The CMS Compliance Crosswalk

2024 Edition


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Introduction

The Centers for Medicare & Medicaid Services (CMS) mandates that states ensure that all non-accredited, non-deemed hospitals and critical access hospitals (CAH) are surveyed at least every three years and targeted surveys occur for not fewer than 5% of all hospitals and CAHs in the state. Given the differences in the survey process (e.g., state inspections versus accreditation surveys/consultations), there is good reason for hospitals to consider accreditation by a deemed-status accreditor.

Any hospital that receives Medicare or Medicaid reimbursement for services must meet the federal requirements outlined by CMS, titled the *Conditions of Participation* (*CoP*). In addition, most hospitals and healthcare systems participate in a voluntary survey process through an accreditation agency, such as The Joint Commission, ACHC, DNV, or CIHQ.

As hospitals work to protect their citizens' health, safety, and welfare, many state agencies are also reporting increases in consumer complaints, adding more justification to increase survey activity.

Accrediting organizations (AO) feel the pressure of CMS. Hospitals may encounter an additional survey because, in approximately 3%–5% of all hospitals, CMS will perform surveys after the AO survey in hospitals to ensure they meet CMS' quality and safety standards. CMS also decided not to accept any accreditation decisions or recommendations from an AO while the provider or supplier is under the jurisdiction of a state agency. Regardless of the accreditor used, it is imperative to comply with the CMS *CoP*s and interpretive guidelines.

Organizations must maintain a state of readiness and ongoing compliance to achieve successful patient care outcomes and upcoming survey activities. Doing so can seem overwhelming when an organization has surveys for which to prepare.

To help healthcare organizations maintain preparations for surveys, this book:

- Outlines and provides tools to assist in assessing compliance and survey readiness
- Helps hospitals understand the requirements and relationships of accrediting organizations' standards to the CMS *CoP*s
- Compares the similarities and differences between requirements
- Provides survey tips for compliance
- Identifies documents or processes that are already in place for survey preparation without duplicating efforts

The main building blocks for survey readiness included throughout this publication are:

1. The CMS *CoP*s, taken from the *State Operations Manual (SOM), Appendix A—Survey Protocol, Regulations, and Interpretive Guidelines for Hospitals* (Revision 216, 7/21/2023) https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_a_hospitals.pdf
2. The CMS Emergency Preparedness *CoP* (§482.15), taken from the *SOM, Appendix Z—Emergency Preparedness for All Provider and Certified Supplier Types—Interpretive Guidance* (Rev 204, Issued: 04/16/2021) https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertEmergPrep/Downloads/Appendix-Z-EP-SOM-February-2019.pdf

3. Related standards from multiple accrediting agencies, including the Center for Improvement in Healthcare Quality (CIHQ), the National Integrated Accreditation for Healthcare Organizations/DNV Healthcare USA (NIAHO/DNV), Accreditation Commission for Health Care (ACHC), and The Joint Commission (TJC)
4. A summary and analysis section outlining the similarities and differences between CMS and these accrediting agencies' standards
5. Other survey tips and recommendations for helpful documents to have available where applicable
6. A variety of tools and resources to assist with survey preparation and readiness (located in the appendixes)

To show similarities, the following is a general table of contents comparison between CMS, TJC, NIAHO/DNV, CIHQ, and ACHC.

CMS	The Joint Commission	DNV	CIHQ	ACHC
Compliance with Federal, State, and Local Law §482.11	Accreditation Participation Requirements and Leadership	Governing Body Legal Responsibility	Governance & Leadership Compliance to Law & Regulation	Administration of the Organizational Environment
Governing Body §482.12	Leadership	Governing Body Chief Executive Officer (CEO)	Governance & Leadership Establishment of a Governing Body	Administration of the Organizational Environment
Patient Rights §482.13	Rights and Responsibilities of the Individual	Patient Rights	Patient Rights	Patient Rights and Safety
Emergency Preparedness §482.15	Emergency Management	Emergency Preparedness	Emergency Preparedness	Emergency Management
Quality Assessment and Performance Improvement (QAPI) Program §482.21	Performance Improvement	Quality Assessment and Performance Improvement Program	Quality Assessment/ Performance Improvement Program; Targeted Patient Quality & Safety Practices	Quality Assessment & Performance Improvement
Medical Staff §482.22	Medical Staff	Medical Staff	Establishment of a Medical Staff	Medical Staff

CMS	The Joint Commission	DNV	CIHQ	ACHC
Nursing Services §482.23	Nursing and Medication Management	Nursing Services and Medication Management	Nursing Services	Nursing Services
Medical Record Services §482.24	Information Management and Record of Care	Medical Record Services	Medical Record Services	Medical Records
Pharmaceutical Services §482.25	Medication Management	Medication Management	Medication Management	Pharmacy Services/ Medication Use
Radiological Services §482.26	Provision of Care, Treatment, and Services; Medical Staff; Performance Improvement; Medical Records; and Human Resources	Medical Imaging	Provision of Radiology Services	Diagnostic Radiology and Radiation Therapy Services
Laboratory Services §482.27	Waived Testing	Laboratory Services	Provision of Laboratory Services	Laboratory Services
Food and Dietetic Services §482.28	Provision of Care, Treatment, and Services, Leadership, and human Resources	Dietary Services	Provision of Dietary Services	Nutritional Services
Utilization Review §482.30	Utilization Review	Utilization Review	Utilization Review	Utilization Review
Physical Environment §482.41	Environment of Care and Life Safety	Physical Environment and Hazardous Material Management	Managing the Care Environment	Physical Environment

CMS	The Joint Commission	DNV	CIHQ	ACHC
Infection Prevention and Control and Antibiotic Stewardship Programs §482.42	Infection Prevention and Control; Medication Management	Infection Prevention and Control	Infection Prevention and Control	Infection Prevention and Control/ Antibiotic Stewardship
Discharge Planning §482.43	Provision of Care, Treatment, and Services, Medical Staff, Performance Improvement; Medical Records; and Human Resources	Discharge Planning	Discharge Planning Services	Discharge Planning
Organ, Tissue, and Eye Procurement §482.45	Transplant Safety	Organ, Tissue, and Eye Procurement	Organ, Tissue, and Eye Procurement	Organ Procurement
Surgical Services §482.51	Provision of Care, Treatment, and Services; Medical Staff; Performance Improvement; Medical Records; and Human Resources	Surgical Services	Provision of Operative & Invasive Services	Surgical Services
Anesthesia Services §482.52	Environment of Care; National Patient Safety Goals; Leadership; Record of Care; Provision of Care	Anesthesia Services	Anesthesia Services	Anesthesia Services
Nuclear Medicine Services §482.53	Environment of Care; National Patient Safety Goals; Leadership; Record of Care; Provision of Care; Human Resources	Nuclear Medicine Services	Organization of Nuclear Medicine Services	Nuclear Medicine

CMS	The Joint Commission	DNV	CIHQ	ACHC
Outpatient Services §482.54	Environment of Care, Record of Care Provision of Care, Rights and Responsibilities of the Individual, Transplant Services	Outpatient Services	Outpatient Services	Outpatient Services
Emergency Services §482.55	Emergency Management; Leadership; Medical Staff; Provision of Care	Emergency Department (ED)	Emergency Services	Emergency Services
Rehabilitation Services §482.56	Human Resources, Infection Control, Leadership, Life Safety, Medical Staff, Provisions of Care, Records of Care	Rehabilitation Services	Rehabilitation Services	Physical Rehabilitation Services
Respiratory Services §482.57	Environment of Care, Infection Control, Leadership, Provision of Care, Performance Improvement	Respiratory Care Services	Respiratory Services	Respiratory Care
Note: Medicare *certifies* healthcare organizations, whereas accreditation organizations *accredit* healthcare organizations. Accreditation from TJC, DNV, ACHC, CIHQ, or Medicare certification qualifies an organization to participate in the Medicare program.				

Survey Procedures

In addition, there are similarities and differences in how the various agencies survey, as outlined in the following sections.

Centers for Medicare and Medicaid Services (CMS)

CMS is part of the U.S. Department of Health and Human Services and is responsible for issuing the *CoP*s as standards of care. Surveys are at no cost and occur annually unless an organization has deemed status.

CMS surveys are typically conducted by surveyors from the state health department agency and focus much more closely on patient care documentation and the corresponding policies and procedures that drive care implementation. Surveyors tend to be less interactive with staff and physicians; they look at patient records documentation for the absence of compliance with relevant *CoP*s and will turn to staff to ask why something was not documented or why a process deviated from stated policy. They typically spend less time on the patient care units than AO surveyors do.

Visit this site to see CMS' *State Operations Manual, Appendix A* Survey Protocol, Regulations and Interpretive Guidelines for Hospitals:

https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_a_hospitals.pdf

The Joint Commission (TJC)

Established in 1951, The Joint Commission is the oldest of the accrediting agencies. Standards were developed in the early 1900s when the American College of Surgeons created its hospital standardization program, the precursor to today's survey process. The Joint Commission is also the most well-known of the accrediting bodies. In addition, it fulfills regulatory and payer requirements and provides education and guidance. Survey cost can be expensive. The Joint Commission has proprietary standards (e.g., National Patient Safety Goals) as well as prescriptive standards, along with complex scoring methods. Over the years, The Joint Commission has become more aligned with CMS *CoP*s, but some differences exist. Using hospital staff's responses to questions to guide further queries, The Joint Commission's surveyors are more interactive than those from CMS. Documentation is examined within the context of validation of elements of performance (EP). The response of clinical staff and physicians can keep The Joint Commission's surveyors from delving too deeply into patient records. Policies and procedures, medical staff bylaws, and other documents are reviewed against actual practice. Additionally, surveyors use tracer methodology to identify areas of noncompliance.

DNV Healthcare

DNV Healthcare USA Inc. is the fastest growing hospital accreditation organization in the United States. DNV received deeming status for acute care hospitals in 2008 and is now the second largest CMS approved national accreditation organization. Since then, DNV has added deemed accreditation programs for critical access and psychiatric hospitals. In addition, there are several certification and Centers of Excellence programs available. The DNV Accreditation program incorporates ISO 9001:2015 Quality Management Standards into the National Integrated Accreditation for Healthcare Organizations/ (NIAHO®) Accreditation Standards as a condition of accreditation. DNV aligns their standards closely to CMS *CoP*s and are collaborative partners with their hospitals working together with them to improve the safety and quality of patient care. The survey process includes tracers, process reviews, record review, observation and interviews of staff, patients, and their families.

Accreditation Commission for Health Care (ACHC)

ACHC was founded to provide education and accreditation services to home care and home health providers and has added hospital, clinical laboratory, and ambulatory surgery center accreditation through a 2020 merger with the Health Facilities Accreditation Program (HFAP) in 2020.

Today, ACHC's 19 accreditation programs include nine approved by CMS with standards that align closely to *CoP*s/*CfC*s.

Non-deemed accreditation programs as well as specialty certifications and distinctions are created in consultation with industry experts to ensure relevance, value, and sustainable business practices. The organization's mission focuses on a superior customer experience. With the specific needs of individual healthcare settings in mind, ACHC takes an educational approach to improve the quality and safety of patient care and the organization's operational efficiency. ACHC maintains its quality management system that is certified to ISO 9001:2015.

Center for Improvement in Healthcare Quality (CIHQ)

CIHQ is the newest accrediting body and was granted deeming authority in July 2013. A former consulting company for accreditation and regulatory compliance support, CIHQ can accredit acute care hospitals, critical access hospitals, and psychiatric hospitals. Almost 95% of CIHQ's standards align with CMS CoPs. CIHQ performs two types of surveys. The first is a full survey, which consists of either an initial survey or a reaccreditation survey. The initial survey typically occurs four months after receiving the application. The recertification survey occurs no later than 36 months from the date of the last full survey unless there is an agreement in place. Focused surveys are hospital-specific except for the extension survey, which occurs six months from the receipt of notification.

State Health Department Agencies

If a hospital does not select an agency with deemed status to perform its triannual survey, the state agency will. All agencies, including the state, use the *Medicare State Operations Manual* to determine compliance with the standards and certification to participate in Medicare and Medicaid programs.

The bottom line is that all healthcare organizations undergo surveys at some point. The key is to understand and educate staff about the changes while at the same time remaining flexible in managing the changes and processes. Many similarities between CMS and the various accrediting agencies exist. Hopefully, by understanding these similarities and nuances, ongoing survey preparation can be efficient and help your organization achieve excellent results. The choice is yours! After all, the goal of all participants—the hospitals, regulatory agencies, and patients—is high-quality care and service that meets or exceeds standards and expectations.

Accreditation Organizations' Contact Information

Accreditation Commission for Health Care (ACHC)
139 Weston Oaks Ct.
Cary, NC 27513
Phone: 855-937-2242
Website: *www.achc.org*

Center for Improvement in Healthcare Quality (CIHQ)
P.O. Box 3620
McKinney, TX 75070
Phone: 866-324-5080
Fax: 805-934-8588
Website: *www.cihq.org*

Centers for Medicare & Medicaid Services (CMS)
7500 Security Blvd.
Baltimore, MD 21244
Phone: 410-786-3000
Website: *www.cms.gov*

DNV Healthcare USA
1400 Ravello Drive
Katy, TX 77449
Phone: 281-396-1000
Website: *www.DNVhealthcare.com*

The Joint Commission (TJC)
One Renaissance Blvd.
Oakbrook Terrace, IL 60181
Phone: 630-792-5000
Fax: 630-792-5005
Website: *www.jointcommission.org*

State Health Departments
See Appendix D

Updates from the State Operations Manual Appendix A – Survey Protocol, Regulations, and Interpretive Guidelines for Hospitals (Rev. 216, 07-21-2023)

A-0144

There are a few changes to this tag under the Interpretive Guidelines. The patient has the right to receive care in a safe setting (§482.13(c)(2)). They specifically called out recommendations in the standard care for people with suicide risks. The information comes from the 2018 National Strategy Report. To obtain a copy of the full report, visit: *theactionalliance.org*. The tag also clarifies that hospitals should implement a patient risk assessment strategy and an environmental safety risk strategy. It is up to individual hospitals to implement strategies that are appropriate. For additional information on this Tag, go to pages 107 – 110 of the SOM Appendix A (cms.gov) and the *National Action Alliance for Suicide Prevention Transforming Health Systems Initiative Work Group. (2018)*

A-0154

§482.13 Standard is on Restraint and Seclusion. While all the data remains the same, the manual added several footnotes for reference.

The Joint Commission Updates

The Joint Commission's efforts to improve and clarify standards continue. The standards continue to be reviewed and revised to further align its standards with CMS requirements. The following information provides a brief synopsis of the main standard revisions beginning January 1, 2024:

- Renumbered Leadership Standard LD.04.03.08 as new National Patient Safety Goal 16, NPSG.16.01.01.
- Deleted the term licensed independent practitioner. The new name is licensed practitioner. In addition, a change to the requirement for licensed practitioners' evaluation time frames.
- Revised, consolidated, and/or deleted requirements to support the standards simplification project and to align with critical access hospitals as they related to its application for redeeming with CMS.
- Standard MM.05.01.07 has been revised related to medication compounding, including a document requirement.
- Added a new requirement for hospitals to comply with the Health Care Facilities Code (2012 edition) EC.01.01.01, EP.12.

Refer to The Joint Commission *Perspectives* (available with a subscription) and prepublication standards (available on the Joint Commission website) for a full description of standard updates. If you do not have a subscription, you can stay abreast of the revisions by checking the Joint Commission website using the following link: https://www.jointcommission.org/standards_information/hap_requirements.aspx.

You can also sign up for News and Alerts located on The Joint Commission's website or click on the following link: E-Alerts | The Joint Commission.

DNV Healthcare USA Updates

There were two revisions to the NIAHO® Critical Access Hospital and Acute Care Hospital Standards in 2023: Rev 23-0. (Effective 7/17/2023 and 9/5/2023 respectively.) Changes include:

- Replaced “QLP” with “LP”
- References to Chapter and Standard Requirement changed from use of commas: QM.1, SR.1 to use of parentheses: QM.1 (SR.1)
- References to "accepted evidence-based professionally recognized standards and guidelines" and related terms have been updated to "nationally recognized standards of practice and guidelines"
- Several chapters have been reorganized to aid in ease of navigation
- Renumbered some Standard Requirements (SR) based on the insertion of new requirements
- Changed/Renamed GB.4 from “Agreements” to “Required Agreements”
- To be consistent with ISO 9001, GB.5 changed verbiage from “contracted services” to “external provider”
- What was “as appropriate” for the Institutional Plan and Budget must now be reviewed and updated annually.

Both manuals were revised to enhance alignment with CMS requirements.

ACHC Updates

Effective June 5, 2023, ACHC dropped the requirement for COVID-19 vaccination of hospital staff to remain aligned with CMS requirements. The vaccine remains a recommendation, but documentation of employee vaccination status is limited to those vaccines required by federal or relevant state law or hospital policy.

On March 15, 2023, ACHC’s laboratory accreditation program received renewal of its deeming authority under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) through March 27, 2029.

On September 6, 2023, CMS renewed ACHC’s deeming authority for acute care hospitals through September 25, 2027.

CIHQ Updates

On May 22, 2023, CIHQ received the final approval from CMS as an Accreditation Organization for Acute Psychiatric Hospitals. The final decision to accept the application was published in the Federal Register. The next step is an observation survey (date TBD).

On May 22, 2023, CMS approved the CIHQ Critical Access Accreditation Program.

On the CIHQ website, you can download several documents to assist in preparing for a survey, including: accreditation policies for hospitals, hospital accreditation standards, and a survey activity guide for hospitals that participate in Medicare. The most up-to-date guide was released in June 2023. You can also find a guide for non-participating hospitals.

§482.2 Provision of Emergency Services by Nonparticipating Hospitals		
Tag #	CMS *CoP* (2023)	CMS Interpretive Guidelines and Survey Procedures
A-0001	Provision of Emergency Services by Nonparticipating Hospitals (a) The services of an institution that does not have an agreement to participate in the Medicare program may, nevertheless, be reimbursed under the program if— (1) The services are emergency services; and (2) The institution meets the requirements of sections 1861(e)(1) through (5) and (7) of the Act. Rules applicable to emergency services furnished by non-participating hospitals are outlined in subpart G of part 424 of this chapter. (b) Section 440.170(e) of this chapter defines emergency hospital services for purposes of Medicaid reimbursement.	*See Interpretive Guidelines for §482.2* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.2 -- Provision of emergency services by nonparticipating hospitals.*
A-0008	Basis and scope. (a) Statutory basis. (1) Section 1861(e) of the [Social Security] Act provides that— (i) Hospitals participating in Medicare must meet certain specified requirements; and (ii) The Secretary may impose additional requirements if they are found necessary in the interest of the health and safety of the individuals who have furnished services in hospitals. (b) Scope. Except as provided in subpart A of part 488 of this chapter, the provisions of this part serve as the basis of survey activities to determine whether a hospital qualifies for a provider agreement under Medicare and Medicaid.	*See Interpretive Guidelines for §482.1(a)(1)* *See Survey Procedures for §482.1(a)(1)* *SOM Appendix A (cms.gov)* *https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-G/part-488/subpart-A*

Related TJC Standards • LD.04.04.01, EP 2
Related DNV Standards • GB.1 (SR.1-SR.1j) and Interpretive Guidelines
Related ACHC Standards • 02.00.00
Related CIHQ Standards • GL-01

§482.11 *CoP*: Compliance With Federal, State, and Local Laws		
Tag #	CMS *CoP* (2023)	CMS Interpretive Guidelines and Survey Procedures
A-0020	*CoP*: Compliance With Federal, State, and Local Laws	*See Interpretive Guidelines for §482.11* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.11 -- Condition of participation: Compliance with Federal, State and local laws.*
A-0021	(a) The hospital must comply with applicable federal laws related to the health and safety of patients.	*See Survey Procedures for §482.11(a)* *SOM Appendix A (cms.gov)*
A-0022	(b) The hospital must be — (1) Licensed; or (2) Approved as meeting standards for licensing established by the agency of the state or locality responsible for licensing hospitals	*See Interpretive Guidelines for §482.11(b)* *See Survey Procedures for §482.11(b)* *SOM Appendix A (cms.gov)*
A-0023	(c) The hospital must ensure that personnel are licensed or meet other applicable standards required by state or local laws.	*See Interpretive Guidelines for §482.11(c)* *See Survey Procedures for §482.11(c)* *SOM Appendix A (cms.gov)*

Related TJC Standards

Leadership:

- LD.04.01.01, EP 1, 2

Human Resources:

- HR.01.01.01, EP 2, 3

Medical Staff:

- MS.06.01.03, EP 6
- MS.06.01.05, EP 1, 2, 8

Related DNV Standards

Governing Body:

- GB.2 Introduction
- GB.2 (SR.1)
- GB.2 (SR.1a)
- GB.2 (SR.1b)
- GB.2 (SR.1d)

Related ACHC Standards

Administration of the Organizational Environment:

- 01.00.00
- 01.00.02
- 01.00.03
- 01.00.04

Related CIHQ Standards

Compliance to Law and Regulation:

- GL-02

Provision of a Safe Environment:

- CE-3

Verification of Licensure and Certification:

- HR-1

Appointment and Reappointment to the Medical Staff:

- MS-4

§482.11 (a–c) *CoP* Analysis/Guidelines

All accreditors are similar when it comes to compliance with federal, state, and local laws. All are looking to see that the hospital and all departments that require a license or certification have a current license or certification and meet the licensure standards for the state in which the hospital resides. All are looking to see that hospital personnel required to be licensed have a current license to practice; these licensure laws vary from state to state. Positions needing a license could include but are not limited to medical doctors (MD), doctors of osteopathy (DO), RN, physician assistants (PA), occupational therapists (OT), physical therapists (PT), speech-language pathologists (SLP), respiratory therapists (RT), registered dietitians (RD), and various procedural staff. This includes nonemployees.

Not all states license all types of care providers; there are several national registrations (i.e., for RDs and registered cardiovascular invasive specialists) that may not be licensed in their states, so it is important to understand and distinguish when differences exist. If states do not license these workers, it will be important to investigate whether there is a state regulation regarding medical delegation and whether an assessment was performed to validate that there is compliance with that regulation. All regulators require primary source verification of licensure. Criminal background checks may also be required as part of the onboarding process, dependent on state law. NIAHO/DNV requires that a process be in place to verify licensure and expirations and that the data are shared with the quality assessment and performance improvement (QAPI) structure or HR team when such activity is completed at the departmental level. Verification of qualifications, training/education, and permits should be checked.

Survey Tips:

- If there is not an electronic mechanism for monitoring renewal of licenses, create a listing of all hospital and departmental licenses (required and voluntary) and ensure responsibility for timely renewal.
- Have HR and managers maintain proof of primary source verification of current licensure (including managers, employees, non-employees, and licensed practitioners [LP]).
- Ensure nonemployee contracts for workers who enter patient care areas have requirements for occupational health screening and background checks that are like those for employees and that primary source verification of licensure is performed for all direct care providers.
- Review medical staff files to verify that credential information is current.
- Verify that workers who are not licensed in your state are operating under state regulatory requirements.
- CMS requires deemed status accreditors to notify the agency when deemed status has been removed for condition-level noncompliance.
- Review the federal, state, and local surveys, inspections, and investigations that have occurred in the hospital since the last accreditation survey. Be prepared to answer questions related to the health and safety of patients.
- Confirm all required corrective actions are complete, successful in that the necessary corrections have been made to be compliant. If the non-compliance was a reportable event, review the report including, corrective actions, and outcomes.
- Verify all required licenses are current throughout the hospital (i.e., pharmacy, laboratory, etc.)

Suggested Documents:

- Hospital's state license, and federal certification, certificate, and accreditation certificate; hospital Drug Enforcement Administration (DEA) license, Clinical Laboratory Improvement Amendments (CLIA) license, and radiotherapeutic and nuclear medicine licensure/certifications in related departments; another voluntary licensure (i.e., trauma designation, psych designation, neonatal intensive care unit [NICU] designation)
- Personnel files/credentials information (paper or electronic) with proof of primary source verification
- Bylaws regarding credentialing and privileging
- Policies and procedures (P&Ps) regarding volunteer LPs and non-LPs during a disaster

§482.12 *CoP*: Governing Body		
Tag #	CMS *CoP* (2023)	CMS Interpretive Guidelines and Survey Procedures
A-0043	There must be an effective governing body that is legally responsible for the conduct of the hospital. If a hospital does not have an organized governing body, the persons legally responsible for the conduct of the hospital must carry out the functions specified in this part that pertain to the governing body.	*See Interpretive Guidelines for §482.12* *See Survey Procedures for §482.12* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.12 -- Condition of participation: Governing body.*
A-0044	(a) Standard: Medical Staff. —The governing body must:	*See Interpretive Guidelines for §482.12(a)* *SOM Appendix A (cms.gov)*
A-0045	[The governing body must:] (1) Determine, in accordance with State law, which categories of practitioners are eligible candidates for appointment to the medical staff;	*See Interpretive Guidelines for §482.12(a)(1)* *See Survey Procedures for §482.12(a)(1)* *SOM Appendix A (cms.gov)*
A-0046	[The governing body must:] (2) Appoint members of the medical staff after considering the recommendations of the existing members of the medical staff;	*See Interpretive Guidelines for §482.12(a)(2)* *See Survey Procedures for §482.12(a)(2)* *SOM Appendix A (cms.gov)*
A-0047	[The governing body must:] (3) Assure that the medical staff has bylaws;	*See Interpretive Guidelines for §482.12(a)(3)* *See Survey Procedures for §482.12(a)(3)* *SOM Appendix A (cms.gov)*

A-0048	[The governing body must:] (4) Approve medical staff bylaws and other medical staff rules and regulations;	*See Interpretive Guidelines for §482.12(a)(4)* *See Survey Procedures for §482.12(a)(4)* *SOM Appendix A (cms.gov)*
A-0049	[The governing body must:] (5) Ensure that the medical staff is accountable to the governing body for the quality of care provided to patients;	*See Interpretive Guidelines for §482.12(a)(5)* *See Survey Procedures for §482.12(a)(5)* *SOM Appendix A (cms.gov)*
A-0050	[The governing body must:] (6) Ensure the criteria for selection are individual character, competence, training, experience, and judgment	*See Interpretive Guidelines for §482.12(a)(6)* *See Survey Procedures for §482.12(a)(6)* *SOM Appendix A (cms.gov)*
A-0051	[The governing body must:] (7) Ensure that under no circumstances is the accordance of staff membership or professional privileges in the hospital dependent solely upon certification, fellowship, or membership in a specialty body or society.	*See Interpretive Guidelines for §482.12(a)(7)* *See Survey Procedures for §482.12(a)(7)* *SOM Appendix A (cms.gov)*
A-0052	[The governing body must:] (8) Ensure that, when telemedicine services are furnished to the hospital's patients through an agreement with a distant-site hospital, the agreement is written and that it specifies that it is the responsibility of the governing body of the distant-site hospital to meet the requirements in paragraphs (a)(1) through (a)(7) of this section with regard to the distant- site hospital's physicians and practitioners providing telemedicine services. The governing body of the hospital whose patients are receiving the telemedicine services may, in accordance with §482.22(a)(3) of this part, grant privileges based on its medical staff recommendations that rely on information provided by the distant-site hospital.	*See Interpretive Guidelines for §482.12(a)(8) & (a)(9)* *See Survey Procedures for §482.12(a)(8) & (a)(9)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.12 -- Condition of participation: Governing body.*

	(9) Ensure that when telemedicine services are furnished to the hospital's patients through an agreement with a distant-site telemedicine entity, the written agreement specifies that the distant-site telemedicine entity is a contractor of services to the hospital and as such, in accordance with §482.12(e), furnishes the contracted services in a manner that permits the hospital to comply with all applicable conditions of participation for the contracted services, including, but not limited to, the requirements in paragraphs (a)(1) through (a)(7) of this section with regard to the distant-site telemedicine entity's physicians and practitioners providing telemedicine services. The governing body of the hospital whose patients are receiving the telemedicine services may, in accordance with §482.22(a)(4) of this part, grant privileges to physicians and practitioners employed by the distant-site telemedicine entity based on such hospital's medical staff recommendations; such staff recommendations may rely on information provided by the distant-site telemedicine entity.	
A-0053	[The governing body must:] (10) 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 multihospital system using a single governing body, the single multihospital 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 of this paragraph (a).	*See Interpretive Guidelines for §482.12(a)(10)* *See Survey Procedures for §482.12(a)(10)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.12 -- Condition of participation: Governing body.*

Related TJC Standards

Leadership:

- LD.01.01.01, EP 1, 2
- LD.01.03.01, EP 1, 2, 12, 13
- LD.01.05.01, EP 6

Medical Staff:

- MS.01.01.01, EP 1, 2, 7, 12, 13
- MS.02.01.01, EP 8, 11
- MS.04.03.09, EP 2 – 6, 23
- MS.06.01.03, EP 6
- MS.06.01.05, EP 2, 7 – 9
- MS.06.01.07, EP 2, 8
- MS.07.01.01, EP 1, 5

Related DNV Standards

Legal Responsibility:

- GB.2, (SR.1c)

Eligibility:

- MS.2 (SR.2)

Governing Body Role:

- MS.4 (SR.1), (SR.3)

Medical Staff Bylaws

- MS.3 (SR.1), (SR.3)

Organization, Accountability, and Responsibility

- MS.1 (SR.1), (SR.3)

Telemedicine

- MS.15 (SR.1), (SR.1a), (SR.1a(1)), 15 (SR.1a(2)), (SR.1a(3)), (SR.1a(4)), (SR.1a(5)), (SR.1a(6)), (SR.1a(7))
- MS.15 (SR.2), (SR.2a), (SR.2a(1)), (SR.2a(2)), (SR.2a(3)), (SR.2a(4)), (SR.2a(5)), (SR.2a(6)), (SR.2a (7))
- MS.15 (SR.1b), (SR.2b)

Related ACHC Standards

Administration of the Organization:

- 01.01.00
- 01.01.01
- 01.01.02
- 01.01.03
- 01.01.04
- 01.01.05
- 01.01.06
- 01.01.07
- 01.01.08
- 01.01.10

Related CIHQ Standards:

Establishment of a Governing Body:

- GL-1

Leadership Responsibilities:

- GL-4

Establishment of a Medical Staff:

- GL-3

Provision of Telemedicine Services by a Distant Site:

- MS-9

§482.12 (a) *CoP* Analysis/Guidelines

All hospitals must have a governing body. CMS allows, but does not require, a multihospital system to operate with a single governing board. CMS notes that a factor to consider when deciding whether to use a system governing body would be the impact on the Medicare payment status of hospitals within hospitals and hospital satellites.

Although CMS allows multihospital system governance, it also specifies that each hospital must independently demonstrate compliance with the *CoP*s. CMS also outlines that departments of separately certified hospitals with one system governing body cannot be operationally integrated. This means that departments cannot be shared across the system. Several *CoP*s specifically state that each certified hospital must have its own of the following departments (if provided):

- Quality Assessment Performance Improvement (QAPI)* program
- Nursing
- Medical Records
- Pharmacy
- Surgical Services
- Nuclear Medicine
- Outpatient Services**
- Emergency Services**
- Rehabilitation Services
- Respiratory Services

**Specific to QAPI: "Likewise, although the system may choose to operate a quality assessment/performance improvement (QAPI) program at the system level which standardizes indicators measured across system hospitals, each separately certified hospital in the system must have a QAPI program that is specific to that hospital. This is required not only to demonstrate compliance, but also for the governing body to function effectively since reviewing QAPI program results only at the system level would make it difficult for the governing body to identify and act upon problems that are localized to one hospital" according to the text of §482.12.*

***Outpatient and Emergency Services must be integrated with Inpatient Services.*

Survey Tips:

- Review hospital board/governing body bylaws and/or responsibility matrix to ensure aspects critical to their role are outlined (e.g., responsibility for medical staff bylaws and credentialing, QAPI, Emergency Medical Treatment and Active Labor Act of 1986 [EMTALA], grievance process, and contracted services).
- Review governing body meeting minutes for documentation on approval/denial of medical staff recommendations and actions. There must be written documentation that identifies the individual or individuals that are legally responsible for the conduct of the hospital operations.
- Review medical staff bylaws/P&Ps and whether the medical staff accepted changes or revisions at large with final approval by the governing body.
- Make governing body meeting minutes available to the surveyors. Surveyors want to ensure the hospital is analyzing quality indicators, adverse patient events, medical errors, performance improvement projects, and if a plan of correction is created if required. If a plan of correction is created, the hospital analyzes the cause and implements preventative actions to mitigate future events.
- Review credentials files to verify the information is up to date and complete and that criteria for selection apply to the discipline and meet minimum components defined by CMS and the accreditor. Ensure that privileges comply with the scope of practice laws and are in accordance with medical staff bylaws, rules, and regulations.
- Review contract for telemedicine privileges if using distant-site information.
- Review medical staff bylaws if using distant-site information for telemedicine providers.
- If working in a multihospital system and staff from other entities within the system are floating in:
  - » Evaluate whether staff working are wearing the correct name badge for the entity being floated to.
  - » Ensure resources shared are properly allocated (i.e., review schedules and verify that their hours are appropriately charged).
  - » Evaluate whether floating staff members are oriented to the hospital and departments served.
  - » Evaluate if facility-specific job descriptions exist and, if so, floating staff members have signed the job descriptions for those facilities.
  - » Ensure floating staff members are appropriately evaluated.

Suggested Documents:

- Hospital/governing body bylaws and/or responsibility matrix outlining hospital board responsibilities
- Medical staff bylaws/P&Ps and organizational chart
- List of governing body members
- Governing body meeting minutes
- List of medical staff executive committee members and minutes
- Credentials files/medical staff privileges
- Listing of contract services agreements, contractor evaluations, and approvals

§482.12 *CoP*: Governing Body

Tag #	CMS *CoP* (2023)	CMS Interpretive Guidelines and Survey Procedures
A-0057	**(b) Standard: Chief Executive Officer** —The governing body must appoint a chief executive officer who is responsible for managing the hospital.	*See Interpretive Guidelines for §482.12(b)* *See Survey Procedures for §482.12(b)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.12 -- Condition of participation: Governing body.*

Related Joint Commission Standard

Leadership:

- LD.01.03.01, EP 4

Related DNV Standard

Chief Executive Officer:

- CE.1 (SR.1)

Related ACHC Standard

Administration of the Organizational Environment:

- 01.01.11

Related CIHQ Standard

Selection of a Chief Executive Officer:

- GL-5

§482.12 (b) *CoP* Analysis/Guidelines

The governing body must appoint one chief executive officer (CEO) responsible for managing the entire hospital.

Survey Tips:

- Verify that the hospital has only one CEO or the entire hospital
- Verify that the governing body has appointed the CEO
- Verify that the CEO is responsible for managing the entire hospital

Suggested Documents:

- Hospital bylaws
- Governing body meeting minutes showing appointment of CEO

Hospital/governing body bylaws and responsibility matrix outlining hospital board responsibilities

§482.12 *CoP*: Governing Body		
Tag #	CMS *CoP* (2023)	CMS Interpretive Guidelines and Survey Procedures
A-0063	**(c) Standard: Care of Patients—** In accordance with hospital policy, the governing body must ensure that the following requirements are met:	*SOM Appendix A (cms.gov)*
A-0064	[…the governing body must ensure that the following requirements are met:] (1) Every Medicare patient is under the care of: (i) A doctor of medicine or osteopathy. (This provision is not to be construed to limit the authority of a doctor of medicine or osteopathy to delegate tasks to other qualified healthcare personnel to the extent recognized under state law or a state's regulatory mechanism) (ii) A doctor of dental surgery or dental medicine who is legally authorized to practice dentistry by the state and who is acting within the scope of his or her license (iii) A doctor of podiatric medicine, but only with respect to functions which he or she is legally authorized by the state to perform (iv) A doctor of optometry who is legally authorized to practice optometry by the State in which he or she practices (v) A chiropractor who is licensed by the state or legally authorized to perform the services of a chiropractor, but only with respect to treatment by means of manual manipulation of the spine to correct a subluxation demonstrated by x-ray to exist; and (vi) A clinical psychologist as defined in §410.71 of this chapter, but only with respect to clinical psychologist services as defined in §410.71 of this chapter and only to the extent permitted by state law	*See Interpretive Guidelines for §482.12(c)(1)* *See Survey Procedures for §482.12(c)(1)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.12 -- Condition of participation: Governing body.*

A-0065	[…the governing body must ensure that the following requirements are met:] (2) Patients are admitted to the hospital only on the recommendation of a licensed practitioner permitted by the state to admit patients to a hospital.	*See Survey Procedures for §482.12(c)(2)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.12 -- Condition of participation: Governing body.*
A-0066	[…the governing body must ensure that the following requirements are met:] (2) *(cont.)* If a Medicare patient is admitted by a practitioner not specified in paragraph (c)(1) of this section, that patient is under the care of a Doctor of Medicine or osteopathy.	*See Interpretive Guidelines for §482.12(c)(2)* *See Survey Procedures for §482.12(c)(2)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.12 -- Condition of participation: Governing body.*
A-0067	[…the governing body must ensure that the following requirements are met:] (3) A Doctor of Medicine or osteopathy is on duty or on call at all times	*See Survey Procedures for §482.12(c)(3)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.12 -- Condition of participation: Governing body.*
A-0068	[…the governing body must ensure that the following requirements are met:] (4) A Doctor of Medicine or osteopathy is responsible for the care of each Medicare patient with respect to any medic or psychiatric problems that: (i) Is present on admission or develops during hospitalization (ii) Is not specifically within the scope of practice of a doctor of dental surgery, dental medicine, podiatric medicine, or optometry; a chiropractor; or clinical psychologist, as that scope is— (A) Defined by the medical staff; (B) Permitted by state law; and (C) Limited, under paragraph (c)	*See Interpretive Guidelines for §482.12(c)(4)* *See Survey Procedures for §482.12(c)(4)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.12 -- Condition of participation: Governing body.*

Related Joint Commission Standards

Medical Staff:

- MS.03.01.01, EP 2
- MS.03.01.03, EP 1, 3, 12, 13

Related DNV Standards

Qualifications:

- CE.1 (SR.1)

Admission Requirements:

- MS.11 Introduction
- MS.11 (SR.1)
- MS.11 (SR.1a-1f)
- MS.11 (SR.2)
- MS.11 (SR.3)
- MS.11 (SR.3a)
- MS.11 (SR.3b)

Related ACHC Standards

Administration of the Organizational Environment:

- 01.01.12
- 01.01.13
- 01.01.14
- 01.01.15

Related CIHQ Standards

Directing Medical Care of the Patient:

- GL-6

§482.12 (c) *CoP* Analysis/Guidelines

CMS hospital regulations permit LPs (e.g., doctors of dental surgery, podiatric medicine, optometry, chiropractors, nurse practitioners (NP), midwives) to admit patients to the hospital (if allowed by the state). CMS requires that all patients be under the care of a member of either the medical staff or a practitioner directly under the supervision of a member of the medical staff; however, CMS also makes note that this provision is not to be construed to limit the authority of a doctor of medicine (MD) or osteopathy (DO) to delegate tasks to other qualified healthcare personnel to the extent recognized under state law or a state's regulatory mechanism. The *State Operations Manual* further states that practitioners other than MDs or DOs may join the medical staff if appropriately licensed and medical staff membership is in accordance with state law. It also states that every Medicare and Medicaid patient must be under the care of an LP as defined in this requirement. LPs include PAs, NPs, clinical nurse specialists (CNS), certified registered nurse anesthetists (CRNA), certified nurse midwives (CNM), clinical social workers (CSW), RDs, anesthesia assistants, and clinical psychologists. CMS also requires an MD/DO to be on call 24/7; The Joint Commission has no corresponding standard for this.

Survey Tips:

- Review bylaws and rules/regulations or operations manuals to verify that patients are admitted to the hospital only by LPs (e.g., physicians, NPs, PAs, midwives, etc.) who have admitting privileges as approved by the governing board.
- Verify Medicare patients are under the care of a licensed practitioner as defined by 482.12(c)(1).
- Review the categories of practitioners who have admitting privileges (as allowed by bylaws and state law).
- Audit medical records to verify that each patient is under the care of an MD/DO and that privileging allows the practitioner to manage the care or that the level of supervision required by state regulation is followed.
- Interview nursing staff about how they identify the on-call physician and if an MD/DO is available at all times. Per EMTALA regulation, on-call schedules must include the name of the on-call practitioner's name and contact information.

Suggested Documents:

- On-call schedules
- Credentials files and privileges
- Medical staff bylaws, rules, regulations, or operation manuals
- P&Ps related to privileging and credentialing, ongoing professional practice evaluation, and focused professional practice evaluation

§482.12 *CoP*: Governing Body		
Tag #	CMS *CoP* (2023)	CMS Interpretive Guidelines and Survey Procedures
A-0073	**(d) Standard: Institutional Plan and Budget—** The institution must have an overall institutional plan that meets the following conditions: (1) The plan must include an annual operating budget that is prepared according to generally accepted accounting principles. (2) The budget must include all anticipated income and expenses. This provision does not require that the budget identify item by item the components of each anticipated income or expense. (3) The plan must provide for capital expenditures for at least a 3-year period, including the year in which the operating budget specified in paragraph (d)(2) of this section is applicable. (4) The plan must include and identify in detail the objective of, and the anticipated sources of financing for, each anticipated capital expenditure in excess of $600,000 (or a lesser amount that is established, in accordance with section 1122(g)(1) of the Act, by the State in which the hospital is located) that relates to any of the following: (i) Acquisition of land (ii) Improvement of land, buildings, and equipment (iii) The replacement, modernization, and expansion of buildings and equipment.	*See Survey Procedures for §482.12(d)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.12 -- Condition of participation: Governing body.*
A-0074	(5) The plan must be submitted for review to the planning agency designated in accordance with section 1122(b) of the Act, or if an agency is not designated, to the appropriate health planning agency in the state. (See Part 100 of this title.)	*See Survey Procedures for §482.12(d)(5)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.12 -- Condition of participation: Governing body.*

A-0075	(5) *(continued)* A capital expenditure is not subject to section 1122 review if 75% of the health care facility's patients who are expected to use the service for which the capital expenditure is made are individuals enrolled in a health maintenance organization (HMO) or competitive medical plan (CMP) that meets the requirements of section 1876(b) of the Act, and if the Department determines that the capital expenditure is for services and facilities that are needed by the HMO or CMP in order to operate efficiently and economically and that are not otherwise readily accessible to the HMO or CMP because: (i) The facilities do not provide common services at the same site; (ii) The facilities are not available under a contract of reasonable duration; (iii) Full and equal medical staff privileges in the facilities are not available; (iv) Arrangements with these facilities are not administratively feasible; or (v) The purchase of these services is more costly than if the HMO or CMP provided the services directly.	*SOM Appendix A (cms.gov)*
A-0076	(6) The plan must be reviewed and updated annually.	*See Survey Procedures for §482.12(d)(6)* *SOM Appendix A (cms.gov)*
A-0077	(7) The plan must be prepared— (i) Under the direction of the governing body, and (ii) By a committee consisting of representatives of the governing body, the administrative staff, and the medical staff of the institution.	*See Survey Procedures for §482.12(d)(7)* *SOM Appendix A (cms.gov)*

Related Joint Commission Standards

Leadership:

- LD.01.01.01, EP 2
- LD.01.03.01, EP 2, 8
- LD.04.01.01, EP 2
- LD.04.01.03, EP 1, 3, 4

Related DNV Standards

Institutional Plan and Budget:

- GB.3 (SR.1)
- GB.3 (SR.2)
- GB.3 (SR.2a)
- GB.3 (SR.2b)
- GB.3 (SR.2c)
- GB.3 (SR.5)
- GB.3 (SR.3)
- GB.3 (SR.4)

Related ACHC Standards

Administration of the Organizational Environment

- 01.01.16
- 01.01.17
- 01.01.18
- 01.01.19

Related CIHQ Standards

Financial Planning and Budgeting:

- GL-7

§482.12 (d) *CoP* Analysis/Guidelines

CMS and other accreditors require the organization to have an operating and capital budget plan that is reviewed, updated, and approved by the governing board on an annual basis. CMS and other accrediting agencies specify that it is not within the scope of activities or responsibility of the surveyor to review and assess the amounts or structure of the institutional plan and budget. CMS also outlines the requirement for the capital expenditures plan to be submitted to the planning agency designated to review capital expenditures. In some cases, facilities used by HMO or CMP patients are exempt from this review.

Survey Tips:

- Review budget process to include governing body, administrative staff, and medical staff participation
- Verify that the plan and budget are reviewed and updated annually

Suggested Documents:

- Hospital's annual financial plan
- Hospital's annual operating and capital budgets
- Governing body meeting minutes reflecting approval of the operational and capital budgets
- Medical staff meeting minutes reflect an opportunity to provide input into the budget process
- Financial audit report
- Hospital/governing body bylaws and responsibility matrix outlining hospital board responsibilities

§482.12 *CoP*: Governing Body		
Tag #	CMS *CoP* (2023)	CMS Interpretive Guidelines and Survey Procedures
A-0083	**(e) Standard: Contracted Services—** The governing body must be responsible for services furnished in the hospital whether or not they are furnished under contracts. The governing body must ensure that a contractor of services (including one for shared services and joint ventures) furnishes services that permit the hospital to comply with all applicable conditions of participation and standards for the contracted services.	*See Interpretive Guidelines for §482.12(e)* *See Survey Procedures for §482.12(e)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.12 -- Condition of participation: Governing body.*
A-0084	(1) The governing body must ensure that the services performed under a contract are provided in a safe and effective manner.	*See Interpretive Guidelines for §482.12(e)(1)* *See Survey Procedures for §482.12 (e)(1)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.12 -- Condition of participation: Governing body.*
A-0085	(2) The hospital must maintain a list of all contracted services, including the scope and nature of the services provided.	*See Survey Procedures for §482.12(e)(2)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.12 -- Condition of participation: Governing body.*
Related Joint Commission Standards Leadership: • LD.01.03.01 EP 5 • LD.04.03.09, EP 2 – 7		

Related DNV Standards

Contracted Services

- GB.4 (SR.1)
- GB.4 (SR.2)
- GB.4 (SR.3)

Related ACHC Standards

Administration of the Organizational Environment:

- 01.01.22

Related CIHQ Standards

Contract Services:

- GL-8

§482.12 (e) *CoP* Analysis/Guidelines

The governing body is responsible for the services provided at the hospital, whether those services are provided directly by hospital staff or indirectly through a contractual arrangement (e.g., formal contracts, joint ventures, informal agreements, shared services, or lease arrangements). Understanding the CMS definition of contract services and the scope of compliance is essential. It is also important to know state licensure regulations regarding contract services. CMS and all accreditors require processes to ensure contracted services are provided safely and effectively. These services should be monitored and evaluated to the same hospital-wide quality and performance improvement expectations as other services provided directly by the organization. DNV requires the governing body to annual management reviews of selected indicators and establish criteria for selection, evaluation, and reevaluation.

Contracted Services

CMS language on contract services includes all clinical and non-clinical contracts; in general, our experience is that this applies to anyone entering patient care areas. There must be a complete list of contract services, and this expectation is consistent among all accreditors. Clinical contract services are recommended to require similar or the same onboarding procedures (e.g., criminal background checks, primary source verification, etc.) as needed for employees. CMS and other accreditors will look for evidence that nonemployees have been oriented to their job description, hospital, and department. Organizations, however, are not required to maintain redundant HR files on contracted staff. Through contractual agreements, it is determined which entity (hospital or contracted service) is responsible for obtaining and maintaining employee files. When a surveyor requests for documentation, only the information to demonstrate compliance should be provided. For example, contracted entities are not required to share the actual results of a criminal background check—only to demonstrate that one has been completed.

All AOs share the same common theme when evaluating contracted services. They all look for the following:

1. The contract itself. Surveyor will review the contract(s) to confirm the nature and scope of services that are being provided.
2. The services provided are meeting expectations for providing safe and effective care (as applicable).
3. The hospital is monitoring overall performance, how they are evaluating, and the results.
4. Results are reviewed and discussed during routine QAPI meetings, including performance improvements for areas not being met.

The Joint Commission standards focus more on clinical contracts, emphasizing safe, high-quality care. Contracted services that perform direct patient care must be evaluated by hospital leadership to determine they are providing safe, effective,

high-quality care. Often the expectations are contained within the written agreement between the hospital and the contracted entity. If expectations are not met, leaders work with the contractor to improve their services to ensure the continuity of care is not disrupted. The governing body has ultimate responsibility for the safety and quality it provides. It must ensure compliance to the standards are being met. With that, The Joint Commission allows the hospital to determine the criteria for evaluation and management review. The bottom line is whether the hospital uses its own employees or contracts out the service with contracted employees, the hospital must still evaluate the service and ensure patients are receiving safe, high-quality care.

DNV requirements are as follows: The organization will prioritize the review of contracted services based on the concept of risk-based thinking with an emphasis on those contracted services related to patient care. Contracts determined to be in this category will have established evaluation processes that are comparable to evaluation processes of similar services that are provided directly by the organization. Other contracts will be assessed in accordance with the organization's policy as defined. It is not the expectation that such contracts as that for cable television or plumbing, for example, would be assessed in the same manner as those related to patient care services. However, if services provided under contract will have an impact in some manner for patient care services, the organization will review these services and monitor the appropriate measures to ensure the expectations of the organization and needs of the patient are being met. There may be arrangements where services are provided through one or more of the following: joint ventures, informal agreements, shared services, or lease arrangements. These services are also subject to the criteria for selection and evaluation process.

In CIHQ hospitals, the list above is performed for all contracted services in the hospital; minor adjustments with clinical versus non-clinical. If a contracted service demonstrates noncompliance to a CIHQ standard or policy identified during the accreditation survey, the hospital will be cited for the contracted service noncompliance (this is true for other AOs as well).

In ACHC hospitals, the director of nursing (DON) is responsible to provide proper supervision for all clinical activities, including contracted services. The DON must routinely confirm there is an evaluation on contracted clinical personnel to ensure they are adhering to the policies and procedures, infection prevention, antibiotic stewardship, etc., as written in the contract.

Survey Tips:

- Review listing of contracted services (clinical and any others that impact a *CoP*, especially if the contractors are entering patient care areas) to ensure they include the scope and nature of services and that they have been reviewed by medical staff and approved by the governing body. For DNV organizations, there should be evidence of criteria for selecting contract services.
- Ascertain that all contractor services provided in the hospital comply with the *CoP*s for hospitals.
- Recommend that there is a document listing all contract services and at least one Performance Expectation/Indicator for that contract service. This should be integrated under your QAPI plan or QAPI reporting calendar and provided to the governing body.
- Ensure the performance of services is evaluated at the frequency required by law, regulation, contract, or hospital policy and procedure (P&P) or contract. The recommended time frame for performance review for all AOs is annual; DNV requires annual review.
- Review contract services agreements to ensure that performance metrics are included. Ensure language in each contract addresses the need to comply with state, federal, and local laws and regulations and accrediting agency standards.
- Review contract services, P&Ps: Ensure there is a mechanism to integrate into one list all contract services; ensure P&Ps address the governing body as ultimately accountable and that performance metrics and frequency of review have been addressed; provide the governing body with approval of the policy.

- Ensure governing body minutes reflect periodic review of all contract services, including a review of performance expectations.
- Ensure there is a check-in process for all nonemployees entering patient care areas who are unescorted.
- Verify all the critical components of orientation have been given to non-employees (including non-licensed or non-clinical).

Suggested Documents:

- Hospital bylaws
- Hospital policy regarding contract process, review, and approval
- Documents that provide a list of contractors and show oversight/evaluation of contracts
- List of contracted services provided to the hospital, including scope and nature of services
- Medical staff and leadership minutes demonstrating their opportunity to give feedback on contracted services (Note: NIAHO/DNV organizations are not required to show review by the medical staff if medical staff are represented on the governing body).
- Contract services evaluation method/tool
- Clinical contract services with performance issues integrated under the hospital's quality program
- Hospital/governing body bylaws and responsibility matrix outlining hospital board responsibilities for contract workers

§482.12 *CoP*: Governing Body		
Tag #	CMS *CoP* (2023)	CMS Interpretive Guidelines and Survey Procedures
A-0091	**(f) Standard: Emergency Services**	*See Interpretive Guidelines for §482.12(f)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.12 -- Condition of participation: Governing body.*
A-0092	(1) If emergency services are provided at the hospital, the hospital must comply with the requirements of §482.55.	*SOM Appendix A (cms.gov)*
A-0093	(2) If emergency services are not provided at the hospital, the governing body must ensure that the medical staff has written policies and procedures for appraisal of emergencies, initial treatment, and referral when appropriate.	*See Interpretive Guidelines for §482.12(f)(2)* *See Survey Procedures for §482.12(f)(2)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.12 -- Condition of participation: Governing body.*
A-0094	(3) If emergency services are provided at the hospital but are not provided at one or more off-campus departments of the hospital, the governing body of the hospital must ensure 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.	*See Interpretive Guidelines for §482.12(f)(3)* *See Survey Procedures for §482.12(f)(3)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.12 -- Condition of participation: Governing body.*

Related Joint Commission Standards

Leadership:

- LD.01.03.01, EP 3
- LD.04.01.01, EP 2
- LD.04.03.01, EP 2

Medical Staff:

- MS.03.01.01, EP 13, 14

Related DNV Standards

Emergency Services

- ED.1 (SR.1)

- ED.3 (SR.1)
- ED.4 (SR.1)

Related ACHC Standards

Administration of the Organizational Environment:

- 01.02.01
- 01.02.02
- 01.02.03
- 01.02.04

Related CIHQ Standards

Provision of Emergency Services at Non-Emergency Department Locations:

- ED-2

§482.12 (f) *CoP* Analysis/Guidelines

This CMS standard applies to off-campus, nonemergency departments/locations of hospitals where patients may present with emergency needs. For hospitals that provide emergency services, see §482.55 *CoP*: Emergency Services. The Joint Commission references emergency services in both the Leadership and Medical Staff chapters and includes the governing body's role as oversight.

Survey Tips:

- Verify that the medical staff and governing body have approved EMTALA procedures and the policy addresses on-campus and off-campus locations.
- Talk with hospital staff at various off-campus locations to see if they know what to do if someone seeks emergency care at their site. If staff members are to call 911, differentiate how staff at these sites would provide patient assessment and initial treatment.
- Ensure EMTALA signage is posted at all points of entry into the ED (e.g., waiting area, ambulance bays) and other applicable departments where emergency screening medical examinations might take place.
- Ensure data are being collected for patients who elope or leave against medical advice or without being seen as well as all transfers out.
- Ensure that anyone presenting to be seen is logged, even those unregistered patients.

Suggested Documents:

- EMTALA and related medical staff P&Ps
- Emergency care P&Ps
- EMTALA logs
- On-call schedules
- Listing of non-credentialed staff (i.e., obstetric RNs) who provide EMTALA screening, evidence of their competence, evidence of medical staff, and governing body approval

§482.13 *CoP*: Patient's Rights		
Tag #	CMS *CoP* (2023)	CMS Interpretive Guidelines and Survey Procedures
A-0115	A hospital must protect and promote each patient's rights.	*See Interpretive Guidelines for §482.13* *See Survey Procedures for §482.13* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.13 -- Condition of participation: Patient's rights.*
A-0116	**(a) Standard: Notice of Rights**	*See Interpretive Guidelines for §482.13(a)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.13 -- Condition of participation: Patient's rights.*
A-0117	(1) A hospital must inform each patient, or, when appropriate, the patient's representative (as allowed under state law), of the patient's rights, in advance of furnishing or discontinuing patient care whenever possible.	*See Interpretive Guidelines for §482.13(a)(1)* *See Survey Procedures for §482.13(a)(1)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.13 -- Condition of participation: Patient's rights.*
A-0118	(2) The hospital must establish a process for prompt resolution of patient grievances and must inform each patient whom to contact to file a grievance.	*See Interpretive Guidelines for §482.13(a)(2)* *See Survey Procedures for §482.13(a)(2)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.13 -- Condition of participation: Patient's rights.*
A-0119	[The hospital must establish a process for prompt resolution of patient grievances and must inform each patient whom to contact to file a grievance.] (a) The hospital's governing body must approve and be responsible for the effective operation of the grievance process and must review and resolve grievances, unless it delegates the responsibility in writing to a grievance committee.	*See Interpretive Guidelines for §482.13(a)(2)* *See Survey Procedures for §482.13(a)(2)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.13 -- Condition of participation: Patient's rights.*

A-0120	[The hospital must establish a process for prompt resolution of patient grievances and must inform each patient whom to contact to file a grievance.] (a) *(continued)* The grievance process must include a mechanism for timely referral of patient concerns regarding quality of care or premature discharge to the appropriate Utilization and Quality Control Quality Improvement Organization. At a minimum:	*See Interpretive Guidelines for §482.13(a)(2)* *See Survey Procedures for §482.13(a)(2)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.13 -- Condition of participation: Patient's rights.*
A-0121	[At a minimum] (i) The hospital must establish a clearly explained procedure for the submission of a patient's written or verbal grievance to the hospital.	*See Interpretive Guidelines for §482.13(a)(2)(i)* *See Survey Procedures for §482.13(a)(2)(i)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.13 -- Condition of participation: Patient's rights.*
A-0122	[At a minimum] (ii) The grievance process must specify time frames for review of the grievance and the provision of a response.	*See Interpretive Guidelines for §482.13(a)(2)(ii)* *See Survey Procedures for §482.13(a)(2)(ii)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.13 -- Condition of participation: Patient's rights.*
A-0123	[At a minimum] (iii) In its resolution of the grievance, the hospital must provide the patient with written notice of its decision that contains the name of the hospital contact person, the steps taken on behalf of the patient to investigate the grievance, the results of the grievance process, and the date of completion.	*See Interpretive Guidelines for §482.13(a)(2)(iii)* *See Survey Procedures for §482.13(a)(2)(iii)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.13 -- Condition of participation: Patient's rights.*

Related Joint Commission Standards

Rights and Responsibilities of the Individual:

- RI.01.01.01, EP 1, 2, 4
- RI.01.01.03, EP 1
- RI.01.02.01, EP 2, 3, 8
- RI.01.07.01, EP 1, 18 – 20

Related DNV Standards

Specific Rights

- PR.2 – Introduction
- PR.2 (SR.1)
- PR.2 (SR.1a)
- PR.2 (SR.1b)
- PR.2 (SR.2)
- PR.2 (SR.3)
- PR.2 (SR.4)
- PR.2 (SR.5)
- PR.2 (SR.6)
- PR.2 (SR.7)
- PR.2 (SR.8)
- PR.2 (SR.9)
- PR.2 (SR.9a)
- PR.2 (SR.10)
- PR.2 (SR.11)
- PR.2 (SR.13)

Nondiscrimination

- PR.1 (SR.1)
- PR.1 (SR.2)

Grievance Procedure

- PR.6 – Introduction
- PR.6 (SR.1)
- PR.6 (SR.2)
- PR.6 (SR.3)
- PR.6 (SR.3a)
- PR.6 (SR.4)
- PR.6 (SR.5)
- PR.6 (SR.5a)
- PR.6 (SR.5b)

- PR.6 (SR.5c)
- PR.6 (SR.5d)

Related ACHC Standards

Patient Rights and Safety:

- 15.00.00
- 15.01.00
- 15.01.15
- 15.01.16
- 15.01.17
- 15.01.18
- 15.01.19
- 15.01.20

Related CIHQ Standards

Recognition of Patient Rights:

- PR-1

Informing Patients of Their Rights:

- PR-2

Provision of Interpretive/Translation Services:

- QS-3

Patient Grievances:

- PR-4

§482.13 (a) *CoP* Analysis/Guidelines

Both CMS and all accreditors require that inpatients and outpatients are informed about their rights, including rights related to the discontinuation of services. CMS and accrediting agencies require that patients or their legal representatives must be notified of their rights. The Joint Commission standards are more specific about rights around care/treatment and around cultural, spiritual, psychosocial, and personal dignity. The Joint Commission also addresses patient responsibility information, whereas CMS does not. Hospitals are required to have a formal patient grievance process and mechanism that have been approved by the organization's governing board.

Accreditors are in alignment with the CMS interpretive guidelines regarding grievances.

A patient grievance is defined as "a written or verbal complaint by a patient, or the patient's representative, regarding the patient's care (when the complaint is not resolved at the time of the complaint by staff present), abuse or neglect, issues related to the hospital's compliance with CMS' Hospital *CoP,* or a Medicare beneficiary billing complaint related to rights and limitations." Billing issues are not considered grievances unless the complaint also contains issues about patient services or care. The hospital must inform the patient of the grievance process and provide a written response to each patient's grievance. If the grievance will not be resolved, or if the investigation is not or will not be completed within seven

days, the hospital should inform the patient or their representative that the hospital is still working to resolve the grievance and will follow up with a written response within a stated number of days based on the hospital's grievance policy.

