also is the diagnostic or therapeutic treatment of conditions or disease processes by any instruments causing localized alteration or transposition of live human tissue which include lasers, ultrasound, ionizing radiation, scalpels, probes, and needles. – American College of Surgeons

Telemedicine
The use of health care information exchanged from one site to another via electronic communications for the health and education of the patient or health care provider, and for the purpose of improving patient care, treatment, or services.

- Telemedicine Distant Site
  The site at which the practitioner providing the professional service is located

- Telemedicine Originating Site
  The site at which the patient is located at the time the service is provided

Translation
Rendition of a written document in which the translator comprehends the source language and can write comprehensively in the target language to convey the meaning intended in the source language.

Waived Testing
Tests that meet the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) requirements for waived tests and are cleared by the Food and Drug Administration for home use. These tests employ methodologies that are so simple and accurate that the likelihood of erroneous results is negligible, or they pose no risk of harm to the patient, resident, or individual served if the test is performed incorrectly. See also Clinical Laboratory Improvement Amendments of 1988 (CLIA '88).

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