The hospital must attempt to resolve all grievances in a timely manner. Some states have regulations related to grievances, so those should be known and understood. If state regulation supersedes CMS and accreditor requirements, the stricter requirements apply. A presidential doctrine changed CMS standards related to visitation rights. These rights require that each patient (or support person, where appropriate) be informed of their visitation rights, including any clinical restriction or limitation on such rights; that each patient can receive the visitors whom they designate, including but not limited to a spouse, domestic partner, family member, or friend, and may withdraw or deny such consent at any time; that the hospital cannot restrict, limit, or otherwise deny visitation privileges on the basis of race, color, national origin, religion, sex, gender identity, sexual orientation, or disability; and that all visitors enjoy full and equal visitation privileges consistent with patient preferences.

Survey Tips:

- Ensure patient rights posters, brochures, and policy match the language of these requirements.
- Audit to ensure patient rights are communicated as appropriate for patients who have limited English proficiency or who are hearing or visually impaired.
- Audit process of registration to ensure that patients are informed of their rights and acknowledge this by signing the facility's related document (i.e., consent for medical treatment performed on admission/ registration). Ensure privacy is provided when registration staff perform this function.
- Audit patient records to ensure that patients have signed the acknowledgment of receiving their rights. If patients do not receive a copy of their rights, observe process to ensure they have time to sufficiently review the information and can answer questions.
- Audit registration and case management process to ensure that Medicare patients receive Important Messages from Medicare within two days of admission and that there is documented acknowledgment by the patient of receiving this information. Also audit case management process to ensure patients are informed of their rights in advance of discontinuing services and according to timeliness requirement.
- Although not addressed in CMS regulation, ensure the OCR's requirements for nondiscrimination notice/ poster to be visible at points of entry and that patients acknowledge receipt of information.
- Review all mechanisms where other notice might be given (e.g., posters, admission packs, website postings, and other educational material) to ensure consistency.
- Review case management or other discharge planning policies to ensure the process is followed, including required timeliness.
- Ensure EMTALA signage is posted at all points of entry into the organization.
- Review hospital policies on patient rights and patient grievance processes. Ensure governing body has signed off on P&Ps. Ensure that P&Ps reflect that the governing body has delegated grievances to hospital leadership unless the governing body is responsible itself for grievances and grievance procedures.
- Review how the hospital meets needs of diverse patients (e.g., language barriers, those needing assistive devices, communication barriers).
- Review policies on abuse, neglect, and harassment. Address the need to report, investigate, and take corrective action as appropriate and that the CMS definition of *abuse* is used.

- Review grievance documentation to see if process is followed and how long it takes to respond to patient grievances. Average turnaround time for grievances should be seven days, unless state requirement is more stringent. Outliers should have a process to update the patient periodically on status of grievance.
- Interview patients or patient representatives to see whether they know how to submit a grievance.
- Check state licensure and certification requirements to ensure there are no differences between state and CMS regulations. Policy should reflect the most stringent requirements applicable.
- Ensure the hospital board is updated with data that reflect timeliness of grievance process and that if issues exist, related performance improvement (PI) must be integrated under the QAPI program.
- Perform tracers to ensure that clinical records are secure and protected and that other aspects of privacy are compliant.
- Review hospital policy on the patient's right to access clinical records.

Suggested Documents:

- Patient rights/responsibilities handout/document
- Hospital policy on patient rights/responsibilities
- Hospital policy on communicating rights to diverse patients
- Hospital policies about patient advocates/representatives
- Hospital policy on visitor support person and visitation
- Hospital policy on patient grievance process
- Hospital policy on abuse, neglect, and harassment
- Hospital policy on privacy and confidentiality of medical records
- Hospital policy on patient rights to access medical records
- Patient discharge materials
- Copies of template or written letters of acknowledgment and grievance investigation and follow-up
- Grievance logs with analysis of trends and average turnaround times; show PI if turnaround times are not compliant; outliers should be explained in writing
- Minutes of governing body in which periodic updates related to efficacy of the grievance process are discussed/presented

§482.13 *CoP*: Patient's Rights		
Tag #	CMS *CoP* (2023)	CMS Interpretive Guidelines and Survey Procedures
A-0129	**(b) Standard: Exercise of Rights**	*See Interpretive Guidelines for §482.13(b)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.13 -- Condition of participation: Patient's rights.*
A-0130	(1) The patient has the right to participate in the development and implementation of his or her plan of care.	*See Interpretive Guidelines for §482.13(b)(1)* *See Survey Procedures for §482.13(b)(1)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.13 -- Condition of participation: Patient's rights.*
A-0131	(2) The patient or his or her representative (as allowed under state law) has the right to make informed decisions regarding his or her care. The patient's rights include being informed of his or her health status, being involved in care planning and treatment, and being able to request or refuse treatment. This right must not be construed as a mechanism to demand the provision of treatment or services deemed medically unnecessary or inappropriate.	*See Interpretive Guidelines for §482.13(b)(2)* *See Survey Procedures for §482.13(b)(2)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.13 -- Condition of participation: Patient's rights.*
A-0132	(3) The patient has the right to formulate advance directives and to have hospital staff and practitioners who provide care in the hospital comply with these directives, in accordance with §489.100 (definition), §489.102 (requirements for providers), and §489.104 (effective dates).	*See Interpretive Guidelines for §482.13(b)(3)* *See Survey Procedures for §482.13(b)(3)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.13 -- Condition of participation: Patient's rights.*
A-0133	(4) 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 hospital.	*See Interpretive Guidelines for §482.13(b)(4)* *See Survey Procedures for §482.13(b)(4)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.13 -- Condition of participation: Patient's rights.*

Related Joint Commission Standards

Leadership:

- LD.04.01.01, EP 2

Rights and Responsibilities of the Individual:

- RI.01.01.01, EP 5
- RI.01.01.03, EP 3
- RI.01.02.01, EP 1 – 4, 8, 20
- RI.01.03.01, EP 1, 2
- RI.01.05.01, EP 1, 9, 10, 17

Record of Care, Treatment, and Services:

- RC.02.01.01, EP 4

Related DNV Standards

Specific Rights

- PR.2
- PR.2 (SR.2)
- PR.2 (SR.3)
- PR.3 (SR.1)
- PR.3 (SR.2)
- PR.3 (SR.3)
- PR.3 (SR.4)
- PR.3 (SR.5)

Related ACHC Standards

Patient Rights and Safety:

- 15.01.03
- 15.01.04
- 15.01.05
- 15.01.06

Related CIHQ Standards

Participation in Care Planning:

- PR-13

Right to Make Informed Decisions:

- PR-5

Informed Consent:

- OI-5

Provision of Interpretive/Translation Services:

- QS-3

Advance Directives:

- PR-6

Access to Personal Health Information:

- PR-11

Notification of Hospitalization:

- PR-3

§482.13 (b) *CoP* Analysis/Guidelines

CMS and accreditors are consistent in requiring patients' involvement with their care plans, care decisions, and decisions at end of life. CMS includes a requirement to notify a family member or the patient's physician as soon as can reasonably be expected upon patient request. All accreditors have standards to address each of the aforementioned CMS tags.

DNV and The Joint Commission are missing the requirement to provide community education on advance directives as outlined in the interpretive guidelines. The Joint Commission has separate requirements for patients receiving behavioral healthcare. See §482.24 Medical Record Services regarding required components of informed consent. The Joint Commission's and CMS' components of informed consent are slightly different.

In the face of the nationwide opioid abuse crisis, The Joint Commission began an in-depth evaluation of its pain management standards in 2016. That culminated in new standards in four chapters of its hospital manual. In 2017, The Joint Commission announced deletions and additions to the PC, LD, MS, and PI chapters affecting a total of six standards and 19 EPs, none of which are reflected directly in the CMS *CoP*. And in March 2018, it formally deleted EP 8 from the standard RI.01.01.01—which previously stated that a hospital must respect the patient's right to pain management.

The Joint Commission continues to have requirements related to the dying patient's needs for comfort, dignity, and emotional and spiritual care, whereas CMS does not. CMS has provided additional instruction for complying with Tag A-133, stating, "The hospital must provide the required notice promptly. 'Promptly' means as soon as possible after the physician's or other qualified practitioner's order to admit the patient has been given. Notice may be given orally in person, by telephone, by email or other electronic means, or by other methods that achieve prompt notification. It is not acceptable for the hospital to send a letter by regular mail."

CMS also noted the following: "The hospital must document that the patient, unless incapacitated, was asked no later than the time of admission whether they 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 and to the patient's physician."

Survey Tips:

- Review current informed consent and advance directive policies and processes for follow-up with family when the patient has an advance directive but has not brought it to the hospital.
- Audit advance directive documentation to ensure that there is evidence in documentation or other source that patients requesting advance directive information are provided that information and that patients with advance directives who have not brought them in have been notified of the need to have the information included in the medical record.
- Review curriculum in general orientation for staff to ensure information on advance directives is included.

- Audit a sample of medical records for presence of care plans and documentation of patient's involvement, informed consent, and advance directive.
- Verify that patient/patient's representative has been notified of their right to be involved with care decisions.
- Assess staff's understanding of informed consent and advance directive processes.
- Verify that there is a mechanism to provide community education regarding advance directives and that those efforts are documented.
- Verify that informed consent tools contain required Joint Commission and CMS components. This assessment should include those informed consent tools coming in from outside sources (e.g., physician practices).
- Verify that hospital policy has been updated to address notification of a patient's family or representative and physician when the patient is admitted as an inpatient.
- Ensure that patients are informed of the right that upon request, the hospital will contact family members and their attending physician to notify them of the admission and that this offer of information is documented or other evidence of proof is available.
- Determine the staff responsible for providing the required notice and interview them to determine how they identify the persons to be notified and the means of notification. Determine how they address the case of an incapacitated person to identify a family member/representative and the patient's physician. Is nursing then to follow up if/when the patient regains their decision-making capacity?
- Review a sample of inpatient medical records. Do the medical records provide evidence that the patient was asked about notifying a family member/representative and his/her physician? Is there a record of when and how notice was provided? Was notice provided promptly? Is there a record of the patient declining to have notice provided to a family member/representative and his/her physician? Is there documentation of whether the patient was incapacitated at the time of admission, and, if so, what follow- up steps were taken to identify a family member/representative and the patient's physician?
- Audit this process, as it is often a vulnerability, particularly for patients bypassing registration (e.g., ED admits).

Suggested Documents:

- Patient rights/responsibilities handout/document
- Hospital policies on domestic, spousal, or child abuse and neglect and HIPAA
- Environment of care plans on environmental safety, infection control and security, and related performance improvement data
- Policies on protections where infants and children are receiving care
- Hospital security P&Ps and risk assessment
- Hospital policy on abuse, neglect, and harassment
- Evidence of staff training on abuse and neglect in personnel files
- Safety, infection control, and security committee minutes
- Provision of curriculum used in orientation and ongoing education that reflect the rights of patients

§482.13 *CoP*: Patient's Rights		
Tag #	CMS *CoP* (2023)	CMS Interpretive Guidelines and Survey Procedures
A-0142	**(c) Standard: Privacy and safety**	*See Interpretive Guidelines for §482.13(c)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.13 -- Condition of participation: Patient's rights.*
A-0143	(1) The patient has the right to personal privacy.	*See Interpretive Guidelines for §482.13(c)(1)* *See Survey Procedures for §482.13(c)(1)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.13 -- Condition of participation: Patient's rights.*
A-0144	(2) The patient has the right to receive care in a safe setting.	*See Interpretive Guidelines for §482.13(c)(2)* *See Survey Procedures for §482.13(c)(2)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.13 -- Condition of participation: Patient's rights.*
A-0145	(3) The patient has the right to be free from all forms of abuse or harassment.	*See Interpretive Guidelines for §482.13(c)(3)* *See Survey Procedures for §482.13(c)(3)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.13 -- Condition of participation: Patient's rights.*

Related Joint Commission Standards

Environment of Care:

- EC.01.01.01, EP 5
- EC.02.01.01, EP 1, 3, 7 – 10
- EC.02.06.01, EP 1
- EC.04.01.01, EP 1, 3, 6

Infection Prevention and Control:

- IC.02.01.01, EP 1

Rights and Responsibilities of the Individual:

- RI.01.01.01, EP 4, 6, 7
- RI.01.06.03, EP 1 – 3

National Patient Safety Goals:

- NPSG.15.01.01, EP 1 – 5, 7

Related DNV Standards

Specific Rights:

- PR.2 (SR.5)
- PR.2 (SR.6)
- PR.2 (SR.7)

Related ACHC Standards

Human Resources Management:

- 04.01.01

Physical Environment:

- 11.01.01
- 11.01.02
- 11.01.08

Patient Rights and Safety:

- 15.01.07
- 15.01.08
- 15.01.09
- 15.03.00
- 15.03.01
- 15.03.02
- 16.01.02

Psychiatric Units:

- 27.03.01
- 27.03.02

Related CIHQ Standards

Personal Privacy:

- PR-7

Right to Receive Care in a Safe Setting:

- PR-8

Protecting Patients from Self-Harm:

- QS-10

Abuse, Neglect, or Harassment:

- PR-9

§482.13 (c) *CoP* Analysis/Guidelines

Survey Tips:

- Observe the environment where patient care is provided to see whether privacy and dignity are protected. Pay particular attention to non-nursing departments, hallway beds (if used) in the ED, procedural areas, and recovery areas.
- Ensure environment of care plans and the infection prevention and control plan include the entire scope of services.
- Observe where protected health information (PHI) is displayed, stored, or left. Is PHI in public view? Are computer screens appropriately signed off when clinicians leave? Is information unnecessarily disclosed when registering patients? Is there a policy to keep the public away from PHI?
- Review hospital policies about processes for investigating allegations of abuse, neglect, or harassment.
- Ensure that people not involved in the care of the patient are not present without patient consent.

Suggested Documents:

- Patient rights and responsibilities policy
- Informed consent policy and associated form(s)
- Advance directive policy and associated form(s)
- Pain assessment and management policy
- Do-not-resuscitate (DNR) policy, DNR suspend policy for patients undergoing operative and invasive procedures, and associated form(s)
- Policy/guidelines for foregoing life-sustaining treatment
- Policy on care planning
- Evidence of staff training on advance directives in personnel files
- Evidence of community education provided by the hospital regarding advance directives
- Policy on family and primary physician notification

The main emphasis of these standards is to protect a patient's basic rights to privacy, safety, dignity, and security while in the hospital. Rights to safety include environmental safety and infection prevention and control. These rights apply to activities (e.g., bathing, dressing, exams) as well as verbal or written patient information (e.g., release of personal patient information without prior consent, discussions about diagnoses, care plan/treatment). The hospital must ensure that abuse, neglect, or harassment of patients does not occur, whether from hospital staff, other patients, or visitors. All accreditors have standards to comply with CMS expectations. DNV has expanded care in a safe setting to include behavioral health patients and a ligature-resistant or a ligature-free environment.

§482.13 *CoP*: Patient's Rights		
Tag #	CMS *CoP* (2023)	CMS Interpretive Guidelines and Survey Procedures
A-0146	**(d) Standard: Confidentiality of Patient Records**	*See Interpretive Guidelines for §482.13(d)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.13 -- Condition of participation: Patient's rights.*
A-0147	(1) The patient has the right to the confidentiality of his or her clinical records.	*See Interpretive Guidelines for §482.13(d)(1)* *See Survey Procedures for §482.13(d)(1)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.13 -- Condition of participation: Patient's rights.*
A-0148	(2) The patient has the right to access their medical records, including current medical records, upon an oral or written request, in the form or format requested by the individual. If it is readily producible in such form and format (including in an electronic form or format when such medical records are maintained electronically); or if not, in a readable hard copy form or such other form or format as agreed by the facility and the individual, and within a reasonable time frame. The hospital must not frustrate the legitimate efforts of individuals to gain access to their own medical records and must actively seek to meet these requests as quickly as its record-keeping system permits.	*See Interpretive Guidelines for §482.13(d)(2)* *See Survey Procedures for §482.13(d)(2)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.13 -- Condition of participation: Patient's rights.*

Related Joint Commission Standards

Information Management:

- IM.02.01.01, EP 1, 3, 4
- IM.02.01.03, EP 1, 2

Rights and Responsibilities of the Individual:

- RI.01.01.01, EP 10

Related DNV Standards

Specific Rights:

- PR.2 (SR.8)
- PR.2 (SR.9)
- PR.2 (SR.9a)

Related ACHC Standards

Patient Rights and Safety:

- 15.01.10
- 15.01.11

Related CIHQ Standards

Confidentiality of Information:

- PR-10

Access to Personal Health Information:

- PR-11

§482.13 (d) *CoP* Analysis/Guidelines

CMS and all accreditors have had confidentiality standards. Although HIPAA standards are not specifically mentioned in their accreditation standards, these regulations are a key piece in today's patient record/management programs. CMS has recently issued a clarification that laboratory reports can be requested by the patient/patient representative as is consistent with CLIA. As more hospitals move toward electronic medical records, the challenge is to manage information in all media (e.g., paper, videos, audiotapes, and information stored on the computer).

CMS and all accreditors agree that confidentiality applies to all forms of clinical records, both in the hospital and at off-campus locations. Patients also have a right to access their medical records. Organizations must provide this information in a timely manner. The Joint Commission specifies that every patient must have a medical record.

Survey Tips:

- Conduct a walk-through of patient care areas and observe whether protected patient information can be viewed or overheard by visitors or is posted in public view.
- Ensure all medical records are maintained in a secure location for all areas, including outpatient locations (e.g., wound care and infusion centers) and provider-based physician practices. It is advisable that health information management directors perform oversight and audits of such locations to ensure compliance with hospital policy. Information on who has keys and card key access into medical record areas should be reviewed to ensure access is limited.
- Review medical record policies on how to release information contained in a patient's record.
- Review medical record policies regarding authorized access and sign-out procedures or automated sign-out.
- Review hospital and laboratory procedures on patients' right to access their own clinical records and lab results.

Suggested Documents:

- Hospital HIPAA policies and associated form(s)
- Laboratory policy on patient/patient representative requests for laboratory results
- Confidentiality policy
- Medical record P&Ps (e.g., release of information, medical record retention)
- Lists of who has access to medical record areas; verify that only essential workers have access to these areas

§482.13 *CoP*: Patient's Rights		
Tag #	CMS *CoP* (2023)	CMS Interpretive Guidelines and Survey Procedures
A-0154	**(e) Standard: Restraint or Seclusion—** All patients have the right to be free from physical or mental abuse and corporal punishment. All patients have the right to be free from restraint or seclusion, of any form, 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.	*See Interpretive Guidelines for §482.13(e)* *See Survey Procedures for §482.13(e)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.13 -- Condition of participation: Patient's rights.*
A-0159	(1) Definitions: (i) A 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	*See Interpretive Guidelines for §482.13(e)(1)(i)(A)* *See Survey Procedures for §482.13(e)(1)(i)(A)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.13 -- Condition of participation: Patient's rights.*
A-0160	[A restraint is—] (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	*See Interpretive Guidelines for §482.13(e)(1)(i)(B)* *See Survey Procedures for §482.13(e)(1)(i)(B)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.13 -- Condition of participation: Patient's rights.*
A-0161	(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).	*See Interpretive Guidelines for §482.13(e)(1)(i)(C)* *See Survey Procedures for §482.13(e)(1)(i)(C)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.13 -- Condition of participation: Patient's rights.*

A-0162	(ii) Seclusion is 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.	*See Interpretive Guidelines for §482.13(e)(1)(ii)* *See Survey Procedures for §482.13(e)(1)(ii)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.13 -- Condition of participation: Patient's rights.*
A-0164	(2) 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.	*See Interpretive Guidelines for §482.13(e)(2)* *See Survey Procedures for §482.13(e)(2)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.13 -- Condition of participation: Patient's rights.*
A-0165	(3) 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.	*See Interpretive Guidelines for §482.13(e)(3)* *See Survey Procedures for §482.13(e)(3)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.13 -- Condition of participation: Patient's rights.*
A-0166	(4) The use of restraint or seclusion must be— (i) In accordance with a written modification to the patient's plan of care.	*See Interpretive Guidelines for §482.13(e)(4)(i)* *See Survey Procedures for §482.13(e)(4)(i)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.13 -- Condition of participation: Patient's rights.*
A-0167	[The use of restraint or seclusion must be—] (ii) [The use of restraint or seclusion must be:] Implemented in accordance with safe and appropriate restraint and seclusion techniques as determined by hospital policy in accordance with state law.	*See Interpretive Guidelines for §482.13(e)(4)(ii)* *See Survey Procedures for §482.13(e)(4)(ii)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.13 -- Condition of participation: Patient's rights.*

A-0168	(5) The use of restraint or seclusion must be in accordance with the order of a physician or other licensed practitioner (LP) who is responsible for the care of the patient and authorized to order restraint or seclusion by hospital policy in accordance with state law.	*See Interpretive Guidelines for §482.13(e)(5)* *See Survey Procedures for §482.13(e)(5)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.13 -- Condition of participation: Patient's rights.*
A-0169	(6) Orders for the use of restraint or seclusion must never be written as a standing order or on an as-needed basis (PRN).	*See Interpretive Guidelines for §482.13(e)(6)* *See Survey Procedures for §482.13(e)(6)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.13 -- Condition of participation: Patient's rights.*
A-0170	(7) The attending physician must be consulted as soon as possible if the attending physician did not order the restraint or seclusion.	*See Interpretive Guidelines for §482.13(e)(7)* *See Survey Procedures for §482.13(e)(7)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.13 -- Condition of participation: Patient's rights.*
A-0171	(8) Unless superseded by state law that is more restrictive: (i) 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: (A) 4 hours for adults 18 years of age or older. (B) 2 hours for children and adolescents 9-17 years of age; or (C) 1 hour for children under 9 years of age; and	*See Interpretive Guidelines for §482.13(e)(8)(i)* *See Survey Procedures for §482.13(e)(8)(i)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.13 -- Condition of participation: Patient's rights.*

A-0172	[Unless superseded by State law that is more restrictive—] (ii) 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 practitioner who is responsible for the care of the patient and authorized to order restraint or seclusion by hospital policy in accordance with state law must see and assess the patient.	*See Interpretive Guidelines for §482.13(e)(8)(ii)* *See Survey Procedures for §482.13(e)(8)(ii)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.13 -- Condition of participation: Patient's rights.*
A-0173	[Unless superseded by State law that is more restrictive—] (iii) 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.	*See Interpretive Guidelines for §482.13(e)(8)(iii)* *See Survey Procedures for §482.13(e)(8)(iii)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.13 -- Condition of participation: Patient's rights.*
A-0174	(9) Restraint or seclusion must be discontinued at the earliest possible time, regardless of the length of time identified in the order.	*See Interpretive Guidelines for §482.13(e)(9)* *See Survey Procedures for §482.13(e)(9)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.13 -- Condition of participation: Patient's rights.*
A-0175	(10) The condition of the patient who is restrained or secluded must be monitored by a physician, other licensed practitioner (LP), or trained staff that have completed the training criteria specified in paragraph (f) of this section at an interval determined by hospital policy.	*See Interpretive Guidelines for §482.13(e)(10)* *See Survey Procedures for §482.13(e)(10)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.13 -- Condition of participation: Patient's rights.*
A-0176	(11) Physician and other licensed practitioner (LP) training requirements must be specified in hospital policy. At a minimum, physicians and other LPs authorized to order restraint or seclusion by hospital policy in accordance with state law must have a working knowledge of hospital policy regarding the use of restraint or seclusion.	*See Interpretive Guidelines for §482.13(e)(11)* *See Survey Procedures for §482.13(e)(11)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.13 -- Condition of participation: Patient's rights.*

A-0178	(12) When restraint or seclusion is used for the management of violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others, the patient must be seen face-to- face within one hour after the initiation of the intervention— (i) By a (A) Physician or other licensed practitioners, or (B) Registered nurse who has been trained in accordance with the requirements specified in paragraph (f) of this section	*See Interpretive Guidelines for §482.13(e)(12)(i)* *See Survey Procedures for §482.13(e)(12)(i)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.13 -- Condition of participation: Patient's rights.*
A-0179	[...the patient must be seen face-to-face within one hour after the initiation of the intervention—] (ii) To evaluate— (A) the patient's immediate situation, (B) the patient's reaction to the intervention, (C) the patient's medical and behavioral condition, and (D) the need to continue or terminate the restraint or seclusion.	*See Interpretive Guidelines for §482.13(e)(12)(ii)* *See Survey Procedures for §482.13(e)(12)(ii)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.13 -- Condition of participation: Patient's rights.*
A-0180	(13) States are free to have requirements by statute or regulation that are more restrictive than those contained in paragraph (e)(12)(i) of this section.	*See Interpretive Guidelines for §482.13(e)(13)* *See Survey Procedures for §482.13(e)(13)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.13 -- Condition of participation: Patient's rights.*
A-0182	(14) If the face-to-face evaluation specified in paragraph (e)(12) of this section is conducted by a trained registered nurse, the trained registered nurse must consult the attending physician or other licensed practitioner who is responsible for the care of the patient as soon as possible after the completion of the one- hour face-to-face evaluation.	*See Interpretive Guidelines for §482.13(e)(14)* *See Survey Procedures for §482.13(e)(14)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.13 -- Condition of participation: Patient's rights.*

A-0183	(15) All requirements specified under this paragraph are applicable to the simultaneous use of restraint and seclusion. Simultaneous restraint and seclusion use is only permitted if the patient is continually monitored— (i) face-to-face by an assigned, trained staff member; or (ii) by trained staff using both video and audio equipment. This monitoring must be in close proximity to the patient.	*See Interpretive Guidelines for §482.13(e)(15)* *See Survey Procedures for §482.13(e)(15)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.13 -- Condition of participation: Patient's rights.*
A-0184	(16) When restraint or seclusion is used, there must be documentation in the patient's medical record of the following: (i) The one-hour face-to-face medical and behavioral evaluation if restraint or seclusion is used to manage violent or self-destructive behavior.	*See Interpretive Guidelines for §482.13(e)(16)* *See Survey Procedures for §482.13(e)(16)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.13 -- Condition of participation: Patient's rights.*
A-0185	[When restraint or seclusion is used, there must be documentation in the patient's medical record of the following:] (ii) A description of the patient's behavior and the intervention used.	*See Interpretive Guidelines for §482.13(e)(16)(ii)* *See Survey Procedures for §482.13(e)(16)(ii)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.13 -- Condition of participation: Patient's rights.*
A-0186	[When restraint or seclusion is used, there must be documentation in the patient's medical record of the following:] (iii) Alternatives or other less restrictive interventions attempted (as applicable).	*See Interpretive Guidelines for §482.13(e)(16)(iii)* *See Survey Procedures for §482.13(e)(16)(iii)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.13 -- Condition of participation: Patient's rights.*
A-0187	[When restraint or seclusion is used, there must be documentation in the patient's medical record of the following:] (iv) The patient's condition or symptom(s) that warranted the use of the restraint or seclusion.	*See Interpretive Guidelines for §482.13(e)(16)(iv)* *See Survey Procedures for §482.13(e)(16)(iv)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.13 -- Condition of participation: Patient's rights.*

A-0188	[When restraint or seclusion is used, there must be documentation in the patient's medical record of the following:] (v) The patient's response to the intervention(s) used, including the rationale for continued use of the intervention.	*See Survey Procedures for §482.13(e)(16)(v)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.13 -- Condition of participation: Patient's rights.*

Related Joint Commission Standards

Provision of Care:

- PC.03.05.01, EP 1 – 5
- PC.03.05.03, EP 1, 2
- PC.03.05.05, EP 1 – 6
- PC.03.05.07, EP 1
- PC.03.05.09, EP 1 – 2
- PC.03.05.11, EP 1 – 3
- PC.03.05.13, EP 1
- PC.03.05.15, EP 1

Rights and Responsibilities of the Individual:

- RI.01.06.03, EP 1 – 3

Related DNV Standards

Restraint or Seclusion

- PR.7 - Intro
- PR.7 (SR.1)
- PR.7 (SR.1a)
- PR.7 (SR.1b)
- PR.7 (SR.1c)
- PR.7 (SR.1d)
- PR.7 (SR.2)
- PR.7 (SR.2a)
- PR.7 (SR.2b)
- PR.7 (SR.2c)
- PR.7 (SR.2d)
- PR.7 (SR.2e)

- PR.7 (SR.2f)
- PR.7 (SR.2f(1))
- PR.7 (SR.2f(2))
- PR.7 (SR.3a)
- PR.7 (SR.3b)
- PR.7 (SR.3b(1))
- PR.7 (SR.3c)
- PR.7 (SR.3d)
- PR.7 (SR.3e)
- PR.7 (SR.3e(1))
- PR.7 (SR.3e(2))
- PR.7 (SR.3e(3))
- PR.7 (SR.3e(4))
- PR.7 (SR.3e(5)(i-ii))
- PR.7 (SR.3f)
- PR.7 (SR.4)
- PR.7 (SR.4a)
- PR.7 (SR.4(a)(1))
- PR.7 (SR.4(a)(2))
- PR.7 (SR.4(a)(3))
- PR.7 (SR.4(a)(4))
- PR.7 (SR.4b)
- PR.7 (SR.5)
- PR.7 (SR.5a)
- PR.7 (SR.5b)
- PR.7 (SR.5c)
- PR.7 (SR.6)
- PR.7 (SR.6a)
- PR.7 (SR.6a(1))

- PR.7 (SR.6a(2))
- PR.7 (SR.6a(3))
- PR.7 (SR.6a(4))
- PR.7 (SR.6a(5))
- PR.7 (SR.6a(6))
- PR.7 (SR.6a(7))
- PR.7 (SR.6a(8))
- PR.7 (SR.6a(9))
- PR.7 (SR.6b))
- PR.8 (SR.6)
- PR.8 (SR.6a)
- PR.8 (SR.6b)
- PR.8 (SR.6c)
- PR.8 (SR.6d)

Staff Training Requirements

- PR.8 (SR.3)
- PR.8 (SR.3a)

Related ACHC Standards

Patient Rights and Safety:

- 15.02.00
- 15.02.01
- 15.02.02
- 15.02.03
- 15.02.04
- 15.02.05
- 15.02.06
- 15.02.07
- 15.02.08
- 15.02.09
- 15.02.10
- 15.02.11

- 15.02.12
- 15.02.13
- 15.02.14
- 15.02.15
- 15.02.16
- 15.02.17
- 15.02.18
- 15.02.19
- 15.02.20

Related CIHQ Standards

Freedom from Restraint or Seclusion:

- RS-1

Definition of Restraint:

- RS-2

Definition of Seclusion:

- RS-3

Use of Restraint/Seclusion:

- RS-4

Type or Technique of Restraint/Seclusion:

- RS-5

Planning and Implementing Restraint/Seclusion:

- RS-6

Initial Order for Restraint/Seclusion:

- RS-7

PRN Orders for Restraint/Seclusion:

- RS-8

Renewal of Orders for Restraint/Seclusion:

- RS-9

Discontinuation of Restraint/Seclusion:

- RS-10

Monitoring the Patient in Restraint/Seclusion:

- RS-11

Training of Practitioners Who Order Restraint/Seclusion:

- RS-12

Evaluation of a Patient in Restraint/Seclusion for Violent/Self-Destructive Behavior:

- RS-13

Simultaneous Use of Restraint/Seclusion:

- RS-14

Documentation of Restraint/Seclusion in the Medical Record:

- RS-15

§482.13 (e) *CoP* Analysis/Guidelines

All accreditors align with CMS requirements on restraint and seclusion requirements. It is important that if law enforcement is using tasers, pepper spray, handcuffs, or other police tools, this is not done as part of a clinical restraint episode. If using these devices/products, CMS' expectation is that recipients of such enforcement are placed into police custody. Although not required, if said forms of law enforcement are used, it is advisable to perform administrative reviews after such law enforcement actions to ensure staff press charges by notifying the police and that the police either ticketed the patient or took them to jail on discharge.

Survey Tips:

- Audit a sample of medical records of patients who are/were in restraints.
- Audit a sample of medical records for patients who are/were in restraints during hospital admission to see whether orders were written for the type(s) of restraint in use and are time-limited, restraint was appropriate, and restraint episode was documented. Also ensure alternatives to use of restraint or seclusion have been documented, unless emergent. Verify that time-limited orders are not exceeded.
- Was it consistent with the hospital's restraint and seclusion policy and procedures when restraints or seclusion was used? With CMS requirements?
- Collect utilization, outcome, and process data to determine whether there is a pattern. Conduct performance improvement to decrease utilization, ensure restraints are discontinued at the earliest time possible, and/or improve compliance with procedures and assessment, monitoring, or documentation.
- Monitor use of tasers, pepper spray, handcuffs, etc., to ensure CMS requirements are met.
- Have a policy on chemical restraint and review your medical record documentation on the use of sedative medications to ensure compliance with your policy. Examine doses, routes of administration, FDA- or literature-supported indications, and documented rationale for administering the medication. Discern between an e-med and chemical restraint.
- Audit intravenous administration of sedative medications and intramuscular sedative medications in the elderly for compliance with your policy.

§482.13 *CoP*: Patient Rights		
Tag #	CMS *CoP* (2023)	CMS Interpretive Guidelines and Survey Procedures
A-0194	**(f) Standard: Restraint or Seclusion: Staff training requirements.** —The patient has the right to safe implementation of restraint or seclusion by trained staff.	*See Interpretive Guidelines for §482.13(f)* *See Survey Procedures for §482.13(f)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.13 -- Condition of participation: Patient's rights.*
A-0196	(1) Training Intervals. Staff must be trained and able to demonstrate competency in the application of restraints, implementation of seclusion, monitoring, assessment, and providing care for a patient in restraint or seclusion (i) before performing any of the actions specified in this paragraph, (ii) as part of orientation, and (iii) subsequently on a periodic basis consistent with hospital policy.	*See Interpretive Guidelines for §482.13(f)(1)(i)-(iii)* *See Survey Procedures for §482.13(f)(1)(i)-(iii)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.13 -- Condition of participation: Patient's rights.*
A-0199	(2) Training Content. The hospital must require appropriate staff to have education, training, and demonstrated knowledge based on the specific needs of the patient population in at least the following: (i) Techniques to identify staff and patient behaviors, events, and environmental factors that may trigger circumstances that require the use of a restraint or seclusion.	*See Interpretive Guidelines for §482.13(f)(2)(i)* *See Survey Procedures for §482.13(f)(2)(i)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.13 -- Condition of participation: Patient's rights.*
A-0200	[The hospital must require appropriate staff to have education, training, and demonstrated knowledge based on the specific needs of the patient population in at least the following:] (ii) The use of nonphysical intervention skills.	*See Interpretive Guidelines for §482.13(f)(2)(ii)* *See Survey Procedures for §482.13(f)(2)(ii)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.13 -- Condition of participation: Patient's rights.*

A-0201	[The hospital must require appropriate staff to have education, training, and demonstrated knowledge based on the specific needs of the patient population in at least the following:] (iii) Choosing the least restrictive intervention based on an individualized assessment of the patient's medical, or behavioral status or condition.	*See Interpretive Guidelines for §482.13(f)(2)(iii)* *See Survey Procedures for §482.13(f)(2)(iii)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.13 -- Condition of participation: Patient's rights.*
A-0202	[The hospital must require appropriate staff to have education, training, and demonstrated knowledge based on the specific needs of the patient population in at least the following:] (iv) 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 or psychological distress (e.g., positional asphyxia).	*See Interpretive Guidelines for §482.13(f)(2)(iii)* *See Survey Procedures for §482.13(f)(2)(iv)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.13 -- Condition of participation: Patient's rights.*
A-0204	[The hospital must require appropriate staff to have education, training, and demonstrated knowledge based on the specific needs of the patient population in at least the following:] (v) Clinical identification of specific behavioral changes that indicate that restraint or seclusion is no longer necessary.	*See Interpretive Guidelines for §482.13(f)(2)(v)* *See Survey Procedures for §482.13(f)(2)(v)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.13 -- Condition of participation: Patient's rights.*
A-0205	[The hospital must require appropriate staff to have education, training, and demonstrated knowledge based on the specific needs of the patient population in at least the following:] (vi) 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.	*See Interpretive Guidelines for §482.13(f)(2)(vi)* *See Survey Procedures for §482.13(f)(2)(vi)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.13 -- Condition of participation: Patient's rights.*

A-0206	(vii) The use of first aid techniques and certification in the use of cardiopulmonary resuscitation, including required periodic recertification.	*See Interpretive Guidelines for §482.13(f)(2)(vii)* *See Survey Procedures for §482.13(f)(2)(vii)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.13 -- Condition of participation: Patient's rights.*
A-0207	(3) Trainer Requirements. Individuals providing staff training must be qualified as evidenced by education, training, and experience in techniques used to address patients' behaviors.	*See Interpretive Guidelines for §482.13(f)(3)* *See Survey Procedures for §482.13(f)(3)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.13 -- Condition of participation: Patient's rights.*
A-0208	(4) Training Documentation. The hospital must document in the staff personnel records that the training and demonstration of competency were successfully completed.	*See Interpretive Guidelines for §482.13(f)(4)* *See Survey Procedures for §482.13(f)(4)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.13 -- Condition of participation: Patient's rights.*

Related Joint Commission Standards

Provision of Care:

- PC.03.05.03, EP 1
- PC.03.05.17, EP 2 – 5

Related DNV Standards

Staff Training Requirements

- PR.8 – Introduction
- PR.8 (SR.1)
- PR.8 (SR.1a)
- PR.8 (SR.1b)
- PR.8 (SR.2)
- PR.8 (SR.2a)
- PR.8 (SR.2b)

- PR.8 (SR.2c)
- PR.8 (SR.2d)
- PR.8 (SR.2e)
- PR.8 (SR.2f)
- PR.8 (SR.2g)
- PR.8 (SR.4)
- PR.8 (SR.5)

Related ACHC Standards

Patient Rights and Safety:

- 15.02.21
- 15.02.22
- 15.02.23
- 15.02.24
- 15.02.25
- 15.02.26
- 15.02.27
- 15.02.28
- 15.02.29
- 15.02.30
- 15.02.31

Related CIHQ Standards

Scope of Staff Training in Restraint/Seclusion:

- RS-16

Content of Staff Training in Restraint/Seclusion:

- RS-17

§482.13 (f) *CoP* Analysis/Guidelines

Staff training on restraint and seclusion must be done prior to their involvement in restraint/seclusion and on an ongoing basis and must include specific content. Trainers must meet requirements, and training must be documented.

Survey Tips:

- Review orientation and ongoing education and training materials to ensure information is current for the standards you are working under.
- Review documentation for training completion.
- Ensure that those who educate and evaluate the competencies of staff are competent themselves to do so.
- Ensure the ongoing education and competency plan addresses restraint and seclusion periodically.
- Consider adding ordering restraint and seclusion as a privilege for medical staff and include attestation of their knowledge of restraint and seclusion P&Ps.

Suggested Documents:

- P&Ps on restraint and seclusion as related to ongoing education and training
- Evidence of medical staff privileging process or training on restraint/seclusion policy
- Staff training and orientation records; ability to show competency of those who educate on restraint and seclusion
- Training materials on restraint and seclusion

§482.13 *CoP*: Patient's Rights		
Tag #	CMS *CoP* (2023)	CMS Interpretive Guidelines and Survey Procedures
A-0213	**(g) Standard: Death Reporting Requirements:** —Hospitals must report deaths associated with the use of seclusion or restraint. (1) With the exception of deaths described under paragraph (g)(2) of this section, the hospital must report the following information to CMS by telephone, facsimile, or electronically, as determined by CMS, no later than the close of business on the next business day following knowledge of the patient's death: (i) Each death that occurs while a patient is in restraint or seclusion (ii) Each death that occurs within 24 hours after the patient has been removed from restraint or seclusion. (iii) Each death known to the hospital 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, regardless of the type(s) of restraint used on the patient during this time. "Reasonable to assume" in this context includes, but is not limited to, deaths related to restrictions of movement for prolonged periods of time, or death related to chest compression, restriction of breathing, or asphyxiation. (3) The staff must document in the patient's medical record the date and time the death was: (i) Reported to CMS for deaths described in paragraph (g)(1) of this section; or	*See Interpretive Guidelines for §482.13(g)(1) & (3)(i)* *See Survey Procedures for §482.13(g)(1) & (3)(i)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.13 -- Condition of participation: Patient's rights.*

A-0214	[Hospitals must report deaths associated with the use of seclusion or restraint.] (2) When no seclusion has been used and when the only restraints used on the patient are those applied exclusively to the patient's wrist(s), and which are composed solely of soft, non-rigid, cloth-like materials, the hospital staff must record in an internal log or other system the following information: (i) any death that occurs while a patient in such restraints. (ii) any death that occurs within 24 hours after a patient has been removed from such restraints. (3) The staff must document in the patient's medical record the date and time the death was: (ii) Recorded in the internal log or other system for deaths described in paragraph (g)(2) of this section. (4) For deaths described in paragraph (g)(2) of this section, entries into the log or other system must be documented as follows: (i) Each entry must be made no later than seven days after the date of death of the patient. (ii) Each entry must document the patient's name, date of birth, date of death, name of the attending physician or other LP who is responsible for the care of the patient as specified under §482.12(c), medical record number, and primary diagnosis(es), and (iii) The information must be made available in either written or electronic form to CMS immediately upon request.	*See Interpretive Guidelines for §482.13(g)(2), §482.13(g)(3)(ii) & §482.13(g)(4)* *See Survey Procedures for §482.13(g)(2), §482.13(g)(3)(ii) & §482.13(g)(4)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.13 -- Condition of participation: Patient's rights.*

Related Joint Commission Standards

Provision of Care, Treatment, and Services:

- PC.03.05.19, EP 1 – 3

Related DNV Standards

Report of Death

- PR.9 (SR.1)
- PR.9 (SR.1a)
- PR.9 (SR.1b)
- PR.9 (SR.1c)
- PR.9 (SR.2)
- PR.9 (SR.3)
- PR.9 (SR.3a)
- PR.9 (SR.3b)
- PR.9 (SR.4)
- PR.9 (SR.4a)
- PR.9 (SR.4a(1))
- PR.9 (SR.4a(2))
- PR.9 (SR.4a(3))

Related ACHC Standards

Patient Rights and Safety:

- 15.02.32

Related CIHQ Standards

Reporting of Death Associated with Restraint/Seclusion:

- RS-18

§482.13 (g) *CoP* Analysis/Guidelines

This CMS requirement is adopted by all accreditors. For patient deaths occurring while a patient is in soft, two- point wrist restraints, hospitals are not required to report those to CMS but must record the deaths in a log or other system within seven days and make the log available immediately upon request.

Survey Tips:

- Conduct audits of deaths to ensure identification of all cases involved in restraint episodes to ensure required reporting.
- Establish concurrent review of all deaths to evaluate whether those patients were restrained/secluded at any time prior to or during death.
- Ensure process of restraint-related death reporting also includes documentation in the patient's medical record that the CMS regional office was notified.
- Maintain a log of deaths reported to CMS and ensure that log reflects that reporting is timely.

Suggested Document:

- Log or list of all patient deaths that were reported to CMS

§482.13 *CoP*: Patient's Rights		
Tag #	CMS *CoP* (2023)	CMS Interpretive Guidelines and Survey Procedures
A-0215	**(h) Standard: Patient visitation rights.** —A hospital must have written policies and procedures regarding the visitation rights of patients, including those setting forth any clinically necessary or reasonable restriction or limitation that the hospital may need to place on such rights and the reasons for the clinical restriction or limitation.	*See Interpretive Guidelines for §482.13(h)* *See Survey Procedures for §482.13(h)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.13 -- Condition of participation: Patient's rights.*
A-0216	(h) [Standard: Patient visitation rights. A hospital must have written policies and procedures regarding the visitation rights of patients, including those setting forth any clinically necessary or reasonable restriction or limitation that the hospital may need to place on such rights and the reasons for the clinical restriction or limitation. A hospital must meet the following requirements:] (1) Inform each patient (or support person, where appropriate) of his or her visitation rights, including any clinical restriction or limitation on such rights, when he or she is informed of his or her other rights under this section. (2) 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 their right to withdraw or deny such consent at any time.	*See Interpretive Guidelines for §482.13(h)(1) & (2)* *See Survey Procedures for §482.13(h)(1) & (2)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.13 -- Condition of participation: Patient's rights.*

A-0217	(h) [Standard: Patient visitation rights. A hospital must have written policies and procedures regarding the visitation rights of patients, including those setting forth any clinically necessary or reasonable restriction or limitation that the hospital may need to place on such rights and the reasons for the clinical restriction or limitation. A hospital must meet the following requirements:] (3) Not restrict, limit, or otherwise deny visitation privileges on the basis of race, color, national origin, religion, sex, gender identity, sexual orientation, or disability. (4) Ensure that all visitors enjoy full and equal visitation privileges consistent with patient preferences.	*See Interpretive Guidelines for §482.13(h)(3) & (4)* *See Survey Procedures for §482.13(h)(3) & (4)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.13 -- Condition of participation: Patient's rights.*

Related Joint Commission Standards

Rights and Responsibilities of the Individual:

- RI.01.01.01, EP 1 – 2, 28 – 29

Related DNV Standards

Specific Rights

- PR.2 (SR.12a)
- PR.2 (SR.12b)
- PR.2 (SR.12c)
- PR.2 (SR.12d)
- PR.2 (SR.12(e))

Related ACHC Standards

Patient Rights and Safety:

- 15.01.12
- 15.01.13
- 15.01.14

Related CIHQ Standard

Right to Visitation:

- PR-12

§482.13 (h) *CoP* Analysis/Guidelines

All accreditors have corresponding requirements.

Survey Tips:

- Review patient visitation policy and ensure that any limitations on visitation are clinically driven.
- Review visitation policy to ensure requirements related to visitation. Ensure that policy addresses when it may be clinically necessary or reasonable to restrict or limit visitation, but that visitation cannot be restricted, limited, or otherwise denied based on race, color, national origin, religion, sex, sexual orientation, gender identity, or disability.
- Review patient rights posters and other materials to ensure that CMS visitation and patient visitor support person are addressed.

Suggested Documents:

- Patient visitation policy
- Patient rights posters, brochures, and policy that reflect visitation requirements

§482.15 *CoP*: Emergency Preparedness		
Tag #	CMS *CoP* (2023)	CMS Interpretive Guidelines and Survey Procedures
E-0001	[For Hospitals §482.15]: The hospital must comply with all applicable federal, state, and local emergency preparedness requirements. The hospital must develop and maintain a comprehensive emergency preparedness program that meets the requirements of this section. The emergency preparedness program must include, but not be limited to, the following elements: NOTE: This does not apply to Transplant Programs.	*State Operations Manual – Appendix Z* *som107ap_z_emergprep.pdf (cms.gov)* *eCFR :: 42 CFR 482.15 -- Condition of participation: Emergency preparedness.*
E-0002	*Conditions of Participation:* Emergency preparedness for transplant programs. A transplant program must be included in the emergency preparedness planning and the emergency preparedness program as set forth in §482.15 for the hospital in which it is located. However, a transplant program is not individually responsible for the emergency preparedness requirements set forth in §482.15.	*See Interpretive Guidelines for §482.78* *som107ap_z_emergprep.pdf (cms.gov)* *eCFR :: 42 CFR 482.15 -- Condition of participation: Emergency preparedness.*
E-0004	(a) Emergency Plan. The [hospital or CAH] must comply with all applicable federal, state, and local emergency preparedness requirements. The [hospital or CAH] must develop and maintain a comprehensive emergency preparedness program that meets the requirements of this section, utilizing an all-hazards approach and updated at least every 2 years.	*See Interpretive Guidelines for §482.15* *som107ap_z_emergprep.pdf (cms.gov)* *eCFR :: 42 CFR 482.15 -- Condition of participation: Emergency preparedness.*
E-0005	**(a) Standard: Policies and Procedures.** A transplant program must have policies and procedures that address emergency preparedness. These policies and procedures must be included in the hospital's emergency preparedness program.	*See Interpretive Guidelines for §482.78(a)* *som107ap_z_emergprep.pdf (cms.gov)* *eCFR :: 42 CFR 482.15 -- Condition of participation: Emergency preparedness.*

E-0006	[(a) Emergency Plan. The [facility] must develop and maintain an emergency preparedness plan that must be reviewed, and updated at least every 2 years. The plan must do the following:] (1) Be based on and include a documented, facility-based and community-based risk assessment, utilizing an all-hazards approach. (2) Include strategies for addressing emergency events identified by the risk assessment	*See Interpretive Guidelines for §482.15(a)(1)* *som107ap_z_emergprep.pdf (cms.gov)* *eCFR :: 42 CFR 482.15 -- Condition of participation: Emergency preparedness.*
E-0007	[(a)(3) Emergency Plan. The [facility] must develop and maintain an emergency preparedness plan that must be reviewed, and updated at least every 2 years. The plan must do the following:] (3) Address patient/client population, including, but not limited to persons at risk, the type of services the hospital has the ability to provide in an emergency; and continuity of operations, including delegations of authority and succession plans. Note: This does not apply to Transplant Programs or OPOs [Organ Procurement Organizations].	*See Interpretive Guidelines for §482.15(a)(3)* *som107ap_z_emergprep.pdf (cms.gov)* *eCFR :: 42 CFR 482.15 -- Condition of participation: Emergency preparedness.*
E-0008	[(a)(3) *Conditions for Participation:* Emergency Plan. The [facility] must develop and maintain an emergency preparedness plan that must be reviewed, and updated at least every 2 years. The plan must do the following:] (3) Address the type of hospitals with which the OPO has agreements; the type of services the OPO has the capacity to provide in an emergency; and continuity of operations, including delegations of authority and succession plans.	*See Interpretive Guidelines for §486.360(a)(3)* *som107ap_z_emergprep.pdf (cms.gov)* *eCFR :: 42 CFR 482.15 -- Condition of participation: Emergency preparedness.*

E-0009	[(a)(4) Emergency Plan. The [facility] must develop and maintain an emergency preparedness plan that must be reviewed, and updated at least every 2 years. The plan must do the following:] (4) Include a process for cooperation and collaboration with local, tribal, regional, state, and federal emergency preparedness officials' efforts to maintain an integrated response during a disaster or emergency situation. Note: This does not apply to Transplant Programs.	*See Interpretive Guidelines for §482.15(a)* *som107ap_z_emergprep.pdf (cms.gov)* *eCFR :: 42 CFR 482.15 -- Condition of participation: Emergency preparedness.*
E-0010	[(a)(4) *Conditions for Participation:* Emergency Plan. The Clinics, Rehabilitation Agencies, and Public Health Agencies as Providers of Outpatient Physical Therapy and Speech- Language Pathology Services ("Organizations") must develop and maintain an emergency preparedness plan that must be reviewed, and updated at least every 2 years. The plan must do the following:] (4) Address the location and use of alarm systems and signals; and methods of containing fire.	*See Interpretive Guidelines for §485.727(a)(4)* *som107ap_z_emergprep.pdf (cms.gov)* *eCFR :: 42 CFR 482.15 -- Condition of participation: Emergency preparedness.*
E-0011	(a)(5) Condition for Participation: [(a) Emergency Plan. The Comprehensive Outpatient Rehabilitation Facility (CORF) must develop and maintain an emergency preparedness plan that must be reviewed, and updated at least every 2 years. The plan must do the following:] (a)(5) Be developed and maintained with assistance from fire, safety, and other appropriate experts. (a)(6) Condition for Participation: [(a) Emergency Plan. The Clinics, Rehabilitation Agencies, and Public Health Agencies as Providers of Outpatient Physical Therapy and Speech-Language Pathology Services ("Organizations") must develop and maintain an emergency preparedness plan that must be reviewed, and updated at least every 2 years. The plan must do the following:] (a)(6) Be developed and maintained with assistance from fire, safety, and other appropriate experts.	*See Interpretive Guidelines for §485.68(a)(5) and §485.727(a)(6)* *som107ap_z_emergprep.pdf (cms.gov)* *eCFR :: 42 CFR 482.15 -- Condition of participation: Emergency preparedness.*

E-0012	Condition of Participation: Emergency preparedness for transplant programs. A transplant program must be included in the emergency preparedness planning and the emergency preparedness program as set forth in §482.15 for the hospital in which it is located. However, a transplant program is not individually responsible for the emergency preparedness requirements set forth in §482.15. (a) Standard: Policies and procedures. A transplant program must have policies and procedures that address emergency preparedness. These policies and procedures must be included in the hospital's emergency preparedness program. (b) Standard: Protocols with hospital and OPO. A transplant program must develop and maintain mutually agreed upon protocols that address the duties and responsibilities of the transplant program, the hospital in which the transplant program is operated, and the OPO designated by the Secretary, unless the hospital has an approved waiver to work with another OPO, during an emergency.	*See Interpretive Guidelines for §482.78(a) and §482.78(b)* *som107ap_z_emergprep.pdf (cms.gov)* *eCFR :: 42 CFR 482.15 -- Condition of participation: Emergency preparedness.*

Related Joint Commission Standards

Emergency Management:

- EM.09.01.01, EP 1, 3
- EM.11.01.01, EP 1 – 4
- EM.12.01.01, EP 1, 2, 6
- EM.13.01.01, EP 1 – 4
- EM.17.01.01, EP 3

Related DNV Standards

Emergency Management System

Emergency Preparedness

- PE.6 Introduction
- PE.6 (SR.1)
- PE.6 (SR.1a)
- PE.6 (SR.2)
- PE.6 (SR.3)
- PE.6 (SR.3a)

Related ACHC Standards

Emergency Management:

- 09.00.01
- 09.00.02
- 09.00.03
- 09.00.04
- 09.00.05
- 09.00.06
- 09.00.07

Related CIHQ Standards

Establishment of an Emergency Preparedness Program:

- EP-1

Emergency Preparedness Plan and Risk Assessment:

- EP-2

§482.15 (a) *CoP* Analysis/Guidelines

CMS issued this new rule to create a consistent foundation of emergency preparedness across the healthcare system, ensuring that providers across the spectrum are better positioned to respond to disasters and ensure continuity of care for some of the most at-risk populations. The providers impacted by this include home health services, dialysis centers, long-term care facilities, community mental health centers, rural health clinics, intermediate care facilities for people with intellectual disabilities, critical access hospitals, and others.

The final rule obligates CMS deemed-status organizations to comply with key best-practice standards, including:

- Emergency plan: After conducting a risk assessment, create an emergency plan employing an all-hazards approach targeting capabilities and capacities essential to preparedness emergencies and disasters particular to the location of a provider or supplier. Policies and procedures support the implementation of the emergency plan.
- Communication planning: As part of emergency planning, create and maintain a communication strategy that conforms to state and federal law, with the goal of patient care being well coordinated within the facility, across healthcare providers, and with local and state emergency systems and health departments.
- Training and testing: Develop and implement training programs (initial and annual trainings included), and conduct exercises that test the plan; evaluate the exercises and responses to actual emergencies to inform improvements in preparedness.
- Emergency and standby power systems.
- Integrated healthcare systems (optional): Healthcare systems that include multiple facilities (each separately certified as a Medicare-participating provider or supplier) have the option of developing a unified and integrated emergency preparedness program that supports coordinated preparedness, response, and recovery across system providers.

In February 2019, CMS issued QSO-19-06 updating Appendix Z of the *SOM* to add emerging infectious diseases to the definition of *all-hazards approach*, new home health agency (HHA) citations, and clarifications under alternative-source power and emergency standby systems. You will also find important emergency preparedness definitions in the *SOM* Appendix Z Interpretive Guidance QSO-21-15-ALL.

Survey Tips:

- Review Emergency Operations Plan against the new requirements, including the update to Appendix Z.
- Develop continuity in Operations Plan.
- Develop the 1135 waiver policy.

Suggested Documents:

- Emergency Operations Plan and addendums to those plans
- After-action analysis of emergency exercises and drills
- Continuity of Operations Plan
- 1135-waiver policy
- Homeland Security Exercise and Evaluation Program (HSEEP) January 2020.

State Health Care Coalitions: *https://www.cms.gov/about-cms/agency-information/emergency/epro/ resources/state-resources.*

§482.15 *CoP*: Emergency Preparedness		
Tag #	CMS *CoP* (2023)	CMS Interpretive Guidelines and Survey Procedures
E-0013	**(b) Policies and procedures.** [Facilities] must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least every two years. *[For LTC (long-term care) facilities at §483.73(b):] Policies and procedures. The LTC facility must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least annually.*	*State Operations Manual—Appendix Z* *See Interpretive Guidelines for §482.15(b)* *See Survey Procedures for §482.15(b)* *som107ap_z_emergprep.pdf (cms.gov)* *eCFR :: 42 CFR 482.15 -- Condition of participation: Emergency preparedness.*
E-0014	(b) Standard: Protocols with hospital and OPO. A transplant program must develop and maintain mutually agreed upon protocols that address the duties and responsibilities of the transplant program, the hospital in which the transplant program is operated, and the OPO designated by the Secretary, unless the hospital has an approved waiver to work with another OPO, during an emergency	*See Interpretive Guidelines for §482.78(b)* *See Survey Procedures for §482.15(b)* *som107ap_z_emergprep.pdf (cms.gov)* *eCFR :: 42 CFR 482.15 -- Condition of participation: Emergency preparedness.*
E-0015	[(b) Policies and procedures. [Facilities] must develop and implement emergency preparedness policies and procedures based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated every 2 years [annually for LTC facilities].	*See Interpretive Guidelines for §482.15(b)(1), §482.15(b)(1)(i), & §482.15(b)(1)(ii)* *See Survey Procedures for §482.15(b)(1)* *som107ap_z_emergprep.pdf (cms.gov)* *eCFR :: 42 CFR 482.15 -- Condition of participation: Emergency preparedness.*

E-0015	At a minimum, the policies and procedures must address the following: (6) The provision of subsistence needs for staff and patients, whether they evacuate or shelter in place, include but are not limited to the following: (iii) Food, water, medical, and pharmaceutical supplies. (iv) Alternative sources of energy to maintain the following: (A) Temperatures to protect patient health and safety and for the safe and sanitary storage of provisions. (B) Emergency lighting. (C) Fire detection, extinguishing, and alarm systems. (D) Sewage and waste disposal. [For Inpatient Hospice at §418.113(b)(6)(iii):] Policies and procedures. (7) The following are additional requirements for hospice-operated inpatient care facilities only. The policies and procedures must address the following: (iii) The provision of subsistence needs for hospice employees and patients, whether they evacuate or shelter in place, include, but are not limited to the following: (A) Food, water, medical, and pharmaceutical supplies. (B) Alternate sources of energy to maintain the following: (1) Temperatures to protect patient health and safety and for the safe and sanitary storage of provisions. (2) Emergency lighting. (3) Fire detection, extinguishing, and alarm systems. (C) Sewage and waste disposal.	

E-0018	[(b) Policies and procedures. The [facilities] must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least every 2 years [annually for LTC facilities]. At a minimum, the policies and procedures must address the following:] (2) A system to track the location of on-duty staff and sheltered patients in the hospital's care during an emergency. If on-duty staff and sheltered patients are relocated during the emergency, the facility must document the specific name and location of the receiving facility or other location.	*See Interpretive Guidelines for §482.15(b)(2)* *See Survey Procedures for §482.15(b)(2)* *som107ap_z_emergprep.pdf (cms.gov)* *eCFR :: 42 CFR 482.15 -- Condition of participation: Emergency preparedness.*
E-0020	[(b) Policies and procedures. The [facilities] must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least every 2 years [annually for LTC facilities]. At a minimum, the policies and procedures must address the following:] (3) Safe evacuation from the hospital, which includes consideration of care and treatment needs of evacuees; staff responsibilities; transportation; identification of evacuation location(s); and primary and alternative means of communication with external sources of assistance.	*See Interpretive Guidelines for §482.15(b)(3)* *See Survey Procedures for §482.15(b)(3)* *som107ap_z_emergprep.pdf (cms.gov)* *eCFR :: 42 CFR 482.15 -- Condition of participation: Emergency preparedness.*

E-0021	*Condition of Participation:* [(b) Policies and procedures. The HHA must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least every 2 years. At a minimum, the policies and procedures must address the following:] (3) The procedures to follow up with on-duty staff and patients to determine services that are needed, in the event that there is an interruption in services during or due to an emergency. The HHA must inform State and local officials of any on-duty staff or patients that they are unable to contact.	*See Interpretive Guidelines for §484.102(b)(3)* *See Survey Procedures for §484.102(b)(3)* *som107ap_z_emergprep.pdf (cms.gov)* *eCFR :: 42 CFR 482.15 -- Condition of participation: Emergency preparedness.*
E-0022	[(b) Policies and procedures. The [facilities] must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least every 2 years [annually for LTC *facilities*]. At a minimum, the policies and procedures must address the following:] (4) A means to shelter in place for patients, staff, and volunteers who remain in the hospital.	*See Interpretive Guidelines for §482.15(b)(4)* *See Survey Procedures for §482.15(b)(4)* *som107ap_z_emergprep.pdf (cms.gov)* *eCFR :: 42 CFR 482.15 -- Condition of participation: Emergency preparedness.*
E-0023	[(b) Policies and procedures. The [facilities] must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least every 2 years [annually for LTC *facilities*]. At a minimum, the policies and procedures must address the following:] (5) A system of medical documentation that preserves patient information, protects confidentiality of patient information, and secures and maintains availability of records.	*See Interpretive Guidelines for §482.15(b)(5)* *See Survey Procedures for §482.15(b)(5)* *som107ap_z_emergprep.pdf (cms.gov)* *eCFR :: 42 CFR 482.15 -- Condition of participation: Emergency preparedness.*

E-0024	[(b) Policies and procedures. The [facilities] must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least every 2 years [annually for LTC *facilities*]. At a minimum, the policies and procedures must address the following:] (6) The use of volunteers in an emergency and other emergency staffing strategies, including the process and role for integration of state and federally designated healthcare professionals to address surge needs during an emergency.	*See Interpretive Guidelines for 482.15(b)(6)* *See Survey Procedures for 482.15(b)(6)* *som107ap_z_emergprep.pdf (cms.gov)* *eCFR :: 42 CFR 482.15 -- Condition of participation: Emergency preparedness.*
E-0025	[(b) Policies and procedures. The [facilities] must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least every 2 years [annually for LTC *facilities*]. At a minimum, the policies and procedures must address the following:] (7) The development of arrangements with other hospitals and other providers to receive patients in the event of limitations or cessation of operations to maintain the continuity of services to hospital patients.	*See Interpretive Guidelines for §482.15(b)(7)* *See Survey Procedures for §482.15(b)(7)* *som107ap_z_emergprep.pdf (cms.gov)* *eCFR :: 42 CFR 482.15 -- Condition of participation: Emergency preparedness.*
E-0026	[(b) Policies and procedures. The [facilities] must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least every 2 years [annually for LTC *facilities*]. At a minimum, the policies and procedures must address the following:]	*See Interpretive Guidelines for §482.15(b)(8)* *See Survey Procedures for §482.15(b)(8)* *som107ap_z_emergprep.pdf (cms.gov)* *eCFR :: 42 CFR 482.15 -- Condition of participation: Emergency preparedness.*

	(8) The role of the hospital under a waiver declared by the Secretary, in accordance with section 1135 of the Act, in the provision of care and treatment of an alternative care site identified by emergency management officials.	

Related Joint Commission Standards

Environment of Care:

- EC.02.03.01, EP 9

Emergency Management:

- EM.12.01.01, EP 1, 3
- EM.12.02.01, EP 6
- EM.17.01.01, EP 3
- EM.12.01.01, EP 3, 4, 9
- EM.12.02.03, EP 1, 2
- EM.12.02.05, EP 1
- EM.12.02.07, EP 2
- EM.12.02.11, EP 4

Information Management:

- IM.01.01.03, EP 1, 2
- IM.02.01.01, EP 1, 4
- IM.02.01.03, EP 1, 5

Related Joint Commission Standards

Emergency Management System

- PE.6 - Introduction
- PE.6 (SR.1)
- PE.6 (SR.2)
- PE.6 (SR.3)
- PE.6 (SR.3b)
- PE.6 (SR.3c)
- PE.6 (SR.3d)
- PE.6 (SR.3e)
- PE.6 (SR.3f)
- PE.6 (SR.3g)
- PE.6 (SR.3i)
- PE.8 (SR.5)
- PE.8 (SR.6)

- PE.8 (SR.8)
- PE.8 (SR.9)
- PE.8 (SR.10)

Related ACHC Standards

Emergency Management

- 09.01.01
- 09.01.02
- 09.01.03
- 09.01.04
- 09.01.05
- 09.01.06
- 09.01.07
- 09.01.08
- 09.01.09
- 09.01.10
- 09.01.11

Related CIHQ Standard

Emergency Preparedness Policies and Procedures:

- EP-3

§482.15 (b) *CoP* Analysis/Guidelines

Same as §482.15(a) above.

§482.15 *CoP*: Emergency Preparedness		
Tag #	CMS *CoP* (2023)	CMS Interpretive Guidelines and Survey Procedures
E-0029	**(c) Communication plan.** The hospital must develop and maintain an emergency preparedness communication plan that complies with federal, state, and local laws and must be reviewed and updated at least annually.	*See Interpretive Guidelines for §482.15(c)* *See Survey Procedures for §482.15(c)* *som107ap_z_emergprep.pdf (cms.gov)* *eCFR :: 42 CFR 482.15 -- Condition of participation: Emergency preparedness.*
E-0030	The communication plan must include all of the following: (1) Names and contact information for the following: (i) Staff (ii) Entities providing services under arrangement (iii) Patients' physicians (iv) Other hospitals and CAHs (v) Volunteers	*See Interpretive Guidelines for §482.15(c)(1)* *See Survey Procedures for §482.15(c)(1)* *som107ap_z_emergprep.pdf (cms.gov)* *eCFR :: 42 CFR 482.15 -- Condition of participation: Emergency preparedness.*
E-0031	(2) Contact information for the following: (i) Federal, state, tribal, regional, and local emergency preparedness staff (ii) Other sources of assistance	*See Interpretive Guidelines for §482.15(c)(2)* *See Survey Procedures for §482.15(c)(2)* *som107ap_z_emergprep.pdf (cms.gov)* *eCFR :: 42 CFR 482.15 -- Condition of participation: Emergency preparedness.*
E-0032	(3) Primary and alternative means for communicating with the following: (i) Hospital staff (ii) Federal, state, tribal, regional, and local emergency management agencies	*See Interpretive Guidelines for §482.15(c)(3)* *See Survey Procedures for §482.15(c)(3)* *som107ap_z_emergprep.pdf (cms.gov)* *eCFR :: 42 CFR 482.15 -- Condition of participation: Emergency preparedness.*

E-0033	(4) A method for sharing information and medical documentation for patients under the hospital's care, as necessary, with other healthcare providers to maintain the continuity of care. (5) A means, in the event of an evacuation, to release patient information as permitted under 45 *CFR* [*Code of Federal Regulations*] 164.510(b)(1)(ii). (6) A means of providing information about the general condition and location of patients under the hospital's care as permitted under 45 *CFR* 164.510(b)(4).	*See Interpretive Guidelines for §482.15(c)(4) – (6)* *See Survey Procedures for §482.15(c)(4) – (6)* *som107ap_z_emergprep.pdf (cms.gov)* *eCFR :: 42 CFR 482.15 -- Condition of participation: Emergency preparedness.*
E-0034	(7) A means of providing information about the hospital's occupancy, needs, and ability to provide assistance to the authority having jurisdiction, the Incident Command Center, or designee.	*See Interpretive Guidelines for §482.15(c)(7)* *See Survey Procedures for §482.15(c)(7)* *som107ap_z_emergprep.pdf (cms.gov)* *eCFR :: 42 CFR 482.15 -- Condition of participation: Emergency preparedness.*

Related Joint Commission Standards

Emergency Management:

- EM.09.01.01, EP 3
- EM.12.01.01, EP 1
- EM.12.02.01, EP 1, 3, 5, 6
- EM.12.02.05, EP 1
- EM.17.01.01, EP 3

Related DNV Standards

Emergency Management System

- PE.6 - Introduction
- PE.6 (SR.1)
- PE.6 (SR.2)
- PE.6 (SR.3j)
- PE.6 (SR.3j(1))
- PE.6 (SR.3i(2))
- PE.6 (SR.3k)
- PE.6 (SR.3l)

Related ACHC Standards

Emergency Management:

- 09.02.01
- 09.02.02
- 09.02.03
- 09.02.04
- 09.02.05
- 09.02.06

Related CIHQ Standard

Emergency Preparedness Communication Plan:

- EP-4

§482.15 (c) *CoP* Analysis/Guidelines

Same as §482.15(a) above.

§482.15 *CoP*: Emergency Preparedness		
Tag #	CMS *CoP* (2023)	CMS Interpretive Guidelines and Survey Procedures
E-0036	**(d) Training and Testing.** The hospital must develop and maintain an emergency preparedness training and testing program that is based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, policies and procedures at paragraph (b) of this section, and the communication plan at paragraph (c) of this section. The training and testing program must be reviewed and updated at least annually.	*See Interpretive Guidelines for §482.15(d)* *See Survey Procedures for §482.15(d)* som107ap_z_emergprep.pdf (cms.gov) eCFR :: 42 CFR 482.15 -- Condition of participation: Emergency preparedness.
E-0037	(1) Training Program. The hospital must do all of the following: (i) Initial training in emergency preparedness policies and procedures to all new and existing staff, individuals providing onsite services under arrangement, and volunteers, consistent with their expected role (ii) Provide emergency preparedness training at least annually (iii) Maintain documentation of the training (iv) Demonstrate staff knowledge of emergency procedures	*See Interpretive Guidelines for §482.15(d)(1)* *See Survey Procedures for §482.15(d)(1)* *som107ap_z_emergprep.pdf (cms.gov)* *eCFR :: 42 CFR 482.15 -- Condition of participation: Emergency preparedness.*
E-0039	(2) Testing. The hospital must conduct exercises to test the emergency plan at least annually. The hospital must do all of the following: (i) Participate in a full-scale exercise that is community-based every 2 years; or (A) When a community-based exercise is not accessible, conduct a facility- based functional exercise every 2 years; or	*See Interpretive Guidelines for §482.15(d)(2)* *See Survey Procedures for §482.15(d)(2)* *som107ap_z_emergprep.pdf (cms.gov)* *eCFR :: 42 CFR 482.15 -- Condition of participation: Emergency preparedness.*

	(B) If the [facility] experiences an actual natural or man-made emergency that requires activation of the emergency plan, the [facility] is exempt from engaging in its next required community-based or individual, facility-based functional exercise following the onset of the actual event. (ii) Conduct an additional exercise at least every 2 years, opposite the year the full-scale or functional exercise under paragraph (d)(2)(i) of this section is conducted, that may include, but is not limited to the following: (A) A second full-scale exercise that is community-based or individual, facility-based functional exercise; or (B) A mock disaster drill; or (C) A tabletop exercise or workshop that is led by a facilitator and includes a group discussion using a narrated, clinically relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan. (iii) Analyze the [facility's] response to and maintain documentation of all drills, tabletop exercises, and emergency events, and revise the [facility's] emergency plan, as needed.	

Related Joint Commission Standards

Emergency Management:

- EM.15.01.01, EP 1, 2, 3
- EM.16.01.01, EP 1, 2
- EM.17.01.01, EP 1, 3

Related DNV Standards

Emergency Management System

Emergency Management

- PE.6 (SR.2)
- PE.6 (SR.3m)
- PE.6 (SR.4)
- PE.6 (SR.4a)
- PE.6 (SR.4b)
- PE.6 (SR.4c)
- PE.6 (SR.4b(1))
- PE.6 (SR.4b(2))
- PE.6 (SR.4b(3))

Related ACHC Standards

Emergency Management:

- 09.03.01
- 09.03.02

Related CIHQ Standards

Emergency Preparedness Training Program:

- EP-5

Testing of the Emergency Preparedness Plan:

- EP-6

§482.15 (d) *CoP* Analysis/Guidelines

Same as §482.15(a) above.

§482.15 *CoP*: Emergency Preparedness		
Tag #	CMS *CoP* (2023)	CMS Interpretive Guidelines and Survey Procedures
E-0041	Condition for Participation: **(e) Emergency and standby power systems.** The hospital must implement emergency and standby power systems based on the emergency plan set forth in paragraph (a) of this section and in the policies and procedures plan set forth in paragraphs (b)(1)(i) and (ii) of this section. (1) Emergency generator location. The generator must be located in accordance with the location requirements found in the Health Care Facilities Code (NFPA 99 and Tentative Interim Amendments [TIA] TIA 12 – 3, TIA 12 – 4, TIA 12 – 5, and TIA 12 – 6), *Life Safety Code* (*LSC*; NFPA 101 and TIA 12 – 1, TIA 12 – 2, TIA 12 – 3, and TIA 12 – 4), and NFPA 110, when a new structure is built or when an existing structure or building is renovated. (2) Emergency generator inspection and testing. The hospital must implement the emergency power system inspection, testing, and maintenance requirements found in the Health Care Facilities Code, NFPA 110, and *Life Safety Code*. (3) Emergency generator fuel. Hospitals that maintain an on-site fuel source to power emergency generators must have a plan for how it will keep emergency power systems operational during the emergency, unless it evacuates. The standards incorporated by reference in this section are approved for incorporation by reference by the Director of the Office of the Federal Register in accordance with 5 U.S.C. [U.S. Code] 552(a) and 1 *CFR* part 51. You may obtain the material from the sources listed below. You may inspect a copy at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to:	*See Interpretive Guidelines for §482.15(e)* *See Survey Procedures for §482.15(e)* *som107ap_z_emergprep.pdf (cms.gov)* *eCFR :: 42 CFR 482.15 -- Condition of participation: Emergency preparedness.*

	http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations. html. If any changes in this edition of the Code are incorporated by reference, CMS will publish a document in the *Federal Register* to announce the changes. (1) National Fire Protection Association 1 Batterymarch Park, Quincy, MA 02169 www.nfpa.org, 617-770-3000. (i) NFPA 99, Health Care Facilities Code, 2012 edition, issued August 11, 2011. (ii) TIA 12 – 2 to NFPA 99, issued August 11, 2011. (iii) TIA 12 – 3 to NFPA 99, issued August 9, 2012. (iv) TIA 12 – 4 to NFPA 99, issued March 7, 2013. (v) TIA 12 – 5 to NFPA 99, issued August 1, 2013. (vi) TIA 12 – 6 to NFPA 99, issued March 3, 2014. (vii) NFPA 101, *Life Safety Code*, 2012 edition, issued August 11, 2011. (viii) TIA 12 – 1 to NFPA 101, issued August 11, 2011. (ix) TIA 12 – 2 to NFPA 101, issued October 30, 2012. (x) TIA 12 – 3 to NFPA 101, issued October 22, 2013. (xi) TIA 12 – 4 to NFPA 101, issued October 22, 2013. (xiii) *NFPA 110 Standard for Emergency and Standby Power Systems,* 2010 edition, including TIAs to Chapter 7, issued August 6, 2009.	

Related Joint Commission Standards

Emergency Management:

- 12.02.11, EP 1, 2, 3

Environment of Care:

- EC.02.06.05, EP 1
- EC.02.05.07, EP 3 – 11

Related DNV Standards

Emergency Management System

- PE.1 - Introduction
- PE.1 (SR.3)
- PE.6 (SR.2)
- PE.6 (SR.5)
- PE.6 (SR.5a)
- PE.6 (SR.5b)
- PE.6 (SR.5c)
- PE.8 (SR.6)

Related ACHC Standard

Emergency Management:

- 09.04.01

Related CIHQ Standard

Emergency and Standby Power Systems:

- EP-7

§482.15 (e) *CoP* Analysis/Guidelines

Same as §482.15(a) above.

§482.15 *CoP*: Emergency Preparedness		
Tag #	CMS *CoP* (2023)	CMS Interpretive Guidelines and Survey Procedures
E-0042	**(f)** ***Condition of Participation:*** **Emergency Preparedness Standard: Integrated Health Systems** Integrated healthcare systems. If a hospital is part of a healthcare system consisting of multiple separately certified healthcare facilities that elects to have a unified and integrated emergency preparedness program, the hospital may choose to participate in the healthcare system's coordinated emergency preparedness program. If elected, the unified and integrated emergency preparedness program must do all of the following: (1) Demonstrate that each separately certified facility within the system actively participated in the development of the unified and integrated emergency preparedness program. (2) Be developed and maintained in a manner that takes into account each separately certified facility's unique circumstances, patient populations, and services offered. (3) Demonstrate that each separately certified facility is capable of actively using the unified and integrated emergency preparedness program and is in compliance with the program. (4) Include a unified and integrated emergency plan that meets the requirements of paragraphs (a)(2), (3), and (4) of this section. The unified and integrated emergency plan must also be based on and include the following: (i) A documented community-based risk assessment, utilizing an all-hazards approach. (ii) A documented individual facility-based risk assessment for each separately certified facility within the health system, utilizing an all-hazards approach.	*See Interpretive Guidelines for §482.15(f)* *See Survey Procedures for §482.15(f)* *som107ap_z_emergprep.pdf (cms.gov)* *eCFR :: 42 CFR 482.15 -- Condition of participation: Emergency preparedness.*

E-0042	(5) Include integrated policies and procedures that meet the requirements set forth in paragraph (b) of this section, a coordinated communication plan, and training and testing programs that meet the requirements of paragraphs (c) and (d) of this section, respectively. Note: This does not apply to Transplant.	

Related Joint Commission Standards

Emergency Management:

- EM.09.01.01, EP 2, 3
- EM.11.01.01, EP 3, 4
- EM.12.01.01, EP 1, 2, 6
- EM.13.01.01, EP 1 – 4
- EM.15.01.01, EP 1
- EM.16.01.01, EP 1
- EM.17.01.01, EP 3

Related DNV Standards

Emergency Management System

- PE.6 (SR.6)
- PE.6 (SR.6a)
- PE.6 (SR.6b)
- PE.6 (SR.6c)
- PE.6 (SR.6d)
- PE.6 (SR.6d(i))
- PE.6 (SR.6(ii))
- PE.6 (SR.6e)

Related ACHC Standards

Emergency Management:

- 09.04.02

Related CIHQ Standards

Healthcare Systems and Emergency Preparedness:

- EP-8

§482.15 (f) *CoP* Analysis/Guidelines

Same as §482.15(a) above.

§482.15 *CoP*: Emergency Preparedness		
Tag #	CMS *CoP* (2023)	CMS Interpretive Guidelines and Survey Procedures
E-043	**(g) Transplant hospitals.** If a hospital has one or more transplant centers (as defined in §482.70): (1) A representative from each transplant center must be included in the development and maintenance of the hospital's emergency preparedness. (2) The hospital must develop and maintain mutually agreed upon protocols that address the duties and responsibilities of the hospital, each transplant center, and the OPO for the DSA [Data Sharing Agreement] where the hospital is situated, unless the hospital has been granted a waiver to work with another OPO, during an emergency.	*See Interpretive Guidelines for §482.15(g)* *See Survey Procedures for §482.15(g)* *som107ap_z_emergprep.pdf (cms.gov)* *eCFR :: 42 CFR 482.15 -- Condition of participation: Emergency preparedness.*
E-044	(e) Continuity of OPO operations during an emergency. Each OPO must have a plan to continue operations during an emergency. (1) The OPO must develop and maintain in the protocols with transplant programs required under §486.344(d), mutually agreed upon protocols that address the duties and responsibilities of the transplant program, the hospital in which the transplant program is operated, and the OPO during an emergency. (2) The OPO must have the capability to continue its operation from an alternate location during an emergency. The OPO could either have: (i) An agreement with one or more other OPOs to provide essential organ procurement services to all or a portion of its DSA in the event the OPO cannot provide those services during an emergency; (ii) If the OPO has more than one location, an alternate location from which the OPO could conduct its operation; or	*See Interpretive Guidelines for §486.360(e)* *See Survey Procedures for §486.360(e)* *som107ap_z_emergprep.pdf (cms.gov)* *eCFR :: 42 CFR 482.15 -- Condition of participation: Emergency preparedness.*

	(iii) A plan to relocate to another location as part of its emergency plan as required by paragraph (a) of this section.	

Related Joint Commission Standard

Emergency Management:

- EM.09.01.01, EP 4

Related DNV Standards

Emergency Management System

- PE.6 (SR.7)

Related ACHC Standard

Emergency Management:

- 09.04.03

Related CIHQ Standard

Transplant Centers and Emergency Preparedness:

- EP-9

§482.15 (g) *CoP* Analysis/Guidelines

Same as §482.15(a) above.

§482.21 *CoP*: Quality Assessment and Performance Improvement Program

Tag #	CMS *CoP* (2023)	CMS Interpretive Guidelines and Survey Procedures
A-0263	*Condition of Participation:* Quality Assessment and Performance Improvement Program The hospital must develop, implement, and maintain an effective, ongoing, hospital-wide, data-driven quality assessment and performance improvement program. The hospital's governing body must ensure that the program reflects the complexity of the hospital's organization and services; involves all hospital departments and services (including those services furnished under contract or arrangement); and focuses on indicators related to improved health outcomes and the prevention and reduction of medical errors. The hospital must maintain and demonstrate evidence of its QAPI program for review by CMS.	*See Interpretive Guidelines for §482.21* *See Survey Procedures for §482.21* *som107ap_z_emergprep.pdf (cms.gov)* *eCFR :: 42 CFR 482.15 -- Condition of participation: Emergency preparedness.*
A-0273	Data Collection & Analysis **(a) Standard: Program Scope** (1) The program must include, but not be limited to, an ongoing program that shows measurable improvement in indicators for which there is evidence that it will improve health outcomes… (2) The hospital must measure, analyze, and track quality indicators … and other aspects of performance that assess processes of care, hospital service, and operations.	*See Interpretive Guidelines for §482.21(a)* *See Survey Procedures for §482.21(a)* *som107ap_z_emergprep.pdf (cms.gov)* *eCFR :: 42 CFR 482.15 -- Condition of participation: Emergency preparedness.*

Related Joint Commission Standards

Leadership:

- LD.01.03.01, EP 21
- LD.03.02.01, EP 1, 4
- LD.03.05.01, EP 1 – 3
- LD.03.07.01, EP 1, 2
- LD.03.09.01, EP 1, 8
- LD.04.03.09, EP 2, 4 – 7

Performance Improvement:

- PI.03.01.01 EP 3, 4, 8
- PI.04.01.01 EP 2, 5

National Patient Safety Goal

- NPSG 16.01.01 EP. 1 – 3

Related DNV Standards

Responsibility and Accountability

- QM.1 (SR.1)
- QM.1 (SR.1a)
- QM.1 (SR.1a(1))

Quality Outline/Plan

- QM.3 (SR.1)

Quality Management System

- QM.6 - Interpretive Guidelines

Patient Safety System

- QM.8 (SR.1)

Measuring, Monitoring, Analysis

- QM.7 – Introduction
- QM.7 (SR.4)
- QM.7 (SR.4a)
- QM.7 (SR.4b)
- QM.7 (SR.4c)
- QM.7 (SR.4d)
- QM.7 (SR.4e)
- QM.7 (SR.4f)
- QM.7 (SR.4g)
- QM.7 (SR.4h)
- QM.7 (SR.4h(1))
- QM.7 (SR.4h(2))
- QM.7 (SR.4i)
- QM.7 (SR.4i(1))
- QM.7 (SR.4i(2))
- QM.7 (SR.4j)

- QM.7 (SR.4k)
- QM.7 (SR.4k(1))
- QM.7 (SR.4l)
- QM.7 (SR.4m)
- QM.7 (SR.4n)
- QM.7 (SR.4o)
- QM.7 (SR.4p)
- QM.7 (SR.4q)
- QM.7 (SR.4r)
- QM.7 (SR.4s)

Related ACHC Standards

Quality Assessment and Performance Improvement (QAPI):

- 12.00.00
- 12.00.01

Related CIHQ Standards

Quality Assessment / Performance Improvement (QA/PI) Program:

- QA-1

§482.21 (a) *CoP* Analysis/Guidelines

CMS standards focus on clinical plans, medically related patient care services, and implementation. Standards also focus on program scope, data, activities, performance improvement projects, and executive responsibilities. The hospital must have an ongoing program and set priorities and expectations, allocate resources, and evaluate the effectiveness and outcomes of its activities. Simply collecting data is not enough; data must be analyzed and used regularly to make decisions and improvements about quality, safety, and care outcomes in the hospital.

CMS focuses not only on organization-wide performance improvement but also wants to see the plan for department-specific performance improvement initiatives. All levels of the organization should demonstrate active participation. All accreditors comply with minimum expectations of CMS, but there are additional expectations by both NIAHO/DNV and The Joint Commission that do not crosswalk CMS expectations.

Survey Tips:

- Review data collection methods, analyze data, and identify trends with appropriate action plans.
- Review the CMS Surveyor Worksheet for QAPI to evaluate your program and program data, located at *www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-15-12-Attachment-2.pdf.*
- Ensure trending of occurrence reporting information. Ensure that steps identified out of occurrence analysis are closed, for an individual occurrence or trended information.

- Demonstrate that occurrences have been investigated and acted on to show performance improvement related to each event.
- Ensure timely closure of root cause analysis projects and peer review. Consider the need for expedited or external peer review when serious medical events occur.
- Review state requirements for reporting and maintain a log of state reportable events.
- Ensure contract services' performance review is integrated into the quality program and moved up through the governing body.
- Provide ongoing education/training to staff on quality processes, tools, hospital-wide projects, and patient safety goals and efforts.
- Coach staff on the activities and projects underway within the organization.
- Ensure there is evidence that the governing body has identified priorities and responsibilities regarding quality and safety.
- Demonstrate process to determine organizational priorities.
- Ensure the QAPI calendar of reporting includes organization-wide, department-level reports and the components of measurement and analysis required by your accrediting body.

Suggested Documents:

- The hospital's written QAPI/patient safety program, program evaluation, and annual calendar of reporting, which includes department initiatives
- List of performance improvement initiatives by the department
- The organizational meeting structure shows the flow of information up through the governing body
- The organizational chart of the quality/patient safety department
- Required quality improvement data collection and analysis
- Policy on sentinel events, adverse events, and occurrence reporting
- Summary of sentinel events, adverse events, and occurrences, which should include an assessment of staff adequacy, reported to leaders at least annually
- Quality committee meeting minutes
- Quality improvement reports to the governing body and medical executive committee
- Examples of the medical staff involved in evidence-based practice teams, clinical effectiveness groups, and quality committees

§482.21 *CoP*: Quality Assessment and Performance Improvement Program		
Tag #	CMS *CoP* (2023)	CMS Interpretive Guidelines and Survey Procedures
A-0273	Quality Improvement Activities Data Data Collection & Analysis **(b) Standard: Program Data** (1) The program must incorporate quality indicator data including patient care data, and other relevant data *such as data submitted to or received from Medicare quality reporting and quality performance programs, including but not limited to data related to hospital readmissions and hospital-acquired conditions.* (2) The hospital must use the data collected to— (i) Monitor the effectiveness and safety of services and quality of care; and… (3) The frequency and detail of data collection must be specified by the hospital's governing body.	*See Interpretive Guidelines for §482.21(a), §482.21(b)(1), §482.21(b)(2)(i), and §482.21(b)(3)* *See Survey Procedures for §482.21(a), 482.21(b)(1), §482.21(b)(2)(i), and §482.21(b)(3)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.21 -- Condition of participation: Quality assessment and performance improvement program.*
A-0283	Quality Improvement Activities Standard: Program Data The hospital must use the data collected to— … (ii) Identify opportunities for improvement and changes that will lead to improvement.	*See Interpretive Guidelines for* §482.21(b)(2)(ii) *See Survey Procedures for* §§482.21(b)(2)(ii) *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.21 -- Condition of participation: Quality assessment and performance improvement program.*

Related Joint Commission Standards

Leadership:

- LD.03.01.01, EP 2
- LD.03.02.01, EP 1, 4
- LD.03.07.01, EP 2
- LD.03.09.01, EP 8

Performance Improvement:

- PI.03.01.01, EP 4, 8

National Patient Safety Goals:

- NPSG.16.01.01 EP 1-3

Related DNV Standards

Measuring, Monitoring, Analysis

- QM.7 - Introduction
- QM.7 (SR.1)
- QM.7 (SR.2)
- OM.7 (SR.3)
- QM.7 (SR.4)
- QM.7 (SR.4s)

Related ACHC Standards

Data collection and analysis:

- 12.00.01

Quality Assessment and Performance Improvement (QAPI):

- 12.00.02
- 12.00.03
- 12.00.05

Related CIHQ Standards

Collection and Use of Data:

- QA-2

§482.21 (b) *CoP* Analysis/Guidelines

Same as §482.21(a) Analysis/Guidelines.

§482.21 *CoP*: Quality Assessment and Performance Improvement Program		
Tag #	CMS *CoP* (2023)	CMS Interpretive Guidelines and Survey Procedures
A-0283	Quality Improvement Activities (continued) **(c) Standard: Program Activities** (1) The hospital must set priorities for its performance improvement activities that — (i) Focus on high-risk, high-volume, or problem-prone areas; (ii) Consider the incidence, prevalence, and severity of problems in those areas; and (iii) Affect health outcomes, patient safety, and quality of care. (2) The hospital must take actions aimed at performance improvement, and, after implementing those actions, the hospital must measure its success and track performance to ensure that improvements are sustained.	*See Interpretive Guidelines for §482.21(c)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.21 -- Condition of participation: Quality assessment and performance improvement program.*
A-0286	Patient Safety, Medical Errors, and Adverse Events— (a) Standard: Program Scope (1) The program must include but not be limited to, an ongoing program that shows measurable improvements in indicators for which there is evidence that it will identify and reduce medical errors. (2) The hospital must measure, analyze, and track adverse patient events. (c) Standard: Program Activities (2) Performance improvement activities must track medical errors and adverse patient events, analyze their causes, and implement preventive actions and mechanisms that include feedback and learning throughout the hospital. (e) Standard: Executive Responsibilities. The hospital's governing body (or organized group or individual who assumes full legal authority and responsibility for operations of the hospital), medical staff, and administrative officials are responsible and accountable for ensuring the following: … (2) That clear expectations for safety are established.	*See Interpretive Guidelines for §§482.21(a)(1), 482.21(a)(2), 482.21(c)(2), & 482.21(e)(3)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.21 -- Condition of participation: Quality assessment and performance improvement program.*

Related Joint Commission Standards

Leadership:

- LD.03.03.01, EP 2
- LD.03.05.1, EP 3
- LD.03.07.01, EP 2
- LD.03.08.01, EP 1
- LD.03.09.01, EP 3, 4, 5, 7 – 10

Performance Improvement:

- PI.03.01.01, EP 4, 8
- PI.04.01.01, EP 2, 5

Related DNV Standards

Patient Safety System

- QM.7 – Introduction
- QM.7 (SR.1)
- QM.7 (SR.3)
- QM.7 (SR.3a)
- QM.7 (SR.3b)
- QM.7 (SR.3c)
- QM.8 (SR.2)
- QM.8 (SR.2a)
- QM.8 (SR.2b)
- QM.8 (SR.2c)
- QM.8 (SR.2d)
- QM.8 (SR.2e)
- QM.8 (SR.2f)
- QM.8 (SR.2g)

Medical Errors and Adverse Events

- QM.8 (SR.1)
- QM.1 (SR.1b)

Related ACHC Standards

Quality Assessment and Performance Improvement (QAPI):

- 12.02.01
- 12.00.02
- 12.00.03

Related CIHQ Standards

Quality Assessment / Performance Improvement (QA/PI) Program:

- QA-1

Collection and Use of Data:

- QA-2

Leadership Responsibility for Performance Improvement:

- QA-5

§482.21 (c) *CoP* Analysis/Guidelines

Same as §482.21(a) Analysis/Guidelines.

§482.21 *CoP*: Quality Assessment and Performance Improvement Program		
Tag #	CMS *CoP* (2023)	CMS Interpretive Guidelines and Survey Procedures
A-0297	Performance Improvement Projects **(d) Standard: Performance Improvement Projects—** As part of its quality assessment and performance improvement program, the hospital must conduct performance improvement projects. (1) The number and scope of distinct improvement projects conducted annually must be proportional to the scope and complexity of the hospital's services and operations. (2) A hospital may, as one of its projects, develop and implement an information technology system explicitly designed to improve patient safety and quality of care. This project, in its initial stage of development, does not need to demonstrate measurable improvement in indicators related to health outcomes. (3) The hospital must document what quality improvement projects are being conducted, the reasons for conducting these projects, and the measurable progress achieved on these projects. (4) A hospital is not required to participate in a QIO [quality improvement organization] cooperative project, but its own projects are required to be of comparable effort. (5) The number and scope of distinct improvement projects conducted annually must be proportional to the scope and complexity of the hospital's services and operations. (6) A hospital may, as one of its projects, develop and implement an information technology system explicitly designed to improve patient safety and quality of care. This project, in its initial stage of development, does not need to demonstrate measurable improvement in indicators related to health outcomes.	*See Interpretive Guidelines for §482.21(d)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.21 -- Condition of participation: Quality assessment and performance improvement program.*

	(7) The hospital must document what quality improvement projects are being conducted, the reasons for conducting these projects, and the measurable progress achieved on these projects. (8) A hospital is not required to participate in a QIO [quality improvement organization] cooperative project, but its own projects are required to be of comparable effort.	
A-0308	*Condition of Participation:* Quality Assessment and Performance Improvement Program The hospital's governing body must ensure that the program reflects the complexity of the hospital's organization and services; involves all hospital departments and services (including those services furnished under contract or arrangement). The hospital must maintain and demonstrate evidence of its QAPI program for review by CMS. Note: Standard Tag for requirements found only in Condition stem statement.	

Related Joint Commission Standards

Leadership:

- LD.01.03.01, EP 21
- LD.03.02.01, EP 1
- LD.03.05.01, EP 1 – 3
- LD.03.07.01, EP 1, 2
- LD.03.09.01, EP 1, 8, 10, 11
- LD.04.03.09, EP 2, 4 – 7

Performance Improvement:

- PI.03.01.01, EP 3, 4, 8
- PI.04.01.01 EP 2, 5

Information Management:

- IM.02.02.03, EP 2

Related DNV Standards

Quality Management Systems

- QM.1 (SR.1)
- QM.1 (SR.1a)
- QM.1 (SR.1e)
- QM.1 (SR.1e(1))
- QM.1 (SR.1e(1)(i)
- QM.1 (SR.1e(2))
- QM.1 (SR.1e(3))

Related ACHC Standards

Quality Assessment and Performance Improvement (QAPI):

- 12.00.04
- 12.00.05

Related CIHQ Standards

QAPI Program:

- QA-1

§482.21 (d) *CoP* Analysis/Guidelines

Same as §482.21(a) Analysis/Guidelines.

§482.21 *CoP*: Quality Assessment and Performance Improvement Program		
Tag #	CMS *CoP* (2023)	CMS Interpretive Guidelines and Survey Procedures
A-0309	Executive Responsibilities **(e) Standard: Executive Responsibilities** — The hospital's governing body (or organized group or individual who assumes full legal authority and responsibility for operations of the hospital), medical staff, and administrative officials are responsible and accountable for ensuring the following: (1) That an ongoing program for quality improvement and patient safety, including the reduction of medical errors, is defined, implemented, and maintained. (2) That the hospital-wide quality assessment and performance improvement efforts address priorities for improved quality of care and patient safety and that all improvement actions are evaluated. (5) That the determination of the number of distinct improvement projects is conducted annually.	*See Interpretive Guidelines for §482.21(e)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.21 -- Condition of participation: Quality assessment and performance improvement program.* *See Interpretive Guidelines for §482.21(e)(1), (2), & (5)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.21 -- Condition of participation: Quality assessment and performance improvement program.*
A-0315	Providing Adequate Resources (e) Standard: Executive Responsibilities The hospital's governing body (or organized group or individual who assumes full legal authority and responsibility for operations of the hospital), medical staff, and administrative officials are responsible and accountable for ensuring the following: (4) That adequate resources are allocated for measuring, assessing, improving, and sustaining the hospital's performance and reducing risk to patients.	*See Interpretive Guidelines for §482.21(e)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.21 -- Condition of participation: Quality assessment and performance improvement program.* *SOM Appendix A -Interpretive Guidelines for 42 CFR 482.21, Quality Assessment & Performance Improvement (QAPI) Program*

A-0320	**(f) Standard: Unified and integrated QAPI program for multihospital systems.** If a hospital is part of a hospital system consisting of multiple separately certified hospitals using a system governing body that is legally responsible for the conduct of two or more hospitals, the system governing body can elect to have a unified and integrated QAPI program for all of its member hospitals after determining that such a decision is in accordance with all applicable State and local laws. The system governing body is responsible and accountable for ensuring that each of its separately certified hospitals meets all of the requirements of this section. Each separately certified hospital subject to the system governing body must demonstrate that:	*See Interpretive Guidelines for §482.21(f)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.21 -- Condition of participation: Quality assessment and performance improvement program.*
A-0321	The unified and integrated QAPI program 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	*See Interpretive Guidelines for §482.21(f)(1)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.21 -- Condition of participation: Quality assessment and performance improvement program.*
A-0322	The unified and integrated QAPI program establishes and implements policies and procedures to ensure that the needs and concerns of each of its separately certified hospitals, regardless of practice or location, are given due consideration, and that the unified and integrated QAPI program has mechanisms in place to ensure that issues localized to particular hospitals are duly considered and addressed.	*See Interpretive Guidelines for §482.21(f)(2)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.21 -- Condition of participation: Quality assessment and performance improvement program.*

Related Joint Commission Standards

Leadership:

- LD.01.03.01, EP 5, 6, 14
- LD.03.05.01, EP 1, 3
- LD.03.07.01, EP 1, 2
- LD.03.09.01, EP 1 – 10
- LD.04.01.05, EP 4
- LD.04.03.09, EP 6
- LD.04.01.11, EP 5

- LD.08.01.01, EP 1, 5, 6, 8

Performance Improvement:

- PI.01.01.01, EP 4, 5, 7, 12, 13
- PI.03.01.01, EP 3, 4, 8
- PI.04.01.01, EP 2, 5

Related DNV Standards

Quality Management Systems:

- QM.1 (SR.1a)
- QM.1 (SR.1a(1))
- QM.1 (SR.1b)
- QM.1 (SR.1c)
- QM.1 (SR.1e(1))
- QM.6 (SR.6)
- QM.6 (SR.6a)
- QM.6 (SR.6b)

Related ACHC Standards

Quality Assessment and Performance Improvement (QAPI):

- 12.00.05
- 12.00.03
- 12.00.06
- 12.00.08

Related CIHQ Standards

Leadership Responsibility for Performance Improvement:

- QA-5

Unified and Integrated Health Systems:

- QA-6

§482.21 (e)–(f) *CoP* Analysis/Guidelines

Same as §482.21(a) Analysis/Guidelines.

§482.22 *CoP*: Medical Staff		
Tag #	CMS *CoP* (2023)	CMS Interpretive Guidelines and Survey Procedures
A-0338	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.	*See Interpretive Guidelines for §482.22* *See Survey Procedures for §482.22* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.22 -- Condition of participation: Medical staff.*
A-0339	**(a) Standard: Eligibility & Process for Appointment to 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 §482.12(c)(1)) and non-physician practitioners who are determined to be eligible for appointment by the governing body.	*See Interpretive Guidelines for §482.22(a)* *See Survey Procedures for §482.22(a)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.22 -- Condition of participation: Medical staff.*
A-0340	(1) The medical staff must periodically conduct appraisals of its members.	*See Interpretive Guidelines for §482.22(a)(1)* *See Survey Procedures for §482.22(a)(1)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.22 -- Condition of participation: Medical staff.*
A-0341	(2) The medical staff must examine the credentials of all eligible candidates for medical staff membership and make recommendations to the governing body on the appointment of the candidates in accordance with State law, including scope-of-practice laws, and the medical staff bylaws, rules, and regulations. A candidate who has recommended by the medical staff and who has been appointed by the governing body is subject to all medical staff bylaws, rules, and regulations, in addition to the requirements contained in this section.	*See Interpretive Guidelines for §482.22(a)(2)* *See Survey Procedures for §482.22(a)(2)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.22 -- Condition of participation: Medical staff.*

A-0342	When telemedicine services are furnished to the hospital's patients through an agreement with a distant-site telemedicine entity (hospital), the governing body of the hospital whose patients are receiving the telemedicine services may choose, in lieu of the requirements in paragraphs (a)(1) and (a)(2) of this section, to have its medical staff rely upon the credentialing and privileging decisions made by the distant-site telemedicine entity (hospital) when making recommendations on privileges for the individual distant-site physicians and practitioners providing such services, if the hospital's governing body ensures, through its written agreement with the distant-site telemedicine entity (hospital), furnishes services that, in accordance with §482.12(e), permit the hospital to comply with all applicable conditions of participation for the contracted services. The hospital's governing body must also ensure, through its written agreement with the distant-site telemedicine entity, that all of the following provisions are met: (i) The distant-site telemedicine entity's (hospital) medical staff credentialing and privileging process and standards at least meet the standards at §482.12(a)(1) through (a)(7) and §482.22(a)(1) through (a)(2). (ii) The individual distant-site physician or practitioner is privileged at the distant-site telemedicine entity (hospital) providing the telemedicine services, which provides the hospital a current list of the distant-site physician's or practitioner's privileges at the distant-site telemedicine entity (hospital). (iii) The individual distant-site physician or practitioner holds a license issued or recognized by the State in which the hospital whose patients are receiving the telemedicine services is located. (iv) With respect to a distant-site physician or practitioner, who holds current privileges at the hospital whose patients are receiving the telemedicine services, the hospital has evidence of an internal review of the distant-site physician's or practitioner's performance of these privileges and sends	*See Interpretive Guidelines for §482.22(a)(3)* *See Survey Procedures for §482.22(a)(3)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.22 -- Condition of participation: Medical staff.*

	the distant-site hospital such performance information for use in the periodic appraisal of the distant-site physician or practitioner. At a minimum, this information must include all adverse events that result from the telemedicine services provided by the distant-site physician or practitioner to the hospital's patients and all complaints the hospital has received about the distant- site physician or practitioner.	
A-0343	(3) When telemedicine services are furnished to the hospital's patients through an agreement with a distant-site telemedicine entity, the governing body of the hospital whose patients are receiving the telemedicine services may choose, in lieu of the requirements in paragraphs (a)(1) and (a)(2) of this section, to have its medical staff rely upon the credentialing and privileging decisions made by the distant-site telemedicine entity when making recommendations on privileges for the individual distant-site physicians and body practitioners providing such services, if the hospital's governing body ensures, through its written agreement with the distant-site telemedicine entity, that the distant-site telemedicine entity furnishes services that, in accordance with §482.22(e), permit the hospital to comply with all applicable conditions of participation for the contracted services. The hospital's governing body must also ensure, through its written agreement with the distant-site telemedicine entity, that all of the following provisions are met: (i) The distant-site telemedicine entity's medical staff credentialing and privileging process and standards at least meet the standards at §482.12(a)(1) through (a)(7) and §482.22(a)(1) through (a)(2). (ii) The individual distant-site physician or practitioner is privileged at the distant- site telemedicine entity providing the telemedicine services, which provides the hospital with a current list of the distant-site physician's or practitioner's privileges at the distant-site telemedicine entity.	*See Interpretive Guidelines for §482.22(a)(4)* *See Survey Procedures for §482.22(a)(4)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.22 -- Condition of participation: Medical staff.*

	(iii) The individual distant-site physician or practitioner holds a license issued or recognized by the State in which the hospital whose patients are receiving such telemedicine services is located. (iv) With respect to a distant-site physician or practitioner, who holds current privileges at the hospital whose patients are receiving the telemedicine services, the hospital has evidence of an internal review of the distant-site physician's or practitioner's performance of these privileges and sends the distant-site telemedicine entity such performance information for use in the periodic appraisal of the distant-site physician or practitioner. At a minimum, this information must include all adverse events that result from the telemedicine services provided by the distant-site physician or practitioner to the hospital's patients, and all complaints the hospital has received about the distant-site physician or practitioner.	

Related Joint Commission Standards

Leadership:

- LD.01.01.01, EP
- LD.01.05.01, EP 1, 6
- LD.04.03.09, EP 1 – 6, 23

Medical Staff:

- MS.01.01.01, EP 1, 2, 5 – 7, 12 – 14
- MS.02.01.01, EP 11
- MS.03.01.01, EP 2
- MS.06.01.03, EP 1, 2, 4, 6
- MS.06.01.05, EP 1 – 3, 6 – 10, 12
- MS.06.01.07, EP 8 – 9
- MS.06.01.09, EP 1 – 4
- MS.07.01.01, EP 1 – 3, 5
- MS.08.01.01, EP 1, 4, 6
- MS.08.01.03, EP 1 – 3
- MS.09.01.01, EP 1, 2
- MS.13.01.01, EP 1

Related DNV Standards

Medical Staff:

- MS.1 (SR.1)
- MS.3 (SR.1)
- MS.2 (SR.2)
- MS.2 (SR.3)
- MS.2 (SR.5)
- MS.2 (SR.6)
- MS.8 - Introduction
- MS.8 (SR.1)
- MS.8 (SR.1a)
- MS.8 (SR.1b)
- MS.8 (SR.1c)
- MS.15 (SR.1b)
- MS.15 SR.1b(1)
- MS.15 SR.1b(2)
- MS.15 SR.1b(3)
- MS.15 SR.1b(4)
- MS.15 (SR.1b(1))
- MS.15 (SR.1b(2))
- MS.15 (SR.1b(3))
- MS.15 (SR.1b(4))
- MS.15 (SR.2b)
- MS.15 SR.2b(1)
- MS.15 SR.2b(2)
- MS.15 SR.2b(3)
- MS.15 SR.2b(4)

Related ACHC Standards

Medical Staff:

- 03.00.00
- 03.00.01
- 03.00.02
- 03.00.06
- 03.00.08
- 03.00.09

Related CIHQ Standards

Organized Medical Staff:

- MS-1

Granting of Clinical Privileges:

- MS-5

Appointment and Reappointment to the Medical Staff:

- MS-4

Appraisal of Practitioners:

- MS-12

Provision of Telemedicine Services by a Distant Site:

- MS-9

§482.22 (a) *CoP* Analysis/Guidelines

CMS and AOs require that there must be an organized medical staff that operates under bylaws. They also require that the medical staff be accountable to the hospital board for the quality of medical care provided.

CMS allows medical staff working in a hospital system made up of multiple, separately certified hospitals to participate in a unified, integrated medical staff for two or more of the system's member hospitals, as long as state law permits.

The system governing body must elect to use a separate and distinct medical staff or unified, system-level integrated medical staff. If using a multisystem medical staff structure, there are several Interpretive Guidelines requirements that must be met and medical staff at each hospital must vote to accept the unified staff structure used. The majority of people on the medical staff executive committee should be MDs and DOs. The medical staff organization must include MDs or DOs but may also include, in accordance with state laws, other categories of physicians listed at §482.12(c)(1) as well as nonphysician practitioners.

The medical staff bylaws should outline the processes necessary to meet both CMS' and AOs' accreditation requirements regarding medical staff membership, organization, and accountability and the role of the governing body in decisions. CMS and AOs have requirements that must be considered when appointing medical staff. Additionally, The Joint Commission and NIAHO/DNV include information that must be considered with peer recommendations.

CMS and all AOs require the use of government-issued identification for initial appointment and primary source verification for initial appointment, reappointment, and any modification of privileges.

CMS and all other AOs state that practitioners cannot perform activities or procedures that haven't been done at their hospital before or are not on their list of privileges. To get permission to do the initial activity or procedure, the practitioner must provide evidence of their qualifications to perform the procedure and that the activity or procedure can be supported by the hospital.

DNV and The Joint Commission require procedures for temporary privileges and consults, as well as a process for acting on concerns related to care provided by the medical staff. The Joint Commission requires a fair hearing and appeal process consistent with the regulations tied to the Health Care Quality Improvement Act of 1986 for medical staff members who have had adverse decisions related to the appointment or reappointment of privileges. However, CMS and other accreditors do not have this requirement.

CMS and AOs are in alignment regarding telemedicine privileges. NIAHO/DNV has a unique standard requiring that all individuals with delineated privileges participate in continuing education that is partially related to their clinical privileges, and that the documentation of continuing education be considered in reappointment decisions and renewal or revision of privileges.

Survey Tips:

- Review contract for telemedicine privileges if using distant-site information.
- Review bylaws for process and time frames for completion of medical staff applications, reapplications, credentialing, and privileging procedures.
- Verify that the bylaws outline the categories of practitioners eligible for appointment to the medical staff and that they outline responsibilities of the medical staff organization, of which a majority must be MD/DOs.
- Ensure that the responsibility and conduct of the medical staff is assigned to an MD/DO or, if permitted by state law, a doctor of dental surgery or dental medicine or doctor of podiatric medicine.
- Verify that bylaws contain all required components required by CMS and accreditor and are approved by the governing body. If Joint Commission accredited, also verify that the bylaws are adopted and amended by the medical staff at large.
- If the hospital is accredited by the Joint Commission, those identified in the bylaws as having voting rights can vote to adopt and amend the medical staff bylaws.
- If Joint Commission accredited, verify the bylaws contain the essential requirements described in MS.01.01.01, EP 12 – 37. Consider tabbing these mandatory requirements to simplify the search during survey.
- Review medical staff bylaws if using distant-site information for telemedicine providers.
- Review credential files to verify information is up to date and complete.
- Ensure the unique requirements of each accreditor are followed regarding appointment, reappointment, practitioner appraisal, and privileging.
- Verify that requirements for occupational health screening and insurance verification are managed annually if the reappointment process required by the accreditor is every two years. Ensure procedures for periodic appraisal are performed in accordance with the accreditor's requirements and at the accreditor's required frequency.
- Ensure nursing staff have access and know how to determine whether an LP is on the medical staff and their privileges.
- Verify that there is a mechanism to verify the licensure status and appropriateness of physicians who order outpatient testing but may not have privileges at the hospital.

Suggested Documents:

- Medical staff bylaws/P&Ps
- Telemedicine agreements, if any
- Medical staff organizational structure, including reporting relationship to governing body
- Chart depicting medical staff meeting structure
- Credentials committee meeting minutes
- Privileging documents
- Medical staff executive committee meeting minutes

§482.22 *CoP*: Medical Staff		
Tag #	CMS *CoP* (2023)	CMS Interpretive Guidelines and Survey Procedures
A-0347	**(b) Standard: Medical Staff Organization and Accountability—** The medical staff must be well organized and accountable to the governing body for the quality of the medical care provided to the patients. (1) The medical staff must be organized in a manner approved by the governing body. (2) If the medical staff has an executive committee, a majority of the members of the committee must be Doctors of Medicine or osteopathy. (3) The responsibility for organization and conduct of the medical staff must be assigned only to one of the following: (i) an individual Doctor of Medicine or osteopathy; (ii) a doctor of dental surgery or dental medicine, when permitted by State law of the State in which the hospital is located; or (iii) a doctor of podiatric medicine, when permitted by State law of the State in which the hospital is located.	*See Interpretive Guidelines for §482.22(b)(1 – 3)* *See Survey Procedures for §482.22(b)(1 – 3)* *SOM Appendix A (cms.gov)* *eCFR: 42 CFR 482.22—Condition of Participation: Medical staff*
A-0348	(4) If a hospital is part of a hospital system consisting of multiple separately certified hospitals and the system elects to have a unified and integrated medical staff for its member hospitals, after determining that such a decision is in accordance with all applicable State and local laws, each separately certified hospital must demonstrate that: ...	*See Interpretive Guidelines for §482.22(b)(4)* *See Survey Procedures for §482.22(b)(4)* *SOM Appendix A (cms.gov)* *eCFR: 42 CFR 482.22—Condition of participation: Medical staff*
A-0349	[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: ...]	*See Interpretive Guidelines for §482.22(b)(4)(i)* *See Survey Procedures for §482.22(b)(4)(i)* *SOM Appendix A (cms.gov)*

	(i) The medical staff members of each separately certified hospital in the system (i.e., 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;	*eCFR :: 42 CFR 482.22 -- Condition of participation: Medical staff.*
A-0350	[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: ...] (ii) 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 (i.e., 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;	*See Interpretive Guidelines for §482.22(b)(4)(ii)* *See Survey Procedures for §482.22(b)(4)(ii)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.22 -- Condition of participation: Medical staff.*
A-0351	[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: ...] (iii) 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 ...	*See Interpretive Guidelines for §482.22(b)(4)(iii)* *See Survey Procedures for §482.22(b)(4)(iii)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.22 -- Condition of participation: Medical staff.*

A-0352	[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: ...] (iv) 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.	*See Interpretive Guidelines for §482.22(b)(4)(iv)* *See Survey Procedures for §482.22(b)(4)(iv)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.22 -- Condition of participation: Medical staff.*

Related Joint Commission Standards

Leadership:

- LD.01.05.01, EP 4, 6, 7

Medical Staff:

- MS.01.01.01, EP 5, 6, 12, 17
- MS.01.01.05, EP 1 – 7, 12 – 15, 17, 22, 26, 27, 34, 37
- MS.02.01.01, EP 4

Related DNV Standards

Medical Staff:

- MS.1 (SR.1)
- MS.1 (SR.2)
- MS.1 (SR.4)
- MS.1 (SR.4a)
- MS.1 (SR.4b)
- MS.1 (SR.4c)
- MS.1 (SR.4d)
- MS.1 (SR.5)

Related ACHC Standards

Medical Staff:

- 03.00.10
- 03.00.11
- 03.00.12
- 03.00.13
- 03.00.14
- 03.00.15

Related CIHQ Standards

Organized Medical Staff:

- MS-1

Appointment and Reappointment to the Medical Staff

- MS-4

Granting of Clinical Privileges

- MS-5

Provision of Telemedicine Services by a Distant Site

- MS-9

Appraisal of Practitioners

- MS-12

§482.22 (b) *CoP* Analysis/Guidelines

Same as §482.22(a) Analysis/Guidelines.

§482.22 *CoP*: Medical Staff		
Tag #	CMS *CoP* (2023)	CMS Interpretive Guidelines and Survey Procedures
A-0353	**(c) Standard: Medical staff bylaws—** The medical staff must adopt and enforce bylaws to carry out its responsibilities. The bylaws must:	*See Interpretive Guidelines for §482.22(c)* *See Survey Procedures for §482.22(c)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.22 -- Condition of participation: Medical staff.*
A-0354	[The bylaws must:] (1) Be approved by the governing body.	*See Interpretive Guidelines for §482.22(c)(1)* *See Survey Procedures for §482.22(c)(1)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.22 -- Condition of participation: Medical staff.*
A-0355	[The bylaws must:] (2) Include a statement of the duties and privileges of each category of medical staff (e.g., active, courtesy, etc.).	*See Interpretive Guidelines for §482.22(c)(2)* *See Survey Procedures for §482.22(c)(2)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.22 -- Condition of participation: Medical staff.*
A-0356	[The bylaws must:] (3) Describe the organization of the medical staff.	*See Interpretive Guidelines for §482.22(c)(3)* *See Survey Procedures for §482.22(c)(3)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.22 -- Condition of participation: Medical staff.*

A-0357	[The bylaws must:] (4) Describe the qualifications to be met by a candidate in order for the medical staff to recommend that the candidate be appointed by the governing body.	*See Interpretive Guidelines for §482.22(c)(4)* *See Survey Procedures for §482.22(c)(4)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.22 -- Condition of participation: Medical staff.*
A-0358	[The bylaws must:] (5) Include a requirement that: (i) A medical history and physical exam be completed and documented 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, and except as provided under paragraph (c)(5)(iii) of this section. The medical history and physical examination must be completed and documented by a physician (as defined in section 1861(r) of the Act), an *oral and* maxillofacial surgeon, or other qualified licensed individual in accordance with State law and hospital policy.	*See Interpretive Guidelines for §482.22(c)(5)(i)* *See Survey Procedures for §482.22(c)(5)(i)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.22 -- Condition of participation: Medical staff.*
A-0359	[The bylaws must:] (ii) An updated exam of the patient, including any changes in the patient's condition, 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 exam are completed within 30 days before admission or registration, and except as provided under paragraph (c)(5) of this section. The updated exam of the patient, including any changes in the patient's condition, must be completed and documented by a physician (as defined in section 1861[r] of the Act), an oral and maxillofacial surgeon, or other qualified licensed individual in accordance with State law and hospital policy.	*See Interpretive Guidelines for §482.22(c)(5)(ii)* *See Survey Procedures for §482.22(c)(5)(ii)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.22 -- Condition of participation: Medical staff.*

A-0360	[The bylaws must:] Include a requirement that— (iii) An assessment of the patient (in lieu of the requirements of paragraphs (c)(5)(i) and (ii) of this section) be completed and documented after registration, but prior to surgery or a procedure requiring anesthesia services, when the patient is receiving specific outpatient surgical or procedural services and when the medical staff has chosen to develop and maintain a policy that identifies, in accordance with the requirements at paragraph (c)(5)(v) of this section, specific patients as not requiring a comprehensive medical history and physical examination, or any update to it, prior to specific outpatient surgical or procedural services. The assessment must be completed and documented by a physician (as defined in section (c)861(r) of the Act), an oral and maxillofacial surgeon, or other qualified licensed individual in accordance with State law and hospital policy.	*See Interpretive Guidelines for §(c)482.22(c)(5)(iii)* *Guidance is pending and will be updated in a future release.* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.22 -- Condition of participation: Medical staff.*
A-0361	[The bylaws must:] Include a requirement that — (iv) The medical staff develop and maintain a policy that identifies those patients for whom the assessment requirements of paragraph (c)(5)(iii) of this section would apply. The provisions of paragraphs (c)(5)(iii), (iv), and (v) of this section do not apply to a medical staff that chooses to maintain a policy that adheres to the requirements of paragraphs of (c)(5)(i) and (ii) of this section for all patients.	*See Interpretive Guidelines for §482.22(c)(5)(iv)* *Guidance is pending and will be updated in a future release.* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.22 -- Condition of participation: Medical staff.*
A-0362	[The bylaws must:] Include a requirement that: (v) The medical staff, if it chooses to develop and maintain a policy for the identification of specific patients to whom the assessment requirements in paragraph (c)(5)(iii) of this section would apply, must demonstrate evidence that the policy applies only to those patients receiving specific outpatient surgical or procedural services as well as evidence that the policy is based on:	*See Interpretive Guidelines for §482.22(c)(5)(v)* *Guidance is pending and will be updated in a future release.* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.22 -- Condition of participation: Medical staff.*

	(A) Patient age, diagnoses, the type and number of surgeries and procedures scheduled to be performed, comorbidities, and the level of anesthesia required for the surgery or procedure. (B) Nationally recognized guidelines and standards of practice for assessment of specific types of patients prior to specific outpatient surgeries and procedures. (C) Applicable state and local health and safety laws.	
A-0363	[The bylaws must:] (6) Include criteria for determining the privileges to be granted to individual practitioners and a procedure for applying the criteria to individuals requesting privileges. For distant- site physicians and practitioners requesting privileges to furnish telemedicine services under an agreement with the hospital, the criteria for determining privileges and the procedure for applying the criteria are also subject to the requirements in §482.12(a)(8) and (a)(9) and §482.22(a)(3) and (a)(4).	*See Interpretive Guidelines for §482.22(c)(6)* *See Survey Procedures for §482.22(c)(6)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.22 -- Condition of participation: Medical staff.*

Related Joint Commission Standards

Leadership:

- LD.04.03.09, EP 23

Medical Staff:

- MS.01.01.01, EP 1 – 36
- MS.03.01.01, EP 9
- MS.05.01.01, EP 9
- MS.07.01.01, EP 1
- MS.13.01.01, EP 1

Provision of Care, Treatment, and Services:

- PC.01.02.03, EP 5

Rights and Responsibilities of the Individual:

- RC.01.03.01, EP 4

Related DNV Standards

Medical Staff:

- MS.2 (SR.1)
- MS.3 (SR.1)
- MS.3 (SR.2)
- MS.6 (SR.1)
- MS.6 (SR.6)
- MS.13
- MS.13 (SR.1)
- MS.13 (SR.1a)
- MS.13 (SR.1b)
- MS.13 (SR.1c)
- MS.13 (SR.1b(1))
- MS.13 (SR.1b(2))
- MS.13 (SR.1b(3))
- MS.13 (SR.1b(4))
- MS.13 (SR.2)
- MS.13 (SR.4)
- MS.13 (SR.4a)
- MS.13 (SR.4a(1)
- MS.13 (SR.4a(2)(iii)
- MS.13 (SR.4a(2))
- MS.13 (SR.4a(2)(i))
- MS.13 (SR.4b)
- MS.13 (SR.4b(1))
- MS.13 (SR.4b(2))
- MS.13 (SR.4a(2)(ii))
- MS.15 (SR.1a)

Related ACHC Standards

Medical Staff:

- 03.01.01
- 03.01.02
- 03.01.03
- 03.01.04
- 03.01.06
- 03.01.07
- 03.01.08
- 03.01.09
- 03.01.10

Related CIHQ Standards

Medical Staff:

- MS-3

Granting of Clinical Privileges:

- MS-5

Provision of Telemedicine Services by a Distant Site:

- MS-9

§482.22 (c) *CoP* Analysis/Guidelines

Same as §482.22(a) Analysis/Guidelines. Additionally, audit histories and physicals for completeness per medical staff requirements, timeliness, and required update notes if performed within 30 days of admission or readmission.

§482.23 *CoP*: Nursing Services		
Tag #	CMS *CoP* (2023)	CMS Interpretive Guidelines and Survey Procedures
A-0385	The hospital must have an organized nursing service that provides 24-hour nursing services. The nursing services must be furnished or supervised by a registered nurse.	*See Interpretive Guidelines for §482.23* *See Survey Procedures for §482.23* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.23 -- Condition of participation: Nursing services.*
A-0386	**(a) Standard: Organization** The hospital must have a well-organized service with a plan of administrative authority and delineation of responsibilities for patient care. The director of the nursing service must be a licensed registered nurse. He or she is responsible for the operation of the service, including determining the types and numbers of nursing personnel and staff necessary to provide nursing care for all areas of the hospital.	*See Interpretive Guidelines for §482.23(a)* *See Survey Procedures for §482.23(a)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.23 -- Condition of participation: Nursing services.*

Related Joint Commission Standards

Leadership:

- LD.03.06.01, EP
- LD.04.03.01, EP 2

Nursing:

- NR.01.01.01, EP 1, 5
- NR.01.02.01, EP 2
- NR.02.03.01, EP 2 – 4, 6

Related DNV Standards

Nursing Service:

- NS.1 (SR.1)
- NS.1 (SR.2)
- NS.1 (SR.3)

Related ACHC Standards

Nursing Services:

- 16.00.00
- 16.00.03

Related CIHQ Standard

Nursing Services:

- NS-1

§482.23 (a) *CoP* Analysis/Guidelines

CMS and all accreditors are similar in the requirements for how the single nursing service is organized and the qualifications and functions of the chief nursing officer/executive who is an RN. CMS and all accreditors do not require the person in this position hold a postgraduate degree. These services must be integrated under the hospital's QAPI program.

Survey Tips:

- Confirm the chief nursing officer/executive file has a current job description and a primary source verification on their license. Also ensure that related onboarding, orientation, and ongoing training/education requirements have been met and performance has been reviewed.
- Review organizational structure and ensure that all areas, including off-campus locations, that provide nursing services report to the nurse executive, directly or indirectly.
- Verify nursing officer's/executive's authority to outline the budget and determine the sufficient numbers, types, and qualifications of supervisory and staff nursing personnel to meet the appropriate nursing needs and care of the patient population of each department or nursing unit.
- Ensure the nursing officer/executive is involved with or approves all nursing care P&Ps (hospital-wide and departmental).

Suggested Documents:

- Organizational chart for nursing services
- Job description for chief nursing officer and nursing personnel
- Policies/procedures and nursing care standards
- Staffing plans specific to nursing service and any acuity instruments for assessment of staffing

§482.23 *CoP*: Nursing Services		
Tag #	CMS *CoP* (2023)	CMS Interpretive Guidelines and Survey Procedures
A-0392	**(b) Standard: Staffing and Delivery of Care—** The nursing service must have adequate numbers of licensed registered nurses, licensed practical (vocational) nurses, and other personnel to provide nursing care to all patients as needed. There must be supervisory and staff personnel for each department or nursing unit to ensure, when needed, the immediate availability of a registered nurse for bedside care of any patient.	*See Interpretive Guidelines for §482.23(b)* *See Survey Procedures for §482.23(b)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.23 -- Condition of participation: Nursing services.*
A-0393	(1) The hospital must provide 24-hour nursing services furnished or supervised by a registered nurse and have a licensed practical nurse or registered nurse on duty at all times, except for rural hospitals that have in effect a 24-hour nursing waiver granted under §488.54(c) of this chapter.	*See Interpretive Guidelines for §482.23(b)(1)* *See Survey Procedures §482.23(b)(1)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.23 -- Condition of participation: Nursing services.*
A-0394	(2) The nursing service must have a procedure to ensure that hospital nursing personnel for whom licensure is required have valid and current licensure.	*See Interpretive Guidelines for §482.23(b)(2)* *See Survey Procedures for §482.23(b)(2)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.23 -- Condition of participation: Nursing services.*
A-0395	(3) A registered nurse must supervise and evaluate the nursing care for each patient.	*See Interpretive Guidelines for §482.23(b)(3)* *See Survey Procedures for §482.23(b)(3)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.23 -- Condition of participation: Nursing services.*

A-0396	(4) The hospital must ensure that the nursing staff develops and keeps current a nursing care plan for each patient that reflects the patient's goals and the nursing care to be provided to meet the patient's needs. The nursing care plan may be part of an interdisciplinary care plan.	*See Interpretive Guidelines for §482.23(b)(4)* *See Survey Procedures for §482.23(b)(4)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.23 -- Condition of participation: Nursing services.*
A-0397	(5) A registered nurse 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.	*See Interpretive Guidelines for §482.23(b)(5)* *See Survey Procedures for §482.23(b)(5)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.23 -- Condition of participation: Nursing services.*
A-0398	(6) All licensed nurses who provide services in the hospital must adhere to the P&Ps of the hospital. The director of nursing service must provide for the adequate supervision and evaluation of all nursing personnel which occur within the responsibility of the nursing service, regardless of the mechanism through which those personnel are providing services (that is, hospital employee, contract, lease, other agreement, or volunteer).	*See Interpretive Guidelines for §482.23(b)(6)* *See Survey Procedures for §482.23(b)(6)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.23 -- Condition of participation: Nursing services.*
A-0399	(7) The hospital must have policies and procedures in place establishing which outpatient departments, if any, are not required under hospital policy to have a registered nurse present. The policies and procedures must: (i) Establish the criteria such outpatient departments must meet, taking into account the types of services delivered, the general level of acuity of patients served by the department, and the established standards of practice for the services delivered (ii) Establish alternative staffing plans (iii) Be approved by the director of nursing (iv) Be reviewed at least once every 3 years	*See Interpretive Guidelines for §482.23(b)(7)* *Guidance is pending and will be updated in a future release.* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.23 -- Condition of participation: Nursing services.*

Related Joint Commission Standards

Human Resources:

- HR.01.01.01, EP 1 – 2
- HR.01.04.01, EP 1
- HR.01.06.01, EP 1, 3, 5, 6

Leadership:

- LD.03.06.01, EP 2, 3
- LD.04.03.09, EP 2, 6, 7

Nursing:

- NR.02.01.01, EP 2 – 4
- NR.02.02.01, EP 1
- NR.02.03.01, EP 2 – 4, 6 – 9

Provision of Care:

- PC.01.02.03, EP 3, 6
- PC.01.02.05, EP 1
- PC.01.03.01, EP 1, 5, 23
- PC.02.01.01, EP 5

Related DNV Standards

Nursing Service:

- NS.1 (SR.2)
- NS.1 (SR.3)
- NS.1 (SR.4)
- NS.1 (SR.5)
- NS.1 (SR.6)
- NS.1 (SR.7)
- NS.1 (SR.8)
- NS.1 (SR.8a)
- NS.1 (SR.8b)
- NS.1 (SR.8c)
- NS.1 (SR.8d)
- NS.3

- NS.3 (SR.1)
- NS.3 (SR.2)
- NS.3 (SR.3)
- NS.3 (SR.4)
- NS.3 (SR.5)

Related ACHC Standards

Nursing Services:

- 16.00.04
- 16.00.05
- 16.00.06
- 16.00.09
- 16.00.10
- 16.00.11
- 16.00.13
- 16.01.14

Related CIHQ Standards

Human Resources:

- HR-1, HR-4

Nursing Services:

- NS-1 – NS-3

§482.23 (b) *CoP* Analysis/Guidelines

CMS and accreditors require development of guidelines for care, delivery, and services. CMS and all accreditors require patient care to be under the supervision of an RN. CMS and all accreditors will ensure that when contracted (nonemployee) personnel are used by the organization, those individuals adhere to the practices and P&Ps of the organization and are well supervised. They will review the process for orienting these contracted individuals to the hospital, unit(s) they are assigned to, P&Ps, documentation requirements (particularly if a computerized medical record is utilized), and mandatory requirements for safety and emergency procedures to be followed. They will also determine the means by which competence is verified for the contracted individual(s) prior to their working in the organization. The competency requirements for contracted staff should be comparable to employed staff performing these similar duties. Lastly, they will evaluate the process by which contract staff's performance is evaluated. CMS has clarified that multidisciplinary care plans are acceptable, but not required, and this is reflected in both NIAHO/DNV and The Joint Commission. CMS and all accreditors focus on current plans of care and that it is initiated within 24 hours of admission. The Joint Commission also focuses on the need for an evaluation of the plan of care/progress toward goals. The Joint Commission and NIAHO/DNV both also address assessment requirements—The Joint Commission addresses those in standards separate from care planning standards, but DNV's are integrated within the care planning standards. There has been focus on centralized telemetry and video monitoring. This is viewed as an extension of a nursing unit so appropriate supervision requirements apply.

Survey Tips:

- Verify that all nursing staff have updated credentials and a current, valid license that has been primary source verified.
- Review medical records to determine whether the multidisciplinary plan of care is provided as ordered/ needed and that progress toward goals has been evaluated and there are interim time frames established for some goals prior to discharge.
- Interview charge nurses regarding what considerations are necessary when making staff assignments (e.g., patient needs, patient complexity, nurse qualifications or experience). Ensure that nonemployees are not in charge of departments, unless there is evidence that they have sufficient qualifications and training to be in charge.
- Ensure HR files are available for nonemployees and that onboarding, orientation, competency, and evaluation of performance are evident in those files.
- Review a sampling of care plans. Verify that the plan was developed within 24 hours of inpatient admission for each patient and that it reflects findings of assessments, outlines patient goals, and is revised as the needs of the patient change.
- If using an electronic medical record (EMR) with a specific tab for the plan of care, consider defining the plan of care more broadly in policy to include other pertinent sections of the EMR, such as physician orders, an SBAR handoff tool, or other documents. Hospitals are often cited for having a plan of care that fails to account for all comorbidities. Broadening the policy definition of what constitutes the plan of care can help you show that active problems are accounted for in the plan of care tab while chronic problems are accounted for in LP orders targeted at treating those chronic problems. Broadening your policy to include additional tabs in the EMR also helps address the frequent citation for a plan of care that lacks time frames as nearly all LP orders are associated with a time frame of sorts (e.g., daily, quarterly, six hours, etc.).

Suggested Documents:

- Staffing matrices/plans
- Nursing staffing schedules/assignments
- Hospital P&Ps related to assignment of care
- Hospital personnel files (including contracts/qualifications/orientation of nonemployee licensed RNs)
- Nursing policies, procedures, clinical pathways, and standards of practice

Evidence of plans for care, evaluation of those plans, and their related policy

§482.23 *CoP*: Nursing Services		
Tag #	CMS *CoP* (2023)	CMS Interpretive Guidelines and Survey Procedures
A-0405	**(c) Standard: Preparation and Administration of Drugs—** (1) Drugs and biologicals must be prepared and administered in accordance with federal and state laws, the orders of the practitioner(s) responsible for the patient's care, and accepted standards of practice. (i) Drugs and biologicals may be prepared and administered on the orders of other practitioners not specified under §482.12(c) only if such practitioners are acting in accordance with State law, including scope of practice laws, hospital policies, and medical staff bylaws, rules, and regulations. (ii) 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 §482.24(c)(3).	*See Interpretive Guidelines for §482.23(c)(1), (c)(1)(i), and (c)(2)* *See Survey Procedures for §482.23(c)(1), (c)(1)(i), and (c)(2)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.23 -- Condition of participation: Nursing services.*
A-0405	**(d) Standard: Preparation and Administration of Drugs—** (1) Drugs and biologicals must be prepared and administered in accordance with federal and state laws, the orders of the practitioner(s) responsible for the patient's care, and accepted standards of practice. (i) Drugs and biologicals may be prepared and administered on the orders of other practitioners not specified under §482.12(c) only if such practitioners are acting in accordance with State law, including scope of practice laws, hospital policies, and medical staff bylaws, rules, and regulations. (ii) 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 §482.24(c)(3).	*See Interpretive Guidelines for §482.23(c)(1), (c)(1)(i), and (c)(2)* *See Survey Procedures for §482.23(c)(1), (c)(1)(i), and (c)(2)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.23 -- Condition of participation: Nursing services.*

	(2) All drugs and biologicals must be administered by, or under supervision of, nursing or other personnel in accordance with federal and state laws and regulations, including applicable licensing requirements, and in accordance with the approved medical staff P&Ps.	
A-0406	(3) With the exception of influenza and pneumococcal polysaccharide vaccines, which may be administered per physician-approved hospital policy after an assessment of contra-indications, 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 as specified under §482.12(c).	*See Interpretive Guidelines for §482.23(c)(1)(ii) and (c)(3)(iii)* *See Survey Procedures for §482.23(c)(1)(ii), (c)(3), and (c)(3)(iii)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.23 -- Condition of participation: Nursing services.*
A-0407	(i) If verbal orders are used, they are to be used infrequently.	*See Interpretive Guidelines for §482.23(c)(2)(i)* *See Survey Procedures for §482.23(c)(2)(i)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.23 -- Condition of participation: Nursing services.*
A-0408	(ii) When verbal orders are used, they must only be accepted by persons who are authorized to do so by hospital P&Ps consistent with federal and state law.	*See Interpretive Guidelines for §482.23(c)(3)(ii)* *See Survey Procedures for §482.23(c)(3)(ii)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.23 -- Condition of participation: Nursing services.*
A-0409	(iii) Orders for drugs and biologicals may be documented and signed by other practitioners not specified under §482.12(c) only if such practitioners are acting in accordance with State law, including scope of practice laws, hospital policies, and medical staff bylaws, rules, and regulations	*See Interpretive Guidelines for §482.23(c)(1)(ii), (c)(3), and (c)(3)(iii)* *See Survey Procedures for §482.23(c)(1)(ii), (c)(3), and (c)(3)(iii)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.23 -- Condition of participation: Nursing services.*

A-0410	(4) Blood transfusions and intravenous medications must be administered in accordance with State law and approved medical staff P&Ps.	*See Interpretive Guidelines for §482.23(c)(4)* *See Survey Procedures for §482.23(c)(4)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.23 -- Condition of participation: Nursing services.*
A-0411	(5) There must be a hospital procedure for reporting transfusion reactions, adverse drug reactions, and errors in administration of drugs	*See Interpretive Guidelines for §482.23(c)(5)* *See Survey Procedures for §482.23(c)(5)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.23 -- Condition of participation: Nursing services.*
A-0412	(6) The hospital may allow a patient (or his/her caregiver/support person where appropriate) to self-administer both hospital-issued medications and the patient's own medications brought into the hospital, as defined and specified in the hospital's policies and procedures. (i) If the hospital allows a patient to self-administer hospital-issued medications, then the hospital must have policies and procedures in place to: (A) Ensure that a practitioner responsible for the care of the patient has issued an order, consistent with hospital policy, permitting self-administration. (B) Assess the capacity of the patient (or the patient's caregiver/support person where appropriate) to self-administer the specified medication(s) (C) Instruct the patient (or the patient's support person where appropriate) in the safe and accurate administration of the specified medication(s). (D) Address the security of the medication(s) for each patient. (E) Document the administration of each medication, as reported by the patient (or the patient's caregiver/support person where appropriate), in the patient's medical record.	*See Interpretive Guidelines for §482.23(c)(6)(i)* *See Survey Procedures for §482.23(c)(6)(i)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.23 -- Condition of participation: Nursing services.*

A-0413	(ii) If the hospital allows a patient to self- administer his/her own specific medications brought into the hospital, then the hospital must have policies and procedures in place to: (A) Ensure that a practitioner responsible for the care of the patient has issued an order, consistent with hospital policy, permitting self-administration of medications the patient brought into the hospital. (B) Assess the capacity of the patient (or the patient's caregiver/support person where appropriate) to self-administer the specified medication(s) and also determine whether the patient (or the patient's caregiver/support person where appropriate) needs instruction in the safe and accurate administration of the specified medication(s). (C) Identify the specified medication(s) and visually evaluate the medication(s) for integrity. (D) Address the security of the medication(s) for each patient. (E) Document the administration of each medication, as reported by the patient (or the patient's caregiver/support person where appropriate), in the patient's medical record.	*See Interpretive Guidelines for §482.23(c)(6)(ii)* *See Survey Procedures for §482.23(c)(6)(ii)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.23 -- Condition of participation: Nursing services.*

Related Joint Commission Standards

Leadership:

- LD.04.01.07, EP 1

Medication Management:

- MM.03.01.01, EP 2 – 3
- MM.03.01.05, EP 1 – 2
- MM.04.01.01, EP 2, 6, 14, 15
- MM.05.01.07, EP.1-7
- MM.05.01.11, EP 2, 3
- MM.06.01.01, EP 1, 3, 9
- MM.06.01.03, EP 1, 7
- MM.07.01.03, EP 1, 3

Medical Staff:

- MS.03.01.01, EP 2

Performance Improvement:

- PI.01.01.01, EP 7, 12, 13

Provision of Care:

- PC.02.01.01, EP 15
- PC.02.01.03, EP 1

Record of Care, Treatment, and Services:

- RC.01.02.01, EP 1 – 5
- RC.02.01.01, EP 2
- RC.02.03.07, EP 1 – 4, 6

Related DNV Standards

Medication Management:

- MM.1 (SR.3)
- MM.1 (SR.3a)
- MM.1 (SR.3b)
- MM.1 (SR.3c)
- MM.1 (SR.8)
- MM.4 (SR.2)
- MM.4 (SR.2a)
- MM.4 (SR.5)
- MM.4 (SR.6)
- MM.4 (SR.7)
- MM.6 (SR.2)
- MM.9 (SR.1)
- MM.9 (SR.1a)
- MM.9 (SR.1b)
- MM.9 (SR.1c)
- MM.9 (SR.1d)
- MM.9 (SR.1e)
- MM.9 (SR.2)
- MM.9 (SR.2a)
- MM.9 (SR.2b)

- MM.9 (SR.2c)
- MM.9 (SR.2d)
- MM.9 (SR.2e)

Related ACHC Standards

Nursing Services:

- 16.01.01
- 16.01.03
- 16.01.04
- 16.01.05
- 16.01.06
- 16.01.07
- 16.01.09
- 16.01.10

Related CIHQ Standards

Quality Assessment and Performance Improvement:

- QA-3

Targeted Patient Quality and Safety Practices:

- QS-4

Medication Management:

- MM-5
- MM-10
- MM-17
- MM-21
- MM-22
- MM-24
- MM-28
- MM-30
- MM-31

Medical Record:

- MR-6

Laboratory Services:

- LB-7

§482.23 (c) *CoP* Analysis/Guidelines

Both CMS and all accreditors' standards highlight that drugs, biologicals, and blood products are ordered and administered safely, timely, and accurately. CMS added additional interpretive guidance under A-0405 regarding assessment/monitoring of patients receiving medications and the timely documentation of medication administration. CMS also added additional interpretive guidelines under A-0409 with regard to safe IV administration and blood transfusions. All accreditors and CMS specify that drugs and biologicals must be given under the direction of an LP order. CMS and accreditors are in alignment that the use of standard orders/protocols must be documented as an order in the patient's medical record and signed by the practitioner responsible for the care of the patient, but the timing of such documentation should not be a barrier to effective emergency response, timely and necessary care, or other patient safety advances (i.e., the orders can be pulled for use but still must be subsequently authenticated). CMS and all accreditors require that protocols or standing orders be reviewed and approved by nursing, pharmacy, and medical staff leadership. CMS and all accreditors require that verbal orders are to be used infrequently, and CMS has adopted language that requires read-back procedures as required by The Joint Commission. Verbal orders must be authenticated as defined by state law, or in the absence of state law, in accordance with hospital policy. The components of a complete medication order are outlined by CMS and hospital accreditors; some more specific than others. For example, The Joint Commission exceeds CMS requirements by being more prescriptive on areas of known safety issues (i.e., range orders, titration order).

Both CMS and all accreditors require appropriate patient identification during medication administration while verifying the appropriate medication, dosing, and route; however, The Joint Commission requires verification that the administration of medication is appropriately matched to the patient.

For blood products, The Joint Commission requires patient blood product bedside matching and identification procedures. CMS and all accreditors require that the effect of medications and transfusions be monitored and that adverse medication reactions, transfusion reactions, and errors be reported. CMS has clarified expectations on timely medication administration, and only time-critical scheduled medications must be administered within 30 minutes of its scheduled time to avoid harm or negative impact.

Hospital policies and procedures (P&Ps) must address the actions to be taken when medications eligible for scheduled dosing times are not administered within their permitted window of time (as outlined by time-critical or non–time-critical). Should an error or adverse drug event occur, CMS and all accreditors require the hospital to have a process to respond and that it should be reported to the patient's LP.

IV medications and blood transfusions are administered to patients by RNs, consistent with state law governing scope of practice and approved medical staff P&Ps. Education and training regarding these procedures are typically included in the nurse's hospital orientation. Nursing staff who receive training for IV medication administration and/or blood transfusion administration during hospital orientation or during other continuing education programs would meet the requirements of this regulation. Other nonphysician personnel, for example, licensed practical nurses or licensed vocational nurses, with demonstrated competence may also administer IV medications and blood transfusions if they are acting in accordance with state law, including scope of practice law, and the hospital's approved medical staff P&Ps.

CMS and accreditors require that medications brought in from home are also controlled and are appropriately inspected and labeled. Patients who self-administer medications must have an order to do so and should be competent. Policies should reflect circumstances for when self-administration is prohibited and what medications or circumstances require that it must be under direct supervision of nursing staff. Evaluation of the patient's knowledge and competency should also be assessed. The Joint Commission also requires that before administering look-alike, sound-alike medications, additional precautions are taken.

Survey Tips:

- Verify that the hospital's policy describes requirements for the administration of identified time-critical medications.
- Verify the P&Ps on medication orders align with minimal components outlined by CMS and accreditor requirements.
- Ensure P&Ps on use of order sets and protocols align with CMS requirements and that those are approved by medical staff but are developed in collaboration with pharmacy and nursing.
- Verify that P&Ps reflect need to minimize verbal orders.
- Verify that bylaws also reflect need to minimize verbal orders.
- Review P&Ps for medications brought from home and self-administration of medication to ensure they comply with CMS and accreditor requirements.
- Audit orders for medications to ensure they are complete and have been authenticated.
- Ensure order sets and protocols are only initiated with a physician order, unless using a standing order approved by nursing, pharmacy, and medical staff leadership. In such cases, the approved standing order can be implemented but must be authenticated by the practitioner after implementation (i.e., the orders can be pulled for use but still must be subsequently authenticated).
- Observe verbal order procedures for staff read-back.
- Review HR files to ensure training in IV medications, blood and blood product administration, and how to report adverse reactions and medication errors. This should occur during orientation and on an ongoing basis.

Suggested Documents:

- Hospital P&Ps on medication management, timely medication administration, complete medication orders, medications brought from home; self-administration of medications; and look-alike, sound-alike, and high-risk medications and investigational medications (if applicable)
- Hospital P&Ps on medical record entries and requirements when aspects of care are not timely (i.e., medications)
- Hospital P&Ps on patient identification
- Medical records (active and closed)
- Medical staff P&Ps related to orders and that verbal orders are to be used minimally
- Blood transfusion and IV administration policies
- Incident report summary regarding medication errors or adverse drug events
- Policy on reporting unusual occurrences and medication errors
- Pharmacy committee meeting minutes

§482.24 *CoP*: Medical Record Services		
Tag #	CMS *CoP* (2023)	CMS Interpretive Guidelines and Survey Procedures
A-0431	The hospital must have a medical record service that has administrative responsibility for medical records. A medical record must be maintained for every individual evaluated or treated in the hospital.	*See Interpretive Guidelines for §482.24* *See Survey Procedures for §482.24* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.24 -- Condition of participation: Medical record services.*
A-0432	**(a) Standard: Organization and staffing—** The organization of the medical record service must be appropriate to the scope and complexity of the services performed. The hospital must employ adequate personnel to ensure prompt completion, filing, and retrieval of records.	*See Interpretive Guidelines for §482.24(a)* *See Survey Procedures for §482.24(a)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.24 -- Condition of participation: Medical record services.*

Related Joint Commission Standards

Human Resources:

- HR.01.01.01, EP 1

Leadership:

- LD.03.06.01, EP 3
- LD.04.03.01, EP 2

Management of Information:

- IM.02.02.03, EP 2, 3

Record of Care, Treatment, and Services:

- RC.01.01.01, EP 1, 7

Related DNV Standards

Medical Record Services:

- MR.1 (SR.1)
- MR.2 (SR.2)
- MR.2 (SR.1)

Related ACHC Standards

Medical Records:

- 10.00.00
- 10.00.02

Related CIHQ Standards

Management of the Medical Record:

- MR-1 – MR-3

Patient Rights:

- PR-11

§482.24 (a) *CoP* Analysis/Guidelines

An organized and adequately staffed medical records department is necessary in order to comply with CMS and accreditors. Staffing must be appropriate to the scope and complexity of the services.

Survey Tips:

- There should be a qualified director/manager of medical record services, and the scope of medical record policies should include outpatient areas and off-campus locations. Suggest review of state regulation that may further define qualifications (i.e., registered health information administrator or registered health information technician).
- Review personnel files of medical records staff to ensure they are up to date and complete.

Suggested Documents:

- Organizational chart for medical record services
- Scope of service for medical records
- Personnel files for medical records staff
- Job descriptions for medical records staff
- Staffing schedules for medical records personnel

§482.24 *CoP*: Medical Record Services		
Tag #	CMS *CoP* (2023)	CMS Interpretive Guidelines and Survey Procedures
A-0438	**(b) Standard: Form and retention of record—** The hospital must maintain a medical record for each inpatient and outpatient. Medical records must be accurately written, promptly completed, properly filed and retained, and accessible. The hospital must use a system of author identification and record maintenance that ensures the integrity of the authentication and protects the security of all record entries	*See Interpretive Guidelines for §482.24(b)* *See Survey Procedures for §482.24(b)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.24 -- Condition of participation: Medical record services.*
A-0439	(1) Medical records must be retained in their original or legally reproduced form for a period of at least 5 years.	*See Interpretive Guidelines for §482.24(b)(1)* *See Survey Procedures for §482.24(b)(1)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.24 -- Condition of participation: Medical record services.*
A-0440	(2) The hospital 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	*See Survey Procedures for §482.24(b)(2)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.24 -- Condition of participation: Medical record services.*
A-0441	(3) The hospital must have a procedure for ensuring the confidentiality of patient records. Information from or copies of records may be released only to authorized individuals.	*See Interpretive Guidelines for §482.24(b)(3)* *See Survey Procedures §482.24(b)(3)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.24 -- Condition of participation: Medical record services.*

Related Joint Commission Standards

Management of Information:

- IM.01.01.01, EP 2
- IM.02.01.01, EP 1, 3, 4
- IM.02.01.03, EP 2
- IM.02.02.03, EP 2, 3

Medical Staff:

- MS.03.01.01, EP 6 – 7
- MS.05.01.03, EP 3

Record of Care, Treatment and Services:

- RC.01.01.01, EP 1, 5
- RC.01.02.01, EP 3 – 5
- RC.01.03.01, EP 1, 2
- RC.01.04.01, EP 1
- RC.01.05.01, EP 1, 8

Related DNV Standards

Medical Record Services:

- MR.2 (SR.1)
- MR.2 (SR.2)
- MR.2 (SR.3)
- MR.3 (SR.1)
- MR.3 (SR.2)
- MR.4 (SR.1)
- MR.4 (SR.2)
- MR.4 (SR.3)
- MR.4 (SR.4)
- MR.6 (SR.1)

Related ACHC Standards

Medical Records:

- 10.00.03
- 10.00.04
- 10.00.05
- 10.00.06

Related CIHQ Standards

Medical Records:

- MR-2, MR-3

Patient Rights:

- PR-11

§482.24 (b) *CoP* Analysis/Guidelines

CMS and all accreditors require systems that provide for timely, complete, and accurate medical records and that ensure data are readily available and retrievable. These systems must also protect the integrity and security of patient information yet provide timely retrieval as needed. HIPAA regulations play a large role in this area as well. The Joint Commission requires that the organization uses standardized terminology, definitions, abbreviations, acronyms, symbols, and dose designations and also has a list of unacceptable abbreviations. CMS, DNV, and CIHQ require retention of medical records for five years, although certain records may have a retention requirement that exceeds five years. The Joint Commission does not specify retention requirements other than they must be retained by law/regulation.

Survey Tips:

- Verify that an established system is in place that protects confidential medical information
- For electronic medical records, check security safeguards for access, altering, damage, or destruction
- Identify all locations in the hospital where records are stored and maintained and evaluate the security of those records
- Review record retention policies, ensuring that it not only aligns with CMS regulation but also state and federal law/regulation (five years is typical, but more specific regulation may apply to non-adults or other populations and diagnostic areas)

Suggested Documents:

- HIPAA policies
- Policies on confidentiality, record retention, record retrieval, and documentation requirements
- Hospital policies/procedures on medical record entries and authentication
- Research policies on confidentiality
- Medical records (open and closed)
- Medical record delinquency rates

§482.24 *CoP*: Medical Record Services		
Tag #	CMS *CoP* (2023)	CMS Interpretive Guidelines and Survey Procedures
A-0449	**(c) Standard: Content of 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.	*See Interpretive Guidelines for §482.24(c)* SOM Appendix A (cms.gov) eCFR :: 42 CFR 482.24 -- Condition of participation: Medical record services.
A-0450	(1) All patient medical record entries must be legible, complete, dated, timed, and authenticated in written or electronic form by the person responsible for providing or evaluating the service provided, consistent with hospital P&Ps.	*See Interpretive Guidelines for §482.24(c)(1)* *See Survey Procedures for §482.24(c)(1)* SOM Appendix A (cms.gov) eCFR :: 42 CFR 482.24 -- Condition of participation: Medical record services.
A-0454	(2) All orders, including verbal orders, must be dated, timed, and authenticated promptly by the ordering practitioner, or by another practitioner who is responsible for the care of the patient only if such a practitioner is acting in accordance with State law, including scope-of-practice laws, hospital policies, and medical staff bylaws, rules, and regulations.	*See Interpretive Guidelines for §482.24(c)(2)* *See Survey Procedures for §482.24(c)(2)* SOM Appendix A (cms.gov) eCFR :: 42 CFR 482.24 -- Condition of participation: Medical record services.
A-0457	(3) Hospitals may use preprinted and electronic standing orders, order sets, and protocols for patient orders only if the hospital: (i) Establishes that such orders and protocols have been reviewed and approved by the medical staff and the hospital's nursing and pharmacy leadership. (ii) Demonstrates that such orders and protocols are consistent with nationally recognized and evidence-based guidelines. (iii) Ensures that the periodic and regular review of such orders and protocols is conducted by	*See Interpretive Guidelines for §482.24(c)(3)* *See Survey Procedures for §482.24(c)(3)* SOM Appendix A (cms.gov) eCFR :: 42 CFR 482.24 -- Condition of participation: Medical record services.

	the medical staff and the hospital's nursing and pharmacy leadership to determine the continuing usefulness and safety of the orders and protocols. (iv) Ensures that such orders and protocols are dated, timed, and authenticated promptly in the patient's medical record by the ordering practitioner or by another practitioner responsible for the care of the patient only if such a practitioner is acting in accordance with State law, including scope-of-practice laws, hospital policies, and medical staff bylaws, rules, and regulations.	
A-0458	(4) All records must document the following, as appropriate: (i) Evidence of: (A) A medical history and physical exam 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, ***and except as provided under paragraph (c)(4)(i)(C) of this section.*** The medical history and physical exam 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.	*See Interpretive Guidelines for §482.24(c)(4)(i)(A)* *See Survey Procedures for §482.24(c)(4)(i)(A)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.24 -- Condition of participation: Medical record services.*
A-0461	(B) An updated examination of the patient, including any changes in the patient's condition, when the medical history and physical exam are completed within 30 days before admission or registration, ***and except as provided under paragraph (c)(4)(i)(C) of this section.*** Documentation of the updated exam 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.	*See Interpretive Guidelines for §482.24(c)(4)(i)(B)* *See Survey Procedures for §482.24(c)(4)(i)(B)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.24 -- Condition of participation: Medical record services.*

A-0462	(C) All records must document the following, as appropriate: (i) Evidence of an assessment of the patient (in lieu of the requirements of paragraphs (c)(4)(i)(A) and (B) of this section) completed and documented after registration, but prior to surgery or a procedure requiring anesthesia services, when the patient is receiving specific outpatient surgical or procedural services and when the medical staff has chosen to develop and maintain a policy that identifies, in accordance with the requirements at §482.22(c)(5)(v), specific patients as not requiring a comprehensive medical history and physical examination, or any update to it, prior to specific outpatient surgical or procedural services.	*See Interpretive Guidelines for §482.24(c)(4)(i)(C)* *See Survey Procedures for §482.24(c)(4)(i)(C)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.24 -- Condition of participation: Medical record services.*
A-0463	(ii) Admitting diagnosis.	*See Interpretive Guidelines for §482.24(c)(4)(ii)* *See Survey Procedures for §482.24(c)(4)(ii)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.24 -- Condition of participation: Medical record services.*
A-0464	(iii) Results of all consultative evaluations of the patient and appropriate findings by clinical and other staff involved in the care of the patient.	*See Interpretive Guidelines for §482.24(c)(4)(iii)* *See Survey Procedures for §482.24(c)(4)(iii)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.24 -- Condition of participation: Medical record services.*
A-0465	(iv) Documentation of complications, hospital-acquired infections, and unfavorable reactions to drugs and anesthesia.	*See Interpretive Guidelines for §482.24(c)(4)(iv)* *See Survey Procedures for §482.24(c)(4)(iv)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.24 -- Condition of participation: Medical record services.*

A-0466	(v) Properly executed informed consent forms for procedures and treatments specified by the medical staff, or by federal or state law if applicable, to require written patient consent.	*See Interpretive Guidelines for §482.24(c)(4)(v)* *See Survey Procedures for §482.24(c)(4)(v)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.24 -- Condition of participation: Medical record services.*
A-0467	(vi) 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.	*See Interpretive Guidelines for §482.24(c)(4)(vi)* *See Survey Procedures for §482.24(c)(4)(vi)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.24 -- Condition of participation: Medical record services.*
A-0468	(vii) Discharge summary with outcome of hospitalization, disposition of care, and provisions for follow-up care.	*See Interpretive Guidelines for §482.24(c)(4)(vii)* *See Survey Procedures for §482.24(c)(4)(vii)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.24 -- Condition of participation: Medical record services.*
A-0469	(viii) Final diagnosis with completion of medical records within 30 days following discharge.	*See Interpretive Guidelines for §482.24(c)(4)(viii)* *See Survey Procedures for §482.24(c)(4)(viii)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.24 -- Condition of participation: Medical record services.*

Related Joint Commission Standards

Medication Management:

- MM.04.01.01, EP 15

Provision of Care:

- PC.01.02.03, EP 4, 5
- PC.02.01.03, EP 1, 4

Record of Care, Treatment and Services:

- RC.01.01.01, EP 5, 7, 13

- RC.01.02.01, EP 3, 4
- RC.01.03.01, EP 1, 3
- RC.01.04.01, EP 1
- RC.02.01.01, EP 2, 4
- RC.02.01.03, EP 1, 3, 8
- RC.02.03.07, EP 3, 4, 6
- RC.02.04.01, EP 3

Rights and Responsibilities of the Individual:

- RI.01.03.01, EP 1, 2
- RI 01.05.01, EP 1, 9

Related DNV Standards

Medical Records Services:

- MR.5 (SR.1)
- MR.5 (SR.1a)
- MR.5 (SR.1b)
- MR.5 (SR.1c)
- MR.5 (SR.2)
- MR.5 (SR.2a)
- MR.5 (SR.2b)
- MR.5 (SR.3)
- MR.5 (SR.4a)
- MR.5 (SR.4b)
- MR.5 (SR.4c)
- MR.5 (SR.4)
- MR.5(SR.5)
- MR.5(SR.5a)
- MR.5(SR.5b)
- MR.5(SR.5c)
- MM.1 (SR.9)
- MM.1 (SR.9a)
- MM.1 (SR.9b)
- MM.1 (SR.9c)
- MM.1 (SR.9d)

Related ACHC Standards

Medical Records:

- 10.01.01
- 10.01.03
- 10.01.04
- 10.01.05
- 10.01.07
- 10.01.08
- 10.01.09
- 10.01.10
- 10.01.11
- 10.01.15
- 10.01.16
- 10.01.17
- 10.01.18
- 10.01.20

Related CIHQ Standards

Medical Records:

- MR-4 – MR-7

Targeted Patient Safety and Quality:

- QS-4

Medication Management:

- MM-1
- MM-28
- MM-31

Operative and Invasive Services:

- OI-5

§482.24 (c) *CoP* Analysis/Guidelines

A patient's medical record must have complete documentation at all times. CMS and all accreditors are aligned regarding legibility, authentication, timed/dated entries, and general content of the record.

Verbal and telephone orders are expected to be limited. There should be a read-back or repeat-back verification process. The CMS standard clarifies that verbal orders (both inpatient and outpatient) require authentication as soon as possible after issuing the order (i.e., the next time the ordering LP accesses the EMR or paper record) unless the requirement is otherwise outlined in state law. When a practitioner other than the ordering practitioner signs a verbal order, that practitioner assumes responsibility for the order being complete, accurate, and final.

Additionally, another qualified LP (i.e., PA or NP) may authenticate the order only if written within their scope of practice and when the patient is under their care.

In late 2017, CMS issued QSO-18-10 addressing the use of texting platforms to communicate healthcare information. This memo was revised slightly in January 2018 to make clear that the memo applied to hospitals and critical access hospitals (CAH). CMS does not permit the texting of orders by physicians or other healthcare providers; the practice isn't in compliance with the *CoP*s.

CMS has held to the long-standing practice that a physician or LP should enter orders into the medical record via a handwritten order or via computerized provider order entry (CPOE), with the latter being the preferred method of order entry. An order entered via CPOE, with an immediate download into the provider's electronic health record (EHR), is permitted, as the order would be dated, timed, authenticated, and promptly placed in the medical record.

CMS recognizes that the use of texting as a means of communication with other members of the hospital and CAH healthcare teams has become an essential and valuable means of communication among the team members. In order to be compliant with the *CoP*s, all providers must utilize and maintain systems/platforms that are secure, are encrypted, and minimize the risks to patient privacy and confidentiality as per HIPAA regulations and the hospital and CAH *CoP*s. It is expected that providers will implement procedures/processes that routinely assess the security and integrity of the texting systems/platforms that are being utilized, in order to avoid negative outcomes that could compromise the care of patients. All accreditors are in alignment with this position.

CMS requires that all orders, including verbal orders, are "promptly" dated, timed, and authenticated by the ordering practitioner or another practitioner responsible for care of the patient.

CMS further outlines requirements related to preprinted order sets in that practitioners should sign, date, and time the last page of paper order sets and the order set should identify the total number of pages in the order set. If there are pages with internal selections, practitioners should sign or initial other internal pages of the order set; if selections or changes have been made, the initial or signature should be at the top or bottom of the pertinent page(s); and if changes have been made (additions, deletions, or strikethroughs), they should initial each place where that change took place, unless the order is electronic.

CMS and accreditors are in alignment on medical history and physical (H&P) requirements. H&Ps must be completed and documented no more than 30 days prior to hospital admission, or 24 hours after hospital admission or registration, and when done upon admission or registration must occur prior to surgery or procedures requiring anesthesia services. H&Ps are required for all inpatient, outpatient, or same-day surgery procedures where anesthesia services are provided. When an H&P is conducted within 30 days prior to admission, it must be updated even if no change has occurred since the H&P was completed. H&Ps must be performed by LPs licensed and privileged by the hospital's medical staff. A hospital may allow submission of an H&P performed prior to admission by a physician or LP who may not be a member of the medical staff as long as that person is acting within their scope of practice, and the content of the history & physical meets the medical staff's expectations.

Hospitals must establish a method to establish the identity of authors for each entry.

Although DNV and CIHQ align with CMS on elements of a properly executed informed consent, The Joint Commission has some elements that exceed those elements. DNV and CIHQ align with CMS on requirements of discharge summaries, but The Joint Commission has additional components. CMS specifies that the physician who admitted the patient or other MDs/DOs who work with the patient's MD/DO and are knowledgeable about the patient may author a discharge summary. The attending may also delegate the discharge to other qualified personnel (PAs and NPs) in accordance with medical staff policy and to the extent recognized under state law/regulation.

CMS modified the language related to discharge summaries. It is notable that although this requirement primarily applies to inpatients, the latest language implies that a discharge summary could apply to significant outpatient encounters where disposition and provision for follow-up care is needed. It is also important to ensure state regulation does not have additional or stringent requirements for discharge summaries.

Both CMS and The Joint Commission require completion of records within 30 days. The Joint Commission has established requirements for processing and auditing medical records, including delinquency rates (maintained at no greater than 50% of the average monthly discharge rate).

Signature stamps may not be used in lieu of a written signature but may be added to a signature to aid identification or provide a numeric identifier for the practitioner.

CMS medical record requirements relative to operative and invasive services are located in the surgical services *CoP*.

Survey Tips:

- Conduct regular medical record reviews/audits to verify if documentation is complete and present in the chart.
- Verify authentication requirements for all verbal orders and ensure all medical record entries are dated, timed, and signed.
- Verify that policy establishing requirements of postoperative notes reflects both CMS and Joint Commission requirements.
- Audit compliance with H&P requirements.
- Audit compliance with dating, timing, and signing of orders, including that each page of the order is dated, timed, and signed.
- Review informed consent P&Ps. Identify all informed consent tools used, both those created internally and externally, and review for compliance with required elements of a properly executed informed consent.
- Review discharge summary requirements to ensure that both CMS and accreditation requirements are reflected.

Suggested Documents:

- Medical record P&Ps (including policies for electronic records), including downtime procedures
- Medical staff bylaws/P&Ps
- Policy on informed consent

§482.25 *CoP*: Pharmaceutical Services		
Tag #	CMS *CoP* (2023)	CMS Interpretive Guidelines and Survey Procedures
A-0489	The hospital must have pharmaceutical services that meet the needs of the patients. The institution must have a pharmacy directed by a registered pharmacist or a drug storage area under competent supervision. The medical staff is responsible for developing P&Ps that minimize drug errors. This function may be delegated to the hospital's organized pharmaceutical service.	*See Interpretive Guidelines for §482.25* SOM Appendix A (cms.gov) eCFR :: 42 CFR 482.25 -- Condition of participation: Pharmaceutical services.
A-0490	Standard-level Tag for §482.25 *Conditions of Participation*: Pharmaceutical Services. The hospital must have pharmaceutical services that meet the needs of the patients	*See Interpretive Guidelines for §482.25* *See Survey Procedures for §482.25* SOM Appendix A (cms.gov) eCFR :: 42 CFR 482.25 -- Condition of participation: Pharmaceutical services.
A-0491	...The medical staff is responsible for developing policies and procedures that minimize drug errors. This function may be delegated to the hospital's organized pharmaceutical service.] **(a) Standard: Pharmacy Management and Administration—** The pharmacy or drug storage area must be administered in accordance with accepted professional principles.	*See Interpretive Guidelines for §482.25 and §482.25(a)* *See Survey Procedures for §482.25(a)* SOM Appendix A (cms.gov) eCFR :: 42 CFR 482.25 -- Condition of participation: Pharmaceutical services.
A-0492	*Condition of Participation:* Pharmaceutical Services The hospital... must have a pharmacy directed by a registered pharmacist or a drug storage area under competent supervision…. (1) A full-time, part-time, or consulting pharmacist must be responsible for developing, supervising, and coordinating all the activities of the pharmacy services.	*See Interpretive Guidelines for §482.25(a)(1)* *See Survey Procedures for §482.25(a)(1)* SOM Appendix A (cms.gov) eCFR :: 42 CFR 482.25 -- Condition of participation: Pharmaceutical services.
A-0493	(2) The pharmaceutical service must have an adequate number of personnel to ensure quality pharmaceutical services, including emergency services.	*Interpretive Guidelines for §482.25(a)(2)* *Survey Procedures for §482.25(a)(2)* SOM Appendix A (cms.gov) eCFR :: 42 CFR 482.25 -- Condition of participation: Pharmaceutical services.

A-0494	(3) Current and accurate records must be kept of the receipt and disposition of all scheduled drugs.	*See Interpretive Guidelines for §482.25(a)(3)* *See Survey Procedures for §482.25(a)(3)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.25 -- Condition of participation: Pharmaceutical services.*

Related Joint Commission Standards

Human Resources:

- HR.01.02.05, EP 28

Leadership:

- LD.04.01.05, EP 3
- LD.04.01.07, EP 1
- LD.04.03.01, EP 2

Medication Management:

- MM.03.01.01, EP 3, 19
- MM.05.01.11, EP 2

Related DNV Standards

Medication Management:

- MM.1 (SR.1)
- MM.1 (SR.2)
- MM.1 (SR.3)
- MM.3 (SR.1)
- MM.6 (SR.1)

Related ACHC Standards

Pharmacy Services/Medication Use:

- 25.00.00
- 25.00.01
- 25.00.04
- 25.00.05
- 25.00.06
- 25.00.07

Related CIHQ Standards

Medication Management:

- MM-1 – MM-3
- MM-5
- MM-7
- MM-12 – MM-16
- MM-19 – MM-20
- MM-22 – MM-23
- MM-25
- MM-27
- MM-31

§482.25 (a) *CoP* Analysis/Guidelines

Similarities between CMS and accreditors exist for this section. The Joint Commission and DNV standards align, but it is difficult to see that alignment.

CMS and accreditors require that activities of the pharmaceutical service be delineated and that the service is run by a qualified individual.

CMS defines accepted professional principles as "compliance with applicable Federal and State laws, regulations, and guidelines governing pharmaceutical services, as well as standards or recommendations promoted by nationally recognized professional organizations." Compliance with law and regulation includes the Environmental Protection Agency's specifications for management of pharmaceutical waste from "cradle to grave."

CMS and accreditors are aligned in the expectation that preparation of radiopharmaceuticals is done by or under the supervision of a pharmacist, MD, or DO.

CMS and accreditors are in alignment that standing orders/protocols are authenticated by the practitioner; however, timing of that authentication should not create barriers for timely care. Protocols used that provide order detail must be included in the medical record.

CMS has clarified its expectations on timely medication administration and scheduled dosing to better align with Institute for Safe Medication Practices recommendations. All accreditors have modified their standards to align with those expectations.

NIAHO/DNV has multiple detailed standards related to sterile compounding, which appear to be consistent with USP 797/800 but also relate to International Organization for Standardization requirements. These requirements are not outlined by CMS.

Survey Tips:

- Review pharmacy P&Ps to see whether they meet accepted professional principles regarding storage, control, compounding, dispensing, labeling, ordering, and administration. Review and implement CDC guidance on storage of vaccine products.
- Review pharmacy systems (e.g., unit dose system, individual prescriptions, floor stock system, IV admixture program) for effectiveness.
- Ensure there are P&Ps that address medication orders, medication security, controlled substance procedures, personnel authorized to administer medications, self-administration of medications, adverse drug events, management of external alerts (i.e., recalls, sentinel events), investigational medications, timely medication administration, and general medication safety practices. Ensure development of P&Ps includes the scope of all hospital departments.
- Verify that pharmacy staff have current licenses and that competencies are up to date. Verify that staff who do sterile compounding have proven competencies.
- Verify chief pharmacist oversight and control of medications for all departments, including outpatient areas, clinics, physician practices, imaging, and nuclear medicine.
- Review P&Ps relative to pharmaceutical waste, ensuring the appropriate waste management processes and controls are in place.
- Evaluate contracted clinical services to ensure medications used are procured, distributed, and controlled by pharmacy.
- Ensure that radiopharmaceutical preparation is under the supervision of a pharmacist, MD, or DO. Be able to prove the person is qualified to oversee this activity

Suggested Documents:

- Pharmacy scope of service
- Job descriptions of pharmacy director and personnel
- Pharmacy P&Ps
- Medication management P&Ps (must have sign-off by medical staff)
- Pharmacy committee meeting minutes
- Pharmacy staffing schedules
- Drug Enforcement Administration (DEA) license (with name of current pharmacy director)
- Organizational chart for pharmacy services
- MD/DO job description, policy, or responsibility charting reflecting oversight of radiopharmaceutical preparation (if applicable and not done by pharmacist)

§482.25 *CoP*: Pharmaceutical Services		
Tag #	CMS *CoP* (2023)	CMS Interpretive Guidelines and Survey Procedures
A-0501	**(b)** All compounding, packaging, and dispensing of drugs and biologicals must be under the supervision of a pharmacist and performed consistent with state and federal laws.	*See Interpretive Guidelines for §482.25(b)(1)* *See Survey Procedures for §482.25(b)(1)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.25 -- Condition of participation: Pharmaceutical services.*
A-0502	Drugs and biologicals must be kept in a secure area, and locked when appropriate	*See Interpretive Guidelines for §482.25(b)(2)(i)* *See Survey Procedures for §482.25(b)(2)(i)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.25 -- Condition of participation: Pharmaceutical services.*
A-0503	Drugs listed in Schedules II, III, IV, and V of the Comprehensive Drug Abuse Prevention and Control Act of 1970 must be kept locked within a secure area.	*See Interpretive Guidelines for §482.25(b)(2)(ii)* *See Survey Procedures for §482.25(b)(2)(iii)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.25 -- Condition of participation: Pharmaceutical services.*
A-0504	(iii) Only authorized personnel may have access to locked areas.	*See Interpretive Guidelines for §482.25(b)(2)(iii)* *See Survey Procedures for §482.25(b)(2)(iii)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.25 -- Condition of participation: Pharmaceutical services.*
A-0505	(3) Outdated, mislabeled, or otherwise unusable drugs and biologicals must not be available for patient use	*See Interpretive Guidelines for §482.25(b)(3)* *See Survey Procedures for §482.25(b)(3)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.25 -- Condition of participation: Pharmaceutical services.*

A-0506	(4) When a pharmacist is not available, drugs and biologicals must be removed from the pharmacy or storage area only by personnel designated in the policies of the medical staff and pharmaceutical service, in accordance with federal and state law.	*See Interpretive Guidelines for §482.25(b)(4)* *See Survey Procedures for §482.25(b)(4)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.25 -- Condition of participation: Pharmaceutical services.*
A-0507	(5) Drugs and biologicals not specifically prescribed as to time or number of doses must automatically be stopped after a reasonable time that is predetermined by the medical staff.	*See Interpretive Guidelines for §482.25(b)(5)* *See Survey Procedures for §482.25(b)(5)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.25 -- Condition of participation: Pharmaceutical services.*
A-0508	(6) Drug administration errors, adverse drug reactions, and incompatibilities must be immediately reported to the attending physician and, if appropriate, to the hospital- wide quality assessment and performance improvement program	*See Interpretive Guidelines for §482.25(b)(6)* *See Survey Procedures for §482.25(b)(6)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.25 -- Condition of participation: Pharmaceutical services.*
A-0509	(7) Abuses and losses of controlled substances must be reported, in accordance with applicable federal and state laws, to the individual responsible for the pharmaceutical service, and to the chief executive officer, as appropriate.	*See Interpretive Guidelines for §482.25(b)(7)* *See Survey Procedures for §482.25(b)(7)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.25 -- Condition of participation: Pharmaceutical services.*
A-0510	(8) Information relating to drug interactions and information of drug therapy, side effects, toxicology, dosage, indications for use, and routes of administration must be available to the professional staff.	*See Interpretive Guidelines for §482.25(b)(8)* *See Survey Procedures for §482.25(b)(8)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.25 -- Condition of participation: Pharmaceutical services.*

A-0511	(9) A formulary system must be established by the medical staff to ensure quality pharmaceuticals at reasonable costs.	*See Interpretive Guidelines for §482.25(b)(9)* *See Survey Procedures §482.25(b)(9)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.25 -- Condition of participation: Pharmaceutical services.*

Related Joint Commission Standards

Environment of Care:

- EC.02.01.01, EP 11

Management of Information:

- IM.03.01.01, EP 1

Medication Management:

- MM.01.01.03, EP 1, 2, 5
- MM.02.01.01, EP 1, 2, 4, 5
- MM.03.01.01, EP 3, 6, 8
- MM.04.01.01, EP 1
- MM.05.01.01, EP 1
- MM.05.01.07, EP 5
- MM.05.01.11, EP 2
- MM.05.01.13
- MM.05.01.17, EP 1, 3, 4
- MM.05.01.19, EP 2
- MM.07.01.03, EP 1 – 3, 6

Improving Organizational Performance:

PI.01.01.01, EP 12, 13

Related DNV Standards

Medication Management:

- MM.1 (SR.4)
- MM.1 (SR.4a)
- MM.1 (SR.4b)
- MM.1 (SR.4c)
- MM.1 (SR.5)
- MM.1 (SR.5a)
- MM.1 (SR.5b)
- MM.1 (SR.6)
- MM.1 (SR.7)

- MM.2 (SR.1)
- MM.3 (SR.2)
- MM.5 (SR.1)
- MM.6 (SR.3)
- MM.7 (SR.1)

Related ACHC Standards

Pharmacy Services/Medication Use:

- 25.01.02
- 25.01.03
- 25.01.04
- 25.01.05
- 25.01.07
- 25.01.08
- 25.01.09
- 25.01.10
- 25.01.11
- 25.01.12
- 25.01.13

Related CIHQ Standards

Medication Management:

- MM-3 – MM-9
- MM-16 – MM-18
- MM-22 – MM-23
- MM-30 – MM-31
- MM-24 – MM-26

Quality Assessment and Performance Improvement:

- QA-3

Radiology Services:

- RD-1

§482.25 (b) *CoP* Analysis/Guidelines

CMS has expectations regarding security and controls of drugs/biologicals. For mobile nursing medication carts (excluding automated distribution units with security features), anesthesia carts, and other medication carts (i.e., Code Blue carts) that do not contain Schedule II, III, IV, and V medications, the expectation is that these are kept in a secure area. Areas where staff are actively providing care to patients, labor and delivery (L&D) suites, critical care units, and operating rooms (OR) that are staffed around the clock are generally considered secure; however, all controlled substances must be kept in locked storage. When departments are closed, all medications must be kept in locked areas at all times to prevent unauthorized access by unmonitored, unauthorized users.

CMS and all accreditors are in alignment regarding reporting of abuses and losses of controlled substances.

CMS and all accreditors place emphasis on high-risk medications and look-alike/sound-alike medications. CMS and all accreditors emphasize pharmacy verification procedures; however, The Joint Commission also addresses safe labeling within the pharmacy and alerts to those administering these medications.

All accreditors and CMS require that medications are prepared in functionally separate areas and use of laminar airflow hoods for sterile preparation of IV admixtures. DNV has numerous standards related to sterile compounding that other accreditors do not have.

CMS and NIAHO/DNV require that information about drug interactions, side effects, indications for use, etc., be available to professional staff; The Joint Commission does not have a specific standard for this.

The Joint Commission and NIAHO/DNV specify the need for a drug recall system and address safe administration of investigational drugs; CMS only addresses that there is an alert process.

CMS and all accreditors have expectations for stop orders.

CMS and all accreditors specify that the attending physician is immediately made aware of drug administration errors, adverse drug reactions, and incompatibilities. When the attending physician is unavailable, the covering physician must be notified. When the covering physician must be notified, the patient's attending physician must be notified as soon as they are available. In addition, when appropriate, such events must be reported to the hospital-wide QAPI program.

CMS and accreditors support self-administration and patient access to self-administered non-controlled drugs and drugs and biologicals.

Survey Tips:

- Review medication orders and verify that appropriate drugs/biologicals were administered to the patient.
- Observe how sterile products are prepared.
- Inspect patient care areas and their medication distribution systems and interview staff to determine whether admixtures are being prepared by those staff.
- Verify diversion mitigation procedures are followed and that the CEO and pharmacy director are notified of losses as appropriate.
- Interview staff to verify that all medication errors are reported to the appropriate practitioner.
- Inspect drug storage areas and evaluate medication carts and kits and anesthesia carts for appropriate control.
- Conduct spot checks of patient care areas to identify unsecured, expired, mislabeled, or unusable medications and evaluate multidose vials for expiration dates.

- Evaluate system for returning unused drugs/biologicals to pharmacy.
- Review medication storage and security policies/procedures to determine definition of authorized personnel and evaluate if only those authorized are permitted access to secure areas and when unauthorized users enter (i.e., housekeeping, maintenance) they are monitored, even when the department is closed (if medications are stored in unlocked locations). Ensure unauthorized users do not have keys or passwords to locked medication areas. Evaluate procedures for and frequency of changing codes for keyless entry systems. Review lists of staff given access to pharmacy and medication areas to ensure unauthorized users do not have access. If by policy a facility has allowed authorization to medication areas, surveyors will scrutinize this and review HR staff files to verify they have received training related to medication security.
- Review drug administration error and adverse drug reaction/incompatibility P&Ps to integrate notification requirements (to attending, covering physician, and QAPI). Educate staff on requirements and monitor for compliance.
- If medications are delivered via tube systems, ensure security of those systems, unless these are in the direct line of vision of staff 24/7.
- In secure areas, evaluate those nonemployees who might have access to medications, if unlocked (e.g., nonemployees brought in by LPs in OR who might access anesthesia carts). If risk exists, it is prudent to lock carts and medications.
- Evaluate medication systems, within and outside the pharmacy, for appropriate oversight and determine that medication segregation and alerts are established for high-alert and look-alike/sound-alike medications.
- If pharmacy is not 24/7 operations, ensure that there is a night Pyxis, night cabinet, or other area to ensure that non-pharmacy staff do not have access to the entire pharmacy. Pharmacy should review medications pulled during off hours and evaluate the need to eliminate, revise, or add medications made available. Oncoming pharmacists should still verify medications that were delivered during off hours.

Suggested Documents:

- Hospital drug formulary
- Medication management and pharmacy P&Ps, including controlled drug policies
- Pharmacy committee meeting minutes
- Drug recall process and evidence of implementation for recall notices
- Sentinel event policy
- List of high-alert and look-alike/sound-alike drugs and P&Ps that specify safe storage and administration of these medications
- Medical staff bylaws/P&Ps
- Incident report summary on medical errors and/or adverse drug events
- Drug information sheets/handouts
- P&Ps for accessing medications when pharmacy is closed (if applicable)
- Records demonstrating evaluation of medications made available in night Pyxis, night cabinet, or other areas and modifications made as a result of that evaluation
- Records of pharmacy inspections for all departments that administer medications

§482.26 *CoP*: Radiologic Services		
Tag #	CMS *CoP* (2023)	CMS Interpretive Guidelines and Survey Procedures
A-0528	The hospital must maintain, or have available, diagnostic radiologic services. If therapeutic services are also provided, they, as well as the diagnostic services, must meet professionally approved standards for safety and personnel qualifications.	*See Interpretive Guidelines for §482.26* *See Survey Procedures for §482.26* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.26 -- Condition of participation: Radiologic services.*
A-0529	**Standard: Radiologic Services—** The hospital must maintain, or have available, radiologic services according to the needs of the patients.	*See Interpretive Guidelines for §482.26(a)* *See Survey Procedures for §482.26(a)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.26 -- Condition of participation: Radiologic services.*

Related Joint Commission Standards

Human Resources:

- HR.01.01.01, EP 1
- HR.01.06.01, EP 1

Leadership:

- LD.01.03.01, EP 3
- LD.04.03.01, EP 1 – 2
- LD.04.03.09, EP 2, 4, 8

Related DNV Standards

Medical Imaging:

- MI.1 (SR.1)
- MI.1 (SR.2)

Related ACHC Standards

Diagnostic Radiology and Radiation Therapy Services:

- 19.00.00
- 19.00.01

Related CIHQ Standards

Radiology Services:

- RD-1
- RD-3

§482.26 (a) *CoP* Analysis/Guidelines

Both CMS and all accreditors will verify that hospitals provide radiological services either directly or through a contractual agreement. Services provided meet laws, regulations, and guidelines governing radiological services and acceptable standards of practice.

Survey Tips

- Ensure scope of services exists
- Verify that quality and performance improvement efforts are integrated under the QAPI program

Suggested Documents:

- Organizational chart and scope of service for radiology services
- Radiology services medical director's job description, or P&Ps or responsibility chart describing roles and responsibilities
- Provide hospital contracts for radiological services and evaluation of those services available, as appropriate
- Radiology P&Ps
- Data demonstrating compliance with defined turnaround times
- Review medical records for appropriate orders

§482.26 *CoP*: Radiologic Services		
Tag #	CMS *CoP* (2023)	CMS Interpretive Guidelines and Survey Procedures
A-0535	**(b) Standard: Safety for patients and personnel—** The radiologic services, particularly ionizing radiology procedures, must be free from hazards for patients and personnel.	*See Interpretive Guidelines for §482.26(b)* *See Survey Procedures for §482.26(b)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.26 -- Condition of participation: Radiologic services.*
A-0536	(1) Proper safety precautions must be maintained against radiation hazards. This includes adequate shielding for patients, personnel, and facilities, as well as appropriate storage, use, and disposal of radioactive materials.	*See Interpretive Guidelines for §482.26(b)(1)* *See Survey Procedures for §482.26(b)(1)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.26 -- Condition of participation: Radiologic services.*
A-0537	(2) Periodic inspection of equipment must be made and hazards identified must be promptly corrected.	*See Interpretive Guidelines for §482.26(b)(2)* *See Survey Procedures for §482.26(b)(2)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.26 -- Condition of participation: Radiologic services.*
A-0538	(3) Radiation workers must be checked periodically, by the use of exposure meters or badge tests, for amount of radiation exposure.	*See Interpretive Guidelines for §482.26(b)(3)* *See Survey Procedures for §482.26(b)(3)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.26 -- Condition of participation: Radiologic services.*
A-0539	(4) Radiologic 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.	*See Interpretive Guidelines for §482.26(b)(4)* *See Survey Procedures for §482.26(b)(4)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.26 -- Condition of participation: Radiologic services.*

Related Joint Commission Standards

Environment of Care:

- EC.01.01.01, EP 4, 6
- EC.02.02.01, EP 1, 3, 6 – 8, 11, 12, 18
- EC.02.04.01, EP 2, 4
- EC.02.04.03, EP 1, 3
- EC.04.01.01, EP 8

Leadership:

- LD.04.01.07, EP 1

Provision of Care:

- PC.02.01.03, EP 1

Record of Care:

- RC 02.01.01, EP 2

Related DNV Standards

Medical Imaging:

- MI.1 (SR.1)
- MI.2 (SR.1)
- MI.2 (SR.2)
- MI.2 (SR.2a)
- MI.3 (SR.1)
- MI.4 (SR.1)

Related ACHC Standards

Diagnostic Radiology and Radiation Therapy Services:

- 19.00.02
- 19.00.02
- 19.00.03
- 19.00.04
- 19.00.05
- 19.00.06

Related CIHQ Standards

Radiology Services:

- RD-1
- RD-4
- RD-5

§482.26 (b) *CoP* Analysis/Guidelines

CMS and all accreditors are aligned when it comes to environment of care issues for hazardous waste (radioactive materials) and medical equipment management, testing, and inspections. The Joint Commission does not have a specific radiology chapter, although the standards listed earlier are important for radiology departments to be compliant with.

Survey Tips:

- Verify that hospital P&Ps address safety standards and have been signed off by the medical staff or medical director.
- Verify that there is an inventory of patient shielding aprons and that all inventories are routinely inspected.
- Verify that dosimetry badges are monitored and principles of ALARA (as low as reasonably achievable) are observed.
- Inspect where hazardous materials are stored for safety.
- Conduct audits to see whether radiology staff are wearing radiation exposure badges.
- Verify that radiation exposure badges are stored properly, and that staff do not take them home. Verify that the radiation badge collection process is compliant with policy and that reporting is timely.
- Verify that quality control (QC) checks are performed regularly.
- Verify that vendors are bringing products to the department in a safe and secure manner.
- Review data on critical tests/results and compliance comparing with departmental standards; verify this information is brought to leadership.
- Observe intradepartmental handoff communication procedures during transfer of patients to and from radiology.
- Verify staff knowledge of hazardous materials and knowledge of personal protective equipment.
- Ensure quality assurance and performance improvement activities are integrated under the QAPI program.

Suggested Documents:

- Radiology licensure for staff and physicists and nuclear medicine certificates, as appropriate
- Radiology P&Ps
- Environment of care plans/procedures for hazardous wastes and medical equipment
- Inspection logs for shields/aprons, exposure meters/badges, and medical equipment checks
- QC documentation
- Any Occupational Safety and Health Administration (OSHA) documentation regarding radiology safety
- Meeting minutes of environment of care/safety committee demonstrating evidence of radiation safety being integrated into the program
- Departmental policy on critical tests/results and related data

§482.26 *CoP*: Radiologic Services		
Tag #	CMS *CoP* (2023)	CMS Interpretive Guidelines and Survey Procedures
A-0546	**(c) Standard: Personnel** (1) A qualified full-time, part-time, or consulting radiologist must supervise the ionizing radiology services and must interpret only those radiologic tests that are determined by the medical staff to require a radiologist's specialized knowledge. For purposes of this section, a radiologist is a doctor of medicine or osteopathy who is qualified by education and experience in radiology.	*See Interpretive Guidelines for §482.26(c)(1)* *See Survey Procedures for §482.26(c)(1)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.26 -- Condition of participation: Radiologic services.*
A-0547	(2) Only personnel designated as qualified by the medical staff may use the radiologic equipment and administer procedures.	*See Interpretive Guidelines for §482.26(c)(2)* *See Survey Procedures for §482.26(c)(2)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.26 -- Condition of participation: Radiologic services.*

Related Joint Commission Standards

Leadership:

- LD.04.01.05, EP 3

Medical Staff:

- MS.01.01.01, EP 36
- MS.03.01.01, EP 16
- MS.06.01.03, EP 9
- MS.06.01.05, EP 2

Related DNV Standards

Medical Imaging:

- MI.5 (SR.1)
- MI.5 (SR.2)
- MI.6 (SR.1)

Related ACHC Standards

Diagnostic Radiology and Radiation Therapy Services:

- 19.00.09
- 19.00.10
- 19.00.11
- 19.00.13

Related CIHQ Standards

Radiology Services:

- RD-2

§482.26 (c) *CoP* Analysis/Guidelines

CMS focuses on who supervises the radiology services. A radiologist member of the hospital's medical staff should be designated, following the credentialing and privileging criteria outlined in the medical staff bylaws/ policies/procedures. CMS notes in the interpretive guidelines that "when telemedicine is used…the radiologist interpreting the radiological test must be licensed and/or meet the other applicable standards that are required by State or local laws in both the State where the practitioners are located and the State where the patient is located." The Joint Commission added standards related to telemedicine—see §482.22 Medical Staff. The Joint Commission has standards focused specifically on MRI safety and burns.

Survey Tips:

- Review privileges and QAPI information for radiologists on staff and teleradiologists
- Evaluate whether a distant site performs telemedicine services after hours or for certain programs
- Review radiology medical director job description, responsibility charting document, or policy and verify that responsibilities include input on budget, staffing, and job descriptions
- Review credential files of medical directors to ensure they are qualified to oversee the program

Suggested Documents:

- Radiology P&Ps
- Credential files of radiologists
- Radiology medical director job description, responsibility charting document, or policy
- Evidence that medical staff approved medical director
- Radiation safety officer job description (if applicable)

§482.26 *CoP*: Radiologic Services		
Tag #	CMS *CoP* (2023)	CMS Interpretive Guidelines and Survey Procedures
A-0553	**(d) Standard: Records—** Records of radiologic services must be maintained. (1) The radiologist or other practitioner who performs radiology services must sign reports of his or her interpretations. (2) The hospital must maintain the following for at least 5 years: (i) copies of reports and printouts and (ii) films, scans, and other image records, as appropriate.	*See Interpretive Guidelines for §482.26(d)* *See Survey Procedures for §482.26(d)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.26 -- Condition of participation: Radiologic services.*

Related Joint Commission Standards

Record of Care, Treatment, and Services:

- RC.01.02.01, EP 3 – 5
- RC.01.05.01, EP 1
- RC.02.01.01, EP 2

Related DNV Standards

Medical Imaging:

- MI.7 (SR.1)
- MI.7 (SR.2)
- MI.7 (SR.2a)
- MI.7 (SR.2a(1))
- MI.7 (SR.2a(2))

Related ACHC Standards

Diagnostic Radiology and Radiation Therapy Services:

- 19.00.15

Related CIHQ Standards

Radiology Services:

- RD-6

§482.26 (d) *CoP* Analysis/Guidelines

CMS and accreditors are in alignment on radiology record retention and the need for any radiology record to be both secure and accessible when needed for patient care/treatment. It is important to note that The Joint Commission has several new requirements related to radiological services. This was done due to feedback from Joint Commission–accredited organizations that some state laws are deficient and therefore additional guidance and safety standards are needed.

Survey Tips:

- Evaluate the process of film storage and process for making films accessible if not electronic
- Review record retention policy
- Review records for appropriate signatures by radiologists
- Evaluate process for overrides of x-ray interpretations in the emergency room

Suggested Documents:

- Medical record documentation (paper, film, and/or electronic versions)
- Record retention policy

§482.27 *CoP*: Laboratory Services		
Tag #	CMS *CoP* (2023)	CMS Interpretive Guidelines and Survey Procedures
A-0576	*Condition of Participation:* Laboratory Services— The hospital must maintain, or have available, adequate laboratory services to meet the needs of its patients. The hospital must ensure that all laboratory services provided to its patients are performed in a facility certified in accordance with Part 493 of this chapter.	*See Interpretive Guidelines for §482.27* *See Survey Procedures for §482.27* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.27 -- Condition of participation: Laboratory services.*
A-0582	**(a) Standard: Adequacy of laboratory services—** The hospital must have laboratory services available, either directly or through a contractual agreement with a certified laboratory that meets requirements of Part 493 of this chapter.	*See Interpretive Guidelines for §482.27(a)* *See Survey Procedures for §482.27(a)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.27 -- Condition of participation: Laboratory services.*
A-0583	(1) Emergency laboratory services must be available 24 hours a day.	*See Interpretive Guidelines for §482.27(a)(1)* *See Survey Procedures for §482.27(a)(1)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.27 -- Condition of participation: Laboratory services.*
A-0584	(2) A written description of services provided must be available to the medical staff.	*See Survey Procedures for §482.27(a)(2)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.27 -- Condition of participation: Laboratory services.*
A-0585	(3) The laboratory must make provision for proper receipt and reporting of tissue specimens.	*See Interpretive Guidelines for §482.27(a)(3)* *See Survey Procedures for §482.27(a)(3)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.27 -- Condition of participation: Laboratory services.*

A-0586	(4) The medical staff and a pathologist must determine which tissue specimens require a macroscopic (gross) examination and which require both macroscopic and microscopic examinations.	*See Interpretive Guidelines for §482.27(a)(4)* *See Survey Procedures for §482.27(a)(4)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.27 -- Condition of participation: Laboratory services.*

Related Joint Commission Standards

Leadership:

- LD.01.03.01, EP 3
- LD.04.01.01, EP 1, 2
- LD.04.03.01, EP 1, 2, 26
- LD.04.03.09, EP 2, 4, 10

Provision of Care:

- PC.01.03.08, EP 1 – 2

Related DNV Standards

Laboratory Services:

- LS.1 (SR.1)
- LS.1 (SR.2)
- LS.1 (SR.3)
- LS.1 (SR.4)
- LS.1 (SR.5)
- LS.1 (SR.6)

Related ACHC Standards

Laboratory Services:

- 22.00.00
- 22.00.01
- 22.00.02
- 22.00.03
- 22.00.04
- 22.00.05

Related CIHQ Standards

Laboratory Services:

- LB-1 – LB-3

Respiratory Services:

- RT-1

§482.27 (a) *CoP* Analysis/Guidelines

CMS is more specific about availability of laboratory services and how tissue specimens are collected, preserved, transported, received, examined, and reported. Emergency lab services must be available on site 24/7 at each location. CMS has clarified how lab services may be delivered: via direct availability, contracted services, or a combination thereof. The Joint Commission does not have laboratory-specific standards, although the standards listed are important for compliance within laboratory departments. At hospitals with off-campus locations, the medical staff must determine which, if any, lab services must be immediately available to meet emergency needs of patients.

Survey Tips:

- Review all locations within the hospital system where lab services are provided and ensure all are integrated with the organization's quality assurance plan
- Observe procedures for lab draws, ensuring appropriate patient identification and specimen labeling procedures are performed
- Interview laboratory staff regarding intradepartmental handoff communication procedures
- Verify staff knowledge of hazardous materials and knowledge of personal protective equipment
- Verify P&Ps address collection, preservation, transportation, receipt, and reporting of tissue results
- Confirm that tissues are stored at a controlled temperature and that the refrigerators, freezers, and other storage equipment have functional alarms and emergency backup plans
- Review P&Ps on tissues and organ donation
- Review records of storage temperatures, outdated procedures, manuals, and publications, ensuring they are maintained for a minimum of 10 years
- Verify that records of donor and lot identification, names of recipients or final disposition of tissues, expiration dates of tissues, and supplier names are retained for 10 years beyond date of distribution, transplantation, or expiration of tissue, whichever is later
- Verify all licenses are current and have not lapsed

Suggested Documents:

- Organizational chart and scope of service for laboratory services
- Laboratory P&Ps approved by medical staff and a pathologist
- Data demonstrating compliance with defined turnaround times
- Minutes reflecting that lab data and performance improvement initiatives have been reported through the hospital's quality structure
- Review data on critical tests/results and compliance comparing with departmental standards and verify this information is brought to leadership
- Listing of waived tests performed throughout the organization and related compliance data demonstrating QC checks and evaluation of competencies
- Tissue records
- CLIA certificate (for all locations)
- College of American Pathologists (CAP), Commission on Office Laboratory Accreditation, or The Joint Commission lab accreditation certificate (as applicable)
- Contracts for laboratory services (if applicable)

§482.27 *CoP*: Laboratory Services		
Tag #	CMS *CoP* (2023)	CMS Interpretive Guidelines and Survey Procedures
A-0592	**(b) Standard: Potentially Infectious Blood and Blood Components** (1) Potentially HIV infectious blood and blood components. Potentially HIV infectious blood and blood components are prior collections from a donor: (i) who tested negative at the time of donation but tests reactive for evidence of HIV infection on a later donation (ii) who tests positive on the supplemental (additional, more specified) test or other follow-up testing required by FDA; and (iii) for whom the timing of seroconversion cannot be precisely estimated. (2) Potentially hepatitis C virus (HCV) infectious blood and blood components. Potentially HCV infectious blood and blood components are the blood and blood components identified in 21 *CFR* 610.47. (3) Services furnished by an outside blood collecting establishment. If a hospital regularly uses the services of an outside blood collecting establishment, it must have an agreement with the blood collecting establishment that governs the procurement, transfer, and availability of blood and blood components. The agreement must require that the blood collecting establishment notify the hospital: (i) Within three calendar days if the blood collecting establishment supplied blood and blood components collected from a donor who tested negative at the time of donation but tests reactive for evidence of HIV or HCV infection on a later donation or who is determined to be at increased risk for transmitting HIV or HCV infection. (ii) Within 45 days of the test of the results of the supplemental (additional, more specific) test for HIV or HCV, as relevant, or other follow-up testing required by the FDA.	*See Interpretive Guidelines for §482.27(b)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.27 -- Condition of participation: Laboratory services.*

(iii) Within three calendar days after the blood collecting establishment supplied blood and blood components collected from an infectious donor, whenever records are available, as set forth at 21 *CFR* 610.48(b)(3).

(4) Quarantine of blood and blood components pending completion of testing. If the blood collecting establishment (either internal or under an agreement) notifies the hospital of the reactive HIV or HCV screening test results, the hospital must determine the disposition of the blood or blood components and quarantine all blood and blood components from previous donations in inventory.

(i) If the blood collecting establishment notifies the hospital that the result of the supplemental (additional, more specific) test or other follow-up testing required by FDA is negative, absent other informative test results, the hospital may release the blood and blood components from quarantine.

(ii) If the blood collecting establishment notifies the hospital that the result of the supplemental (additional, more specific) test or other follow-up testing required by FDA is positive, the hospital must

(A) dispose of the blood and blood components and

(B) notify the transfusion recipients as set forth in paragraph (b)(6) of this section.

(iii) If the blood collecting establishment notifies the hospital that the result of the supplemental (additional, more specific) test or other follow-up testing required by FDA is indeterminate, the hospital must destroy or label prior collections of blood or blood components held in quarantine as set forth at 21 *CFR* 610.46(b)(2), 610.47(b)(2), and 610.48(c)(2).

(5) Record keeping by the hospital. The hospital must maintain:

(i) Records of the source and disposition of all units of blood or blood components for at least 10 years from the date of disposition in a manner that permits prompt retrieval and

	(ii) A fully funded plan to transfer these records to another hospital or other entity if such hospital ceases operation for any reason. (6) Patient notification. If the hospital has administered potentially HIV or HCV infectious blood or blood components (either directly through its own blood collecting establishment or under an agreement) or released such blood or blood components to another entity or appropriate individual, the hospital must take the following actions: (i) Make reasonable attempts to notify the patient, or to notify the attending physicians who ordered the blood or blood component and ask the physician to notify the patient, or other individual as permitted under paragraph (b)(10) of this section, that potentially HIV or HCV infectious blood or blood components were transfused to the patient and that there may be a need for HIV or HCV testing and counseling (ii) If the physician is unavailable or declines to make the notification, make reasonable attempts to give this notification to the patient, legal guardian, or relative (iii) Document in the patient's medical record the notification or attempts to give the required notification. (7) Time frame for notification: For donors tested on or after February 20, 2008. For notifications resulting from donors tested on or after February 20, 2008, as set forth at 21 *CFR* 610.46 and 21 *CFR* 610.47, the notification effort begins when the blood collecting establishment notifies the hospital that it received potentially HIV or HCV infectious blood or blood components. The hospital must make reasonable attempts to give notification over a period of 12 weeks unless: (i) The patient is located and notified; or (ii) The hospital is unable to locate the patient and documents in the patient's medical record the extenuating circumstances beyond the hospital's control that caused the notification timeframe to exceed 12 weeks. (8) Content of notification. The notification must include the following information:	

	(i) A basic explanation of the need for HIV or HCV testing and counseling. (ii) Enough oral or written information so that an informed decision can be made about whether to obtain HIV or HCV testing and counseling (iii) A list of programs where the person can obtain HIV or HCV testing and counseling, including any requirements or restrictions the program may impose. (9) Policies and Procedures. The hospital must establish policies and procedures for notification and documentation that conform to federal, state, and local laws, including requirements for the confidentiality of medical records and other patient information. (10) Notification to legal representative or relative. If the patient has been adjudged incompetent by a state court, the physician or hospital must notify a legal representative designated in accordance with state law. If the patient is competent, but state law permits a legal representative or relative to receive the information on the patient's behalf, the physician or hospital must notify the patient of or their legal representative or relative. For possible HIV infectious transfusion recipients who are deceased, the physician or hospital must inform the deceased patient's legal representative or relative. If the patient is a minor, the parents or legal guardian must be notified.	

Related Joint Commission Standards

Provision of Care:

- PC.05.01.09, EP 1, 2

Leadership:

- LD.04.03.09, EP 2, 4, 5

Related DNV Standards

Laboratory Services:

Potentially Infectious Blood and Products

- LS.2 Intro
- LS.2 (SR.1)
- LS.2 (SR.2)

- LS.2 (SR.2a)
- LS.2 (SR.2b)
- LS.2 (SR.2c)
- LS.2 (SR.2d)
- LS.2 (SR.3)
- LS.2 (SR.4)
- LS.2 (SR.5)
- LS.2 (SR.6)
- LS.2 (SR.6a)

Patient Notification

- LS.3 Intro
- LS.3 (SR.1)
- LS.3 (SR.2)
- LS.3 (SR.3)
- LS.3 (SR.4)
- LS.3 (SR.5a)
- LS.3 (SR.5a)
- LS.3 (SR.5b)
- LS.3 (SR.6)
- LS.3 (SR.6a)
- LS.3 (SR.6b)
- LS.3 (SR.6c)
- LS.3 (SR.7)
- LS.3 (SR.7a)
- LS.3 (SR.7b)
- LS.3 (SR.7c)
- LS.3 (SR.7d)

Related ACHC Standards

Laboratory Services:

- 22.01.01

Related CIHQ Standards

Laboratory Services:

- LB-4

§482.27 (b) *CoP* Analysis/Guidelines

CMS requirements are extremely detailed about HIV infectious blood and blood products. An appropriate system is required to notify when blood products are at a higher risk for transmitting HIV. As stated in the Interpretive Guidelines, CMS regulations "apply only to transfusion services in hospitals that participate in Medicare, where the transfusion service does not include more than the performance of compatibility testing." FDA regulations "apply to facilities collecting, processing, and storing blood/blood products" as well as those facilities that do not participate in Medicare. FDA's regulation to the CMS requirements (21 *CFR* 610.45) required that within 72 hours, blood banks notify the hospital they have supplied blood/blood products to about the increased risk of HIV infection and follow up within 30 days of the confirming test results for HIV. FDA also requires appropriate disposal of contaminated blood or blood products. CMS also has expectations for blood source and blood disposition records, look-back, and notification procedures. Both CMS and all accreditors require the laboratory to have policies and procedures for notification, documentation, confidentiality, and medical records.

Survey Tips:

- Review the laboratory (and blood bank if applicable) policies and procedures and verify that they are being followed
- Review the hospital's notification procedures
- Develop and review a written description of the organization's emergency lab services
- Verify that blood sources and disposition of all units of blood and blood components are retained for at least 10 years from the date of disposition in a manner that allows prompt retrieval
- Review look-back and notification procedures to ensure compliance with CMS expectations
- If using blood from an outside blood bank, review agreement with the blood bank to ensure it governs the procurement, transfer, and availability of blood and blood products

Suggested Documents:

- Laboratory and blood bank policies/procedures
- CAP survey certificate and AABB certificate (as applicable)

§482.27 *CoP*: Laboratory Services

Tag #	CMS *CoP* (2023)	CMS Interpretive Guidelines and Survey Procedures
A-0593	**(c) Standard: General Blood Safety Issues—** For look-back activities only related to new blood safety issues that are identified after August 24, 2007, hospitals must comply with FDA regulations as they pertain to blood safety issues in the following areas: (1) Appropriate testing and quarantining of infectious blood and blood components. (2) Notification and counseling of recipients that may have received infectious blood and blood components.	*See Interpretive Guidelines for §482.27(c)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.27 -- Condition of participation: Laboratory services.*

Related Joint Commission Standards

Provision of Care

- PC.05.01.09, EP 1, 2

Related DNV Standards

Laboratory Services:

- LS.4
- LS.4 (SR.1)
- LS.4 (SR.2)

Related ACHC Standards

Laboratory Services:

- 22.01.03

Related CIHQ standards

Laboratory Services:

- LB-4

§482.27 (c) *CoP* Analysis/Guidelines

Same as §482.27 *CoP* (b) Analysis/Guidelines.

§482.28 *CoP*: Food and Dietetic Services		
Tag #	CMS *CoP* (2023)	CMS Interpretive Guidelines and Survey Procedures
A-0618	The hospital must have organized dietary services that are directed and staffed by adequate qualified personnel. However, a hospital that has a contract with an outside food management company may be found to meet this *CoP* if the company has a dietitian who serves the hospital on a full-time, part-time, or consultant basis, and if the company maintains at least the minimum standard specified in this section and provides for constant liaison with the hospital medical staff for recommendations on dietetic policies affecting patient treatment.	*See Interpretive Guidelines for §482.28* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.28 -- Condition of participation: Food and dietetic services.*
A-0619	**(a) Standard: Organization**	*See Interpretive Guidelines for §482.28(a)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.28 -- Condition of participation: Food and dietetic services.*
A-0620	(1) The hospital must have a full-time employee who (i) Serves as director of the food and dietetic services (ii) Is responsible for daily management of the dietary services (iii) Is qualified by experience or training.	*See Interpretive Guidelines for §482.28(a)(1)* *See Survey Procedures for §482.28(a)(1)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.28 -- Condition of participation: Food and dietetic services.*
A-0621	(2) There must be a qualified dietitian, full-time, part-time, or on a consultant basis.	*See Interpretive Guidelines for §482.28(a)(2)* *See Survey Procedures for §482.28(a)(2)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.28 -- Condition of participation: Food and dietetic services.*

A-0622	(3) There must be administrative and technical personnel competent in their respective duties.	*See Interpretive Guidelines for §482.28(a)(3)* *See Survey Procedures for §482.28(a)(3)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.28 -- Condition of participation: Food and dietetic services.*

Related Joint Commission Standards

Human Resources:

- HR.01.01.01, EP 1, 3
- HR.01.02.05, EP 2
- HR.01.06.01, EP 1, 5, 6

Leadership:

- LD.03.06.01, EP 2
- LD.04.01.05, EP 2, 3
- LD.04.03.01, EP 2
- LD.04.03.09, EP 1 – 7

Related DNV Standards

Dietary Services:

Organization:

- DS.1
- DS.1 (SR.1)
- DS.1 (SR.2)
- DS.1 (SR.3)
- DS.1 (SR.4)

Related ACHC Standards

Nutritional Services:

- 24.00.00
- 24.00.01
- 24.00.02
- 24.00.03
- 24.00.04

Related CIHQ Standards

Nutrition Services:

- NU-1
- NU-2

§482.28 (a) *CoP* Analysis/Guidelines

Like other sections of this manual, both CMS and all accreditors require a food and dietetic services function. CMS and all accreditors require a full-time food services director who is granted authority and delegated responsibility by the medical staff and governing body for dietary services. CMS and accreditors also require a qualified dietitian (licensed in the state or national registration) be available on a full-time, part-time, or consultant basis. The program should ensure dietary manuals, menu planning, safe food storage, preparation and sanitation procedures, emergency food supplies, and systems for diet ordering and tray delivery. Related staff all must be qualified, trained, and competent. The food and dietetic program must be integrated under the hospital's QAPI program.

Survey Tips:

- Ensure authorities and responsibilities described in the interpretive guidelines are outlined in the job description of the food services director and dietitian(s)
- Review director's file to ensure the file is complete and compliant and that education, training, and qualifications are demonstrated
- Understand whether state licensure applies; if not, the dietitian should be a registered dietitian (listed on the national registry)

Suggested Documents:

- Organizational chart and scope of service for nutrition services
- Job descriptions for food service director, personnel, and registered dietitian personnel
- Nutrition P&Ps
- Personnel files with current licensure that is primary source verified

§482.28 *CoP*: Food and Dietetic Services		
Tag #	CMS *CoP* (2023)	CMS Interpretive Guidelines and Survey Procedures
A-0629	**(b)** Menus must meet the needs of the patients. (1) Individual patient nutritional needs must be met in accordance with recognized dietary practices.	*See Interpretive Guidelines for §482.28(b)(1)* *See Survey Procedures for §482.28(b)(1)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.28 -- Condition of participation: Food and dietetic services.*
A-0630	(2) 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 nutritional professional as authorized by the medical staff and in accordance with State law governing dietitians and nutrition professionals.	*See Interpretive Guidelines for §482.28(b)(2)* *See Survey Procedures for §482.28(b)(2)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.28 -- Condition of participation: Food and dietetic services.*
A-0631	(3) A current therapeutic diet manual approved by the dietitian and medical staff must be readily available to all medical, nursing, and food service personnel.	*See Interpretive Guidelines for §482.28(b)(3)* *See Survey Procedures for §482.28(b)(3)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.28 -- Condition of participation: Food and dietetic services.*

Related Joint Commission Standards

Human Resources:

- HR.01.02.05, EP 2

Leadership:

- LD.03.10.01, EP 3

Provision of Care:

- PC.01.02.01, EP 3
- PC.01.03.01, EP 1
- PC.02.01.03, EP 1, 7
- PC.02.02.03, EP 7, 22
- RC.02.01.01, EP 2

Related DNV Standards

Services and Diets

- DS.2 Introduction
- DS.2 (SR.2)
- DS.2 (SR.3)
- DS.2 (SR.4)

Related ACHC Standards

Nutritional Services:

- 24.00.06
- 24.00.08
- 24.00.08

Related CIHQ Standards

Dietary (Nutrition) Services:

- NU-1
- NU-4 – NU-7

§482.28 (b) *CoP* Analysis/Guidelines

As part of medical record review, both CMS and all accreditors will look to see if nutritional assessments were done, how nutritional needs were met, and which patients need to be reevaluated. CMS and accreditors are in alignment that a dietitian may assess a patient's nutritional needs and provide recommendations or consultations for patients. CMS has revised its standard to allow for flexibility in patient diet orders, including therapeutic diets, by stating they must be ordered by a practitioner responsible for the care of the patient, or by a qualified dietitian or other clinically qualified nutrition professional as authorized by the medical staff and in accordance with state law, thus removing the requirement that a patient's diet must be ordered only by an LP. State licensure of dietitians must be considered because dietitians are not licensed in all states. This would also require privileging of dietitians to order diets or other nutritional needs. CMS and accreditors are also aligned in that therapeutic diet manuals must not be more than five years old and must be approved by the dietitian and medical staff.

Survey Tips:

- Review diet orders and ensure patient received the correct diet.
- Review entire food service/diet process. Be prepared to show how nutritional adequacy of diets is assessed.
- Update the hospital's diet manual and have it approved by the medical staff.
- Ensure current diet manuals are available in all patient areas.
- Verify that therapeutic diets are ordered by the LP and authenticated. Registered dietitians writing diet orders should have them authenticated or written as a VO/TO if protocol driven and must have an order to use protocol.
- Verify nutrition screening procedures are performed upon admission and that patients with identified needs receive timely nutritional assessments by a qualified dietitian and as defined by P&P.
- Tour kitchen and observe for staff, equipment, and storage areas for appropriate sanitation procedures.
- Observe trays being passed to patients with specialized diets and ensure appropriate patient identification procedures.
- Review food service/nutrition policies/procedures. If a contracted service, the hospital should approve their policies.

Suggested Documents:

- Hospital's diet manual/sample patient menus
- Medical records
- Food service/nutrition P&Ps
- Medical staff and governing body meeting minutes that reflect that the food services director has been granted authority and delegated responsibility for the operation of the dietary service
- Food storage and sanitation records

§482.30 *CoP*: Utilization Review		
Tag #	CMS *CoP* (2023)	CMS Interpretive Guidelines and Survey Procedures
A-0652	The hospital 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.	*See Interpretive Guidelines for §482.30* *See Survey Procedures for §482.30* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.30 -- Condition of participation: Utilization review.*
A-0653	**(a) Standard: Applicability—** The provisions of this section apply except in either of the following circumstances: (1) A Utilization and Quality Control Quality Improvement Organization (QIO) has assumed binding review for the hospital. (2) CMS has determined that the UR procedures established by the state under Title XIX of the Act are superior to the procedures required in this section, and has required hospitals in that State to meet the UR plan requirements under §456.50 through §456.245 of this chapter.	*See Interpretive Guidelines for §482.30(a)* *See Survey Procedures for §482.30(a)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.30 -- Condition of participation: Utilization review.*
Related Joint Commission Standards Leadership: • LD.04.01.01, EP 17 – 18		
Related DNV Standards Utilization Review: Documented Plan • UR.1 – Introduction • UR.1 Surveyor Guidance		
Related ACHC Standards Utilization Review: • 06.00.00 • 06.00.01		

Related CIHQ Standards

Utilization Review Plan:

- UR-1

§482.30 (a) *CoP* Analysis/Guidelines

CMS expects hospitals to have a UR plan, which delineates responsibilities and authority for those involved in UR activities. It should include procedures for the review of the medical necessity of admissions and the medical necessity of professional services. If the hospital has an agreement with a QIO to review admissions, quality, appropriateness, and diagnostic information, CMS anticipates that hospitals will comply with the *CoP* by means of the QIO exception and therefore a plan would not be required under those circumstances. CMS had determined that the UR procedures established by some states are superior to these requirements, and in those cases, the state requirements are applied for Medicare and Medicaid patients. All accreditors are aligned with these nuances.

Survey Tips:

- Ensure there is a UR plan and that it is reviewed annually by the UR committee. Verify that the governing body has approved the plan and has delegated authority to carry out the UR function to the UR committee.
- Ensure there is a UR committee, and that the committee has approved the UR plan.
- Be able to demonstrate through UR committee minutes where issues with admission, continued stay, professional services, and avoidable days were discussed.

Suggested Documents:

- UR P&Ps
- UR committee meeting minutes
- UR plan and annual review of the plan (if there is no agreement with QIO to perform this function)

§482.30 *CoP*: Utilization Review		
Tag #	CMS *CoP* (2023)	CMS Interpretive Guidelines and Survey Procedures
A-0654	**(b) Standard: Composition of Utilization Review Committee—** A UR committee consisting of two or more practitioners must carry out the UR function. At least two of the members of the committee must be doctors of medicine or osteopathy. The other members may be any of the other types of practitioners specified in § 482.12(c)(1). (1) Except as specified in paragraphs (b)(2) and (3) of this section, the UR committee must be one of the following: (i) A staff committee of this institution. (ii) A group outside the institution (A) established by the local medical society and some or all of the hospitals in the locality or (B) established in a manner approved by CMS. (2) If, because of the small size of the institution, it is impracticable to have a properly functioning staff committee, the UR committee must be established as specified in paragraph (b)(1)(ii) of this section. (3) The committee or group's review may not be conducted by any individual who: (i) Has a direct financial interest (e.g., an ownership interest) in that hospital. (ii) Was professionally involved in the care of the patient whose case is being reviewed.	*See Survey Procedures for §482.30(b)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.30 -- Condition of participation: Utilization review.*

Related Joint Commission Standards

Leadership:

- LD.04.01.01, EP 17, 18

Related DNV Standards

Utilization Review:

Documented Plan

- UR.1 (SR.1)
- UR.1 (SR.1a)
- UR.1 (SR.1b)
- UR.1 (SR.1c)
- UR.1 (SR.1d)
- UR.1 (SR.1d(1))
- UR.1 (SR.1d(1)(i))
- UR.1 (SR.1d(1)(ii))
- UR.1 (SR.3)

Related ACHC Standards

Utilization Review:

- 06.00.02

Related CIHQ Standards

Utilization Review:

- UR-2

§482.30 (b) *CoP* Analysis/Guidelines

The UR committee must include at least two members who are MDs/DOs. Review of outliers should not be performed by those who are professionally involved in the care of the patient or those with financial interest in the hospital (ownership of 5% or greater). For small hospitals where it is impractical to have a staff committee, they may delegate the function to an outside group. DNV and CIHQ are in alignment with these requirements.

Survey Tips:

- For organizations that perform their own UR function, determine whether the UR committee is a staff committee of the organization, a group outside the organization, or one established by a local medical society. Establish that at least two members of the committee are MDs/DOs. Establish that group reviews are not done by those professionally involved in the care of the patient or those with financial interest.

Suggested Documents:

- List of UR committee members, their credentials, and charter

§482.30 *CoP*: Utilization Review		
Tag #	CMS *CoP* (2023)	CMS Interpretive Guidelines and Survey Procedures
A-0655	**(c) Standard: Scope and Frequency of Review** (1) The UR plan must provide for review for Medicare and Medicaid patients with respect to the medical necessity of— (i) admissions to the institution, (ii) the duration of stays, and (iii) professional services furnished, including drugs and biologicals. (2) Review of admissions may be performed before, at, or after hospital admission. (3) Except as specified in paragraph (e) of this section, reviews may be conducted on a sample basis. (4) Hospitals that are paid for inpatient hospital services under the prospective payment system set forth in Part 412 of this chapter must conduct review of duration of stays and review of professional services as follows: (i) For duration of stays, these hospitals need review only cases that they reasonably assume to be outlier cases based on extended length of stay, as described in §412.80(a)(1)(i) of this chapter. (ii) For professional services, these hospitals need review only cases that they reasonably assume to be outlier cases based on extraordinarily high costs, as described in §412.80(a)(1)(ii) of this chapter.	*See Interpretive Guidelines for §482.30(c)* *See Survey Procedures for §482.30(c)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.30 -- Condition of participation: Utilization review.*

Related Joint Commission Standards

Leadership:

- LD.04.01.01, EP 17, 18

Related DNV Standards

Utilization Review:

Documented Plan

- UR.1 Intro
- UR.1 (SR.4)
- UR.1 (SR.4a)
- UR.1 (SR.4b)
- UR.1 (SR.4c)
- UR.2 (SR.1)
- UR.2 (SR.2)
- UR.3 (SR.1)
- UR.3 (SR.3)
- UR.3 (SR.3a)
- UR.3 (SR.3b)
- UR.4 (SR.1)
- UR.4 (SR.2)

Related ACHC Standards

Utilization Review:

- 06.00.03

Related CIHQ Standards

Utilization Review:

- UR-3

§482.30 (c) *CoP* Analysis/Guidelines

CMS specifies that the plan addresses medical necessity review of admissions, duration of stay, and professional services. Reviews can be conducted on a sample basis, except for reviews of extended stays.

Survey Tips:

- Ensure the UR plan addresses required frequency of review and CMS *CoP* requirements
- Ensure there are policies related to issues with admission, continued stay, professional services, and avoidable days; ensure P&Ps meet interpretive requirements in CMS *CoP*
- Audit outliers to determine that reviews were conducted and were timely

Suggested Documents:

- UR plan and annual review of the plan (if there is no agreement with QIO to perform this function)

§482.30 *CoP*: Utilization Review (continued)		
Tag #	CMS *CoP* (2023)	CMS Interpretive Guidelines and Survey Procedures
A-0656	**(d) Standard: Determination Regarding Admissions or Continued Stays** (1) The determination that an admission or continued stay is not medically necessary (i) May be made by one member of the UR committee if the practitioner(s) responsible for the care of the patient, as specified at §482.12(c), concurs with the determination or fails to present their views when afforded the opportunity. (ii) Must be made by at least two members of the UR committee in all other cases. (2) Before making a determination that an admission or continued stay is not medically necessary, the UR committee must consult the practitioner(s) responsible for the care of the patient, as specified in §482.12(c), and afford the practitioner(s) the opportunity to present their views. (3) If the committee decides that admission to or continued stay in the hospital is not medically necessary, written notification must be given, no later than 2 days after the determination, to the hospital, the patient, and practitioner(s) responsible for the care of the patient, as specified in §482.12(c).	*See Interpretive Guidelines for §482.30(d)* *See Survey Procedures for §482.30(d)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.30 -- Condition of participation: Utilization review.*

Related Joint Commission Standards

Leadership:

- LD.04.01.01, EP 17, 18

Related DNV Standards

Medical Necessity Determination

- UR.5
- UR.5 (SR.1)
- UR.5 (SR.2)
- UR.5 (SR.2a)
- UR.5 (SR.2b)
- UR.5 (SR.3)
- UR.5 (SR3a)

Related ACHC Standards

Utilization Review:

- 06.00.04

Related CIHQ Standards

Utilization Review:

- UR-3

§482.30 (d) *CoP* Analysis/Guidelines

Stays determined to be medically unnecessary require clearly defined processes. For these medical necessity reviews, CMS expects that a UR subcommittee or QAPI subgroup must include one physician from the UR committee and two members of the QAPI committee. If that group agrees that the admission or extended stay is not medically necessary or appropriate, they must notify the attending physician. The physician must be notified within two days of the decision and given opportunity to present their own views and any additional information related to the patient's need for admission or extended stay. If the physician contests the finding, at least one additional physician member of the committee must review the case. If the attending does not respond, the findings should be deemed final. DNV and CIHQ have standards to this effect.

Survey Tips:

- Review sampling of medically unnecessary decisions and verify practitioners were informed of the expected decision of the committee and that the practitioner was given opportunity to comment. Also verify that all involved parties are notified of the decision no later than two days following the decision.
- Interview UR committee members regarding extended-stay procedures. Verify that one physician from the UR committee and two members of the quality committee are present. If the practitioner contests the findings, a second physician from the UR committee should have been brought into the discussion.
- Review UR committee meeting minutes for data and discussion related to evaluation of professional services.
- Ensure there are policies related to issues with admission, continued stay, professional services, and avoidable days; ensure P&Ps meet interpretive requirements in CMS *CoP*.
- Consider creating a log of actions taken related to issues with admission, continued stay, professional service, or duration of stay.

Suggested Documents:

- UR minutes/documents reflecting stays determined to be medically unnecessary
- Any related patient flow data related to discharge delays
- Outlier duration of care data
- UR plan (if there is no agreement with QIO to perform this function)
- UR extended stay P&Ps
- Form letter that goes to practitioners with issues

§482.30 *CoP*: Utilization Review		
Tag #	CMS *CoP* (2023)	CMS Interpretive Guidelines and Survey Procedures
A-0657	**(e) Standard: Extended-Stay Review** (1) In hospitals that are not paid under the prospective payment system, the UR committee must make a periodic review, as specified in the UR plan, or each current inpatient receiving hospital services during a continuous period of extended duration. The scheduling of the periodic reviews may (i) Be the same in all cases or (ii) Differ for different classes of cases (2) In hospitals paid under the prospective payment system, the UR committee must review all cases reasonably assumed by the hospital to be outlier cases because the extended length of stay exceeds the threshold criteria for the diagnosis, as described in §482.80(a) (1)(i). The hospital is not required to review an extended stay that does not exceed the outlier threshold for the diagnosis. (3) The UR committee must make the periodic review no later than seven days after the day required in the UR plan.	*See Survey Procedures for §482.30(e)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.30 -- Condition of participation: Utilization review.*

Related Joint Commission Standards

Leadership:

- LD.04.01.01, EP 17, 18

Related DNV Standards

Length of Stay (Extended Stay) Review

- UR.3
- UR.3 (SR.2)
- UR.3 (SR.2a)
- UR.3 (SR.2a (1))
- UR.3 (SR.2a (2))
- UR.3 (SR.3)
- UR.3 (SR.3a)
- UR.3 (SR.3b)

Related ACHC Standards

Utilization Review:

- 06.00.05

Related CIHQ Standards

Utilization Review:

- UR-3

§482.30 (e) *CoP* Analysis/Guidelines

Outliers in duration of care should be evaluated; however, CMS does not require the frequency of review to be the same for all patients. See §482.30 (d) for details on case review, survey tips, and suggested documents.

§482.30 *CoP*: Utilization Review		
Tag #	CMS *CoP* (2023)	CMS Interpretive Guidelines and Survey Procedures
	(f) Standard: Review of Professional Services The committee must review professional services provided, to determine medical necessity and to promote the most efficient use of available health facilities and services.	*See Interpretive Guidelines for §482.30(f)* *See Survey Procedures for §482.30(f)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.30 -- Condition of participation: Utilization review.*

Related Joint Commission Standards

Leadership:

- LD.04.01.01, EP 17, 18

Related DNV Standards

Review of Professional Services

- UR.4 (SR.1)

Related ACHC Standards

Utilization Review:

- 06.00.06

Related CIHQ Standards

Utilization Review:

- UR-5

§482.30 (f) *CoP* Analysis/Guidelines

Review of professional services would be inclusive of turnaround times for completing diagnostic testing and procedures and other aspects of care (e.g., timeliness of completing nutritional evaluations, respiratory services evaluations, physical medicine evaluations) and timeliness of physician services (including consulting physicians). See §482.30 (d) for details on case review, survey tips, and suggested documents.

§482.41 *CoP*: Physical Environment		
Tag #	CMS *CoP* (2023)	CMS Interpretive Guidelines and Survey Procedures
A-0700	The hospital must be constructed, arranged, and maintained to ensure the safety of the patient and to provide facilities for diagnosis and treatment and for special hospital services appropriate to the needs of the community.	*See Interpretive Guidelines for §482.41* *See Survey Procedures for §482.41* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.30 -- Condition of participation: Utilization review.*
A-0701	**(a) Standard: Buildings—** The condition of the physical plant and the overall hospital environment must be developed and maintained in such a manner that the safety and well-being of patients are ensured.	*See Interpretive Guidelines for §482.41(a)* *See Survey Procedures for §482.41(a(* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.30 -- Condition of participation: Utilization review.*
A-0702	(1) There must be emergency power and lighting in at least the operating, recovery, intensive care, and emergency rooms and stairwells. In all other areas not serviced by the emergency supply source, battery lamps and flashlights must be available.	*See Interpretive Guidelines for §482.41(a)(1)* *See Survey Procedures for §482.41(a)(1)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.30 -- Condition of participation: Utilization review.*
A-0703	(2) There must be facilities for emergency gas and water supply.	*See Interpretive Guidelines for §482.41(a)(2)* *See Survey Procedures for §482.41(a)(2)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.30 -- Condition of participation: Utilization review.*

Related Joint Commission Standards

Environment of Care:

- EC.01.01.01, EP 4, 6 – 9
- EC.02.01.01, EP 1, 3, 5, 11
- EC.02.02.01, EP 1, 3 – 5, 8, 10 – 12
- EC.02.04.01, EP 9
- EC.02.05.01, EP 9 – 13, 17
- EC.02.05.03, EP 2 – 7, 12, 13, 16
- EC.02.06.01, EP 1, 11, 20, 26
- EC.04.01.01, EP 15
- EC.04.01.03, EP 2
- EC.04.01.05, EP 1
- EC.02.06.05, EP 1 – EP 3

Related DNV Standards

Facility

- PE.1 Introduction
- PE.1 (SR.1)

Utility Management System

- PE.8 (SR.8)
- PE.8 (SR.8a)
- PE.8 (SR.9)

Related ACHC Standards

Emergency Management:

- 09.01.04

Physical Environment:

- 11.00.01
- 11.01.02
- 11.02.01
- 11.06.01

Life Safety:

- 13.00.01
- 13.00.02
- 13.00.03
- 13.00.05
- 13.01.06
- 13.05.09
- 13.06.03
- 13.06.04
- 13.06.05

Related CIHQ Standards

Managing the Care Environment:

- CE-2
- CE-3
- CE-4
- CE-12
- CE-13
- CE-14

§482.41 (a) *CoP* Analysis/Guidelines

All accreditors align with CMS, yet it is difficult to see direct alignment. DNV and Joint Commission standards are more detailed than CMS in this section. The Joint Commission has individual standards that require plans and annual evaluations of those plans for security, safety, hazardous waste, medical equipment, utility systems, emergency power sources, and medical gas. CMS is more general in terms of the overall hospital environment, emergency power and lighting, and emergency gas/water supplies.

CMS published expectations on the use of power strips.

- If line-operated medical equipment is used in a patient care room/area, inside the patient care vicinity:
    - UL power strips must be a permanent component of a rack-, table-, pedestal-, or cart-mounted and tested medical equipment assembly
    - Power strips providing power to medical equipment in a patient care room/area must be UL 1363A or UL 60601-1
    - Power strips cannot be used for non-medical equipment

- If line-operated medical equipment is used in a patient care room/area, outside the patient care vicinity:
    - UL power strips could be used for medical and non-medical equipment with precautions as described in the memo
    - Power strips providing power to medical equipment in a patient care room/area must be UL 1363A or UL 60601-1
    - Power strips providing power to non-medical equipment in a patient care room/area must be UL 1363
- If line-operated medical equipment is not used in a patient care room/area, inside and outside the patient care vicinity:
    - UL power strips could be used with precautions
- Power strips providing power to non-medical equipment in a patient care room/area must be UL 1363. In non-patient care areas/rooms, other UL strips could be used with general precautions.

CMS has also published expectations for ligature risk reduction, becoming an area of intense focus.

Important note: CMS reviewed its existing emergency preparedness regulations and found them to be insufficient. They have published new regulations to ensure a comprehensive, consistent, flexible, and dynamic regulatory approach to emergency preparedness and response that incorporates the lessons learned from the past, combined, and proven best practices of the present. However, accreditors and CMS require emergency preparedness plans coordinated with federal, state, local emergency preparedness, and health authorities regarding important aspects of those plans. The Joint Commission's emergency management chapter details those aspects more specifically.

This information was published on September 16, 2016, with an expected implementation date of November 15, 2019. The guidance is in Appendix Z SC-17-29. It includes many detailed requirements in their E-tags, and the expectations vary by provider type. Accredited organizations should have very little work to do with a couple of exceptions. Those exceptions include:

- The need to develop a Continuity of Operations Plan (COOP) (which is a succession plan to replace EOP leaders if unable to carry out duties and a delegation of authority plan that should address decisions and policies implemented by authorized successors with criteria and triggers to initiate delegation)
- The need to create a process to request waiver and treatment at an alternative care site (an 1135 waiver)
- Specifications for emergency and standby power systems for inpatient providers

Survey Tips:

- Conduct walk-throughs of hospital facilities (on campus and off campus) and observe the condition of the hospital (condition of ceilings, walls, floors, presence of patient hazards, etc.). Ensure power strips are used in accordance with guidelines.
- Audit required testing and maintenance. Ensure all components are identified and tested. Ensure that issues noted with testing have been resolved.
- Ensure that a ligature risk assessment has been conducted and that environmental risks have been mitigated for those patients with serious risk of harm to self (i.e., on a mental health hold).
- Audit emergency operations plan, training, and testing documents.

- Verify procedures have been established to comply with 42 *CFR* Section 482.15(b)(8), which addresses a hospital's role under an 1135 waiver. (Note: Emergencies/disasters that may warrant a waiver under Section 1135 include but are not limited to the following: flu or coronavirus pandemics; hurricanes; tornados; fires; earthquakes; power outages; chemical spills; nuclear/biological terrorist attack.)
- UL power strips could be used with precautions.
- Power strips providing power to non-medical equipment in a patient care room/area must be UL 1363. In non-patient care areas/rooms, other UL strips could be used with the general precautions.
- Verify that there is a Continuity of Operations Plan.
- Evaluate whether those responsible for emergency planning have evaluated Appendix Z and conducted a gap analysis to identify potential compliance gaps and that any issues have been resolved.

Suggested Documents:

- Facility management plans
- Environment of care and emergency preparedness policies/procedures
- Required management plans, their related risk assessments, and annual evaluations
- Emergency management exercises and their after-action reports
- Environment of care/safety minutes from the past 12 months
- Required testing documentation
- Preventive maintenance schedules and inspection logs
- Emergency management and preparedness plans (for both internal and external disasters, plus catastrophic emergencies), also called Emergency Operations Plan or Hazard Vulnerability Analysis
- Patient influx policies/procedures
- Contracts with outside resources and vendors for backup in the event of emergencies
- E-Statement of Conditions, evidence of assessment for needed interim life safety measures, and the introduction of those measures as applicable
- Facility layout maps
- Minutes reflecting that environment of care, safety, and emergency preparedness are integrated with the hospital's quality infrastructure
- Safety officer and emergency preparedness officer letters of authority

§482.41 *CoP*: Physical Environment		
Tag #	CMS *CoP* (2023)	CMS Interpretive Guidelines and Survey Procedures
A-0709	**(b) Standard: Life Safety from Fire—** The hospital must ensure that the life safety from fire requirements is met.	*See Interpretive Guidelines for §482.41(b)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.41 -- Condition of participation: Physical environment.*
A-0710	(1) Except as otherwise provided in this section: (i) The hospital must meet the applicable provisions and must proceed in accordance with the *Life Safety Code* (NFPA 101 and Tentative Interim Amendments TIA 12–1, TIA 12–2, TIA 12–3, and TIA 12–4). Outpatient surgical departments must meet the provisions applicable to Ambulatory Health Care Occupancies, regardless of the number of patients served. (ii) Notwithstanding paragraph (b)(1)(i) of this section, corridor doors and doors to rooms containing flammable or combustible materials must be provided with positive latching hardware. Roller latches are prohibited on such doors. (2) In consideration of a recommendation by the State survey agency or Accrediting Organization or at the discretion of the Secretary, may waive, for periods deemed appropriate, specific provisions of the *Life Safety Code*, which would result in unreasonable hardship upon a hospital, but only if the waiver will not adversely affect the health and safety of the patients. (3) 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.	*See Interpretive Guidelines for §482.41(b)(1)–(3)* *Guidance is pending and will be updated in a future release.* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.41 -- Condition of participation: Physical environment.*

A-0713	(4) The hospital must have procedures for the proper routine storage and prompt disposal of trash.	*See Interpretive Guidelines for §482.41(b)(4)* *Guidance is pending and will be updated in a future release.* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.41 -- Condition of participation: Physical environment.*
A-0714	(5) The hospital must have written fire control plans that contain provisions for prompt reporting of fires; extinguishing fires; protection of patients, personnel, and guests; evacuation; and cooperation with firefighting authorities.	*See Survey Procedures for §482.41(b)(5)* *Guidance is pending and will be updated in a future release.* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.41 -- Condition of participation: Physical environment.*
A-0715	(6) The hospital must maintain written evidence of regular inspection and approval by State or local fire control agencies.	*See Survey Procedures for §482.41(b)(6)* *Guidance is pending and will be updated in a future release.* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.41 -- Condition of participation: Physical environment.*
A-0716	(7) A hospital may install alcohol-based hand rub dispensers in its facility if the dispensers are installed in a manner that adequately protects against inappropriate access.	*See Interpretive Guidelines for §482.41(b)(7)* *See Survey Procedures for §482.41(b)(7)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.41 -- Condition of participation: Physical environment.*

A-0717	(8) When a sprinkler system is shut down for more than 10 hours, the hospital must: (i) Evacuate the building or portion of the building affected by the system outage until the system is back in service, or (ii) Establish a fire watch until the system is back in service	*See Interpretive Guidelines for §482.41(b)(8)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.41 -- Condition of participation: Physical environment.*
A-0718	(9) Buildings must have an outside window or outside door in every sleeping room, and for any building constructed after July 5, 2016, the sill height must not exceed 36 inches above the floor. Windows in atrium walls are considered outside windows for the purposes of this requirement. (i) The sill height requirement does not apply to newborn nurseries and rooms intended for occupancy for less than 24 hours. (ii) The sill height in special nursing care areas of new occupancies must not exceed 60 inches	*See Interpretive Guidelines for §482.41(b)(9)* *Guidance is pending and will be updated in a future release.* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.41 -- Condition of participation: Physical environment.*
A-0720	**(c) Standard: Building Safety—** Except as otherwise provided in this section, the hospital must meet the applicable provisions and must proceed in accordance with the Healthcare Facilities Code (NFPA 99 and Tentative Interim Amendments TIA 12–2, TIA 12–3, TIA 12–4, TIA 12–5 and TIA 12–6). (1) Chapters 7, 8, 12, and 13 of the adopted Healthcare Facilities Code do not apply to a hospital. (2) If the application of the Healthcare Facilities Code required under paragraph (c) of this section would result in unreasonable hardship for the hospital, CMS may waive specific provisions of the Healthcare Facilities Code, but only if the waiver does not adversely affect the health and safety of patients.	*See Interpretive Guidelines for §482.41(c)(1) and (2)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.41 -- Condition of participation: Physical environment.*

Related Joint Commission Standards

Environment of Care:

- EC.01.01.01, EP 1
- EC.02.01.03, EP 4
- EC.02.02.01, EP 5, 6, 19
- EC.02.03.01, EP 1, 4, 9
- EC.02.03.03, EP 1 – 5, 7, 8, 27
- EC.02.03.05, EP 28
- EC.02.05.01, EP 2, 18, 19
- EC.02.05.05, EP 8
- EC.02.05.09, EP 14
- EC.03.01.01, EP 1, 2

Life Safety:

- LS.01.01.01, EP 1 – 5
- LS.01.02.01, EP 2
- LS.02.01.10, EP 1, 3 – 5, 8 – 15
- LS.02.01.20, EP 1 – 12, 14 – 18, 20 – 27, 32, 35 – 42
- LS.02.01.30, EP 1 – 8, 11 – 16, 18 – 26
- LS.02.01.34, EP 1 – 8, 10
- LS.02.01.35, EP 1 – 6, 10 – 14
- LS.02.01.40, EP 1
- LS.02.01.50, EP 1 – 4, 6 – 14
- LS.02.01.70, EP 3 – 9, 11 – 14
- LS.03.01.10, EP 1 – 11
- LS.03.01.20, EP 1 – 17
- LS.03.01.30, EP 1 – 4, 6 – 10, 12 – 17
- LS.03.01.34, EP 1 – 10
- LS.03.01.35, EP 1 – 6, 10, 11
- LS.03.01.40, EP 1 – 3
- LS.03.01.50, EP 1 – 10

- LS.03.01.70, EP 3 – 9
- LS.05.01.20, EP 1 – 9
- LS.05.01.30, EP 1 – 4
- LS.05.01.34, EP 1 – 3
- LS.05.01.35, EP 3– 6

Human Resources:

- HR.01.04.01, EP 1

Related DNV Standards

Life Safety Management System

- PE.2
- PE.2 (SR.1)
- PE.2 (SR.1a)
- PE.2 (SR.1b)
- PE.2 (SR.1c)
- PE.2 (SR.1d)
- PE.2 (SR.3)
- PE.2 (SR.4)
- PE.2 (SR.6)
- PE.2 (SR.6d)
- PE.2 (SR.8)
- PE.2 (SR.8a)
- PE.2 (SR.8b)
- PE.2 (SR.9)
- PE.2 (SR.9a)
- PE.2 (SR.9b)
- PE.2 (SR.10)

Facility

- PE.1 (SR.3)
- PE.1 (SR.3a)
- PE.1 (SR.3b)

Safety Management System

- PE.3 (SR.8)

Hazardous Material Management System

- PE.5 (SR.2)
- PE.5 (SR.7)

Related ACHC Standards

Life Safety:

- Introduction (page 3)
- 13.00.00
- 13.00.01
- 13.00.04
- 13.00.05
- 13.00.08
- 13.00.09
- 13.01.01
- 13.01.02
- 13.01.03
- 13.01.04
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- 13.05.09
- 13.05.11

- 13.05.12
- 13.06.01
- 13.06.02
- 13.06.04
- 13.06.05
- 11.03.02
- 11.04.01
- 11.04.04
- 11.07.01

Related CIHQ Standards

Care Environment:

- CE-2 – CE-7
- CE-12 – CE-21

§482.41 (b–c) *CoP* Analysis/Guidelines

CMS now surveys hospitals using the 2012 editions of NFPA 99 and NPFA 101. However, Chapters 7, 8, 12, and 13 of NFPA 99 do not apply. CMS has developed guidance for hospitals to ensure alignment with the *LSC* occupancy classification provisions in their interpretive guidelines. They provided clarification on determining the appropriate occupancy classifications for separated non-contiguous or off-site facilities that are part of a certified hospital. The *LSC* permits certain hospital component facilities to be classified as occupancy types other than healthcare occupancy, including ambulatory healthcare, business, and others. CMS offers options for equipment maintenance, which includes that equipment can be maintained in accordance with manufacturer recommendations or via an alternative equipment management program. CMS has increased focus on water systems to prevent transmission of Legionnaires' disease. There is also intense focus on compliance with ventilation systems (air exchanges, pressure relationships, etc.).

Survey Tips:

- Review how the hospital stores and disposes trash (including biohazardous and pharmaceutical waste).
- Interview staff regarding fire, evacuation, and medical gas shutdown procedures.
- Verify that fire control plans are up to date.
- Verify that fire, smoke, heat detection, and alarm systems are inspected and maintained according to NFPA requirements.
- Ensure all areas of the hospital have conducted fire drills based on a plan.
- Ensure there are water management policies and procedures to reduce the risk of growth and spread of *Legionella* and other opportunistic pathogens in building water systems.
- Ensure ventilation systems are appropriately managed. Ensure staff in high-risk areas understand how temperature, humidity, and pressure relationships are evaluated.

Suggested Documents:

- Organizational chart of facilities, biomedical, and other related staff
- Environment of care plans and related performance improvement
- Environment of care P&Ps
- Fire drill schedules and logs; make sure drills are conducted at random times
- Copies of inspection and approval reports from State and local fire control agencies
- Building maintenance plan
- Applicable contracts

§482.41 *CoP*: Physical Environment		
Tag #	CMS *CoP* (2023)	CMS Interpretive Guidelines and Survey Procedures
A-0722	**(d) Standard: Facilities—** The hospital must maintain adequate facilities for its services.	*See Interpretive Guidelines for §482.41(d)* *See Survey Procedures for §482.41(d)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.41 -- Condition of participation: Physical environment.*
A-0723	(1) Diagnostic and therapeutic facilities must be located for the safety of patients.	*See Interpretive Guidelines for §482.41(d)(1)* *Guidance is pending and will be updated in a future release.* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.41 -- Condition of participation: Physical environment.*
A-0724	(2) Facilities, supplies, and equipment must be maintained to ensure an acceptable level of safety and quality.	*See Interpretive Guidelines for §482.41(d)(2)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.41 -- Condition of participation: Physical environment.*
A-0725	(3) The extent and complexity of facilities must be determined by the services offered.	*See Interpretive Guidelines for §482.41(d)(3)* *See Survey Procedures for §482.41(d)(3)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.41 -- Condition of participation: Physical environment.*

A-0726	(4) There must be proper ventilation, light, and temperature controls in pharmaceutical, food preparation, and other appropriate areas.	*See Interpretive Guidelines for §482.41(d)(4)* *Guidance is pending and will be updated in future release.* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.41 -- Condition of participation: Physical environment.*
A-0730	The standards incorporated by reference in this section are approved for incorporation by reference by the Director of the Office of the *Federal Register* in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may inspect a copy at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030 or go to *https://www.archives.gov/federal-register/cfr.* If any changes in this edition of the code are incorporated by reference, CMS will publish a document in the *Federal Register* to announce the changes. (1) National Fire Protection Association 1 Batterymarch Park, Quincy, MA 02169 *www.nfpa.org*, 1.617.770.3000 (i) NFPA 99, Standards for Health Care Facilities Code of the National Fire Protection Association 99, 2012 edition, issued August 11, 2011. (ii) TIA 12 – 2 to NFPA 99, issued August 11, 2011. (iii) TIA 12 – 3 to NFPA 99, issued August 9, 2012. (iv) TIA 12 – 4 to NFPA 99, issued March 7, 2013. (v) TIA 12 – 5 to NFPA 99, issued August 1, 2013. (vi) TIA 12 – 6 to NFPA 99, issued March 3, 2014. (vii) NFPA 101, *Life Safety Code*, 2012 edition, issued August 11, 2011 (i) TIA 12 – 1 to NFPA 101, issued August 11, 2011. (ix) TIA 12 – 2 to NFPA 101, issued October 30, 2012.	*See Interpretive Guidelines for §482.41(e)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.41 -- Condition of participation: Physical environment.*

	(x) TIA 12 – 3 to NFPA 101, issued October 22, 2013. (xi) TIA 12 – 4 to NFPA 101, issued October 22, 2013. (2) [Reserved]	

Related Joint Commission Standards

Environment of Care:

- EC.01.01.01, EP 1, 3, 8, 9
- EC.02.02.01, EP 9
- EC.02.03.05. EP 1 – 6, 9 – 20, 25, 27
- EC.02.04.01, EP 2 – 7, 9, 11
- EC.02.05.01, EP 3, 4, 6 – 8, 11, 15, 16, 20 – 27
- EC.02.05.02, EP 1 – 4
- EC.02.05.05, EP 2, 4 – 8
- EC.02.05.07, EP 1 – 3, 5 – 7, 9, 10
- EC.02.05.09, EP 1 – 7, 10, 11, 13
- EC.02.06.01, EP 11
- EC.02.06.05, EP 1
- EC.04.01.01, EP 1, 9 – 11, 15
- EC.04.01.03, EP 2
- EC.04.01.05, EP 1

Emergency Management:

- EM.12.01.01, EP 4
- EM.12.02.09, EP 1

Leadership:

- LD.04.01.11, EP 3, 5

Infection Prevention and Control:

- IC.02.02.01, EP 1

Related DNV Standards

Facility

- PE.1
- PE.1 (SR.2)
- PE.1 (SR.2a)
- PE.1 (SR.2b)
- PE.1 (SR.2c)
- PE.3 (SR.1)
- PE.3 (SR.2)

Utility Management System

- PE.8 (SR.2)
- PE.8 (SR.3)
- PE.8 (SR.4)
- PE.8 (SR.10)

Safety Management System

- PE.3 (SR.3)
- PE.8 (SR.7)
- PE.8 (SR.8)
- PE.8 (SR.8a)

Related ACHC Standards

Physical Environment:

- 11.07.01
- 11.07.03
- 13.07.01

Related CIHQ Standards

Care Environment:

- CE-1
- CE-8
- CE-9
- CE-10
- CE-11
- CE-21

Nutrition Services:

- NU-3

§482.41 (d) *CoP* Analysis/Guidelines

Same as §482.41 (b–c) *CoP* Analysis/Guidelines.

§482.42 *CoP*: Infection Prevention and Control and Antibiotic Stewardship Programs		
Tag #	CMS *CoP* (2023)	CMS Interpretive Guidelines and Survey Procedures
A-0747	The hospital must have active hospital-wide programs for the surveillance, prevention, and control of HAIs and other infectious diseases and for the optimization of antibiotic use through stewardship. The programs must demonstrate adherence to nationally recognized infection prevention and control guidelines, as well as to best practices for improving antibiotic use where applicable, and for reducing the development and transmission of HAIs and antibiotic-resistant organisms. Infection prevention and control problems and antibiotic use issues identified in the programs must be addressed in collaboration with the hospital-wide quality assessment and performance improvement (QAPI) program.	*See Interpretive Guidelines for §482.42* *See Survey Procedures for §482.42* *Guidance is pending and will be updated in a future release.* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.42 -- Condition of participation: Infection prevention and control and antibiotic stewardship programs.*
A-0748	**(a) Standard: Infection prevention and control program organization and policies.** The hospital must demonstrate that: (1) An individual (or individuals), who is qualified through education, training, experience, or certification in infection prevention and control, is appointed by the governing body as the infection preventionist(s)/infection control professional(s) responsible for the infection prevention and control program and that the appointment is based on the recommendations of medical staff leadership and nursing leadership.	*See Interpretive Guidelines for §482.42(a)(1)* *See Survey Procedures for §482.42(a)(1)* *Guidance is pending and will be updated in a future release.* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.42 -- Condition of participation: Infection prevention and control and antibiotic stewardship programs.*
A-0749	(2) The hospital infection prevention and control program, as documented in its policies and procedures, employs methods for preventing and controlling the transmission of infections within the hospital and between the hospital and other institutions and settings.	*See Interpretive Guidelines for §482.42(a)(2)* *See Survey Procedures for §482.42(a)(2)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.42 -- Condition of participation: Infection prevention and control and antibiotic stewardship programs.*

A-0750	(3) The infection prevention and control program include surveillance, prevention, and control of HAIs, including maintaining a clean and sanitary environment to avoid sources and transmission of infection, and addresses any infection control issues identified by public health authorities; and	*See Interpretive Guidelines for §482.42(a)(3)* *See Survey Procedures for §482.42(a)(3)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.42 -- Condition of participation: Infection prevention and control and antibiotic stewardship programs.*
A-0751	(4) The infection prevention and control program reflect the scope and complexity of the hospital services provided.	*See Interpretive Guidelines for §482.42(a)(4)* *See Survey Procedures for §482.42(a)(4)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.42 -- Condition of participation: Infection prevention and control and antibiotic stewardship programs.*
A-0770	**(c) Standard: Leadership Responsibilities** (1) The governing body must ensure all of the following: (i) Systems are in place and operational for the tracking of all infection surveillance, prevention, and control, and antibiotic use activities, in order to demonstrate the implementation, success, and sustainability of such activities.	*See Interpretive Guidelines for §482.42(c)(1)(i)* *See Survey Procedures for §485.640(c)(1)(i)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.42 -- Condition of participation: Infection prevention and control and antibiotic stewardship programs.*
A-0771	(ii) All HAIs and other infectious diseases identified by the infection prevention and control program as well as antibiotic use issues identified by the antibiotic stewardship program are addressed in collaboration with hospital QAPI leadership.	*See Interpretive Guidelines for §482.42(c)(1)(ii)* *See Survey Procedures for §482.42(c)(1)(ii)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.42 -- Condition of participation: Infection prevention and control and antibiotic stewardship programs.*

A-0772	(2) The infection preventionist(s)/infection control professional(s) is responsible for: (i) The development and implementation of hospital-wide infection surveillance, prevention, and control policies and procedures that adhere to nationally recognized guidelines.	*See Interpretive Guidelines for §482.42(c)(2)(i)* *See Survey Procedures for §482.42(c)(2)(i)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.42 -- Condition of participation: Infection prevention and control and antibiotic stewardship programs.*
A-0773	(ii) All documentation, written or electronic, of the infection prevention and control program and its surveillance, prevention, and control activities.	*See Interpretive Guidelines for §482.42(c)(2)(ii)* *See Survey Procedures for §482.42c)(2)(ii)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.42 -- Condition of participation: Infection prevention and control and antibiotic stewardship programs.*
A-0774	(iii) Communication and collaboration with the hospital's QAPI program on infection prevention and control issues.	*See Interpretive Guidelines for §482.42(c)(2)(iii)* *See Survey Procedures for §485.640(c)(2)(iii)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.42 -- Condition of participation: Infection prevention and control and antibiotic stewardship programs.*
A-0775	(iv) Competency-based training and education of hospital personnel and staff, including medical staff, and, as applicable, personnel providing contracted services in the hospital, on the practical applications of infection prevention and control guidelines, policies, and procedures.	*See Interpretive Guidelines for §482.42(c)(2)(iv)* *See Survey Procedures for §482.42(c)(2)(iv)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.42 -- Condition of participation: Infection prevention and control and antibiotic stewardship programs.*

A-0776	(v) The prevention and control of HAIs, including auditing of adherence to infection prevention and control policies and procedures by hospital personnel.	*See Interpretive Guidelines for §482.42(c)(2)(v)* *See Survey Procedures for §482.42(c)(2)(v)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.42 -- Condition of participation: Infection prevention and control and antibiotic stewardship programs.*
A-0777	(vi) Communication and collaboration with the antibiotic stewardship program.	*See Interpretive Guidelines for §482.42(c)(2)(vi)* *See Survey Procedures for §482.42(c)(2)(vi)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.42 -- Condition of participation: Infection prevention and control and antibiotic stewardship programs.*
A-0778	(3) The leader(s) of the antibiotic stewardship program is responsible for: (i) The development and implementation of a hospital-wide antibiotic stewardship program, based on nationally recognized guidelines, to monitor and improve the use of antibiotics.	*See Interpretive Guidelines for §482.42(c)(3)(i)* *See Survey Procedures for §482.42(c)(3)(i)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.42 -- Condition of participation: Infection prevention and control and antibiotic stewardship programs.*
A-0779	(ii) All documentation, written or electronic, of antibiotic stewardship program activities.	*See Interpretive Guidelines for §482.42(c)(3)(ii)* *See Survey Procedures for §482.42(c)(3)(ii)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.42 -- Condition of participation: Infection prevention and control and antibiotic stewardship programs.*
A-0780	(iii) Communication and collaboration with medical staff, nursing, and pharmacy leadership, as well as with the hospital's infection prevention and control and QAPI programs, on antibiotic use issues.	*See Interpretive Guidelines for §482.42(c)(3)(iii)* *See Survey Procedures for §485.640(c)(3)(iii)* *SOM Appendix A (cms.gov)*

		eCFR :: 42 CFR 482.42 -- Condition of participation: Infection prevention and control and antibiotic stewardship programs.
A-0781	(iv) Competency-based training and education of hospital personnel and staff, including medical staff, and, as applicable, personnel providing contracted services in the hospital, on the practical applications of antibiotic stewardship guidelines, policies, and procedures.	*See Interpretive Guidelines for §482.42(c)(3)(iv)* *See Survey Procedures for §482.42(c)(3)(iv)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.42 -- Condition of participation: Infection prevention and control and antibiotic stewardship programs.*
A-0785	**(d) Standard: Unified and integrated infection prevention and control and antibiotic stewardship programs for multi-hospital systems.** If a hospital is part of a hospital system consisting of multiple separately certified hospitals using a system governing body that is legally responsible for the conduct of two or more hospitals, the system governing body can elect to have unified and integrated infection prevention and control and antibiotic stewardship programs for all of its member hospitals after determining that such a decision is in accordance with all applicable State and local laws. The system governing body is responsible and accountable for ensuring that each of its separately certified hospitals meets all of the requirements of this section. Each separately certified hospital subject to the system governing body must demonstrate that:	*See Interpretive Guidelines for §482.42(d)* *See Survey Procedures for §482.42(d)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.42 -- Condition of participation: Infection prevention and control and antibiotic stewardship programs.*
A-0786	(1) The unified and integrated infection prevention and control and antibiotic stewardship programs are 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.	*See Interpretive Guidelines for §482.42(d)(1)* *See Survey Procedures for §482.42(d)(1)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.42 -- Condition of participation: Infection prevention and control and antibiotic stewardship programs.*

A-0787	(2) The unified and integrated infection prevention and control and antibiotic stewardship programs establish and implement policies and procedures to ensure that the needs and concerns of each of its separately certified hospitals, regardless of practice or location, are given due consideration.	*See Interpretive Guidelines for §482.42(d)(2)* *See Survey Procedures for §482.42(d)(2)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.42 -- Condition of participation: Infection prevention and control and antibiotic stewardship programs.*
A-0788	(3) The unified and integrated infection prevention and control and antibiotic stewardship programs have mechanisms in place to ensure that issues localized to particular hospitals are duly considered and addressed.	*See Interpretive Guidelines for §482.42(d)(3)* *See Survey Procedures for §482.42(d)(3)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.42 -- Condition of participation: Infection prevention and control and antibiotic stewardship programs.*
A-0789	(4) A qualified individual (or individuals) with expertise in infection prevention and control has been designated at the hospital as responsible for communicating with the unified infection prevention and control and antibiotic stewardship programs, for implementing and maintaining the policies and procedures governing infection prevention and control and antibiotic stewardship as directed by the unified infection prevention and control and antibiotic stewardship programs, and for providing education and training on the practical applications of infection prevention and control and antibiotic stewardship to hospital staff.	*See Interpretive Guidelines for §482.42(d)(4)* *See Survey Procedures for §482.42(d)(4)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.42 -- Condition of participation: Infection prevention and control and antibiotic stewardship programs.*

Related Joint Commission Standards

Environment of Care:

- EC.02.05.01, EP 15
- EC.02.05.02, EP 1 – 4
- EC.02.05.05, EP 5
- EC.02.06.01, EP 20
- EC.02.06.05, EP 2 – 3

Human Resources:

- HR.01.05.03, EP 1
- HR.01.06.01, EP 1, 5, 6

Infection Control:

- IC.01.01.01, EP 4
- IC.01.02.01, EP 1, 2, 3
- IC.01.03.01, EP 1 – 3, 27
- IC.01.04.01, EP 1
- IC.01.05.01, EP 1, 2, 5, 6
- IC.02.01.01, EP 1 – 3, 5 – 9
- IC.02.02.01, EP 1, 2, 4
- IC.03.01.01, EP 1, 6

Leadership:

- LD.03.06.01, EP 3

Medication Management:

- MM.09.01.01, EP. 10-12, 14 -15, 18, 20 - 21

Related DNV Standards

Infection Prevention and Control Program

- IC.1 Introduction
- IC.1 (SR.1)
- IC.1 (SR.1a)
- IC.1 (SR.2)
- IC.1 (SR.2a)

- IC.1 (SR.2a(1))
- IC.1 (SR.2b)
- IC.1 (SR.2b)
- IC.1 (SR.2c)
- IC.1 (SR.2d)

Leadership Responsibilities

- IC.3 Introduction
- IC.3 (SR.1)
- IC.3 (SR.1b)
- IC.3 (SR.1b)
- IC.3 (SR.2)
- IC.3 (SR.2a)
- IC.3 (SR.2b)
- IC.3 (SR.2c)
- IC.3 (SR.2d)
- IC.3 (SR.2e)
- IC.3 (SR.2f)
- IC.3 (SR.3)
- IC.3 (SR.3a)
- IC.3 (SR.3a(1))
- IC.3 (SR.3b)
- IC.3 (SR.3c)
- IC.3 (SR.3d)

Unified and Integrated Infection Prevention and Control and Antibiotic Stewardship Programs For Multi-Hospital Systems:

- IC.4 Introduction
- IC.4 (SR.1)
- IC.4 (SR.2)
- IC.4 (SR.2)
- IC.4 (SR.2a)

- IC.4 (SR.2b)
- IC.4 (SR.2c)
- IC.4 (SR.2d)
- IC.4 (SR.2d(1))
- IC.4 (SR.2d(2))
- IC.4 (SR.2d(3))

Related ACHC Standards

Infection Prevention and Control/Antibiotic Stewardship:

- 07.00.00
- 07.00.01
- 07.00.02
- 07.00.03
- 07.00.06
- 07.00.07
- 07.00.08
- 07.01.01
- 07.02.01
- 07.02.02

Related CIHQ Standards

Infection Prevention and Control Plan:

- IC-1 – IC-12

§482.42 (a–d) *CoP* Analysis/Guidelines

An infection control program must be in place that addresses the scope of all hospital units, campuses, and off-site locations and should cover both patients and staff. The program should exist to prevent, control, and investigate infections and communicable diseases. The program should address issues like defining, identifying, investigating, and reporting nosocomial infections and communicable diseases; controlling postoperative infections; prevention of infections (e.g., those caused by antibiotic-resistant organisms, communicable disease outbreaks like tuberculosis, severe acute respiratory syndrome, hepatitis A, methicillin-resistant *Staphylococcus aureus*); isolation procedures and use of standard precautions, etc. CMS specifies that a sanitary environment is required to avoid sources and transmission of infections and communicable diseases and that the hospital's program should be conducted in accordance with national organizations, including the Centers for Disease Control and Prevention, Association for

Professionals in Infection Control and Epidemiology, Society for Healthcare Epidemiology of America, and the Association of periOperative Registered Nurses.

The Joint Commission and DNV require an annual review of the infection control plan. DNV also specifies that infection control data are disseminated to the organization no less than quarterly.

Note: There is much more emphasis on infection prevention and control by survey teams than in times past. This is partly related to enhanced competency of survey teams but also part of the movement to reduce hospital- acquired conditions.

In July 2018, CMS revised its prior memo QSO-17-30 outlining requirements for Medicare and Medicare/ Medicaid-certified healthcare facilities to have water management policies and procedures to reduce the risk of growth and spread of *Legionella* and other opportunistic pathogens in building water systems. Facilities must have water management plans and documentation that, at a minimum, ensure each facility:

- Conducts a facility risk assessment to identify where *Legionella* and other opportunistic waterborne pathogens (e.g., *Pseudomonas*, *Acinetobacter*, *Burkholderia*, *Stenotrophomonas*, nontuberculous mycobacteria, and fungi) could grow and spread in the facility water system.
- Develops and implements a water management program that considers the ASHRAE industry standard and the CDC toolkit.
- Specifies testing protocols and acceptable ranges for control measures, and document the results of testing and corrective actions taken when control limits are not maintained.
- Maintains compliance with other applicable federal, state, and local requirements.

Note: CMS does not require water cultures for *Legionella* or other opportunistic waterborne pathogens. Testing protocols are at the discretion of the provider.

Healthcare facilities are expected to comply with CMS requirements and *CoP* to protect the health and safety of their patients. Those facilities unable to demonstrate measures to minimize the risk of Legionnaires' disease are at risk of citation for noncompliance. This policy memorandum clarifies expectations for providers, accrediting organizations, and surveyors and does not impose any new expectations nor requirements for hospitals, CAHs, and surveyors of hospitals and CAHs. For these provider types, the memorandum is merely clarifying already existent expectations.

Survey Tips:

- Review the infection control plan to ensure that it addresses multidrug-resistant organisms (MDRO), ambulatory care, communicable disease outbreaks, and bioterrorism; ensure it also includes the entire scope applicable under the hospital's provider number
- Review the CMS Surveyor Worksheet for Infection Control in detail; conduct a gap analysis as appropriate
- Conduct observations of hand hygiene practices for all levels of care providers
- Ensure staff are appropriately precleaning surgical instruments sent to central sterile for processing
- Ensure staff are appropriately precleaning and high-level disinfecting semi-critical medical devices and that such devices remain free of contamination until used
- Ensure staff who perform high-level disinfection, precleaning for sterilization, immediate use sterilization, and sterilization have documented competencies
- Ensure the environments where medical instruments are cleaned or sterilized meet the appropriate air pressure requirements and that staff are aware of these requirements
- Ensure maintenance of sterilizers is performed per the manufacturers' instructions for use

- Ensure chemical and biological indicators are used and documented per clinical practice guidelines adopted by the hospital
- Conduct observations of compliance with isolation procedures
- Verify that the infection preventionists understand the scope of their oversight to include housekeeping, maintenance, food preparation and storage, autoclave rooms, ventilation systems, waste handling, etc.
- Verify that staff follow appropriate precautions and procedures for patients admitted who have prior history of MDRO and that the individuals are qualified
- Verify that an individual or group of individuals have been designated as the infection control officer(s)
- Review housekeeping P&Ps and those related to cleaning, storage, and disposal of medical equipment/devices
- Review clinical P&Ps related to blood cultures, IV insertion, MDRO, ventilator-associated pneumonia, surgical site infection, central line–associated bloodstream infection, hand hygiene, etc.
- Ensure there are facility P&Ps on ventilation and air handling and pest control
- Verify that a water management risk assessment has been conducted and based on the findings a water management plan is created and carried out
- Ensure key occupational health P&Ps are current (i.e., injury, exposures, and screening)
- Ensure there are food and nutrition P&Ps on refrigerator temperatures
- Review surgery, procedural area, and sterile processing P&Ps on cleaning, high-level disinfection and sterilization, and staff attire
- Review NICU/nursing P&Ps on breast milk storage

Suggested Documents:

- Job description of infection control professional (hospital epidemiologist, infection control nurse, infection control director, etc.)
- Hospital's infection control plan, the annual risk assessment, goals, and evidence of progress toward goals
- Infection control P&Ps
- Agenda and curriculum of infection prevention and control training provided upon orientation
- Competencies for all staff performing high-level disinfection or sterilization
- Listing of ongoing education and competencies related to infection prevention and control
- Personnel file of infection control professional reflecting qualifications, current certifications, and training
- Infection control medical direct job description/responsibility charting or other document showing authority and responsibilities (if applicable)
- Log of infection control or communicable disease incidents, including those identified through employee health services
- Logs of surveillance activity/plans
- Infection control committee meeting minutes
- Water management risk assessment, plan, and evidence of plan deployment

§482.43 *CoP*: Discharge Planning		
Tag #	CMS *CoP* (2023)	CMS Interpretive Guidelines and Survey Procedures
A-0799	Condition of participation: Discharge Planning The hospital must have an effective discharge planning process that focuses on the patient's goals and treatment preferences and includes the patient and his or her caregivers/support person(s) as active partners in the discharge planning for post-discharge care. The discharge planning process and the discharge plan must be consistent with the patient's goals for care and his or her treatment preferences, ensure an effective transition of the patient from hospital to post-discharge care, and reduce the factors leading to preventable hospital readmissions.	*See Interpretive Guidelines for §482.43* *See Survey Procedures for §482.43* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.43 -- Condition of participation: Discharge planning.*
A-0800	**(a) Standard: Discharge Planning Process** The hospital's discharge planning process must identify, at an early stage of hospitalization, those patients who are likely to suffer adverse health consequences upon discharge in the absence of adequate discharge planning and must provide a discharge planning evaluation for those patients so identified as well as for other patients upon the request of the patient, patient's representative, or patient's physician.	*See Interpretive Guidelines for §482.43(a)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.43 -- Condition of participation: Discharge planning.*
A-0805	1. Any discharge planning evaluation must be made on a timely basis to ensure that appropriate arrangements for post-hospital care will be made before discharge and to avoid unnecessary delays in discharge.	*See Interpretive Guidelines for §482.43(a)(1)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.43 -- Condition of participation: Discharge planning.*

A-0807	2. A discharge planning evaluation must include an evaluation of a patient's likely need for appropriate post-hospital services, including, but not limited to, hospice care services, post-hospital extended care services, home health services, and non-health care services and community-based care providers, and must also include a determination of the availability of the appropriate services as well as of the patient's access to those services.	*See Interpretive Guidelines for §482.43(a)(2)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.43 -- Condition of participation: Discharge planning.*
A-0808	3. The discharge planning evaluation must be included in the patient's medical record for use in establishing an appropriate discharge plan and the results of the evaluation must be discussed with the patient (or the patient's representative).	*See Interpretive Guidelines for §482.43(a)(3)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.43 -- Condition of participation: Discharge planning.*
A-0801	4. Upon the request of a patient's physician, the hospital must arrange for the development and initial implementation of a discharge plan for the patient.	*See Interpretive Guidelines for §482.43(a)(4)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.43 -- Condition of participation: Discharge planning.*
A-0809	5. Any discharge planning evaluation or discharge plan required under this paragraph must be developed by, or under the supervision of, a registered nurse, social worker, or other appropriately qualified personnel.	*See Interpretive Guidelines for §482.43(a)(5)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.43 -- Condition of participation: Discharge planning.*
A-0802	6. The hospital's discharge planning process must require regular re-evaluation of the patient's condition to identify changes that require modification of the discharge plan. The discharge plan must be updated, as needed, to reflect these changes.	*See Interpretive Guidelines for §482.43(a)(6)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.43 -- Condition of participation: Discharge planning.*
A-0803	7. The hospital must assess its discharge planning process on a regular basis. The assessment must include ongoing, periodic review of a representative sample of discharge plans, including those patients who were readmitted within 30 days of a previous admission, to ensure that the plans are responsive to patient post-discharge needs.	*See Interpretive Guidelines for §482.43(a)(7)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.43 -- Condition of participation: Discharge planning.*

A-0804	8. The hospital must assist patients, their families, or the patient's representative in selecting a post-acute care provider by using and sharing data that includes, but is not limited to, HHA, SNF, IRF, or LTCH data on quality measures and data on resource use measures. The hospital must ensure that the post-acute care data on quality measures and data on resource use measures is relevant and applicable to the patient's goals of care and treatment preferences.	*See Interpretive Guidelines for §482.43(a)(8)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.43 -- Condition of participation: Discharge planning.*

Related Joint Commission Standards

Provision of Care:

- PC.01.02.03, EP 3
- PC.01.03.01, EP 22, 23
- PC.02.02.01, EP 1 – 3
- PC.02.01.05, EP 1
- PC.04.02.01, EP 1
- PC.04.04.01, EP 22, 25, 31 – 33
- PC.04.01.03, EP 1 – 4, 7, 10

Record of Care:

- RC.02.01.01, EP 2

Human Resources:

- HR.01.01.01, EP 1

Information Management:

- IM.02.01.01, EP 4

Related DNV Standards

Discharge Planning Evaluation

- DC.2 (SR.1)
- DC.2 (SR.2)

- DC.2 (SR.2a)
- DC.2 (SR.2b)
- DC.2 (SR.2b(1))
- DC.2 (SR.2b(2))
- DC.2 (SR.2b(3))
- DC.2 (SR.2b(3)(i))
- DC.2 (SR.2b(3)(ii))
- DC.2 (SR.2b(3)(iii))
- DC.2 (SR.2b(3)(iv))
- DC.2 (SR.2b(3)(v))
- DC.2 (SR.2b(3)(vi))
- DC.2 (SR.2b(3)(vii))
- DC.2 (SR.2c)
- DC.2 (SR.3)
- DC.2 (SR.3a)

Written Policies

- DC.1 (SR.1)
- DC.1 (SR.1a)
- DC.1 (SR.1a(1))
- DC.1 (SR.1a(2))
- DC.1 (SR.1a(3))
- DC.1 (SR.2)
- DC.1 (SR.2a)
- DC.1 (SR.3)

Plan Implementation

- DC.3 (SR.1)
- DC.3 (SR.2)
- DC.3 (SR.2b)
- DC.3 (SR.3)
- DC.3 (SR.3a)

- DC.3 (SR.3a(1))
- DC.3 (SR.3a(2))

Post Acute Care Services

- DC.5 Introduction
- DC.5 (SR.1)
- DC.5 (SR.2)
- DC.5 (SR.3)
- DC.5 (SR.4)
- DC.5 (SR.5)
- DC.5 (SR.6)
- DC.5 (SR.7)

Evaluation

- DC.4 (SR.1)

Related ACHC Standards

Discharge Planning:

- 21.00.00
- 21.00.01
- 21.00.02
- 21.00.03
- 21.00.04
- 21.00.05
- 21.00.07
- 21.00.09
- 21.00.10
- 21.00.11
- 21.00.12

Related CIHQ Standards

Discharge Planning Services:

- DC-1 – DC-4
- DC-6

§482.43 (a) *CoP* Analysis/Guidelines

CMS expects discharge planning procedures are in place and communicated. Factors important to the process and important to identify those who are high risk include the functional status of the patients, their cognitive ability, and support systems. CMS states that discharge planning applies to all inpatients and outpatients who may have complicated recoveries. There is not a set time frame for the identification of patients requiring a discharge plan other than it must be done as early as possible. In addition, there are no national criteria or standards for identifying patients who are likely to have adverse outcomes after discharge without adequate discharge planning.

Survey Tips:

- Review the CMS Surveyor Worksheet for Discharge Planning in detail. Conduct a gap analysis as appropriate.
- Interview staff about how and when discharge planning (DCP) begins.
- Review patient care plans for discharge information.
- Review DCP and UR P&Ps; ensure they are current, and that the UR committee chair has signed off on them.

Suggested Documents:

- DCP P&Ps, including those related to initial assessment and reassessment by discharge planning, case management, social services, or other related staff
- Clinical P&Ps related to multidisciplinary rounds and care planning
- Tool for documenting UR/DCP, multidisciplinary rounds, and discharge planning
- Patient care plans

§482.43 *CoP*: Discharge Planning		
Tag #	CMS *CoP* (2023)	CMS Interpretive Guidelines and Survey Procedures
A-0806	B. ***Standard: Discharge of the patient and provision and transmission of the patient's necessary medical information.*** The hospital must discharge the patient, and also transfer or refer the patient where applicable, along with all necessary medical information pertaining to the patient's current course of illness and treatment, post-discharge goals of care, and treatment preferences, at the time of discharge, to the appropriate post-acute care service providers and suppliers, facilities, agencies, and other outpatient service providers and practitioners responsible for the patient's follow-up or ancillary care.	*See Interpretive Guidelines for §482.43(b)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.43 -- Condition of participation: Discharge planning.*

Related Joint Commission Standards

Human Resources:

- HR.01.01.01, EP 1

Provision of Care:

- PC.02.01.05, EP 1
- PC.02.02.01, EP 3
- PC.04.01.01, EP 1, 22, 25, 31
- PC.04.01.03, EP 1 – 5
- PC.04.01.05, EP 1, 2, 7

Record of Care, Treatment, and Services:

- RC.02.01.01, EP 2

Related DNV Standards

Plan Implementation

- DC.3 (SR.3)
- DC.3 (SR.3a)
- DC.3 (SR.3a(1))
- DC.3 (SR.3a(2))

Related ACHC Standards

Discharge Planning:

- 21.00.11

Related CIHQ Standards

Discharge Planning Services:

- DC-5

§482.43 (b) *CoP* Analysis/Guidelines

In most hospitals, discharge planning is coordinated by a central person; however, the responsibility is not limited to a single discipline. Nurses, physicians, social workers, other care providers, home health agencies, and the patient's primary care provider should all be involved as necessary based on the patient's needs. A discharge planning evaluation should outline what a patient's care needs will be once they leave the hospital setting. Both CMS and all accreditors expect hospitals to document the patient's discharge planning evaluation and steps for implementation and that results are shared with the patient or their representative. The patient has a right to refuse discharge planning services, and if done, this refusal should be documented. CMS and all accreditors require that patient choice for home health and skilled nursing is honored and that ownership of those agencies is disclosed. The hospital should maintain a list of home health agencies (HHA) and skilled nursing facilities, which include those qualified to receive patients from their managed care organizations, where applicable. The hospital can take no part in leading, directing, or otherwise limiting the selection of the home health agency or skilled nursing facility. It is important to also know state regulations, as these aspects of choice may apply to other posthospital services.

Note: CMS made numerous changes to the interpretive guidelines as outlined in the May 2019 S&C, which hospitals should review. The S&C includes advisory practices to promote better patient outcomes. The information found in these advisory boxes is not required for hospital compliance but serves only as resource information or references for process improvement.

Survey Tips:

- Review discharge planning documents for accuracy, thoroughness, and timeliness
- Ensure lists of HHAs and skilled nursing facilities (SNF) are maintained and that there is disclosure when financial interest applies
- Evaluate discharge planning documentation to ensure that it reflects that complete lists of referring agencies are provided, how patient choice was determined, and that patient choice was respected
- Interview staff to determine whether multidisciplinary team is involved in discharge planning

Suggested Documents:

- Discharge planning P&Ps
- Policy on choice for HHA, SNF, and/or durable medical equipment (DME)
- Patient medical records
- Lists of HHA, SNF, and DME companies provided to patients
- Length-of-stay data
- Medicare observation letter and Important Message from Medicare
- Patient rights and responsibilities (P&Ps) and other related patient educational materials

§482.43 *CoP*: Discharge Planning		
Tag #	CMS *CoP* (2023)	CMS Interpretive Guidelines and Survey Procedures
A-0814 A-0818	**C. Standard: Requirements related to post-acute care services.** For those patients discharged home and referred for HHA services, or for those patients transferred to a SNF for post-hospital extended care services, or transferred to an IRF or LTCH for specialized hospital services, the following requirements apply, in addition to those set out at paragraphs (a) and (b) of this section:	*See Interpretive Guidelines for §482.43(c)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.43 -- Condition of participation: Discharge planning.*
A-0815	i. The hospital must include in the discharge plan a list of HHAs, SNFs, IRFs, or LTCHs that are available to the patient, that are participating in the Medicare program, and that serve the geographic area (as defined by the HHA) in which the patient resides, or in the case of a SNF, IRF, or LTCH, in the geographic area requested by the patient. HHAs must request to be listed by the hospital as available ii. This list must only be presented to patients for whom home health care post-hospital extended care services, SNF, IRF, or LTCH services are indicated and appropriate as determined by the discharge planning evaluation. iii. The hospital must document in the patient's medical record that the list was presented to the patient or to the patient's representative.	*See Interpretive Guidelines for §482.43(c)(1)(i)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.43 -- Condition of participation: Discharge planning.* *See Interpretive Guidelines for §482.43(c)(1)(ii)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.43 -- Condition of participation: Discharge planning.* *See Interpretive Guidelines for §482.43(c)(1)(iii)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.43 -- Condition of participation: Discharge planning.*
A-0816 A-0819	2. The hospital, as part of the discharge planning process, must inform the patient or the patient's representative of their freedom to choose among participating Medicare providers and suppliers of post-discharge services and must, when possible, respect the patient's or the patient's representative's goals of care and treatment preferences, as well as other preferences they express. The hospital must not specify or otherwise limit the qualified providers or suppliers that are available to the patient.	*See Interpretive Guidelines for §482.43(c)(2)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.43 -- Condition of participation: Discharge planning.*

A-0817 A-0820	3. The discharge plan must identify any HHA or SNF to which the patient is referred in which the hospital has a disclosable financial interest, as specified by the Secretary, and any HHA or SNF that has a disclosable financial interest in a hospital under Medicare. Financial interests that are disclosable under Medicare are determined in accordance with the provisions of part 420, subpart C, of this chapter.	*See Interpretive Guidelines for §*482.43(c)(3) *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.43 -- Condition of participation: Discharge planning.*

Related Joint Commission Standards

Provision of Care, Treatment, and Services:

- PC.01.02.03, EP 3
- PC.04.01.01, EP 22 – 25, 32, 33
- PC.04.01.03, EP 1 – 4
- PC.04.01.05, EP 1, 2, 7

Related DNV Standards

Post Acute Care Services

- DC.5 Introduction
- DC.5 (SR.1)
- DC.5 (SR.2)
- DC.5 (SR.3)
- DC.5 (SR.4)
- DC.5 (SR.5)
- DC.5 (SR.7)

Related ACHC Standards

Discharge Planning:

- 21.00.12

Related CIHQ Standards

Discharge Planning Services:

- DC-4

§482.43 (c) *CoP* Analysis/Guidelines

Once a discharge planning evaluation is done, it should be updated to address a patient's needs based on reassessments done. Educating the patient, the patient's family, and/or caregivers is an important component of implementing the discharge plan. Information and instructions for posthospital care should be shared, including timing and dosage of medications and potential side effects, treatments, and therapy schedules and routine.

Note: The CMS Interpretive Guidelines include advisory practices to promote better patient outcomes. The information found in these advisory boxes is not required for hospital compliance but is only resource information or references for process improvement.

Survey Tips:

- Review hospital P&Ps on discharge planning and reassessment
- Ask families/patients whether discharge planning has been discussed with them by staff
- Audit documentation to ensure compliance with choice has been discussed with patients
- Evaluate discharge planning documentation to ensure that documentation reflects how patient choice was determined and that patient choice was respected
- Evaluate whether there are procedures to evaluate efficacy of discharge planning reassessment, including the effectiveness of criteria and screening procedures used to identify patients requiring discharge plans, the timeliness and accuracy/completeness of evaluations and patient/family involvement, and notification of the plan

Suggested Documents:

- Organizational chart of the department, listing credentials of staff
- Job descriptions of related staff
- Discharge planning P&Ps, including policy on choice for extended care facility, HHA, or SNF and policies on patient/family education
- Disclosure letters regarding designation of choice
- Community-based services guidebooks
- Department PI plan (if aspects of discharge plan are included)
- UR committee minutes where PI and actions are discussed
- Patient medical records

§482.45 *CoP*: Organ, Tissue, and Eye Procurement		
Tag #	CMS *CoP* (2023)	CMS Interpretive Guidelines and Survey Procedures
A-0884	**(a) Standard: Organ procurement responsibilities**	*See Interpretive Guidelines for §482.45* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.45 -- Condition of participation: Organ, tissue, and eye procurement.*
A-0885	The hospital must have and implement written protocols that:	*See Interpretive Guidelines for §482.45(a)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.45 -- Condition of participation: Organ, tissue, and eye procurement.*
A-0886	(1) Incorporate an agreement with an organ procurement organization (OPO) designated under Part 486 of this chapter, under which it 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. The OPO determines medical suitability for organ donation and, in the absence of alternative arrangements by the hospital, the OPO determines medical suitability for tissue and eye donation, using the definition of potential tissues and eye donor and the notification protocol developed in consultation with the tissue and eye banks identified by the hospital for this purpose.	*See Interpretive Guidelines for §482.45(a)(1)* *See Survey Procedures for §482.45(a)(1)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.45 -- Condition of participation: Organ, tissue, and eye procurement.*
A-0887	(2) 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 ensure that all usable tissues and eyes are obtained from potential donors, insofar as such an agreement does not interfere with organ procurement.	*See Interpretive Guidelines for §482.45(a)(2)* *See Survey Procedures for §482.45(a)(2)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.45 -- Condition of participation: Organ, tissue, and eye procurement.*

A-0888	(3) 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.	*See Interpretive Guidelines for §482.45(a)(3)* *See Survey Procedures for §482.45(a)(3)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.45 -- Condition of participation: Organ, tissue, and eye procurement.*
A-0889	(3, *continued*) The individual designated by the hospital 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.	*See Interpretive Guidelines for §482.45(a)(3)* *See Survey Procedures for §482.45(a)(3)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.45 -- Condition of participation: Organ, tissue, and eye procurement.*
A-0890	(4) Encourage discretion and sensitivity with respect to the circumstances, views, and beliefs of the families of potential donors.	*See Interpretive Guidelines for §482.45(a)(4)* *See Survey Procedures for §482.45(a)(4)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.45 -- Condition of participation: Organ, tissue, and eye procurement.*
A-0891	(5) Ensure that the hospital works cooperatively with the designated OPO, tissue bank, and eye bank in educating staff on donation issues.	*See Interpretive Guidelines for §482.45(a)(5)* *See Survey Procedures for §482.45(a)(5)* SOM Appendix A (cms.gov) eCFR :: 42 CFR 482.45 -- Condition of participation: Organ, tissue, and eye procurement.
A-0892	(5, *continued*) Reviewing death records to improve identification of potential donors.	*See Interpretive Guidelines for §482.45(a)(5)* *See Survey Procedures for §482.45(a)(5)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.45 -- Condition of participation: Organ, tissue, and eye procurement.*

A-0893	(5, *continued*) Maintaining potential donors while necessary testing and placement of potential donated organs, tissues, and eyes takes place.	*See Interpretive Guidelines for §482.45(a)(5)* *See Survey Procedures for §482.45(a)(5)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.45 -- Condition of participation: Organ, tissue, and eye procurement.*

Related Joint Commission Standards

Transplant Safety:

- TS.01.01.01, EP 1, 3 – 7, 9, 11

Related DNV Standards

Organ Procurement Organization (OPO Written Agreement)

- TO.2 Introduction
- TO.2 (SR.1)
- TO.2 (SR.2)
- TO.2 (SR.3)
- TO.2 (SR.4)
- TO.2 (SR.6)

Respect for Patient Rights

- TO.4 (SR.1)

Related ACHC Standards

Organ Procurement:

- 14.00.00
- 14.00.01
- 14.00.03
- 14.00.04
- 14.00.05
- 14.00.06
- 14.00.07

Related CIHQ Standards

Organ, Tissue, and Eye Procurement:

- OP-1

§482.45 (a) *CoP* Analysis/Guidelines

CMS and all accreditors are in alignment relative to organ, tissue, and eye procurement and organ, tissue, and eye transplantation. It is important to note that no specific type of hospital is exempt from participation, including psychiatric, rehabilitation, LTACH, or others. The responsibility of the hospital is particularly important to recognize since sensitivity, discretion, and respect are paramount when interacting with a grieving family. Staff training on P&Ps and how to approach a family are also important. Organizations performing organ transplantation must be a member of the Organ Procurement and Transplantation Network (OPTN) and must comply with CMS organ transplant *CoP*s (which are under a distinctly separate manual) and under separate survey procedures. DNV standards align with CMS with a couple of exceptions: In addition to governing body approval or procurement protocols, the medical staff must also approve these protocols and also include criteria for referral to the OPO. The Joint Commission standards align with CMS and also identify standards that are not addressed by CMS, including the tracking, storage, issuance, and preparation of tissues that apply to human and nonhuman cellular- based transplantable and implantable products.

Survey Tips:

- Verify that in written agreements with OPO, tissue and eye banks exist and are current
- Verify that the organ donation program is incorporated in hospital quality improvement activities
- Ensure appropriate personnel have completed required designated requestor training
- Verify P&Ps address collection, preservation, transportation, receipt, and reporting of tissue results
- Review tissue policies and reports to ensure compliance
- Confirm that tissues are stored at a controlled temperature and that the refrigerators, freezers, and other storage equipment have functional alarms and emergency backup plans
- Review P&Ps on tissues and organ donation
- Review records of storage temperatures, outdated procedures, manuals, and publications, ensuring they are maintained for a minimum of 10 years
- Verify that records of donor and lot identification, names of recipients or final disposition of tissues, expiration dates of tissues, and supplier names are retained for 10 years beyond date of distribution, transplantation, or expiration of tissue, whichever is later

Suggested Documents:

- Organ and tissue procurement and donation P&Ps
- Organ, tissue, and eye conversion rates and other applicable data
- Copy of written agreements/contracts with designated OPO, tissue bank(s), and eye bank(s)
- Designated requestor lists and curriculum
- Training records of designated requestors; records should demonstrate that training is annual, when P&P changes, and/or if there is need for patient information due to data
- Organ, tissue, and procurement curriculum for all staff
- Personnel files supporting education and competencies of designated requestors
- Death records demonstrating compliance with reporting expectations
- Organ donation data submitted to OPTN and the scientific registry
- Hospital complaint file for organ donation complaints

§482.45 *CoP*: Organ, Tissue, and Eye Procurement		
Tag #	CMS *CoP* (2023)	CMS Interpretive Guidelines and Survey Procedures
A-0899	**(b) Standard: Organ transplantation responsibilities.** (1) A hospital in which organ transplants are performed 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 in accordance with section 372 of the PHS Act which are enforceable under 42 *CFR* 121.10. No hospital is considered to be out of compliance with section 1138(a)(1)(B) of the Act, or with the requirements of this paragraph, unless the secretary has given the OPTN formal notice that he or she approves the decision to exclude the hospital from the OPTN and has notified the hospital in writing. (2) For purposes of these standards, the term "organ" means a human kidney, liver, heart, lung, or pancreas. (3) If a hospital performs any type of transplants, it must provide organ transplant-related data, as requested by the OPTN, the Scientific Registry, and the OPOs. The hospital must also provide such data directly to the department when requested by the secretary.	*See Interpretive Guidelines for §482.45(b)(1)–(3)* *See Survey Procedures for §482.45(b)(1)–(3)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.45 -- Condition of participation: Organ, tissue, and eye procurement.*

Related Joint Commission Standards

Transplant Safety:

- TS.02.01.01, EP 1, 2

Related DNV Standards

Organ Transplantation

- TO.6 (SR.1)
- TO.6 (SR.2)
- TO.6 (SR.3)

Related ACHC Standards

Organ Procurement:

- 14.00.08
- 14.00.09

Related CIHQ Standards

Organ, Tissue, and Eye Procurement:

- OP-2

§482.45 (b) *CoP* Analysis/Guidelines

Same as §482.45(a) *CoP* Analysis/Guidelines.

§482.51 *CoP*: Surgical Services		
Tag #	CMS *CoP* (2023)	CMS Interpretive Guidelines and Survey Procedures
A-0940	If the hospital provides surgical services, the services must be well organized and provided in accordance with acceptable standards of practice. If outpatient surgical services are offered, the services must be consistent in quality with inpatient care in accordance with the complexity of services offered.	*See Interpretive Guidelines for §482.51* *See Survey Procedures for §482.51* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.51 -- Condition of participation: Surgical services.*
A-0941	**(a) Standard: Organization and staffing—** The organization of the surgical services must be appropriate to the scope of the services offered.	*See Interpretive Guidelines for §482.51(a)* *See Survey Procedures for §482.51(a)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.51 -- Condition of participation: Surgical services.*
A-0942	(1) The operating rooms must be supervised by an experienced registered nurse or a doctor of medicine or osteopathy.	*See Interpretive Guidelines for §482.51(a)(1)* *See Survey Procedures for §482.51(a)(1)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.51 -- Condition of participation: Surgical services.*
A-0943	(2) Licensed practical nurses (LPNs) and surgical technologists (operating room technicians) may serve as "scrub nurses" under the supervision of a registered nurse.	*See Interpretive Guidelines for §482.51(a)(2)* *See Survey Procedures for §482.51(a)(2)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.51 -- Condition of participation: Surgical services.*
A-0944	(3) Qualified registered nurses may perform circulating duties in the operating room. In accordance with applicable State laws and approved medical staff P&Ps, LPNs and surgical technologists may assist in circulatory duties under the supervision of a qualified registered nurse who is immediately available to respond to emergencies.	*See Interpretive Guidelines for §482.51(a)(3)* *See Survey Procedures for §482.51(a)(3)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.51 -- Condition of participation: Surgical services.*

A-0945	(4) 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 privilege of each practitioner.	*See Interpretive Guidelines for §482.51(a)(4)* *See Survey Procedures for §482.51(a)(4)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.51 -- Condition of participation: Surgical services.*

Related Joint Commission Standards

Human Resources:

- HR.01.01.01, EP 1, 3
- HR.01.02.07, EP 2
- HR.01.05.03, EP 1
- HR.01.06.01, EP 1, 5, 6

Infection Control:

- IC.02.01.01, EP 1 – 3, 6
- IC.02.02.01, EP 1 – 2, 4

Leadership:

- LD.01.03.01, EP 3
- LD.03.01.01, EP 5
- LD.03.06.01, EP 2, 3
- LD.03.10.01, EP 3
- LD.04.01.05, EP 2
- LD.04.01.07, EP 1
- LD.04.03.01, EP 3
- LD.04.03.07, EP 1

Medical Staff:

- MS.03.01.01, EP 2
- MS.06.01.03, EP 4
- MS.06.01.05, EP 15
- MS.06.01.07, EP 1, 2, 5
- MS.06.01.09, EP 3

Provision of Care, Treatment, and Services:

- PC.03.01.01, EP 5

Related DNV Standards

Organization

- SS.1 (SR.1)
- SS.1 (SR.2)
- SS.1 (SR.3)

Staffing and Supervision

- SS.2 (SR.1)
- SS.2 (SR.2)
- SS.2 (SR.2a)
- SS.2 (SR.2b)
- SS.2 (SR.2c)
- SS.2 (SR.3)

Practitioner Privileges

- SS.3 (SR.1)
- SS.3 (SR.2)

Related ACHC Standards

Surgical Services:

- 30.00.00
- 30.00.01
- 30.00.02
- 30.00.03
- 30.00.04
- 30.00.05

Related CIHQ Standards

Operative and Invasive Services:

- OI-1
- OI-2

§482.51 (a) *CoP* Analysis/Guidelines

CMS has stated that surgical services are an optional hospital service and references recognized professional association standards, which should be followed. This may include AORN, AAMI, SGNA, or other professional standards. NIAHO/DNV does have standards specific to surgical services but does not include all of CMS' recognized professional association standards to be followed (missing American College of Surgeons [which founded The Joint Commission] and American Medical Association). The Joint Commission does not have standards specific to surgical services but does have numerous standards that relate to but are not inclusive of those required within this *CoP*. CMS' definition of surgery includes the structural alteration of the human body by incision or destruction of tissues; the diagnostic or therapeutic treatment of conditions or disease processes by any instrument causing localized alteration or transposition of live human tissue; and the injection of diagnostic or therapeutic substances into body cavities, internal organs, joints, sensory organs, and the central nervous system. Through this definition, there is potential that these *CoP*s apply to more than surgery suites; areas such as interventional radiology, gastrointestinal labs, cath labs, and other procedural areas might also be considered within its scope. CMS emphasizes that acceptable standards of practice promoted by or established by recognized professional organizations are to be maintained.

CMS also clarifies that outpatient surgical services must be consistent with the quality of inpatient services (also refer to the CMS Outpatient Services *CoP §482.54*). The services should be outlined along with staffing requirements and competencies.

Survey Tips:

- Verify that job descriptions are up to date for staff.
- Review surgery schedule and validate practitioners performing surgical procedures are privileged for the procedure being performed.
- Interview scheduling staff to determine what processes they use to validate privileges.
- Tour operative/procedural areas and inspect sterilization procedures, packaging and handling of sterilized materials, appropriate attire, including no visible hair, and proper room cleaning between cases.
- Evaluate how temperature and humidity controls are monitored and how proper air pressure relationships are assessed.
- Verify that the OR is supervised by an experienced RN or MD/DO.
- Interview staff to determine whether LPN or operating room technicians are being used. If used, clarify role of RNs in the supervision of those staff.
- Verify that there is a process to ensure that medical staff suspensions are handed off to surgical areas and that those practitioners have been restricted from performing surgical services when appropriate.

Suggested Documents:

- Scope of service for surgical services
- Organizational chart showing relationship to other procedural departments (as applicable) and lines of authority
- Personnel files, including documented competencies for all staff performing high-level disinfection or sterilization
- Policy on temperature and humidity monitoring and actions taken for variances
- Risk assessment on the safe storage and use of medical supplies and equipment if the low humidity range authorized is less than 30%
- Job descriptions for leaders in surgical services
- Medical staff credentials and privileges files
- OR and procedural schedules
- List of suspended medical staff
- Immediate use steam sterilization logs, including rationale
- Staffing matrices and current schedules
- Current roster listing each practitioner's surgical privileges as applicable to the surgical/procedural area
- P&Ps related to assignment of care, supervision, and delegation for all areas impacted by the scope of surgical services definition

§482.51 *CoP*: Surgical Services		
Tag #	CMS *CoP* (2023)	CMS Interpretive Guidelines and Survey Procedures
A-0951	**(b) Standard: Delivery of service—** Surgical services must be consistent with needs and resources. Policies governing surgical care must be designed to ensure the achievement and maintenance of high standards of medical practice and patient care.	*See Interpretive Guidelines for §482.51(b)* *See Survey Procedures for §482.51(b)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.51 -- Condition of participation: Surgical services.*
A-0952	(1) Prior to surgery or a procedure requiring anesthesia services and except in the case of emergencies: (i) A medical history and physical examination must be completed and documented no more than 30 days before or 24 hours after admission or registration, and except as provided under paragraph (b)(1)(iii) of this section.	*See Interpretive Guidelines for §482.51(b)(1)(i)* *See Survey Procedures for §482.51(b)(1)(i)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.51 -- Condition of participation: Surgical services.*
A-0953	(ii) 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 when the medical history and physical examination are completed within 30 days before admission or registration, and except as provided under paragraph (b)(1)(iii) of this section.	*See Interpretive Guidelines for §482.51(b)(1)(ii)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.51 -- Condition of participation: Surgical services.*
A-0954	(iii) An assessment of the patient must be completed and documented after registration (in lieu of the requirements of paragraphs (b)(1)(i) and (ii) of this section) when the patient is receiving specific outpatient surgical or procedural services and when the medical staff has chosen to develop and maintain a policy that identifies, in accordance with the requirements at § 482.22(c)(5)(v), specific patients as not requiring a comprehensive medical history and physical examination, or any update to it, prior to specific outpatient surgical or procedural services.	*See Interpretive Guidelines for §482.51(b)(1)(iii)* *See Survey Procedures for §482.51(b)(1)(iii)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.51 -- Condition of participation: Surgical services.*

A-0955	(2) A properly executed informed consent form for the operation must be in the patient's chart before surgery, except in emergencies.	*See Interpretive Guidelines for §482.51(b)(2)* *See Survey Procedures for §482.51(b)(2)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.51 -- Condition of participation: Surgical services.*
A-0956	(3) The following equipment must be available to the operating room suites: call-in system, cardiac monitor, resuscitator, defibrillator, aspirator, and tracheotomy set.	*See Survey Procedures for §482.51(b)(3)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.51 -- Condition of participation: Surgical services.*
A-0957	(4) There must be adequate provisions for immediate post-operative care.	*See Interpretive Guidelines for §482.51(b)(4)* *See Survey Procedures for §482.51(b)(4)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.51 -- Condition of participation: Surgical services.*
A-0958	(5) The operating room register must be complete and up to date.	*See Interpretive Guidelines for §482.51(b)(5)* *See Survey Procedures for §482.51(b)(5)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.51 -- Condition of participation: Surgical services.*
A-0959	(6) An operative report describing techniques, findings, and tissues removed or altered must be written or dictated immediately following surgery and signed by the surgeon.	*See Interpretive Guidelines for §482.51(b)(6)* *See Survey Procedures for §482.51(b)(6)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.51 -- Condition of participation: Surgical services.*

Related Joint Commission Standards

Environment of Care:

- EC.02.03.01, EP 11, 12

Infection Control:

- IC.02.01.01, EP 1 – 3, 4, 6

Leadership:

- LD.01.03.01, EP 3
- LD.04.01.05, EP 7, 9
- LD.04.01.07, EP 1
- LD.04.01.11, EP 5
- LD.04.03.01, EP 1

Provision of Care, Treatment, and Services:

- PC.01.02.03, EP 4, 5, 7
- PC.02.01.11, EP 5
- PC.03.01.07, EP 1 – 2

Record of Care, Treatment, and Services:

- RC.01.02.01, EP 4
- RC.01.03.01, EP 3
- RC.02.01.01, EP 4
- RC.02.01.03, EP 2, 3, 5 – 8, 11, 15

Rights and Responsibilities of the Individual:

- RI.01.03.01, EP 1, 2

Related DNV Standards

Organization

- SS.1 (SR.3)
- SS.1 (SR.4)
- SS.1 (SR.4a)
- SS.1 (SR.4b)
- SS.1 (SR.4c)
- SS.1 (SR.4d)
- SS.1 (SR.4e)
- SS.1 (SR.4f)

- SS.1 (SR.4g)
- SS.1 (SR.4g(1))
- SS.1 (SR.4g(2))
- SS.1 (SR.4g(3))
- SS.1 (SR.4h)
- SS.1 (SR.4i)
- SS.1 (SR.4h(i)(1))
- SS.1 (SR.4j)
- SS.1 (SR.4k)

History and Physical or Outpatient Assessment

- SS.4 (SR.1)
- SS.4 (SR.2)
- SS.4 (SR.2a)
- SS.4 (SR.2b)
- SS.4 (SR.2b(1))
- SS.4 (SR.2b(2))
- SS.4 (SR.2b(3))
- SS.4 (SR.2c)
- SS.4 (SR.4)
- SS.4 (SR.5)
- SS.4 (SR.5a)
- SS.4 (SR.5b)
- SS.4 (SR.5b(1))
- SS.4 (SR.5b(2))

Surgical Informed Consent

- SS.9 (SR.1)
- SS.9 (SR.1a)
- SS.9 (SR.1b)
- SS.9 (SR.1c)
- SS.9 (SR.1d)
- SS.9 (SR.1e)
- SS.9 (SR.1f)
- SS.9 (SR.1g)

Available Equipment

- SS.5 Introduction
- SS.5 (SR.1)
- SS.5 (SR.2)
- SS.5 (SR.1a)
- SS.5 (SR.1b)
- SS.5 (SR.1c)
- SS.5 (SR.1d)
- SS.5 (SR.1e)
- SS.5 (SR.1f)

Post Operative Care

- SS.6 (SR.1)
- SS.6 (SR.1a)
- SS.6 (SR.1b)
- SS.6 (SR.1c)
- SS.6 (SR.1d)
- SS.6 (SR.1e)
- SS.6 (SR.1f)
- SS.6 (SR.1g)
- SS.6 (SR.1h)
- SS.6 (SR.1i)
- SS.6 (SR.1j)

Operative Report

- SS.8 (SR.1)
- SS.8 (SR.1a)
- SS.8 (SR.1b)
- SS.8 (SR.1c)
- SS.8 (SR.1d)
- SS.8 (SR.1e)
- SS.8 (SR.1f)
- SS.8 (SR.1g)
- SS.8 (SR.1h)
- SS.8 (SR.1i)

- SS.8 (SR.1j)
- SS.8 (SR.1k)

Related ACHC Standards

Surgical Services:

- 30.00.09
- 30.00.10
- 30.00.11
- 30.00.12
- 30.00.17
- 30.00.18
- 30.00.19
- 30.02.06

Related CIHQ Standards

Operative and Invasive Services:

- OI-3
- OI-5 – OI-8

Infection Control:

- IC-7

Medical Record of Care:

- MR-5

§482.51 (b) *CoP* Analysis/Guidelines

These requirements are verifying that the services provided in the surgical/OR suites are delivered according to standards of care. Policies, H&Ps before surgical procedures, informed consent, available equipment, provision for postoperative recovery, patient, OR log, and documented OR reports are all included in the CMS requirements. Although not discussed in this *CoP*, CMS *LSC* requires that ORs designated as wet locations must be protected by line isolation monitors or ground fault relay outlets. Additionally, CMS has clarified expectations related to use of alcohol-based skin preparation. DNV addresses dry time in PE.5 (SR.6) (SR.6a – d) CMS also clarified expectations related to preoperative H&Ps and informed consent (see medical record services and patient rights *CoP*s as well). CMS does reference "timeout" procedures but does not define expectations as does The Joint Commission. CMS will look for a timeout after use of flammable skin disinfectants to allow for evaporation and drying. DNV looks at the requirements for dry time as noted above in PE.5 (SR.6) (SR.6a – d).

NIAHO/DNV includes informed consent requirements for both inpatients and outpatients' policies as outlined by CMS. DNV addresses this in (PR.5). All patients receiving either inpatient and outpatient care shall complete an informed written consent form for all procedures and treatments specified by the hospital's medical staff, or state or federal laws or regulations. In the event of a medical emergency, the hospital is not required to obtain a written consent, but timely efforts should be made to obtain an informed written consent from the patient's authorized representative. Postop care and planning is addressed in SS.7 (SR.1) (SR.2). The Joint Commission is silent on required policies. Both CMS and all accreditors require postoperative reports; however, requirements of those reports differ depending on the accreditor and are not 100% aligned with CMS expectations.

DNV does allow for an immediate postop note in SS.8 (SR.4). In the event that an operative report cannot be dictated and placed on the patient's chart before transfer to the next level of care, an immediate postoperative/ postprocedure note is required to be documented. The note shall include identification or description of:

- SR.4a: The surgeon and assistants
- SR.4b: Preoperative and postoperative diagnosis
- SR.4c: Procedures performed
- SR.4d: Specimens removed
- SR.4e: Estimated blood loss (specify N/A if no blood loss)
- SR.4f: Complications (if any encountered)
- SR.4g: Type of anesthesia administered
- SR.4h: Grafts or implants (may indicate where in chart for detail, if any)
- SR.5: If information identified in the immediate postoperative/postprocedure note is available elsewhere in the medical record; it is acceptable if referred to and authenticated as accurate by the attending surgeon. The Joint Commission does differentiate what is required in the immediate postop note versus the full report. DNV has added additional requirements beyond CMS specifications for equipment that must be available in the OR, which include airway intervention and malignant hyperthermia materials (including the availability of sufficient doses of antidotes and diluents for dantrolene or Ryanodex®). This is consistent with what CMS surveyors also assess.

Survey Tips:

- Review P&Ps for surgical and applicable procedural areas fitting the CMS definition of surgical services. Ensure they are compliant and that they are up to date with current practice.
- Conduct medical record reviews, especially focusing on informed consent, H&Ps, and operative reports. Ensure a brief operative note is available at the time of handoff to the recovery area and that a full operative report is completed in a timely manner. Review requirements of operative reports to verify that it is consistent with accreditor requirements.
- Verify CMS equipment requirements are met, including electrical protection in ORs and procedural areas that are designated as wet locations. Also evaluate the availability of emergency and malignant hyperthermia equipment.
- Ensure OR temperature and humidity are monitored. Document actions taken for out of range. If policies permit and physician preference is to maintain out-of-range temperatures, ensure core body temperature of the patient is maintained through the post-anesthesia care unit and provide evidence that there are no untoward outcomes.
- Verify that an OR register exists.
- Verify that informed consent is performed or updated within required time frames.
- Verify that informed consent tools included required components, including those informed consent tools coming in from the outside.
- Review medical staff medical record guidelines for postoperative notes to ensure they include requirements specified by both CMS and The Joint Commission.

Suggested Documents:

- Surgical services P&Ps as defined in CMS requirements, including:
  - Medical records (open and closed)
  - Informed consent policy
  - DNR P&P and consent makes it clear if DNR is waived during surgical procedures
  - Medical equipment preventive maintenance logs
  - OR register/patient log reflective of CMS requirements

§482.52 *CoP*: Anesthesia Services		
Tag #	CMS *CoP* (2023)	CMS Interpretive Guidelines and Survey Procedures
A-1000	If the hospital furnishes anesthesia services, they must be provided in a well-organized manner under the direction of a qualified Doctor of Medicine or osteopathy. The service is responsible for all anesthesia administered in the hospital.	*See Interpretive Guidelines for §482.52* *See Survey Procedures for §482.52* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.52 -- Condition of participation: Anesthesia services.*
A-1001	**(a) Standard: Organization and Staffing—** The organization of anesthesia services must be appropriate to the scope of the services offered. Anesthesia must be administered only by: (1) A qualified anesthesiologist. (2) A Doctor of Medicine or osteopathy (other than an anesthesiologist). (3) A dentist, oral surgeon, or podiatrist who is qualified to administer anesthesia under State law. (4) A certified registered nurse anesthetist (CRNA), as defined in §410.69(b) of this chapter, who, unless exempted in accordance with paragraph (c) of this section, is under the supervision of the operating practitioner or of an anesthesiologist who is immediately available if needed, or (5) An anesthesiologist's assistant, as defined in section 410.69(b) of this chapter, who is under the supervision of an anesthesiologist who is immediately available if needed.	*See Interpretive Guidelines for §482.52(a) and (c)* *See Survey Procedures for §482.52(a) and (c)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.52 -- Condition of participation: Anesthesia services.*

Related Joint Commission Standards

Human Resources:

- HR.01.02.07, EP 2

Leadership:

- LD.01.03.01, EP 3
- LD.03.06.01, EP 2

- LD.04.01.05, EP 7, 9
- LD.04.01.11, EP 5

Medical Staff:

- MS.03.01.01, EP 2

Provision of Care, Treatment, and Services:

- PC.03.01.01, EP 10

Related DNV Standards

Organization:

- AS.1 (SR.1)
- AS.1 (SR.2)

Administration:

- AS.2 (SR.1)
- AS.2 (SR.2)
- AS.2 (SR.3)
- AS.2 (SR.4)

Related ACHC Standards

Anesthesia Services:

- 18.00.00
- 18.00.01
- 18.00.02

Related CIHQ Standards

Anesthesia Services:

- AN-1
- AN-3

§482.52 (a) *CoP* Analysis/Guidelines

CMS has clarified the scope of anesthesia regulation to include general anesthesia, regional anesthesia, monitored anesthesia care (MAC), and deep sedation (which falls into the category of MAC). Propofol is listed as a form of deep sedation. The CMS *CoP* does not apply to topical or local anesthesia, minimal or moderate sedation, or administration of medication via epidural or spinal route during L&D; however, Joint Commission standards apply. All anesthesia providers must be under the direction of a qualified MD/DO. If there are several anesthesia providers, it is expected that anesthesia services are organized under one anesthesia service and under the direction of one medical director. CMS and accreditors require that anesthesia is only done by those privileged to do so; however, CMS outlines specific practitioners allowed to administer anesthesia. NIAHO/DNV lists those practitioners in a related standard, whereas The Joint Commission does not. NIAHO/DNV specifies that use of anesthesia assistants must be in accordance with state law. CRNAs in non–opt-out states must be supervised by either the operating practitioner or an anesthesiologist who is immediately available. It is advisable

to ensure compliance with this concept of "immediately available." Although assumed to be a practice that would be required by other accreditors, NIAHO/DNV has an additional stipulation that if a patient has received epidural analgesia, there will be a practitioner immediately available to manage any complication for the analgesia or the specific obstetrical condition. CMS and accreditors include exemption requirements related to the supervision of CRNAs by MD/DOs; a letter from the governor of the state in question can attest quality of CRNA services, consultation used, and best interest of the state's citizens have resulted in decision to opt out of MD/DO supervision for these providers. CMS does not allow delegation of anesthesia administration or assessment of individuals receiving anesthesia. These new requirements have created some difficulties where deep sedation is occurring in that the practitioner performing a procedure cannot also administer and monitor deep sedation. The Joint Commission and CMS have some differences in requirements for assessment, monitoring, and documentation.

The Anesthesia Society of America (ASA) outlines what components should be included in the pre-sedation/ pre-anesthesia and post-sedation/post-anesthesia evaluation, and CMS is in alignment with those requirements, although other associations may not be (i.e., EMA).

Survey Tips:

- Verify that credentials and privileging for medical staff performing anesthesia services are current and based on current regulation.
- If CRNA supervision is performed by an anesthesiologist, verify that the supervising anesthesiologist is immediately available, meaning that they are not involved in another case at the time.
- Verify that a single anesthesia medical director is responsible for the hospital-wide anesthesia services.
- Verify that practitioners privileged to perform or assist with anesthesia services meet the minimum qualifications required by CMS. RNs or other nonqualified providers should not be administering deep sedation.
- Consider privileging for moderate and deep sedation as separate privileges.
- Update organizational chart and job descriptions as necessary.

Suggested Documents:

- Scope of service for anesthesia services and locations for those services
- Listing of all locations providing anesthesia and sedation services
- Organizational chart for anesthesia department
- Job descriptions for the anesthesia medical director
- Medical staff credentials files
- Privileging forms for anesthesia, deep and moderate sedation
- Bylaws or rules and regulations or policies that specify for requirements related to supervision of CRNAs and others
- Other anesthesia P&Ps reflective of CMS requirements

§482.52 *CoP*: Anesthesia Services (continued)		
Tag #	CMS *CoP* (2023)	CMS Interpretive Guidelines and Survey Procedures
A-1002	**(b) Standard: Delivery of Services—** Anesthesia services must be consistent with needs and resources. Policies on anesthesia procedures must include the delineation of pre-anesthesia and post-anesthesia responsibilities. The policies must ensure that the following are provided to each patient:	*See Interpretive Guidelines for §482.52(b)* *See Survey Procedures for §482.52(b)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.52 -- Condition of participation: Anesthesia services.*
A-1003	(1) A pre-anesthesia evaluation completed and documented by an individual qualified to administer anesthesia, as specified in paragraph (a) of this section, performed within 48 hours prior to surgery or a procedure requiring anesthesia services.	*See Interpretive Guidelines for §482.52(b)(1)* *See Survey Procedures for §482.52(b)(1)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.52 -- Condition of participation: Anesthesia services.*
A-1004	(2) An intraoperative anesthesia record.	*See Interpretive Guidelines for §482.52(b)(2)* *See Survey Procedures for §482.52(b)(2)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.52 -- Condition of participation: Anesthesia services.*
A-1005	(3) A post-anesthesia evaluation completed and documented by an individual qualified to administer anesthesia, as specified in paragraph (a) of this section, no later than 48 hours after surgery or a procedure requiring anesthesia services. The post-anesthesia evaluation for anesthesia recovery must be completed in accordance with state law and with hospital P&Ps that have been approved by the medical staff and that reflect current standards of anesthesia care.	*See Interpretive Guidelines for §482.52(b)(3)* *See Survey Procedures for §482.52(b)(3)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.52 -- Condition of participation: Anesthesia services.*

Related Joint Commission Standards

Environment of Care:

- EC.02.04.03, EP 26

Leadership:

- LD.01.03.01, EP 3, 5
- LD.04.01.07, EP 1

Provision of Care, Treatment, and Services:

- PC.03.01.01, EP 6
- PC.03.01.03, EP 1, 8, 18
- PC.03.01.05, EP 1
- PC.03.01.07, EP 7, 8

Record of Care, Treatment, and Services:

RC.02.01.03, EP 1

Related DNV Standards

Policies and Procedures

- AS.3 (SR.1)
- AS.3 (SR.2)
- AS.3 (SR.2a)
- AS.3 (SR.2a(1))
- AS.3 (SR.2b)
- AS.3 (SR.2c)
- AS.3 (SR.2c)
- AS.3 (SR.2c(1))
- AS.3 (SR.2c(1))
- AS.3 (SR.2c(1))
- AS.3 (SR.2c(1))
- AS.3 (SR.2c(1))
- AS.3 (SR.2c(2))
- AS.3 (SR.2c(3))
- AS.3 (SR.2c(4))

- AS.3 (SR.2c(5))
- AS.3 (SR.3)
- AS.3 (SR.4)
- AS.3 (SR.4a)
- AS.3 (SR.4a(1))
- AS.3 (SR.4a(2))
- AS.3 (SR.4a(3))
- AS.3 (SR.4a(4))
- AS.3(SR.4a(5))
- AS.3 (SR.4a(6))
- AS.3 (SR.4a(7))

Related ACHC Standards

Anesthesia Services:

- 18.00.04
- 18.00.05
- 18.00.06
- 18.00.07

Related CIHQ Standards

Anesthesia Services:

- AN-2
- AN-3

§482.52 (b) *CoP* Analysis/Guidelines

These requirements are verifying that the anesthesia services provided are delivered according to standards of care. Policies, pre-anesthesia evaluations, and intra- and post-anesthesia record document should be outlined. Accreditors have expectations that post-anesthesia evaluations are to be performed and documented within 48 hours of surgery or procedures requiring anesthesia.

CMS and all accreditors both require a pre-sedation/anesthesia evaluation for deep sedation, monitored anesthesia care (MAC), regional anesthesia, and general anesthesia. DNV specifications for pre-anesthesia evaluation exceed that required by CMS. DNV states that a pre-anesthesia evaluation is not required for moderate sedation but that patients must be monitored and evaluated before, during, and after the procedure. The Joint Commission also requires a pre-sedation assessment prior to moderate sedation. Neither DNV nor The Joint Commission specifies who is required to perform this pre–moderate sedation assessment. While The Joint Commission does specify components of assessment required for the pre-sedation assessment, DNV does not.

The Joint Commission requires an immediate reevaluation prior to administration of all forms of anesthesia, including moderate sedation. The Joint Commission does not specify who has to perform that immediate reevaluation; however, due to anesthesia regulation, it is most appropriately done by the qualified anesthesia provider for general, regional, MAC, or deep sedation. For moderate sedation, the immediate reevaluation may be delegated. The immediate reevaluation is supported by the ASA. DNV is silent on this requirement.

CMS and other accreditors require intraprocedural monitoring. NIAHO/DNV does not outline the components required by CMS; The Joint Commission does but is not consistent with components required by CMS, likely because their requirements include moderate sedation. DNV does not outline components of intraprocedural monitoring during moderate sedation but does state it must occur.

CMS and other accreditors require a post-sedation/anesthesia evaluation for general, regional, MAC, and deep sedation. A post-sedation evaluation is not required for moderate sedation. CMS specifies the timing of the post-anesthesia/post-deep sedation evaluation. It must be conducted within 48 hours but may be done after transfer to the recovery area if the patient is sufficiently awake. Accreditors are also in alignment with the timing requirements. DNV outlines components of post-anesthesia evaluation, and these are in alignment with CMS.

The Joint Commission also outline components of the evaluation that are not exacting to CMS required components, but their outline encompasses moderate sedation. DNV requires evaluation after moderate sedation but gives no guidance on the components of moderate sedation.

Survey Tips:

- Verify that medical staff medical record guidelines differentiate requirements for pre-deep sedation/pre-anesthesia evaluations, immediate reevaluations, intraprocedural monitoring, and post-deep sedation/ post-anesthesia evaluation. Ensure those requirements define which aspects can and cannot be delegated. Verify that the requirements align with CMS and the requirements of your accreditor. If the accreditor is silent on required components of any of the aforementioned, contact them.
- Conduct medical record reviews, especially focusing on whether pre-anesthesia evaluations, immediate reevaluation, operative anesthesia records, and post-anesthesia/post-deep sedation evaluations meet accreditor and CMS specifications.
- Review deep sedation and anesthesia practices and P&Ps for compliance with current regulation.
- Review anesthesia and sedation documentation tools to ensure that the stages of evaluation are documented in a way that it is clear that the timing of those activities occurred as required by regulation.
- Ensure deep sedation privileging exists for non-anesthesia providers who administer anesthetizing agents and/or that there are clear guidelines on dosing of anesthetizing agents so that it does not move into deep sedation for practitioners with moderate sedation privileges.
- Consider the creation of a sedation grid, which encompasses aspects important to minimal sedation, moderate sedation, and deep sedation, which align with CMS and the requirements of your accreditor.

Suggested Documents:

- Anesthesia and sedation P&Ps reflective of CMS and Joint Commission requirements that have been approved by the anesthesia medical director
- Medical staff bylaws/P&Ps
- Schedules for operative and invasive areas
- Anesthesia and sedation documentation tools
- Medical records

§482.52 *CoP*: Anesthesia Services		
Tag #	CMS *CoP* (2023)	CMS Interpretive Guidelines and Survey Procedures
A-1001	**(c) Standard: State Exemption** (1) A hospital may be exempted from the requirements for MD/DO supervision of CRNAs as described in paragraph (a)(4) of this section. To obtain this exemption, the State in which the hospital is located must submit a letter to CMS signed by the governor, following consultation with the State's Board of Medicine and Nursing. The letter from the governor must attest that he/she has consulted with State Boards of Medicine and Nursing about issues related to access to and the quality of anesthesia services in the State and has concluded that it is in the best interests of the State's citizens to opt-out of the current MD/DO supervision requirement and that the opt-out is consistent with State law. (2) The request for exemption and recognition of State laws, and the withdrawal of the request may be submitted at any time, and are effective upon submission.	*See Interpretive Guidelines for §482.52(a) and (c)* *See Survey Procedures for §482.52(a) and (c)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.52 -- Condition of participation: Anesthesia services.*

Related Joint Commission Standards

Medical Staff:

- MS.03.01.01, EP 2

Provision of Care, Treatment, and Services:

- PC.03.01.01, EP 10

Related DNV Standards

Organization

- AS.1 (SR.2)

Administration

- AS.2 (SR.1)
- AS.2 (SR.1)
- AS.2 (SR.5)
- AS.2 (SR.5)
- AS.2 (SR.5a)

Related ACHC Standards

Anesthesia Services:

- 18.00.02

Related CIHQ Standards

Anesthesia Services:

- AN-2

§482.52 (c) *CoP* Analysis/Guidelines

Same as §482.52 (b) *CoP* Analysis/Guidelines for A-1000 and A-1001.

§482.53 *CoP*: Nuclear Medicine Services		
Tag #	CMS *CoP* (2023)	CMS Interpretive Guidelines and Survey Procedures
A-1026	If the hospital provides nuclear medicine services, those services must meet the needs of the patients in accordance with acceptable standards of practice.	*See Interpretive Guidelines for §482.53* *See Survey Procedures for §482.53* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.53 -- Condition of participation: Nuclear medicine services.*
A-1027	**(a) Standard: Organization and Staffing—** The organization of the nuclear medicine service must be appropriate to the scope and complexity of the services offered. (1) There must be a director who is a Doctor of Medicine or osteopathy qualified in nuclear medicine. (2) The qualifications, training, functions, and responsibilities of the nuclear medicine personnel must be specified by the service director and approved by the medical staff.	*See Interpretive Guidelines for §482.53(a), §482.53(a)(1), & §482.53(a)(2)* *See Survey Procedures for §482.53(a), §482.53(a)(1), & §482.53(a)(2)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.53 -- Condition of participation: Nuclear medicine services.*

Related Joint Commission Standards

Human Resources:

- HR.01.01.01, EP 1
- HR.03.06.01, EP 2

Leadership:

- LD.01.03.01, EP 3, 5
- LD.03.10.01, EP 3
- LD.04.01.05, EP 7
- LD.04.03.01, EP 2
- LD.04.01.11, EP 5

Medical Staff:

- MS.03.01.01, EP 17

Related DNV Standards

Organization:

- NM.1 (SR.1)
- NM.1 (SR.2)
- NM.1 (SR.3)
- NM.1 (SR.4)

Related ACHC Standards

Nuclear Medicine:

- 23.00.00
- 23.00.01

Related CIHQ Standards

Nuclear Medicine Services:

- NM-1

Radiology Services:

- RD-1
- RD-2
- RD-3

§482.53 (a) *CoP* Analysis/Guidelines

This is an optional service for hospitals; however, if a hospital provides nuclear medicine services, it is usually part of the radiological services area. The Joint Commission standards for this entire section are the same as listed under the Radiological Services section. See §482.26 Radiological Services for analysis, survey tips, and suggested documents. Also see §482.25 Pharmaceutical Services related to required oversight of medication management functions.

Suggested Documents:

- Organizational chart for nuclear medicine services; ensure medical director and MD/DO or pharmacist who has oversight of radiopharmaceuticals is included
- Scope of service for nuclear medicine service
- Nuclear medicine medical director job description, responsibility matrix, or P&P related to medical directorship
- Radiation safety officer job description (if applicable) and other nuclear medicine staff job descriptions
- Staffing matrices, assignments, and logs
- Nuclear medicine P&Ps
- Inspection records for nuclear medicine services and certifications

§482.53 *CoP*: Nuclear Medicine Services		
Tag #	CMS *CoP* (2023)	CMS Interpretive Guidelines and Survey Procedures
A-1035	**(b) Standard: Delivery of Service—** Radioactive materials must be prepared, labeled, used, transported, stored, and disposed of in accordance with acceptable standards of practice.	*See Interpretive Guidelines for §482.53(b)* *See Survey Procedures for §482.53(b)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.53 -- Condition of participation: Nuclear medicine services.*
A-1036	(1) In-house preparation of radio pharmaceuticals is by, or under, the supervision of an appropriately trained registered pharmacist or doctor of medicine or osteopathy.	*See Interpretive Guidelines for §482.53(b)(1)* *See Survey Procedures for §482.53(b)(1)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.53 -- Condition of participation: Nuclear medicine services.*
A-1037	(2) There is proper storage and disposal of radioactive material.	*See Survey Procedures for §482.53(b)(2)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.53 -- Condition of participation: Nuclear medicine services.*
A-1038	(3) If laboratory tests are performed in the nuclear medicine service, the service must meet the applicable requirement for laboratory services specified in §482.27.	*See Interpretive Guidelines for §482.53(b)(3)* *See Survey Procedures for §482.53(b)(3)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.53 -- Condition of participation: Nuclear medicine services.*

Related Joint Commission Standards

Environment of Care:

- EC.02.01.01, EP 8
- EC.02.02.01, EP 3 – 4, 6 – 8, 11 – 12

Leadership:

- LD.04.01.01, EP 1

Medication Management:

- MM.01.01.03, EP 1, 2
- MM.05.01.07, EP 6

Related DNV Standards

Radioactive Materials

- NM.2 (SR.1)
- NM.2 (SR.3)
- NM.2 (SR.4)

Related ACHC Standards

Nuclear Medicine:

- 23.00.04
- 23.00.05
- 23.00.10

Related CIHQ Standards

Nuclear Medicine Services:

- NM-2
- NM-3

§482.53 (b) *CoP* Analysis/Guidelines

CMS and accreditors are similar when it comes to environment of care issues for hazardous waste (radioactive materials) and medical equipment management, testing, and inspections. CMS also focuses on radiation exposure badge checks that are not specified in the Joint Commission standards. CMS revised the requirement for "direct supervision of" in-house preparation of radiopharmaceuticals. The presence of a pharmacist, MD, or DO will no longer be required during the delivery of off-hour nuclear medicine tests.

Survey Tips:

- Verify that nuclear medicine P&Ps address safety standards and inspect where hazardous materials are stored safely
- Verify that P&Ps involving medication management have been appropriately signed off by the chief pharmacist
- Verify chief pharmacist oversight of radiopharmaceutical preparation; evaluate that USP 797 compliance assessment was performed if medications are prepared but not immediately administered

- Review medical records for appropriate orders
- Verify that QC checks are performed regularly
- Verify records are maintained for five years
- Verify competencies of nuclear medicine staff
- Verify radiopharmaceutical records are maintained and include receipt, distribution, and waste of radiopharmaceuticals

Suggested Documents:

- Nuclear medicine P&Ps
- Environment of care P&Ps for hazardous wastes and medical equipment
- Inspection logs for medical equipment checks, QC documentation, and any OSHA documentation regarding radiology safety

§482.53 *CoP*: Nuclear Medicine Services

Tag #	CMS *CoP* (2023)	CMS Interpretive Guidelines and Survey Procedures
A-1044	**(c) Standard: Facilities—** Equipment and supplies must be appropriate for the types of nuclear medicine services offered and must be maintained for safe and efficient performance. The equipment must be: (1) Maintained in safe operating condition; and (2) Inspected, tested, and calibrated at least annually by qualified personnel.	*See Interpretive Guidelines for §482.53(c)* *See Survey Procedures for §482.53(c)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.53 -- Condition of participation: Nuclear medicine services.*

Related Joint Commission Standards

Environment of Care:

- EC.02.04.01, EP 4
- EC.02.04.03, EP 1 – 3, 16

Leadership:

- LD.01.03.01, EP 5

Related DNV Standards

Equipment and Supplies

- NM.3 (SR.1)
- NM.3 (SR.2)
- NM.3 (SR.3)

Related ACHC Standards

Nuclear Medicine:

- 23.00.11

Related CIHQ Standards

Nuclear Medicine Services:

- NM-1

§482.53 (c) *CoP* Analysis/Guidelines

Same as §482.53(b) *CoP* Analysis/Guidelines.

Survey Tips:

- Review logs of medical equipment checks to verify they have been inspected, tested, and calibrated at least annually
- Verify labeling of reagents

§482.53 *CoP*: Nuclear Medicine Services		
Tag #	CMS *CoP* (2023)	CMS Interpretive Guidelines and Survey Procedures
A-1051	**(d) Standard: Records—** The hospital must maintain signed and dated reports of nuclear medicine interpretations, consultations, and procedures. (1) The hospital must maintain copies of nuclear medicine reports for at least five years. (2) The practitioner approved by the medical staff to interpret diagnostic procedures must sign and date the interpretations of these tests.	*See Interpretive Guidelines for §482.53(d) (1) and (2)* *See Survey Procedures for §482.53(d)(1) and (2)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.53 -- Condition of participation: Nuclear medicine services.*
A-1054	(3) The hospital must maintain records of the receipt and distribution of radiopharmaceuticals.	*See Interpretive Guidelines for §482.53(d)(3)* *See Survey Procedures for §482.53(d)(3)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.53 -- Condition of participation: Nuclear medicine services.*
A-1055	(4) Nuclear medicine services must be ordered only by practitioners whose scope of federal or state licensure and whose defined staff privileges allow such referrals.	*See Interpretive Guidelines for §482.53(d)(4)* *See Survey Procedures for §482.53(d)(4)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.53 -- Condition of participation: Nuclear medicine services.*

Related Joint Commission Standards

Medical Staff:

- MS.03.01.01, EP 2, 4, 8, 24

Medication Management:

- MM.03.01.01, EP 2, 4, 8, 24

Record of Care, Treatment, and Services:

- RC.01.01.01, EP 7
- RC.01.02.01, EP 3 – 5
- RC.01.05.01, EP 1
- RC.02.01.01, EP 2

Related DNV Standards

Interpretation:

- NM.4 (SR.2)
- NM.4 (SR.1)
- NM.4 (SR.3)

Radioactive Materials:

- NM.2 (SR.2)
- NM.2 (SR.2a)

Organization:

- NM.1 (SR.5)

Nuclear Medicine Services:

- RS.3, SR.3

Related ACHC Standards

Nuclear Medicine:

- 23.00.16
- 23.00.19
- 23.00.20

Related CIHQ Standards

Nuclear Medicine Services:

- NM-2

§482.53 (d) *CoP* Analysis/Guidelines

All accreditors are aligned on the topic of record requirements.

Survey Tips:

- Verify records are being maintained for five years or longer if otherwise required (i.e., pediatric records)
- Verify radiopharmaceutical records are maintained and include receipt, distribution, and waste of radiopharmaceuticals

Suggested Documents:

- Medical staff privileging documents
- Nuclear medicine P&Ps
- Environment of care P&Ps for hazardous wastes

§482.54 *CoP*: Outpatient Services		
Tag #	CMS *CoP* (2023)	CMS Interpretive Guidelines and Survey Procedures
A-1076	If the hospital provides outpatient services, the services must meet the needs of the patients in accordance with acceptable standards of practice.	*See Interpretive Guidelines for §482.54* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.54 -- Condition of participation: Outpatient services.*
A-1077	**(a) Standard: Organization—** Outpatient services must be appropriately organized and integrated with inpatient services.	*See Interpretive Guidelines for §482.54(a)* *See Survey Procedures for §482.54(a)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.54 -- Condition of participation: Outpatient services.*

Related Joint Commission Standards

Leadership:

- LD.01.03.01, EP 3, 5
- LD.03.10.01, EP 3
- LD.04.01.11, EP 5
- LD.04.03.01, EP 1

Related DNV Standards

Organization

- OS.1 (SR.1)

Related ACHC Standards

Outpatient Services:

- 31.00.00
- 31.00.01

Related CIHQ Standards

Outpatient Services:

- OS-1

§482.54 (a) *CoP* Analysis/Guidelines

CMS and other accreditors are verifying that hospitals that provide outpatient services, either directly or through a contractual agreement, do so according to standards of care and that services are provided consistently in all locations. CMS changed their requirement related to responsibility for outpatient services and now allow one or more individuals with appropriate qualifications and competencies assigned responsibility for services provided in outpatient settings (some examples of outpatient services include outpatient radiology, outpatient physical medicine, clinics/office practices that are departments of the hospital).

OS.2 (SR.1) The organization shall assign one or more individuals to be responsible for outpatient services. This matches the IG. There should also be sufficient evidence of integration with outpatient services by applicable functional areas (i.e., medical records, laboratory, radiology, etc.). The services should be outlined along with staffing requirements and competencies.

Outpatient services ordered by a practitioner not appointed to the medical staff must meet the following: must be responsible for the care of the patient; must be licensed in the state where they provide care to the patient; must be acting within their scope of practice under state law; and must be authorized in accordance with state law and policies adopted by the medical staff and approved by the governing body. CMS and NIAHO/DNV guidance state that pertinent information from the outpatient medical record should be included in the inpatient record. This is defined in MR.5.

Survey Tips:

- Verify that policies/procedures and job descriptions are current.
- Verify that structures exist to integrate inpatient and outpatient services (e.g., pharmacy, imaging, medical records, lab, other diagnostic services, quality, safety, etc.).
- Verify appropriate oversight of outpatient areas by key functional areas (e.g., pharmacy, imaging, medical records, lab, other diagnostic services, quality, safety, etc.). Consider creating a listing of all outpatient areas and create calendar of oversight activities by applicable functional areas. When preparing for this, consider all scopes of services.
- Ensure organizational chart reflects oversight of outpatient services.
- Verify procedures exist to ensure that providers ordering outpatient services are licensed and in good standing.
- Ensure medical staff policy addresses referring providers ordering of outpatient services and process to verify licensure.

Suggested Documents:

- Scope of service for all outpatient service areas/clinics
- Organizational chart for outpatient service structure demonstrating one or more individuals are responsible for coordinating outpatient services whether via direct authority (straight line) or indirect authority (dotted line)
- Outpatient service P&Ps
- Personnel files, competency records, and job descriptions
- Medical records
- Staffing logs

§482.54 *CoP*: Outpatient Services

Tag #	CMS *CoP* (2023)	CMS Interpretive Guidelines and Survey Procedures
A-1079	**(b) Standard: Personnel—** The hospital must: (1) Assign one or more individuals to be responsible for outpatient services (2) Have appropriate professional and non-professional personnel available at each location where outpatient services are offered, based on the scope and complexity of outpatient services.	*See Interpretive Guidelines for §482.54(b)* *See Survey Procedures for §482.54(b)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.54 -- Condition of participation: Outpatient services.*

Related Joint Commission Standards

Human Resources:

- HR.01.01.01, EP 1, 3
- HR.01.06.01, EP 1

Leadership:

- LD.03.06.01, EP 2
- LD.04.01.05, EP 8

Related DNV Standards

Staffing:

- OS.2 (SR.1)
- OS.2 (SR.2)

Related ACHC Standards

Outpatient Services:

- 31.00.02

Related CIHQ Standards

Outpatient Services:

- OS-1

§482.54 (b) *CoP* Analysis/Guidelines

Same as §482.54 (a) *CoP* Analysis/Guidelines.

§482.54 *CoP*: Outpatient Services		
Tag #	CMS *CoP* (2023)	CMS Interpretive Guidelines and Survey Procedures
A-1080	**(c) Standard: Orders for Outpatient Services—** Outpatient services must be ordered by a practitioner who meets the following conditions: (1) Is responsible for the care of the patient. (2) Is licensed in the state where he or she provides care to the patient. (3) Is acting within his or her scope of practice under state law. (4) Is authorized in accordance with state law and policies adopted by the medical staff, and approved by the governing body, to order the applicable outpatient services.	*See Interpretive Guidelines for §482.54(c)* *See Survey Procedures for §482.54(c)* SOM Appendix A (cms.gov) eCFR :: 42 CFR 482.54 -- Condition of participation: Outpatient services.
	This applies to the following: (i) All practitioners who are appointed to the hospital's medical staff and who have been granted privileges to order the applicable outpatient services. (ii) 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.	SOM Appendix A (cms.gov) eCFR :: 42 CFR 482.54 -- Condition of participation: Outpatient services.
A-1081	If the hospital provides outpatient services, the services must meet the needs of the patients in accordance with acceptable standards of practice.	*See Interpretive Guidelines for §482.54* *See Survey Procedures for §482.54* SOM Appendix A (cms.gov) eCFR :: 42 CFR 482.54 -- Condition of participation: Outpatient services.

Related Joint Commission Standards

Medical Staff:

- MS.06.01.05, EP 2 – 3

Provision of Care, Treatment, and Services:

- PC.02.01.03, EP 1

Related DNV Standards

Orders

- OS.4 Introduction
- OS.4 (SR.1)
- OS.4 (SR.2)
- OS.4 (SR.3)
- OS.4 (SR.4)
- OS.4 (SR.4a)
- OS.4 (SR.4b)

Related ACHC Standards

Outpatient Services:

- 31.00.11

Related CIHQ Standards

Outpatient Services:

- OS-1

§482.54 (c) *CoP* Analysis/Guidelines

Same as §482.54(a) *CoP* Analysis/Guidelines.

§482.55 *CoP*: Emergency Services		
Tag #	CMS *CoP* (2023)	CMS Interpretive Guidelines and Survey Procedures
A-1100	The hospital must meet the emergency needs of patients in accordance with acceptable standards of practice.	*See Interpretive Guidelines for §482.55* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.55 -- Condition of participation: Emergency services.*
A-1101	**(a) Standard: Organization and Direction—** If emergency services are provided at the hospital:	*See Interpretive Guidelines for §482.55(a)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.55 -- Condition of participation: Emergency services.*
A-1102	(1) The services must be organized under the direction of a qualified member of the medical staff.	*See Interpretive Guidelines for §482.55(a)(1)* *See Survey Procedures for §482.55(a)(1)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.55 -- Condition of participation: Emergency services.*
A-1103	(2) The services must be integrated with other departments of the hospital.	*See Interpretive Guidelines for §482.55(a)(2)* *See Survey Procedures for §482.55(a)(2)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.55 -- Condition of participation: Emergency services.*
A-1104	(3) The policies and procedures governing medical care provided in the emergency service or department are established by and are a continuing responsibility of the medical staff.	*See Interpretive Guidelines for §482.55(a)(3)* *See Survey Procedures for §482.55(a)(3)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.55 -- Condition of participation: Emergency services.*

Related Joint Commission Standards

Leadership

- LD.01.03.01, EP 3, 5
- LD.04.01.05, EP 5, 6
- LD.04.01.07, EP 1
- LD.04.03.01, EP 2
- LD.04.03.11, EP 1

Medical Staff:

- MS.01.01.01, EP 36
- MS.03.01.03, EP 6

Provision of Care, Treatment, and Services:

- PC.02.01.05, EP 1
- PC.02.02.01, EP 3

Related DNV Standards

Organization

- ED.1 (SR.1)
- ED.1 (SR.2)
- ED.1 (SR.3)

Related ACHC Standards

Emergency Services:

- 20.00.00
- 20.00.01
- 20.00.02
- 20.00.03

Related CIHQ Standards

Emergency Services:

- ED-1

§482.55 (a) *CoP* Analysis/Guidelines

CMS states that hospitals that provide ER services do so according to standards of care. The Joint Commission and other accreditors are in alignment that emergency services must be under the medical direction of a qualified member of the medical staff. There should be a scope of services document outlined along with staffing requirements and competencies. Urgent care services that are separate from the ED and clearly state that they only provide urgent care and are not an ED are not held to the Emergency Services *CoP* but are held to the Outpatient Services *CoP*.

Survey Tips:

- Ensure that orders are under the direction of an MD/DO or qualified PA/advanced practice registered nurse (APRN). If protocols are used, there must be an order to use; however, "standing order" protocols approved by the medical staff and medical director may be initiated to protect critical patients from treatment delays or gaps in medical care without LP prior approval as long as this practice is approved via P&Ps and/or medical staff rules and regulations.
- Verify that there is a scope of services document and that the medical director and governing body approved that document. Verify that services provided are consistent with the scope of services defined.
- Verify that a medical director has been appointed by the medical staff.
- Review the job description, responsibility chart, contract, or other document explaining the role and responsibility of the medical director.
- Verify that the medical director is responsible to oversee operations and approve P&Ps and related order sets and protocols.
- If the medical director has not been delegated authority by the medical staff to approve emergency services P&Ps, protocols, order sets, and staff qualifications, it will also need to be approved by the medical staff.

Suggested Documents:

- Scope of service and organizational chart for emergency services
- Current ED P&Ps authorized by the medical staff
- Job descriptions of emergency service personnel (medical director, nurses, emergency medical technicians, mid-level providers)
- Medical staff credentials files
- Emergency services on-call schedules for emergency physicians, including specialty positions

§482.55 *CoP*: Emergency Services (continued)		
Tag #	CMS *CoP* (2023)	CMS Interpretive Guidelines and Survey Procedures
A-1110	**(b) Standard: Personnel**	*See Interpretive Guidelines for §482.55(b)* *SOM Appendix A (cms.gov)* eCFR :: 42 CFR 482.55 -- Condition of participation: Emergency services.
A-1111	(1) The emergency services must be supervised by a qualified member of the medical staff.	*See Interpretive Guidelines for §482.55(b)(1)* *See Survey Procedures for §482.55(b)(1)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.55 -- Condition of participation: Emergency services.*
A-1112	(2) There must be adequate medical and nursing personnel qualified in emergency care to meet the written emergency procedures and needs anticipated by the facility.	*See Interpretive Guidelines for §482.55(b)(2)* *See Survey Procedures for §482.55(b)(2)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.55 -- Condition of participation: Emergency services.*

Related Joint Commission Standards

Human Resources:

- HR.01.01.01, EP 1, 3
- HR.01.06.01, EP 2, 3

Leadership:

- LD.03.06.01, EP 3
- LD.04.01.05, EP 6

Related DNV Standards

Organization

- ED.1 (SR.2)

Staffing

- ED.2 (SR.1)

Related ACHC Standards

Emergency Services:

- 20.00.05
- 20.00.06

Related CIHQ Standards

Emergency Services:

- ED-1

§482.55 (b) *CoP* Analysis/Guidelines

CMS requires that emergency services must be supervised by a qualified member of the medical staff 24/7.

If more than one member of the medical staff is working on any given shift, it must be identified which of the medical staff is "supervising" the department for that shift. This supervision must be reflective of an immediate form of oversight; the supervisor may be briefly absent but is expected to be immediately available. Because the practitioner must be on-site and available to staff during the period of "supervision," it should not be confused with being the responsibility of the medical director, who is not available 24/7.

Survey Tips:

- Review schedules of medical staff; when more than one physician is scheduled, there should be one designated as supervisor
- Review how the appropriate staffing is determined and applied for emergency services
- Audit personnel files for emergency services staff to determine that the qualifications, licensure (consistent with state law), education, training, and experience of personnel are met

Suggested Documents:

- Physician and practitioner schedules
- Policy or other document outlining roles and responsibilities of supervising ED practitioners
- Staffing matrices, assignment sheets

§482.56 *CoP*: Rehabilitation Services		
Tag #	CMS *CoP* (2023)	CMS Interpretive Guidelines and Survey Procedures
A-1123	If the hospital provides rehabilitation, physical therapy, occupational therapy, audiology, or speech pathology services, the services must be organized and staffed to ensure the health and safety of patients.	*See Interpretive Guidelines for §482.56* *See Survey Procedures for §482.56* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.56 -- Condition of participation: Rehabilitation services.*
A-1124	**(a) Standard: Organization and staffing—** The organization of the service must be appropriate to the scope of the services offered.	*See Interpretive Guidelines for §482.56(a)* *See Survey Procedures for §482.56(a)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.56 -- Condition of participation: Rehabilitation services.*
A-1125	(1) The director of the services must have the necessary knowledge, experience, and capabilities to properly supervise and administer the services.	*See Interpretive Guidelines for §482.56(a)(1)* *See Survey Procedures for §482.56(a)(1)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.56 -- Condition of participation: Rehabilitation services.*
A-1126	(2) 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 as defined in Part 484 of this chapter.	*See Interpretive Guidelines for §482.56(a)(2)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.56 -- Condition of participation: Rehabilitation services.*

Related Joint Commission Standards

Human Resources:

- HR.01.01.01, EP 1, 3
- HR.01.06.01, EP 1

Leadership:

- LD.01.03.01, EP 3, 5
- LD.03.06.01, EP 2, 3
- LD.04.01.05, EP 2, 3
- LD.04.01.11, EP 5
- LD.04.03.01, EP 1, 2

Related DNV Standards

Organization

- RS.1 (SR.1)

Management and Support

- RS.2 (SR.1)
- RS.2 (SR.1a)
- RS.2 (SR.1b)
- RS.2 (SR.1c)

Related ACHC Standards

Physical Rehabilitation Services:

- 26.00.00
- 26.00.01
- 26.00.02
- 26.00.03

Related CIHQ Standards

Rehabilitation Services:

- RB-1

§482.56 (a) *CoP* Analysis/Guidelines

CMS states that hospitals that provide rehabilitation services do so according to standards of care. Rehabilitation services include rehabilitation (i.e., cardiac rehab), physical therapy (PT), OT, and audiology or speech-language pathology services. The services should be outlined in a scope of services document along with staffing requirements and competencies. CMS and accreditors require that rehabilitation services are under the orders of an MD/DO or another qualified practitioner who is privileged to do so. CMS and accreditors require that the director/manager of the department has the qualifications, experience, and/or training defined by the organization and appropriate for this position. CMS requires that the provision of care and the personnel qualifications must be in accordance with national acceptable standards of practice. Guidance also indicates that PT, OT, or speech therapy (ST) must be furnished under a plan of care. The plan must be established before treatment and (1) prescribes the type, amount, frequency, and duration of the PT, OT, or ST services to be furnished to the individual and (2) indicates the diagnosis and anticipated goals. Any changes in the plan are implemented.

Survey Tips:

- Ensure that orders for rehabilitation services are under the direction of an MD/DO or qualified PA/APRN. Those ordering rehabilitation services must be privileged to do so.
- If protocols are used, verify that there must be an order to use the protocol.
- Ensure there are orders for rehabilitation services and that those ordering respiratory services are privileged to do so. If outpatient, there should be a process for referring providers to ensure they are licensed and in good standing.
- Verify that there is a scope of services document that was approved by the governing body. Verify that services provided are consistent with the scope of services defined.
- Verify qualifications of the manager/director.
- Review how the appropriate staffing is determined and applied for all disciplines within rehabilitation services.
- Audit personnel files for rehabilitation staff to determine that the qualifications, licensure (consistent with state law), education, training, and experience of personnel are met and that the job descriptions coincide with requirements outlined by the medical director/medical staff.
- Ensure plan of care requirements are met as indicated in the interpretive guidelines and that related P&Ps are compliant with those requirements.

Suggested Documents:

- Scope of services and organizational chart for rehabilitation services
- Job descriptions and competency records
- Staffing matrices, assignments/log
- Patients' care plans

§482.56 *CoP*: Rehabilitation Services		
Tag #	CMS *CoP* (2023)	CMS Interpretive Guidelines and Survey Procedures
A-1132	**(b) Standard: Delivery of Services—** Services must only be provided under the orders of a qualified and licensed practitioner who is responsible for the care of the patient, acting within his or her scope of practice under state law, and who is authorized by the hospital's medical staff to order the services in accordance with hospital P&Ps and state laws.	*See Interpretive Guidelines for §482.56(b)* *See Survey Procedures for §482.56(b)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.56 -- Condition of participation: Rehabilitation services.*
A-1133	(1) All rehabilitation services orders must be documented in the patient's medical record in accordance with the requirements at §482.24.	*See Interpretive Guidelines for §482.56(b)(1)* *See Survey Procedures for §482.56(b)(1)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.56 -- Condition of participation: Rehabilitation services.*
A-1134	(2) The provision of care and the personnel qualifications must be in accordance with national acceptable standards of practice and must also meet the requirements of §409.17 of this chapter.	*See Interpretive Guidelines for §482.56(b)(2)* *See Survey Procedures for §482.56(b)(2)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.56 -- Condition of participation: Rehabilitation services.*

Related Joint Commission Standards

Human Resources:

- HR.01.01.01, EP 1, 3
- HR.01.02.07, EP 2
- HR.01.06.01, EP 1

Leadership:

- LD.03.06.01, EP 3
- LD.03.10.01, EP 3
- LD.04.01.01, EP 2

Provision of Care, Treatment, and Services:

- PC.02.01.03, EP 1, 7

Record of Care, Treatment, and Services:

- RC.02.01.01, EP 2

Related DNV Standards

Treatment Plan/Orders

- RS.3 (SR.1)
- RS.3 (SR.2)
- RS.3 (SR.3)
- RS.3 (SR.3a)
- RS.3 (SR.3a(1))
- RS.3 (SR.3a(2))
- RS.3 (SR.3a(3))
- RS.3 (SR.3a(4))
- RS.3 (SR.3a(5))

Related ACHC Standards

Physical Rehabilitation Services:

- 26.00.06
- 26.00.07
- 26.00.08

Related CIHQ Standards

Rehabilitation Services:

- RB-01

§482.56 (b) *CoP* Analysis/Guidelines

Same as §482.56(a) *CoP* Analysis/Guidelines.

§482.57 *CoP*: Respiratory Services		
Tag #	CMS *CoP* (2023)	CMS Interpretive Guidelines and Survey Procedures
A-1151	The hospital must meet the needs of the patients in accordance with acceptable standards of practice. The following requirements apply if the hospital provides respiratory care services.	*See Interpretive Guidelines for §482.57* *See Survey Procedures for §482.57* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.57 -- Condition of participation: Respiratory care services.*
A-1152	**(a) Standard: Organization and Staffing—** The organization of the respiratory care services must be appropriate to the scope and complexity of the services offered.	*See Interpretive Guidelines for §482.57(a)* *See Survey Procedures for §482.57(a)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.57 -- Condition of participation: Respiratory care services.*
A-1153	(1) There must be a director of respiratory care services who is a Doctor of Medicine or osteopathy with the knowledge, experience, and capabilities to supervise and administer the service properly. The director may serve on either a full-time or part-time basis.	*See Interpretive Guidelines for §482.57(a)(1)* *See Survey Procedures for §482.57(a)(1)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.57 -- Condition of participation: Respiratory care services.*
A-1154	(2) There must be adequate numbers of respiratory therapists, respiratory therapy technicians, and other personnel who meet the qualifications specified by the medical staff, consistent with state law.	*See Interpretive Guidelines for §482.57(a)(2)* *See Survey Procedures for §482.57(a)(2)* *SOM Appendix A (cms.gov)* *eCFR :: 42 CFR 482.57 -- Condition of participation: Respiratory care services.*

Related Joint Commission Standards

Human Resources:

- HR.01.01.01, EP 1, 7
- HR.01.06.01, EP 1

Leadership:

- LD.01.03.01, EP 3, 5

- LD.03.06.01, EP 2, 3
- LD.03.10.01, EP 3
- LD.04.01.05, EP 7
- LD.04.01.11, EP 5
- LD.04.03.01, EP 1, 2

Related DNV Standards

Organization

- RC.1 (SR.1)
- RC.1 (SR.4)
- RC.1 (SR.5)

Related ACHC Standards

Respiratory Care:

- 17.00.00
- 17.00.01
- 17.00.02
- 17.00.03

Related CIHQ Standards

Respiratory Services:

- RT-1

§482.57 (a) *CoP* Analysis/Guidelines

CMS states that hospitals provide respiratory care services according to standards of care. CMS and accredited organizations require that these services are under the direction of a qualified MD/DO. The medical staff must approve the appointment of the medical director. NIAHO/DNV also requires that the governing body approve this appointment. CMS interpretive guidance and accreditors require that the practitioner must have medical staff privileges to write orders for these services.

CMS outlines that practitioners who may be granted privileges to order respiratory care services include physicians and may also, in accordance with hospital policy, be extended to NPs, physicians' assistants, clinical nurse specialists, CRNAs, and certified nurse midwives as long as they meet the parameters of this requirement. The services should be outlined in a scope of service document along with staffing requirements and competencies.

Survey Tips:

- Ensure that orders for respiratory care are under the direction of an MD/DO or another qualified practitioner who is privileged to do so.
- If protocols are used, verify that there is an order to use the protocol.
- Ensure there are orders for respiratory services and that those ordering respiratory services are privileged to do so. If outpatient, there should be a process for referring providers to ensure they are licensed and in good standing.
- Verify that there is a scope of services document and that the medical director and governing body approved that document. Verify that services provided are consistent with the scope of services defined.
- Verify that a medical director has been appointed by the medical staff.
- Review the job description, responsibility chart, contract, or other document explaining the role and responsibility of the medical director.
- Verify that the medical director is responsible to oversee operations and approve P&Ps and related order sets and protocols. Verify that the medical director has approved the qualifications, licensure (consistent with state law), education, training, and experience of personnel authorized to perform each type of respiratory care service and whether they may perform services without supervision, and if applicable, personnel who are qualified to provide direct supervision.
- If the medical director has not been delegated authority by the medical staff to approve P&Ps, protocols, order sets, and staff qualifications, it will also need to be approved by the medical staff.
- Review how the appropriate staffing is determined and applied for respiratory care services.
- Audit personnel files for respiratory care staff to determine that the qualifications, licensure (consistent with state law), education, training, and experience of personnel are met and that the job descriptions coincide with requirements outlined by the medical director/medical staff.
- Ensure P&Ps addressing the following are in place: equipment operation and respective PMs/calibration; 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 patients; cardiopulmonary resuscitation; pulmonary function testing; therapeutic percussion and vibration; broncho-pulmonary drainage; mechanical ventilatory and oxygenation support; aerosol, humidification, and therapeutic gas administration; storage, access, control, administration of medications, and medication errors; and procedures for obtaining and analyzing blood samples (e.g., arterial blood gases).

Suggested Documents:

- Scope of service and organizational chart for respiratory care services
- Job descriptions and competencies for medical director and respiratory care services personnel
- Respiratory P&Ps as specified by CMS and authorized by medical staff
- Medical staff credentials files
- Staffing matrices, assignments/logs
- Patients' care plans

§482.57 *CoP*: Respiratory Services		
Tag #	CMS *CoP* (2023)	CMS Interpretive Guidelines and Survey Procedures
A-1160	**(b) Standard: Delivery of services—** Services must be delivered in accordance with medical staff directives.	*See Interpretive Guidelines for §482.57(b)* SOM Appendix A (cms.gov) eCFR :: 42 CFR 482.57 -- Condition of participation: Respiratory care services.
A-1161	(1) Personnel qualified to perform specific procedures and the amount of supervision required for personnel to carry out specific procedures must be designated in writing.	*See Interpretive Guidelines for §482.57(b)(1)* *See Survey Procedures for §482.57(b)(1)* SOM Appendix A (cms.gov) eCFR :: 42 CFR 482.57 -- Condition of participation: Respiratory care services.
A-1162	(2) 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 §482.27.	*See Interpretive Guidelines for §482.57(b)(2)* SOM Appendix A (cms.gov) eCFR :: 42 CFR 482.57 -- Condition of participation: Respiratory care services.
A-1163	(3) Services must only be provided under the orders of a qualified and licensed practitioner who is responsible for the care of the patient, acting within his or her scope of practice under state law, and who is authorized by the hospital's medical staff to order the services in accordance with hospital P&Ps and state laws.	*See Interpretive Guidelines for §482.57(b)(3)* *See Survey Procedures for §482.57(b)(3)* SOM Appendix A (cms.gov) eCFR :: 42 CFR 482.57 -- Condition of participation: Respiratory care services.
A-1164	(4) All respiratory care services orders must be documented in the patient's medical record in accordance with the requirements at §482.24.	*See Interpretive Guidelines for §482.57(b)(4)* *See Survey Procedures for §482.57(b)(4)* SOM Appendix A (cms.gov) eCFR :: 42 CFR 482.57 -- Condition of participation: Respiratory care services.

Related Joint Commission Standards

Human Resources:

- HR.01.01.01, EP 1
- HR.01.06.01, EP 1

Leadership:

- LD.04.01.07, EP 1
- LD.04.04.01, EP 1

Medical Staff:

- MS.01.01.01, EP 36

Provision of Care, Treatment, and Services:

- PC.02.01.03, EP 1, 7

Record of Care, Treatment, and Services:

- RC.02.01.01, EP 2

Related DNV Standards

Organization

- RC.1 (SR.3)

Policies or Protocols

- RC.3 Introduction
- RC.3 (SR.1)
- RC.3 (SR.1a)
- RC.3 (SR.1b)
- RC.3 (SR.1c)

Tests Outside the Laboratory

- RC.4 (SR.1)

Orders for Treatment and Interventions

- RC.2 (SR.1)
- RC.2 (SR.2)

Related ACHC Standards

Respiratory Care:

- 17.00.04
- 17.00.05
- 17.00.06

- 17.00.07
- 17.00.08

Related CIHQ Standards

Respiratory Services:

- RT-1

§482.57 (b) *CoP* Analysis/Guidelines

Same as §482.57(a) *CoP* Analysis/Guidelines.

§482.58 *CoP*: Special Requirements for Hospital Providers of Long-Term Care Services ("Swing Beds")		
Tag #	CMS *CoP* (2023)	CMS Interpretive Guidelines and Survey Procedures
A-1500	A hospital that has a Medicare provider agreement must meet the following requirements in order to be granted an approval from CMS to provide post-hospital extended care services, as specified in §409.30 of this chapter, and be reimbursed as a swing-bed hospital, as specified in §413.114 of this chapter.	*See Interpretive Guidelines for §482.58* *SOM - Appendix PP (cms.gov)* *eCFR :: 42 CFR 482.58 -- Special requirements for hospital providers of long-term care services ("swing-beds").*
A-1501	**(a) Eligibility.** A hospital must meet the following eligibility requirements: (1) 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 this chapter). (2) 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. (3) The hospital does not have in effect a 24-hour nursing waiver granted under §488.54(c) of this chapter. (4) The hospital has not had a swing-bed approval terminated within the two years previous to application.	*See Interpretive Guidelines for §482.58(a)* *See Survey Procedures for §482.58(a)* *SOM - Appendix PP (cms.gov)* *eCFR :: 42 CFR 482.58 -- Special requirements for hospital providers of long-term care services ("swing-beds").*
A-1562	**(b) Skilled nursing facility services.** The facility is substantially in compliance with the following skilled nursing facility requirements contained in Subpart B of part 483 of this chapter §482.58(b)(1) Resident rights (§483.10(b)(7), (c)(1), (c)(2)(iii), (c)(6), (d), (e)(2), and (4), (f)(4)(ii) and (iii), (h), (g)(8) and (17), and (g)(18) introductory text of this chapter).	*See Interpretive Guidelines for §482.58(b)(1)* *See Survey Procedures for §482.58(b)(1)* *SOM - Appendix PP (cms.gov)* *eCFR :: 42 CFR 482.58 -- Special requirements for hospital providers of long-term care services ("swing-beds").*

A-1564	(b)(2) Admission, transfer, and discharge rights (§483.5 definition of transfer and discharge)	*See Interpretive Guidelines for §482.58(b)(2)* *See Survey Procedures for §482.58(b)(2)* *SOM - Appendix PP (cms.gov)* *eCFR :: 42 CFR 482.58 -- Special requirements for hospital providers of long-term care services ("swing-beds").*
A-1566	(b)(3) Freedom from abuse, neglect, and exploitation	*See Interpretive Guidelines for §482.58(b)(3)* *See Survey Procedures for §482.58(b)(3)* *SOM - Appendix PP (cms.gov)* *eCFR :: 42 CFR 482.58 -- Special requirements for hospital providers of long-term care services ("swing-beds").*
A-1567	(b)(4) Social services (§483.40(d) of this chapter). • §483.40(d): The facility must provide medically-related social services to attain or maintain the highest practicable physical, mental and psychosocial well-being of each resident.	*See Interpretive Guidelines for §482.58(b)(4)* *See Survey Procedures for §482.58(b)(4)* *SOM - Appendix PP (cms.gov)* *eCFR :: 42 CFR 482.58 -- Special requirements for hospital providers of long-term care services ("swing-beds").*
A-1568	(b)(4) Patient activities (§483.24(c)) (c):Activities (1) The facility must provide, based on the comprehensive assessment and care plan and the preferences of each resident, an ongoing program to support residents in their choice of activities, both facility-sponsored group and individual activities and independent activities, designed to meet the interests of and support the physical, mental, and psychosocial well-being of each resident, encouraging both independence and interaction in the community. (2) The activities program must be directed by a qualified professional who is a qualified therapeutic recreation specialist or an activities professional who— (i) Is licensed or registered, if applicable, by the State in which practicing; and	*See Interpretive Guidelines for §482.58(b)(4)* *See Survey Procedures for §482.58(b)(4)* *SOM - Appendix PP (cms.gov)* *eCFR :: 42 CFR 482.58 -- Special requirements for hospital providers of long-term care services ("swing-beds").*

	(ii) Is: (A) Eligible for certification as a therapeutic recreation specialist or as an activities professional by a recognized accrediting body on or after October 1, 1990; or (B) Has 2 years of experience in a social or recreational program within the last 5 years, one of which was full-time in a therapeutic activities program; or (C) Is a qualified occupational therapist or occupational therapy assistant; or (D) Has completed a training course approved by the State.	
A-1569	(b)(5) Discharge summary (§483.20(l)) [Note: The regulations at §483.20(l) setting forth the requirements for a nursing home resident discharge summary was revised and re-designated as §483.21(c)(2) in 2016 (81 *FR* 68858, Oct. 4, 2016) which provides, "When the facility anticipates discharge a resident must have a discharge summary that includes, but is not limited to: (i) A recapitulation of the resident's stay that includes, but is not limited to, diagnoses, course of illness/treatment or therapy, and pertinent lab, radiology, and consultation results. (ii) A final summary of the resident's status to include items in paragraph (b)(2) of§483.20, at the time of the discharge that is available for release to authorized persons and agencies, with the consent of the resident or legal representative. (iii) Reconciliation of all pre-discharge medications with the resident's post-discharge medications (both prescribed and over-the-counter). (iv) A post-discharge plan of care that is developed with the participation of the resident and, with the resident's consent, the resident representative(s), which will assist the resident to adjust to his or her new living environment. The post-discharge plan of care must indicate where the individual plans to reside, any arrangements that have been made for the resident's follow up care and any post-discharge medical and non-medical services."]	*See Interpretive Guidelines for §482.58(b)(5)* *SOM - Appendix PP (cms.gov)* *eCFR :: 42 CFR 482.58 -- Special requirements for hospital providers of long-term care services ("swing-beds").*

A-1570	(b)(5) Social services (§483.40(d) and 483.70(p)) • §483.40 (d): The facility must provide medically-related social services to attain or maintain the highest practicable physical, mental and psychosocial well-being of each resident. • §483.70 (p): Social worker. Any facility with more than 120 beds must employ a qualified social worker on a full-time basis. A qualified social worker is: (1) An individual with a minimum of a bachelor's degree in social work or a bachelor's degree in a human services field including, but not limited to, sociology, gerontology, special education, rehabilitation counseling, and psychology; and (2) One year of supervised social work experience in a health care setting working directly with individuals	*See Interpretive Guidelines for §482.58(b)(5)* *See Survey Procedures for §482.58(b)(5)* *SOM - Appendix PP (cms.gov)* *eCFR :: 42 CFR 482.58 -- Special requirements for hospital providers of long-term care services ("swing-beds").*
A-1572	(b)(6) Discharge planning (§483.20(e)) • §483.20(e) Coordination. A facility must coordinate assessments with the preadmission screening and resident review (PASARR) program under Medicaid in Subpart C of this part to the maximum extent practicable to avoid duplicative testing and effort. Coordination includes— (1) Incorporating the recommendations from the PASARR level II determination and the PASARR evaluation report into a resident's assessment, care planning, and transitions of care. (2) Referring all level II residents and all residents with newly evident or possible serious mental disorder, intellectual disability, or a related condition for level II resident review upon a significant change in status assessment	*See Interpretive Guidelines for §482.58(b)(6)* *See Survey Procedures for §482.58(b)(6)* *SOM - Appendix PP (cms.gov)* *eCFR :: 42 CFR 482.58 -- Special requirements for hospital providers of long-term care services ("swing-beds").*

A-1573	(b)(7) Dental services (§483.55(a)(2), (3), (4), and (5) and (b) of this chapter) • §483.55 Dental services. The facility must assist residents in obtaining routine and 24- hour emergency dental care. (a) Skilled nursing facilities. A facility… (2) May charge a Medicare resident an additional amount for routine and emergency dental services; (3) Must have a policy identifying those circumstances when the loss or damage of dentures is the facility's responsibility and may not charge a resident for the loss or damage of dentures determined in accordance with facility policy to be the facility's responsibility; (4) Must if necessary or if requested, assist the resident— (i) In making appointments; and (ii) By arranging for transportation to and from the dental services location; and (5) Must promptly, within 3 days, refer residents with lost or damaged dentures for dental services. If a referral does not occur within 3 days, the facility must provide documentation of what they did to ensure the resident could still eat and drink adequately while awaiting dental services and the extenuating circumstances that led to the delay. (b) Nursing facilities. The facility (1) Must provide or obtain from an outside resource, in accordance with §483.70(g), the following dental services to meet the needs of each resident: (i) Routine dental services (to the extent covered under the State plan); and (ii) Emergency dental services;	*See Interpretive Guidelines for §482.58 and §482.58(b)* *SOM - Appendix PP (cms.gov)* *eCFR :: 42 CFR 482.58 -- Special requirements for hospital providers of long-term care services ("swing-beds").*

A-1573 *(cont.)*	(2) Must, if necessary or if requested, assist the resident— (i) In making appointments; and (ii) By arranging for transportation to and from the dental services locations; (3) Must promptly, within 3 days, refer residents with lost or damaged dentures for dental services. If a referral does not occur within 3 days, the facility must provide documentation of what they did to ensure the resident could still eat and drink adequately while awaiting dental services and the extenuating circumstances that led to the delay; (4) Must have a policy identifying those circumstances when the loss or damage of dentures is the facility's responsibility and may not charge a resident for the loss or damage of dentures determined in accordance with facility policy to be the facility's responsibility; and (5) Must assist residents who are eligible and wish to participate to apply for reimbursement of dental services as an incurred medical expense under the State plan.	
A-1574	(b)(7) Specialized rehabilitative services • §483.65(a) Provision of services. If specialized rehabilitative services such as but not limited to physical therapy, speech-language pathology, occupational therapy, respiratory therapy, and rehabilitative services for a mental disorder and intellectual disability or services of a lesser intensity as set forth at §483.120(c), are required in the resident's comprehensive plan of care, the facility must— (1) Provide the required services; or (2) In accordance with §483.70(g), obtain the required services from an outside resource that is a provider of specialized rehabilitative services and is not excluded from participating in any federal or state health care programs pursuant to section 1128 and 1156 of the Act. • §483.65(b) Qualifications. Specialized rehabilitative services must be provided under the written order of a physician by qualified personnel.	*SOM - Appendix PP (cms.gov)* *eCFR :: 42 CFR 483.65 -- Specialized rehabilitative services.* *eCFR :: 42 CFR 483.70 -- Administration.*

A-1576	(b)(8) Dental services (§483.55) Dental services. The facility must assist residents in obtaining routine and 24-hour emergency dental care. (c) Skilled nursing facilities. A facility (1) Must provide or obtain from an outside resource, in accordance with §483.70(g), routine and emergency dental services to meet the needs of each resident (2) May charge a Medicare resident an additional amount for routine and emergency dental services (3) Must have a policy identifying those circumstances when the loss or damage of dentures is the facility's responsibility and may not charge a resident for the loss or damage of dentures determined in accordance with facility policy to be the facility's responsibility (4) Must if necessary or if requested, assist the resident— (iii) In making appointments; and (iv) By arranging for transportation to and from the dental services location; and (5) Must promptly, within 3 days, refer residents with lost or damaged dentures for dental services. If a referral does not occur within 3 days, the facility must provide documentation of what they did to ensure the resident could still eat and drink adequately while awaiting dental services and the extenuating circumstances that led to the delay. (d) Nursing facilities. The facility— (1) Must provide or obtain from an outside resource, in accordance with §483.70(g), the following dental services to meet the needs of each resident: (iii) Routine dental services (to the extent covered under the State plan); and (iv) Emergency dental services	*SOM - Appendix PP (cms.gov)* *eCFR :: 42 CFR 483.55 -- Dental services.* *eCFR :: 42 CFR 483.70 -- Administration.*

	(2) Must, if necessary or if requested, assist the resident— (i) In making appointments; and (ii) By arranging for transportation to and from the dental services locations; (3) Must promptly, within 3 days, refer residents with lost or damaged dentures for dental services. If a referral does not occur within 3 days, the facility must provide documentation of what they did to ensure the resident could still eat and drink adequately while awaiting dental services and the extenuating circumstances that led to the delay; (4) Must have a policy identifying those circumstances when the loss or damage of dentures is the facility's responsibility and may not charge a resident for the loss or damage of dentures determined in accordance with facility policy to be the facility's responsibility; and (5) Must assist residents who are eligible and wish to participate to apply for reimbursement of dental services as an incurred medical expense under the State plan.	

Related Joint Commission Standards

Information Management:

- IM.02.01.01, EP 1, 3, 4

Leadership:

- LD.03.06.01, EP 2, 3
- LD.04.02.03, EP 13, 14, 16

Medical Staff:

- MS.06.01.03, EP 6

Rights and Responsibilities of the Individual:

- RI.01.01.01, EP 1, 2, 5 – 7
- RI.01.01.03, EP 1, 3
- RI.01.02.01, EP 1 – 4
- RI.01.03.05, EP 3

- RI.01.05.01, EP 1
- RI.01.06.01, EP 1
- RI.01.06.03, EP 1, 3, 5
- RI.01.06.05, EP 4, 8, 14, 15
- RI.01.06.09, EP 1
- RI.01.06.11, EP 1, 3
- RI.01.07.05, EP 1, 3, 5, 6
- RI.01.07.13, EP 1

Provision of Care, Treatment, and Services:

- PC.01.02.09, EP 7, 8, 53
- PC.01.03.01, EP 1
- PC.02.01.01, EP 1
- PC.02.01.05, EP 1
- PC.02.02.01, EP 3, 9, 10, 12, 29, 30
- PC.03.05.01, EP 1 – 5
- PC.04.01.03, EP 3, 5, 6
- PC.04.01.05, EP 1, 2
- PC.04.01.07, EP 1

Record of Care, Treatment, and Services:

- RC.01.01.01, EP 5
- RC.02.04.01, EP 1 – 3

Rights and Responsibilities of the Individual:

- RI.01.01.01, EP 5
- RI.01.01.03, EP 1
- RI.01.06.03, EP 1, 3 – 5
- RI.01.06.11, EP 3
- RI.01.07.13, EP 1

Human Resources:

- HR.01.01.01, EP 1, 18

Related DNV Standards

Facility Eligibility

- FS.2 Social Services
- SB Introduction
- SB.1 (SR.1)
- SB.1 (SB.1a)
- SB.1 (SB.1b)
- SB.1 (SB.1c)
- SB.1 (SB.1d)
- FS.2 (SR.1)
- FS.3 (SR.5)
- FS.4

Resident Rights

- RR.1
- RR.2
- RR.3
- RR.4
- RR.5
- RR.6
- RR.7
- RR.8

Admission, Transfer and Discharge

- TD.1
- TD.2
- TD.3
- TD.4
- TD.5
- TD.6

Related ACHC Standards

Swing Beds

- 32.00.00
- 32.00.01
- 32.00.02
- 32.01.01
- 32.01.02
- 32.01.03
- 32.01.04
- 32.01.05
- 32.01.06
- 32.01.08
- 32.01.09
- 32.01.10
- 32.01.12
- 32.02.02

Related CIHQ Standards

- SB-1 – SB-14
- SB-16 – SB-17

§482.58 (a–b) *CoP* Analysis/Guidelines

Same as §482.57(a) *CoP* Analysis/Guidelines.

§482.60 *CoP*: Special Provisions Applying to Psychiatric Hospitals		
Tag #	CMS *CoP* (2023)	CMS Interpretive Guidelines and Survey Procedures
A-1600	Special Provisions Applying to Psychiatric Hospitals — Psychiatric hospitals.	*See Interpretive Guidelines for §482.60* *eCFR :: 42 CFR 482.60 -- Special provisions applying to psychiatric hospitals.*
A-1601	(a) Be primarily engaged in providing, by or under the supervision of a Doctor of Medicine or osteopathy, psychiatric services for the diagnosis and treatment of mentally ill persons.	*See Interpretive Guidelines for §482.60(a)* *eCFR :: 42 CFR 482.60 -- Special provisions applying to psychiatric hospitals.*
A-1605	(b) Meet the *Conditions of Participation* specified in §§482.1 through 482.23 and §§482.25 through 482.57;	*See Interpretive Guidelines for §482.60(b)* *eCFR :: 42 CFR 482.60 -- Special provisions applying to psychiatric hospitals.*
A-1610	(c) Maintain clinical records on all patients, including records sufficient to permit CMS to determine the degree and intensity of treatment furnished to Medicare beneficiaries as specified in §482.61; and	*See Interpretive Guidelines for §482.60(c)* *eCFR :: 42 CFR 482.60 -- Special provisions applying to psychiatric hospitals.*
A-1615	(d) Meet the staffing requirements specified in §482.62.	*See Interpretive Guidelines for §482.60(d)* *eCFR :: 42 CFR 482.60 -- Special provisions applying to psychiatric hospitals.*

§482.61 *CoP*: Special Medical Records Requirements for Psychiatric Hospitals		
Tag #	CMS *CoP* (2023)	CMS Interpretive Guidelines and Survey Procedures
A-1620	The medical records maintained by a psychiatric hospital must permit determination of the degree and intensity of the treatment provided to individuals who are furnished services in the institution.	*See Interpretive Guidelines for §482.61* *eCFR :: 42 CFR 482.61 -- Condition of participation: Special medical record requirements for psychiatric hospitals.*
A-1621	(a) Standard: Development of Assessment/ Diagnostic Data Medical records must stress the psychiatric components of the record, including history of findings and treatment provided for the psychiatric condition for which the patient is hospitalized.	*eCFR :: 42 CFR 482.61 -- Condition of participation: Special medical record requirements for psychiatric hospitals.*
A-1622	(a)(1) The identification data must include the patient's legal status.	*See Interpretive Guidelines for §482.61(a)(1)* *eCFR :: 42 CFR 482.61 -- Condition of participation: Special medical record requirements for psychiatric hospitals.*
A-1623	(a)(2) A provisional or admitting diagnosis must be made on every patient at the time of admission, and must include the diagnosis of intercurrent diseases as well as the psychiatric diagnosis.	*See Interpretive Guidelines for §482.61(a)(2)* *See Survey Procedures for §482.61(a)(2)* *eCFR :: 42 CFR 482.61 -- Condition of participation: Special medical record requirements for psychiatric hospitals.*
A-1624	(a)(3) The reasons for admission must be clearly documented as stated by the patient and/or others significantly involved.	*See Interpretive Guidelines for §482.61(a)(3)* *See Survey Procedures for §482.61(a)(3)* *eCFR :: 42 CFR 482.61 -- Condition of participation: Special medical record requirements for psychiatric hospitals.*
A-1625	§482.61(a)(4) The social service records, including reports of interviews with patients, family members, and others, must provide an assessment of home plans and family attitudes, and community resource contacts as well as a social history.	*See Interpretive Guidelines for §482.61(a)(4)* *See Survey Procedures for§482.61(a)(4)* *eCFR :: 42 CFR 482.61 -- Condition of participation: Special medical record requirements for psychiatric hospitals.*

A-1626	(a)(5) When indicated, a complete neurological examination must be recorded at the time of the admission physical examination.	*See Interpretive Guidelines for §482.61(a)(5)* *See Survey Procedures for §482.61(a)(5)* *eCFR :: 42 CFR 482.61 -- Condition of participation: Special medical record requirements for psychiatric hospitals.*
A-1630	(b) Standard: Psychiatric Evaluation. Each patient must receive a psychiatric evaluation that must—	*See Interpretive Guidelines for §482.61(b)* *See Survey Procedures for §482.61(b)* *eCFR :: 42 CFR 482.61 -- Condition of participation: Special medical record requirements for psychiatric hospitals.*
A-1631	(b)(1) Be completed within 60 hours of admission;	*See Interpretive Guidelines for §482.61(b)(1)* *eCFR :: 42 CFR 482.61 -- Condition of participation: Special medical record requirements for psychiatric hospitals.*
A-1632	(b)(2) Include a medical history	*See Interpretive Guidelines for §482.61(b)(2)* *See Survey Procedures for §482.61(b)(2)* *eCFR :: 42 CFR 482.61 -- Condition of participation: Special medical record requirements for psychiatric hospitals.*
A-1633	(b)(3) Contain a record of mental status;	*See Interpretive Guidelines for §482.61(b)(3)* *eCFR :: 42 CFR 482.61 -- Condition of participation: Special medical record requirements for psychiatric hospitals.*
A-1634	(b)(4) Note the onset of illness and the circumstances leading to admission;	*See Interpretive Guidelines for §482.61(b)(4)* *See Survey Procedures for §482.61(b)(4)* *eCFR :: 42 CFR 482.61 -- Condition of participation: Special medical record requirements for psychiatric hospitals.*
A-1635	(b)(5) Describe attitudes and behavior;	*See Interpretive Guidelines for §482.61(b)(5)* *eCFR :: 42 CFR 482.61 -- Condition of participation: Special medical record requirements for psychiatric hospitals.*

A-1636	(b)(6) Estimate intellectual functioning, memory functioning and orientation; and	*See Interpretive Guidelines for §482.61(b)(6)* *eCFR :: 42 CFR 482.61 -- Condition of participation: Special medical record requirements for psychiatric hospitals.*
A-1637	(b)(7) Include an inventory of the patient's assets in descriptive, not interpretive fashion.	*See Interpretive Guidelines for §482.61(b)(7)* *eCFR :: 42 CFR 482.61 -- Condition of participation: Special medical record requirements for psychiatric hospitals.*
A-1640	(c)(1) Standard Treatment Plan. Each patient must have an individualized, comprehensive treatment plan based on an inventory of the patient's strengths and disabilities.	*See Interpretive Guidelines for §482.61(c)(1)* *See Survey Procedures for §482.61(c)(1)* *eCFR :: 42 CFR 482.61 -- Condition of participation: Special medical record requirements for psychiatric hospitals.*
A-1641	(c)(1)(i) The written plan must include—A substantiated diagnosis;	*See Interpretive Guidelines for §482.61(c)(1)(i)* *See Survey Procedures for §482.61(c)(1)(i)* *eCFR :: 42 CFR 482.61 -- Condition of participation: Special medical record requirements for psychiatric hospitals.*
A-1642	(c)(1)(ii) Short-term and long-range goals;	*See Interpretive Guidelines for §482.61(c)(1)(ii)* *See Survey Procedures for §482.61(c)(1)(ii)* *eCFR :: 42 CFR 482.61 -- Condition of participation: Special medical record requirements for psychiatric hospitals.*
A-1643	(c)(1)(iii) The specific treatment modalities utilized;	*See Interpretive Guidelines for §482.61(c)(1)(iii)* *See Survey Procedures for §482.61(c)(1)(iii)* *eCFR :: 42 CFR 482.61 -- Condition of participation: Special medical record requirements for psychiatric hospitals.*

A-1644	(c)(1)(iv) The responsibilities of each member of the treatment team; and	*See Interpretive Guidelines for §482.61(c)(1)(iv)* *See Survey Procedures for §482.61(c)(1)(iv)* *eCFR :: 42 CFR 482.61 -- Condition of participation: Special medical record requirements for psychiatric hospitals.*
A-1645	(c)(1)(v) Adequate documentation to justify the diagnosis and the treatment and rehabilitation activities carried out.	*See Interpretive Guidelines for §482.61(c)(1)(v)* *See Survey Procedures for §482.61(c)(1)(v)* *eCFR :: 42 CFR 482.61 -- Condition of participation: Special medical record requirements for psychiatric hospitals.*
A-1650	(c)(2) The treatment received by the patient must be documented in such a way to assure that all active therapeutic efforts are included.	*See Interpretive Guidelines for §482.61(c)(2)* *See Survey Procedures for §482.61(c)(2)* *eCFR :: 42 CFR 482.61 -- Condition of participation: Special medical record requirements for psychiatric hospitals.*
A-1655	(d) Standard: Recording Progress— Progress notes must be recorded by the physician(s), psychologists, or other licensed practitioner(s) responsible for the care of the patient as specified in §482.12(c); nurse, social worker and, when appropriate, others significantly involved in active treatment modalities.	*See Interpretive Guidelines for §482.61(d)* *See Survey Procedures for §482.61(d)* *eCFR :: 42 CFR 482.61 -- Condition of participation: Special medical record requirements for psychiatric hospitals.*
A-1660	(d) . . .The frequency of progress notes is determined by the condition of the patient but must be recorded at least weekly for the first 2 months and at least once a month thereafter.	*See Interpretive Guidelines for §482.61(d)* *See Survey Procedures for §482.61(d)* *eCFR :: 42 CFR 482.61 -- Condition of participation: Special medical record requirements for psychiatric hospitals.*
A-1661	(d) . . .and must contain recommendations for revisions in the treatment plan as indicated . . .	*See Interpretive Guidelines for §482.61(d)* *See Survey Procedures for §482.61(d)* *eCFR :: 42 CFR 482.61 -- Condition of participation: Special medical record requirements for psychiatric hospitals.*

A-1662	(d) . . . as well as [must contain] a precise assessment of the patient's progress in accordance with the original or revised treatment plan.	*See Interpretive Guidelines for §482.61(d)* *See Survey Procedures for §482.61(d)* *eCFR :: 42 CFR 482.61 -- Condition of participation: Special medical record requirements for psychiatric hospitals.*
A-1670	(e) Standard: Discharge planning and discharge summary. The record of each patient who has been discharged must have a discharge summary that includes a recapitulation of the patient's hospitalization and…	*See Interpretive Guidelines for §482.61(e)* *eCFR :: 42 CFR 482.61 -- Condition of participation: Special medical record requirements for psychiatric hospitals.*
A-1671	(e) [The record of each patient who has been discharged must have a discharge summary that includes] ... recommendations from appropriate services concerning follow-up or aftercare as well as …	*See Interpretive Guidelines for §482.61(e)* *See Survey Procedures for §482.61(e)* *eCFR :: 42 CFR 482.61 -- Condition of participation: Special medical record requirements for psychiatric hospitals.*
A-1672	(e) [The record of each patient who has been discharged must have a discharge summary that includes] … a brief summary of the patient's condition on discharge.	*See Interpretive Guidelines for §482.61(e)* *eCFR :: 42 CFR 482.61 -- Condition of participation: Special medical record requirements for psychiatric hospitals.*

Related Joint Commission Standards

Leadership:

- LD.04.01.01, EP 16

Provision of Care, Treatment, and Services:

- PC.01.02.03, EP 4, 5
- PC.01.02.13, EP 1 – 7
- PC.01.03.01, EP 1, 5, 6, 22, 23, 43
- PC.02.01.01, EP 1
- PC.02.01.05, EP 1

Record of Care, Treatment, and Services:

- RC.01.01.01, EP 5
- RC.02.01.01, EP 1, 2, 7
- RC.02.04.01, EP 3

Rights and Responsibilities of the Individual:

- RI.01.04.01, EP 1

Information Management:

- IM.02.02.07, EP 2 – 5

Related DNV Standards

General Requirements

- PH-GR (SR.1)
- PH-GR (SR.1a)
- PH-GR (SR.1b)
- PH-GR (SR.1c)
- PH-GR (SR.1d)

Medical Records Service

- Introduction
- PH-MR (SR.1)
- PH-MR (SR.2)
- PH-MR (SR.3)
- PH-MR (SR.4)
- PH-MR (SR.4a)
- PH-MR (SR.4b)
- PH-MR (SR.4)
- PH-MR (SR.4c)
- PH-MR (SR.4)
- PH-MR (SR.4d)
- PH-MR (SR.4)
- PH-MR (SR.4e)
- PH-NE (SR.1)
- PH-MR (SR.4)
- PH-MR (SR.4f)

Neurological Examination

- Introduction
- PH-NE (SR.1)

Psychiatric Evaluation

- Introduction

- PH-E (SR.1)
- PH-E (SR.1a)
- PH-E (SR.2)
- PH-E (SR.2a)
- PH-E (SR.2b)
- PH-E (SR.2c)
- PH-E (SR.2d
- PH-E (SR.2e)
- PH-E (SR.2f)
- PH-E (SR.2g)

Treatment Plan

- Introduction
- PH-TP (SR.1)
- PH-TP (SR.1a)
- PH-TP (SR.1b)
- PH-TP (SR.2)
- PH-TP (SR.2a)
- PH-TP (SR.2b)
- PH-TP (SR.2c)
- PH-TP (SR.2d)
- PH-TP (SR.2e)
- PH-TP (SR.3)
- PH-TP (SR.3a)
- PH-TP (SR.4)
- PH-TP (SR.5)
- PH-TP (SR.6)
- PH-TP (SR.6a)
- PH-TP (SR.6a (1))
- PH-TP (SR.6a(2))
- PH-TP (SR.6b)
- PH-TP (SR.7)

- PH-TP (SR.7a)
- PH-TP (SR.7a(1))
- PH-TP (SR.7a(2))

Progress Notes

- Introduction
- PH-PN (SR.1)
- PH-PN (SR.1a)
- PH-PN (SR.1b)
- PH-PN (SR.2)
- PH-PN (SR.2a)
- PH-PN (SR.2b)
- PH-PN (SR.2c)
- PH-PN (SR.3)
- PH-PN (SR.3a)
- PH-PN (SR.3b)
- PH-PN (SR.4)

Discharge Planning

- (PH-DP)
- PH-DP (SR.1)
- PH-DP (SR.1a)
- PH-DP (SR.1b)
- PH-DP (SR.1c)
- PH-DP (SR.2)
- PH-DP (SR.2a)

Related ACHC Standards

None provided

Related CIHQ Standards

None provided

§482.61 *CoP* Analysis/Guidelines

***DNV/NIAHO 20.1 Appendix B: Standards for Psychiatric Hospitals was added in 2021.**

*These standards apply to freestanding psychiatric hospitals, not to hospital-based units.

§482.62 *CoP*: Special Staff Requirements for Psychiatric Hospitals		
Tag #	CMS *CoP* (2023)	CMS Interpretive Guidelines and Survey Procedures
A-1680	The hospital must have adequate numbers of qualified professional and supportive staff to evaluate patients, formulate written, individualized comprehensive treatment plans, provide active treatment measures and engage in discharge planning.	*See Interpretive Guidelines for §482.62* *See Survey Procedures for §482.62* *eCFR :: 42 CFR 482.62 -- Condition of participation: Special staff requirements for psychiatric hospitals.*
A-1685	(1) Standard: Personnel. The hospital must employ or undertake to provide adequate numbers of qualified professional, technical, and consultative personnel to: (1) Evaluate Patients.	*See Interpretive Guidelines for §482.57(b)(1)* *See Survey Procedures for §482.57(b)(1)* *eCFR :: 42 CFR 482.62 -- Condition of participation: Special staff requirements for psychiatric hospitals.*
A-1686	The hospital must employ or undertake to provide adequate numbers of qualified professional, technical, and consultative personnel to:] (2) Formulate written individualized, comprehensive treatment plans	*See Interpretive Guidelines for §482.62(a)(2)* *See Survey Procedures for §482.62(a)(2)* *eCFR :: 42 CFR 482.62 -- Condition of participation: Special staff requirements for psychiatric hospitals.*
A-1687	[The hospital must employ or undertake to provide adequate numbers of qualified professional, technical, and consultative personnel to:] (3) Provide active treatment measures; and	*See Interpretive Guidelines for §482.62(a)(3)* *See Survey Procedures for §482.62(a)(3)* *eCFR :: 42 CFR 482.62 -- Condition of participation: Special staff requirements for psychiatric hospitals.*
A-1688	[The hospital must employ or undertake to provide adequate numbers of qualified professional, technical, and consultative personnel to:] (1) Engage in discharge planning.	*See Interpretive Guidelines for §482.62(a)(4)* *See Survey Procedures for §482.62(a)(4)* *eCFR :: 42 CFR 482.62 -- Condition of participation: Special staff requirements for psychiatric hospitals.*
A-1690	(b) Standard: Director of inpatient psychiatric services; medical staff. Inpatient psychiatric services must be under the supervision of a clinical director, service chief, or equivalent who is qualified to provide the leadership required for an intensive treatment program…	*See Interpretive Guidelines for §482.62(b)* *See Survey Procedures for §482.62(b)* *eCFR :: 42 CFR 482.62 -- Condition of participation: Special staff requirements for psychiatric hospitals.*

A-1691	(b) The number and qualifications of Doctor of Medicine and osteopathy must be adequate to provide essential psychiatric services.	*See Interpretive Guidelines for §482.62(b)* *See Survey Procedures for §482.62(b)* *eCFR :: 42 CFR 482.62 -- Condition of participation: Special staff requirements for psychiatric hospitals.*
A-1692	1. 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.	*See Interpretive Guidelines for §482.62(b)(1)* *See Survey Procedures for §482.62(b)(1)* *eCFR :: 42 CFR 482.62 -- Condition of participation: Special staff requirements for psychiatric hospitals.*
A-1693	2. The director must monitor and evaluate the quality and appropriateness of services and treatment provided by the medical staff.	*See Interpretive Guidelines for §482.62(b)(2)* *See Survey Procedures for §482.62(b)(2)* *eCFR :: 42 CFR 482.62 -- Condition of participation: Special staff requirements for psychiatric hospitals.*
A-1695	(c) Standard: Availability of medical personnel. Doctors of medicine or osteopathy and other appropriate professional personnel must be available to provide necessary medical and surgical diagnostic and treatment services. If medical and surgical diagnostic services and treatment are not available within the 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	*See Interpretive Guidelines for §482.62(c)* *See Survey Procedures for §482.62(c)* *eCFR :: 42 CFR 482.62 -- Condition of participation: Special staff requirements for psychiatric hospitals.*
A-1700	(d) Standard: Nursing services. The hospital or unit 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 patient's active treatment program and to maintain progress notes on each patient.	*See Interpretive Guidelines for §482.62(d)* *See Survey Procedures for §482.62(d)* *eCFR :: 42 CFR 482.62 -- Condition of participation: Special staff requirements for psychiatric hospitals.*

A-1701	(1) 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 ...	*See Interpretive Guidelines for §482.62(d)(1)* *See Survey Procedures for §482.62(d)(1)* *eCFR :: 42 CFR 482.62 -- Condition of participation: Special staff requirements for psychiatric hospitals.*
A-1702	... 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.	*See Interpretive Guidelines for §482.62(d)(1)* *eCFR :: 42 CFR 482.62 -- Condition of participation: Special staff requirements for psychiatric hospitals.*
A-1703	(d)(2) The staffing pattern must ensure the availability of a registered nurse 24 hours each day ...	*See Interpretive Guidelines for §482.62(d)(2)* *eCFR :: 42 CFR 482.62 -- Condition of participation: Special staff requirements for psychiatric hospitals.*
A-1704	(d)(2) ... There must be adequate numbers of registered nurses, licensed practical nurses, and mental health workers to provide the nursing care necessary under each patient's active treatment program.	*See Interpretive Guidelines for §482.62(d)(2)* *See Survey Procedures for §482.62(d)(2)* *eCFR :: 42 CFR 482.62 -- Condition of participation: Special staff requirements for psychiatric hospitals.*
A-1710	e. Standard: Psychological Services. The hospital must provide or have available psychological services to meet the needs of the patients	*See Interpretive Guidelines for §482.62(e)* *See Survey Procedures for §482.62(e)* *eCFR :: 42 CFR 482.62 -- Condition of participation: Special staff requirements for psychiatric hospitals.*
A-1715	f. Standard: Social Services. 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	*See Interpretive Guidelines for §482.62(f)* *See Survey Procedures for §482.62(f)* *eCFR :: 42 CFR 482.62 -- Condition of participation: Special staff requirements for psychiatric hospitals.*

A-1716	f. 1. The director of the social work department or service must have a master's degree from an accredited school of social work or must be qualified by education and experience in the social services needs of the mentally ill. If the director does not hold a master's degree in social work, at least one staff member must have this qualification.	*See Interpretive Guidelines for §482.62(f)(1)* *See Survey Procedures for §482.62(f)(1)* *eCFR :: 42 CFR 482.62 -- Condition of participation: Special staff requirements for psychiatric hospitals.*
A-1717	f. 2. 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.	*See Interpretive Guidelines for §482.62(f)(2)* *See Survey Procedures for §482.62(f)(2)* *eCFR :: 42 CFR 482.62 -- Condition of participation: Special staff requirements for psychiatric hospitals.*
A-1720	g. Standard: Therapeutic Activities The hospital must provide a therapeutic activities program.	*See Interpretive Guidelines for §482.62(g)* *eCFR :: 42 CFR 482.62 -- Condition of participation: Special staff requirements for psychiatric hospitals.*
A-1725	g. 1. The program must be appropriate to the needs and interests of patients and be directed toward restoring and maintaining optimal levels of physical and psychosocial functioning	*See Interpretive Guidelines for §482.62(g)(1)* *eCFR :: 42 CFR 482.62 -- Condition of participation: Special staff requirements for psychiatric hospitals.*
A-1726	g. 2. The number of qualified therapists, support personnel, and consultants must be adequate to provide comprehensive therapeutic activities consistent with each patient's active treatment program.	*See Interpretive Guidelines for §482.62(g)(2)* *See Survey Procedures for §482.62(g)(2)* *eCFR :: 42 CFR 482.62 -- Condition of participation: Special staff requirements for psychiatric hospitals.*

Related Joint Commission Standards

Leadership:

- LD.03.03.01, EP 1, 2
- LD.03.06.01, EP 2, 3
- LD.04.01.05, EP 2, 3, 10
- LD.04.01.07, EP 1
- LD.04.03.01, EP 1, 14
- LD.04.03.09, EP 2

Provision of Care, Treatment, and Services:

- PC.01.02.15, EP 2
- PC.01.03.01, EP 1, 5, 22, 23
- PC.02.01.01, EP 1
- PC.04.01.01, EP 1
- PC.04.01.03, PC 1 – 3
- PC.04.01.05, EP 1, 3
- PC.04.04.03, EP 1 – 3

Medical Staff:

- MS.01.01.01, EP 36
- MS.03.01.03, EP 1, 3, 4, 12
- MS.05.01.01, EP 2, 7, 8
- MS.06.01.03, EP 7

Nursing:

- NR.02.03.01, EP 3, 4

Human Resources:

- HR.01.01.01, EP 30, 31

Related DNV Standards

Introduction:

- PH-PR (SR.1)
- PH-PR (SR.1a)
- PH-PR (SR.1b)
- PH-PR (SR.1c)
- PH-PR (SR.1d)

Medical Staff:

- PH-MS (SR.1)
- PH-MS (SR.1a)
- PH-MS (SR.1b)
- PH-MS (SR.2)
- PH-MS (SR.2a)
- PH-MS (SR.2b)

- PH-MS (SR.2c)
- PH-MS (SR.2d)
- PH-MS (SR.3)
- PH-MS (SR.4)
- PH-MS (SR.5)
- PH-MS (SR.5a)

Nursing Services

- PH-NS (SR.1)
- PH-NS (SR.1a)
- PH-NS (SR.1b)
- PH-NS (SR.2)
- PH-NS (SR.2a)

Psychological Services

- PH-PS (SR.1)

Social Work Services

- Introduction
- PH-SS (SR.1)
- PH-SS (SR.1a)
- PH-SS (SR.1b)
- PH-SS (SR.2)
- PH-SS (SR.2a)
- PH-SS (SR.2a(1))
- PH-SS (SR.3)
- PH-SS (SR.3a)
- PH-SS (SR.4)
- PH-SS (SR.5)
- PH-SS (SR.5a)

Therapeutic Activities

- PH-TA (SR.1)
- PH-TA (SR.1a)
- PH-TA (SR.2)

- PH-TA (SR.2a)
- PH-TA (SR.3)
- PH-TA (SR.4)
- PH-TA (SR.5)

Related CIHQ Standards

None provided

§482.62 *CoP* Analysis/Guidelines

***DNV/NIAHO 20.1 Appendix B: Standards for Psychiatric Hospitals was added in 2021.**

*These standards apply to freestanding psychiatric hospitals, not to hospital-based units.

Appendix A

Comparison Element	The Joint Commission (TJC)	Center for Improvement in Healthcare Quality (CIHQ)	DNV Healthcare USA (DNV)	Accreditation Commission for Health Care (ACHC)
Hospitals Accredited	Approximately 4,168 hospitals Approximately 378 critical access hospitals TJC accredits and/or certifies more than 21,000 hospitals, critical access hospitals, ambulatory, behavioral, home care, laboratory, and nursing home organizations	Approximately 132 hospitals	Approximately 610 acute care hospitals, critical access hospitals, psychiatric hospitals	Approximately 130 hospitals ACHC accredits more than 24,000 healthcare organizations nationwide
Centers for Medicare & Medicaid Services (CMS)– Deemed Authority	Accredited by CMS	Accredited by CMS	Accredited by CMS	Accredited by CMS
Alignment with *Conditions of Participation (CoPs)*	Meets approximately 70% of standards tied to CMS *CoP* — the rest are derived from the influence and direction of advisory groups Exceeds—patient safety and other proprietary standards New focus on high reliability and evaluating International Organization for Standardization (ISO) certification option	Most standards align with CMS *CoP*s (approximately 95% are directly linked to *CoP*s). Exceeds—developed additional standards that address additional areas of patient safety and quality care.	Directly tied to CMS *CoPs* (approximately 80% directly linked to *CoPs*); some discretionary standards Exceeds—ISO/performance improvement foundation The survey process supports CMS' quality initiatives with a focus on continual improvement prioritized by the organization	ACHC standards closely align with the CMS *CoP*. Approximately 90% of standards crosswalk to a CFR. Standards create a framework for continuous quality improvement without the need for additional requirements.

Accreditation Cycle/Survey Frequency	18–36-month accreditation cycle—unannounced	Three years—unannounced Mid-survey scale—16–20 months after last triennial survey; focus is on new/revised patient care processes—unannounced	3-year accreditation but also conduct on-site annual survey; all unannounced Can achieve accreditation without being ISO certified but must become ISO compliant or certified within 3 years of initial accreditation. A series of annual surveys roughly follow this timeline: • Year 1 – NIAHO® accreditation and high-level introduction to ISO 9001. • Year 2 – NIAHO® accreditation and ISO 9001 pre-assessment survey (much like a mock survey, the pre-assessment survey measures readiness and identifies any gaps in compliance with ISO). • Year 3 – NIAHO® accreditation and stage one ISO 9001 surveys (to confirm hospital readiness for an ISO 9001 Compliance/ Certification Audit). • Year 4 – NIAHO® accreditation and ISO 9001 compliance/ certification audit. ISO 9001	3-year accreditation cycle. Customers can expect a renewal survey within 180 days of their expiration date. Additional scheduled check-ins are available based on customer preference.

			compliance is a requirement for DNV Healthcare accreditation. ISO 9001 certification is not a requirement. • Year 5 – NIAHO® accreditation and ISO 9001 periodic audit. • Year 6 – NIAHO® accreditation and ISO 9001 periodic audit.	
Surveyor Complement	Clinical, administrative, and life safety engineer Administrative surveyor—some surveys	Two to four surveyors, including administrative (at least one registered nurse [RN]) and facilities specialist	Clinical surveyor (physician and/or RN), generalist surveyor, and physical environment surveyor Additional generalist surveyor and/or additional clinical surveyor and/or physical environment surveyor, dependent on the scope and complexity of the organization All have DNV ISO 9001 lead auditor training	Clinical, administrative, and life safety specialists. Survey team size and specialties are determined by the scope and complexity of the organization being reviewed.

Survey Methodology	Tracer methodology, including system tracers throughout the organization for compliance and high-risk areas, such as lab integration, patient flow, and suicide prevention Include: • Staff, MD, patient/family interviews • Formal system interviews—data management, infection control, medication management, competence assessment, medical staff, and leadership • Medical record review— closed and open • Medical staff and human resources (HR) file review • Building tour/inspection	Closely follow CMS *Conditions of Participation* and other industry-set standards (i.e., NFPA, CDC, etc.). Activities include: • Building tour/inspection • Staff, MD, patient/family interviews • Emergency preparedness • Review of medical & utilities equipment • Facilities and life safety • Medical record review—closed and open • Medical staff credentialing & privileging review • Focused assessments • Tour of patient care areas as appropriate	Tracer methodology Include: • Staff, MD, patient/family interviews • Observation of care, including surgery and procedures, dressing changes, med pass, sterile processing, EVS, environmental cleaning, etc. • Formal system interviews for system surveys—medication management, medical staff, leadership, quality management, and infection control, to name a few • Formal system interviews for hospitals accredited and or surveyed as a system • Medical record review • Medical staff and HR file review • Building tour/inspection	Education-based approach to the survey. Evidence of compliance is established by direct observation, interview, and/or document review by surveyors assigned to areas of focus based on subject matter expertise. Activities include: • Building/department tour • Medical staff, personnel, and patient interviews • Document review: ○ Policies and procedures ○ Personnel and credentialing files ○ Committee meeting minutes ○ Medical records (open and closed) ○ Maintenance and inspection logs

Structure of Standards	18 chapters; do not coincide with section names in CMS but do with departments/ functions within a hospital Prescriptive standards yet more consistent application by surveyors Have improved frequency of revisions; recent focus to reduce standards that are not value-based; provide an opportunity for field review prior to publication Scoring— • Use Survey Analysis For Evaluating Risk (SAFER) methodology. Noncompliant scoring is evaluated based on the likelihood of harm (low, moderate, high) and the scope of the problem (limited, pattern, or widespread). Surveyor reports are aggregated into a grid and enable leaders to grasp risks and priorities at a glance. The horizontal axis of the grid shows the scope of the	Less prescriptive standards but have processes to improve consistently application by surveyors Infrequent changes unless CMS alignment is required; no field review component prior to publication of new standards Scoring— • Compliant or non-compliant • Noncompliant findings are scored at the standard level, at the condition level, or as an immediate threat to health or safety	24 chapters; most of the chapter names coincide with the section names in the CMS *CoP*s or departments/ functions within a hospital. Contains additional chapters for swing beds in both acute care and critical access, an appendix for psychiatric hospitals, and standards for Pennsylvania hospitals deeming authority. Standard changes are either mandatory or discretionary. • Mandatory changes occur when NIAHO® standards are altered to conform to a change in the CMS *CoP*s. • Discretionary changes clarify existing standards or incorporate practices and principles to enhance the NIAHO® accreditation program. Such changes occur through a thorough review process, involving input from the field and applicable agencies	31 chapters aligned with the CMS requirements For each requirement, ACHC identifies: **1. Standard:** The requirement to be met. Where applicable, Medicare conditions and standards are indicated by the CFR reference (§482.xx, §483.xx, §485.xx) immediately after the requirement. **2. Required Elements/ Additional Explanation** Describes the intent of the standard and when the standard comes from the *CoP*, supplementary detail is often taken directly from CMS Interpretive Guidelines in the State Operations Manual (SOM). **3. Scoring Procedure** Identifies what and how surveyors will review to assess compliance.

	problem identified and whether it is limited, patterned, or widespread. The vertical axis of the grid shows the likelihood of harm and whether it is low, moderate, or high • Corrective actions are required for all areas of finding		and review by DNV GL's accreditation management team Less prescriptive standards but have processes to improve the consistent application by surveyors Infrequent changes unless CMS alignment is required; opportunity to provide feedback on proposed changes Scoring— • Nonconformity Level 1 – major nonconformance • Nonconformity Level 1 – condition level – Major nonconformance with a follow-up survey required • Nonconformity Level 2 – minor nonconformance Immediate jeopardy as defined by CMS No aggregate "scoring" but there are requirements for *CoP* to address nonconformities	

Corrective Actions	Submission of Evidence of Standards Compliance is due within 60 days unless immediate threat to health and safety. Must be compliant with deficiencies at the time of submission.	As with CMS surveys, must submit corrective action plan (CAP) within 10 calendar days. Expectation is that whenever possible, corrective action has already occurred by the time the corrective action plan is submitted. **Implementation Timelines:** An immediate threat to health and safety deficiency requires a CAP within 72 hours of determination. Condition level deficiency: Cap not to exceed 45 days. Standard deficiency: CAP not to exceed 60 days (A time limit waiver can be re-quested for some deficiencies related to code violations)	As with CMS surveys, must submit a corrective action plan within 10 calendar days; must implement the corrective action within 60 days. For NC 1 Level nonconformities: objective evidence that the CAP is implemented and improvement is occurring within 60 days of the acceptance of the CAP.	Per CMS requirement, a corrective action plan must be submitted within 10 calendar days of the last survey day. Plans of correction must have an estimated compliance date within 60 days of the last day of the survey.
Other Monitoring	Have had Intracycle Monitoring and Focused Standards Assessment (FSA) options to assist with continuous compliance efforts. In June 2019, TJC announced it was suspending APR.03.01.01, the standard requiring the FSA. For-cause surveys *CoP* follow-up surveys	Focused surveys— Unannounced: • Mid-cycle survey • Complaint surveys • *CoP* follow-up surveys	Annual survey Follow-up surveys For cause/ complaint surveys Special surveys Psychiatric hospital accreditation program (for freestanding psychiatric hospitals)	Dependent Survey: A re-survey conducted for a deemed status organization that was not in compliance with the CMS *CoP*s as identified during an initial or Renewal survey. Dependent Surveys are unannounced. Focused Survey: Conducted to ensure ongoing and continued compliance with ACHC accreditation standards

	Submit four-month Measure of Success for some standard findings Submission of ORYX data		State deeming authority for Pennsylvania hospitals	or subsequent to organizational changes. Extension Survey: Performed when an accredited organization undergoes significant change outside of the regular application and survey cycle. For example, a major renovation of patient care areas, the acquisition of a new building, or the addition of a new service. Complaint Survey: Conducted following initial investigation of a complaint when necessary to determine if the complaint is substantiated. Disciplinary Action Survey: Conducted for noncompliance with previous survey results.
Appeals	Special issue resolution offered daily during the survey May appeal accreditation decisions Preliminary denial of accreditation – may appeal in writing within five business days of being notified.	A two-level appeal processes. The first level: For the validity of a deficiency hospital must notify CIHQ in writing within 5 calendar days following receipt of the report. For an accreditation decision, the hospital must notify CIHQ in writing within 10 business days following the issuance of the decision.	Daily opening and closing sessions that allow discussion and presentation of additional evidence for discrepancy resolution. May appeal nonconformities and accreditation decisions.	Issues or disputes should be brought to the team leader or the organization's account advisor while the survey is underway. Deficiency dispute: the organization submits a written statement to its account advisor no later than 10 calendar days from the receipt of the survey report.

	Denial of accreditation— There is no opportunity for a review or appeal.	The second-level appeal for findings can be completed if the first level is not accepted. This appeal is in writing to the CEO of CIHQ. It is then reviewed by the Accreditation Review Board (a 3-member panel).		Decision appeal: In the rare instance of a dispute related to a denial of accreditation, there is a formal appeal process.
Certifications	Offers certification programs in several categories but with separate surveys Options: • Integrated Care • Primary Care Medical Home • Patient Blood Management	CIHQ offers disease-specific certification for: • Acute stroke ready hospital • Primary stroke center • Heart failure • Joint replacement surgery • Primary heart attack center	Offers certification programs in numerous categories. Program certifications are separate surveys Certification programs include: • Primary and Comprehensive Stroke Certification • Cardiac Center of Excellence • VAD • ECMO • Advanced Heart Failure • Advanced Chest Pain • Orthopedic & Spine Center of Excellence • Advanced Hip and Knee Replacement • Advanced Shoulder Surgery Program	ACHC offers certifications to recognize excellence in specialty care including: • Stroke Certification (Stroke Ready, Primary Stroke, Thrombectomy, Comprehensive) • Joint Replacement Certification (Advanced with Distinction and Comprehensive) • Wound Care Certification (Advanced with Distinction and Comprehensive)

			• Advanced Foot and Ankle Palliative Care Program • Advanced Glycemic Management Advanced Certification in Infection Prevention • Advanced Sterile Processing Certification • Collaborative High Reliability Management Team Qualification	
Online Free Offerings	Certifications Survey Activity Guide Standards FAQs National Patient Safety Goals Pre-publication standards Surveyor insight blogs covering several topics Performance improvement resources Leading practices library with tools, forms, and policies to assist with standards compliance Core performance measure for hospitals Organizational assessment tool and website for high reliability	CIHQ Survey Activity Guide CIHQ accreditation standards CIHQ accreditation policies CIHQ accreditation FAQs Accreditation resource services CIHQ newsletter CIHQ Hospital Accreditation Division webpage Listing of CIHQ hospitals	DNV Healthcare standards NIAHO accreditation process DNV certification process Healthcare Advisory Notices DNV Healthcare email list Hospital accreditation status check Downloads for all accreditation and program standards	ACHC standards *Surveyor* –bi-annual publication featuring the Quality Review Edition, program-based review of top-cited deficiencies. Annual report Complimentary webinars on trending topics, including Accreditation 101, 102, and 103. Did You Know? – monthly newsletters for individual accreditation programs written by clinical program staff. Coffee Chat – a monthly discussion forum with ACHC subject matter experts

	Patient Safety Systems chapter E-Alerts on changing regulations or important aspects of regulation Center for Transforming Healthcare website Find a Gold Seal of Approval healthcare organization Patient safety topics and portals Infection prevention and control If you are a hospital accredited by The Joint Commission, the hospital receives: • Print version of the CAMH manual, including the fall print update. • Access to the E-dition to the Joint Commission extranet. This contains accreditation tools and resources to help prepare for survey. • The portal is the primary communication hub between TJC and the hospital.		Free open access to the Dropbox for questions on standards interpretations Education and training: • Fee based • Public and private training sessions on accreditation, implementing a quality management system, ISO, internal audits, managing infection risk, and proactive risk assessments.	Beyond the Standard – podcast featuring industry professionals Certified consultant listing – find a consultant that has a thorough understanding of ACHC's process Access to clinical and life safety staff via customer-service@achc.org (48-hour turnaround) or by virtual conference Tools and resources in ACHC's customer portals Find ACHC accredited organizations

Appendix B

Types of Surveys

Centers for Medicare and Medicaid Services (CMS)

CMS contracts state survey agencies to conduct Medicare surveys annually. Hospitals that have chosen an accreditation organization (AO) also under contract with CMS are not required to undergo annual certification surveys. Instead, they must complete a reaccreditation survey every three years.

The types of state surveys include:

- **Initial surveys:** A hospital must have an initial survey by either the state survey agency or an AO with deemed status to qualify for reimbursement for the care of Medicare beneficiaries. The initial survey will include a review of all hospital departments and will be limited to the care of patients treated since the hospital's opening. In most states, this survey will also serve as the initial survey for the applicable state hospital licensing requirement.
- **Recertification surveys:** All hospitals are subject to recertification surveys. Suppose an AO does not accredit the hospital with deemed status. In that case, state survey agencies will conduct these surveys on behalf of CMS about every three years. The actual frequency will depend on funds available to the state survey agency and other priorities.
- **Revisit surveys:** If a state survey results in the citation of multiple or serious findings, CMS will authorize a revisit to determine the correction of those deficient practices. Condition-level findings generally require confirmation of correction by a revisit survey.
- **Annual certification surveys:** These surveys are conducted yearly for non–deemed status facilities, typically within 12–15 months of the last certification survey. A review of all the *Conditions of Participation* (*CoP*) is conducted, with deficiencies cited by tag number. The hospital must complete a plan of correction for each tag noted as noncompliant.
- **Complaint survey:** Applies to all CMS-certified organizations. A complaint survey may be conducted if a patient, family member, resident, or hospital employee submits a concern or complaint to CMS or the state's department of health. For hospitals that are deemed status providers, state-level complaints/incidents are entered and forwarded to the CMS regional office for review. Surveys can be focused on the area outlined in the complaint/incident and surveyed based on state regulation or can be expanded by CMS to include some or all the *CoP*s. The statutory authority for the CMS complaint/incident process is found in Sections 1864(c) and 1865 of the Social Security Act. Regulations authorizing such surveys are found in *CFR* 488.7(a)(2). Complaints/incidents that allege immediate jeopardy are investigated immediately. Complaints/incidents triaged and determined to be non-immediate jeopardy are typically investigated within 45 days.
- **Validation surveys:** State survey agencies conduct a complete CMS survey for 3%–5% of the accredited hospitals annually for CMS. The purpose of the state survey is to validate that the findings of the AO

survey are equivalent to the findings of a CMS survey. The validation surveys are scheduled six to eight weeks after the initial survey by the applicable accreditation organization.

- **Extension surveys:** Conducted as needed based on findings of annual certification surveys or complaint/incident surveys; may also be conducted when expansions or significant organizational changes occur.

The Joint Commission (TJC)

Organizations that chose The Joint Commission as their accreditation organization must be able to provide evidence of compliance with each standard that is applicable. Organizations must demonstrate compliance with these Standards and their elements of performance (EPs). In addition, The Joint Commission uses the National Patient Safety Goals, Accreditation Participation Requirements or APRs, and performance measurement data (when applicable) to evaluate an organization's performance.

Initial survey. Conducted if:

- An organization is seeking Joint Commission accreditation for the first time
- Undergoing an initial survey for deemed status
- It has been at least four months since being denied accreditation by The Joint Commission

The accreditation will be awarded if:

- The hospital complies with all the standards at the time of the survey
- Will be added to the 2% pool that receive random unannounced validation surveys
- The hospital has enough inpatient records "to review to adequately determine compliance equal to 10% of the average daily census but not fewer than 30 inpatient records or for small general hospitals (with an average daily census of 20 patients or less), not fewer than 20 inpatient records. Specialty hospitals (such as cardiac, orthopedic, or surgical hospitals) have a minimum of 30 inpatients."
- "The organization meets parameters for the minimum amount of patients/volume of services required for organizations seeking Joint Commission accreditation for the first time, that is, 10 inpatients served, with one active at the time of the survey, if the hospital is not using Joint Commission accreditation to meet deemed status requirements. A hospital that uses Joint Commission accreditation for deemed status purposes must have two active inpatient cases at the time of survey."
  Reference: The Joint Commission CAMH Jan 2022 ACC-5.

Survey notification is one of the following three types:

1. **Unannounced:** Since 2006, The Joint Commission has conducted unannounced surveys during an organization's survey window, 18–36 months after its last Joint Commission survey. Unannounced surveys are posted by 7:30 a.m. on the day of the survey on the Joint Commission Connect extranet site. After the official notice is posted, an email notification is sent to the CEO and the primary accreditation or certification contact to advise the event has been scheduled and to review the details.

   Organizations can identify up to 15 days in their survey eligibility dates where The Joint Commission should not schedule an unannounced survey. Once submitted, the dates cannot be modified. Every effort is made to accommodate the dates provided; however, The Joint Commission may still survey the "avoid period." The only

exemptions for unannounced surveys are U.S. Department of Defense facilities, prisons, foster care programs, and very small organizations.

2. **Announced:** Thirty calendar days before the scheduled event, The Joint Commission will post the letter of introduction, the survey agenda, and the biography and picture of each surveyor assigned to conduct the event on their extranet site. Like unannounced events, the official notice will be posted on the upcoming event, followed by email notification to the CEO and primary accreditation or certification contact to advise that the event has been scheduled and to review the details.
3. **Short-Notice:** The letter of introduction, the survey agenda, and the biography and picture of each surveyor assigned to conduct the event is posted on the Joint Commission Connect extranet site. Once posted, an email notification will be sent to the CEO and the primary accreditation or certification contact, who will advise reviewing the event details. This notification is considered a courtesy notification, not an opportunity to request a new date.

Surveys that may occur during the accreditation cycle include:

- **Extension survey:** Conducted if the hospital's current accreditation is not due to expire for a minimum of nine months and one or more of the following is met:

  1. The organization began offering a new service
  2. Change in ownership or management or clinical staff
  3. Merged with another nonaccredited site or program
  4. Started services in a new location
  5. The hospital's capacity has increased by 50% or more

  Extension surveys ensure that the accreditation decision previously awarded to the hospital is still appropriate under the changed conditions. A change in accreditation decision may result based on findings during the survey.

- **For-cause survey:** Not the same as regular unannounced surveys and can occur at any time within the organization's accreditation cycle. Suppose The Joint Commission is informed that a serious patient care or patient safety issue has occurred or that information shared with The Joint Commission is not accurate or truthful.
  In that case, a for-cause survey will be conducted. A change in accreditation decision may result from findings during the survey or if the hospital does not allow The Joint Commission to conduct an unannounced or unscheduled survey. The Joint Commission will post the results of the survey on the organization's Connect extranet site.

- **Random validation of Evidence of Standards Compliance survey:** Applies to all accredited organizations. The Joint Commission randomly selects 2% of all hospitals for this type of survey. The purpose is to verify that the organization has implemented the corrective actions outlined in its Evidence of Standards Compliance (ESC).

- **Follow-up survey for a condition-level deficiency:** A follow-up survey must be conducted whenever a Medicare *CoP* is not in compliance at the time of the survey. If a condition-level deficiency is identified at the time of a new or initial hospital survey seeking a new CMS certification number (CCN), The Joint Commission cannot recommend to CMS that the hospital be made Medicare-certified. Instead, the hospital must undergo a second survey to evaluate whether it meets all Medicare requirements. When a condition-level finding is found during a survey for deemed status, The Joint Commission must conduct a Medicare deficiency follow-up within 45 days to evaluate the hospital's implementation of corrective action to demonstrate compliance with the *CoP*. If this survey is not successful in demonstrating compliance with the *CoP*, the hospital will have a second Medicare

deficiency follow-up survey within 30 days. If noncompliant with the *CoP*, CMS must be told that the organization is no longer being recommended for Medicare certification. A preliminary Denial of Accreditation decision is determined.

- ***CoP* follow-up survey:** This applies to organizations that use deemed status. The Joint Commission will not recommend CMS certification if there is a condition-level deficiency in a "new hospital" or a hospital seeking a new CCN. The hospital will be required to undergo an additional full accreditation survey. A change in accreditation decision may result based on findings during the survey if surveyors find that an organization is not in compliance with the CMS *CoP* during a triennial or other Joint Commission survey. In that case, a follow-up survey is conducted to evaluate the hospital's implementation of the corrective actions within 45 days of the original survey's final report.
- **Complex organization survey:** Conducted if an organization provides care in more than one care setting and standards are applicable from at least two accreditation manuals. Integration across the whole organization is reviewed. For example, this type of survey would be employed if an acute care hospital also offers ambulatory care and home care or hospice services.
- **Multiorganization survey:** The Joint Commission offers a multiorganization system that owns or leases at least two organizations the option of using a modified survey process that includes either a corporate orientation, a corporate summation, or both, and that the surveys of participating organizations will have the same survey team leader. The findings and decisions for one organization within a system will not impact another organization within the system. The Joint Commission still accredits the individual healthcare organizations that are part of a multiorganization system, not the system itself.
- **Concurrent survey:** The Joint Commission offers a concurrent survey option for healthcare systems with more than one accredited entity, including in a single system, even if the organizations maintain distinct CCNs. Each organization must also demonstrate compliance with all requirements independent of any other organization within the system and, as such, will receive a separate survey report and accreditation decision. Each participating organization must demonstrate compliance with all Joint Commission requirements independent of any other organization within the system.
- **Accreditation with follow-up survey:** If this decision is made, a survey could occur within 30 days to six months after the decision was determined. Should an organization fail to successfully address all requirements of the survey decision and does not have a required license or similar issue at the time of the survey, the organization will be contingently accredited, and a follow-up survey in 30 days will occur. These conditions are AFS01, AFS02, AFS05, AFS06, AFS08, AFS09, AFS10, AFS11, AFS12, and AFS13.
- **Clarification validation survey (CVS):** After reviewing the hospital's clarifying information, a CVS may be performed to validate the clarifying information submitted and determine whether such information or data was available to the previous on-site survey team. If it is discovered that the hospital knowingly falsified its clarifying information, the Information Accuracy and Truthfulness Policy will apply and affect the accreditation decision.

Center for Improvement in Healthcare Quality (CIHQ)

There are two basic types of surveys: full and focused. All surveys are unannounced. *Note: CIHQ has a detailed Accreditation Survey Activity Guide outlining specifics of the different types of surveys on its website,* www.cihq.org. *It is free of charge to all applicants and accredited hospitals.*

Full Surveys

Initial survey: The first time a hospital applies for accreditation, an initial full survey will be conducted. All applicants must submit evidence of its 855A completeness notification by CMS before a survey can be scheduled. Initial surveys typically occur four months from the date of application.

Reaccreditation survey: A full survey for existing accredited hospitals. The survey team will complete this survey no later than 36 months after the hospital's last full survey.

Focused Surveys

Complaint survey: A survey will be conducted in response to a complaint received from an accredited hospital. The scheduling of these surveys is hospital specific.

Follow-up survey: Conducted for any accredited organization with an immediate threat to health and safety or a condition-level deficiency. The scheduling of these surveys is hospital specific.

For-cause survey: Completed at the discretion of CIHQ to validate the implementation of a plan of correction. CIHQ evaluates the plan of correction for reasons such as:

- Deficiencies identified during the reaccreditation survey, which the survey team accepted in a prior written and plan of correction
- A sufficient number of standard-level deficiencies to justify an on-site survey to verify the hospital had implemented the accepted plan of correction.

The scheduling of these surveys is hospital specific.

Extension survey: Completed at the discretion of CIHQ if the hospital has a change in ownership, acquires another healthcare entity who will share the same CCN, opens a new location or site of care, adds a new service, or notably modifies an existing service. The scheduling of these surveys is within six months of notification.

The assessment of the hospital's compliance with CIHQ standards, requirements, and policies during a survey as well as complaint review of any events reported determine the way in which a deficiency will be scored.

Based on the severity of the deficiency and the impact it has on the care and safety of the patients and employees, CIHQ will score a deficiency identified as a standard level, condition level, or immediate threat to health and safety deficiency.

DNV Healthcare USA

DNV/NIAHO® provides: accreditation, annual, follow-up, and special surveys. All surveys (apart from some special audits such as scope extension or ISO-only audits) are unannounced. To qualify for accreditation, DNV requires implementation of the ISO Quality Management System, ISO 9001:2015.

A sample survey cycle:

- Initial three-year contract
  - Year one: NIAHO® accreditation survey (including informal ISO 9001 education)
  - Year two: annual survey and ISO 9001 pre-assessment
  - Year three: annual survey and ISO 9001 Stage 1 audit

- Second three-year contract
  - Year one: re-accreditation survey and ISO 9001 Stage 2 audit
  - Year two: annual survey and ISO 9001 periodic audit
  - Year three: annual survey and ISO 9001 periodic audit
- Third three-year and all subsequent contracts
  - Year one: re-accreditation survey and ISO 9001 re-certification (or compliance) audit
  - Year two: annual survey and ISO 9001 periodic audit
  - Year three: annual survey and ISO 9001 periodic audit
- Triennial accreditation surveys*
  - Conducted on or before 36 months of initial accreditation

**ISO 9001:2015 compliance or certification is a required condition of accreditation. An ISO report is provided after a Stage 1 ISO audit in addition to a NIAHO nonconformity report for all hospitals whether they are seeking ISO compliance or certification. Only ISO-certified hospitals receive an annual ISO report as well as marketing rights to ISO 9001:2015 Quality Management System.*

Annual periodic surveys: Surveyors validate the effectiveness of corrective action plans and survey to conformance to NIAHO and ISO standards.

System-level surveys: Option for multihospital systems with opportunities for concurrent surveys (based on size, scope, and complexity of the system) and having consistent team leader(s) assigned.

Complaint for cause: Focused survey conducted by one surveyor from a department dedicated to complaint investigations.

Special audits and scope extension audits: Conducted for new buildings, spaces, and/or service lines.

ISO-only audits for system ISO-certified hospitals: One or two surveyors perform a comprehensive audit of the organization's Quality Management System in advance of the accreditation/reaccreditation survey.

Accreditation Commission for Health Care (ACHC)

1. **Initial Survey*:** An Initial Survey is conducted for an organization seeking ACHC accreditation for the first time. Initial Surveys for deemed status are unannounced. Initial Surveys without deemed status are announced unless the state requires unannounced surveys.
2. **Renewal Survey*:** A Renewal Survey is conducted for an organization that is currently accredited by ACHC. The Renewal Survey format is the same as an Initial Survey; however, the surveyor also reviews previous deficiencies for compliance. Renewal surveys for organizations seeking to maintain deeming authority are unannounced. Renewal surveys for organizations not seeking deeming authority are announced.
3. **Dependent Survey:** A Dependent Survey is conducted on a deemed-status organization that was not in compliance with the *CoP* as identified during an on-site survey. Dependent surveys are unannounced.
4. **Focus Survey:** A Focus Survey is conducted on an organization to ensure ongoing and continued compliance with ACHC accreditation standards. A Focus survey can take place at any time throughout the accreditation period or for any organizational changes. Focus surveys for organizations maintaining deeming authority are unannounced. Focus surveys for organizations not maintaining deeming authority are announced unless the state requires unannounced surveys.
5. **Extension Survey:** An Extension Survey is performed when an accredited organization undergoes significant change outside of the regular application and survey cycle (for example, major renovation of patient care

areas, acquisition of a new building, or the addition of a new service). The organization should contact its ACHC account advisor to discuss the scope of the change and its documentation.

6. **Complaint Survey:** A complaint Survey is conducted on an organization that has a complaint filed against it. Should ACHC determine during the investigation that a site visit is required, ACHC will conduct a Complaint Survey to determine if the complaint is substantiated. Complaint surveys are unannounced.
7. **Disciplinary Action Survey:** A Disciplinary Action Survey is conducted on an organization because of noncompliance with previous survey results, noncompliance with the ACHC accreditation standards or process, and/or a breach in the ACHC business associate agreement (BAA). Disciplinary action surveys are unannounced.

** Full survey: This is a comprehensive survey examining all ACHC accreditation standards and, if the organization is seeking deeming authority, the* CoP*.*

Appendix C

How to Respond to an Action Plan or Plan of Correction

When surveyors cite an organization for noncompliance with standards or *Conditions of Participation* (*CoP*), corrections must be completed within a specified time period. For The Joint Commission, action must be completed and submitted as an Evidence of Standards Compliance (ESC) within 60 days following the receipt of the final written report, which will occur within 10 business days of the survey's close. For Centers for Medicare & Medicaid Services (CMS) or state agency surveys, a plan of correction (POC) is required for all deficiencies noted in the Form 2567 report. They are due within 10 calendar days. CMS usually requires that the length of time for a correction to roll out cannot exceed 60 days unless an extension is requested separately. If immediate jeopardy is cited at your hospital, all efforts must be made to resolve the deficiency before the survey team's exit. In this case, the time for correction cannot exceed 23 days.

For CMS *CoP*-level deficiencies identified by any accrediting agency, a return visit by that organization will occur within 45 days to ensure that the POC was implemented as written and to verify that the POC has resulted in sustained improvement. On these 45-day surveys, surveyors are free also to complete a review of all the *CoP*s, but typically they focus only on the issues that rolled up to cause the *CoP*-level finding(s).

The Action Plan or Plan of Correction

The action plan will demonstrate what must be improved, the requirements to measure the plan's performance, and a method to monitor the plan, analyze the process, and determine how the hospital will sustain compliance. One option to describe performance improvement priorities is performing a root cause analysis (RCA). An RCA will identify why the failure occurred, evidence of actions taken, educational tools used, staff compliance with education, and the quality monitoring results as one option to describe performance improvement priorities. Details of education (e.g., individual department rosters showing each employee received information or emails to medical staff or board) and individual audit tools should also be available. These details should be available only upon the surveyor's request (maintained in a separate notebook).

The keys to writing an acceptable ESC/POC are specificity, brevity, and realism. Also, avoid relying simply on "we re-educated staff" as your sole action. For most areas of noncompliance, staff lacking knowledge about a process is usually not the root cause. Instead, some process flaw or failure of management to oversee staff is the root cause. Just as the medical record should tell the story of the care provided to a patient, the ESC/POC should tell the story of what has been done to correct the deficiency, how ongoing monitoring will maintain compliance with the regulatory requirements, and who is ultimately responsible for the ESC's/POC's implementation.

ESC/POC actions may include, but are not limited to, the following:

- Review, revision, and approval of existing policies or procedures
- Implementation of a new policy or procedure
- Modifications to building infrastructure and support services
- Modifications to job descriptions; performance reviews; and competency assessment processes, forms, or other tools
- Reeducation or reassignment of responsibilities to qualified individuals assigned to complete specific tasks
- Education of individuals responsible for the delivery of care, treatment, and services, including but not limited to nursing, pharmacy, respiratory care, rehabilitation services, and licensed practitioners
- Leadership involvement with corrective action to assist in ongoing sustainability
- Preventive analysis to ensure potential underlying causes surrounding the finding are identified and addressed

Appendix D

Websites for State Departments of Health

State	Website Address
Alabama	www.alabamapublichealth.gov
Alaska	www.dhss.alaska.gov
Arizona	www.azdhs.gov
Arkansas	www.healthy.arkansas.gov
California	www.cdph.ca.gov
Colorado	www.colorado.gov/cdphe
Connecticut	www.ct.gov/dph
Delaware	www.dhss.delaware.gov
Florida	www.floridahealth.gov
Georgia	www.dph.georgia.gov
Hawaii	https://health.hawaii.gov
Idaho	www.healthandwelfare.idaho.gov
Illinois	www.idph.state.il.us
Indiana	www.in.gov/health
Iowa	www.idph.iowa.gov
Kansas	www.kdhe.ks.gov
Kentucky	https://www.chfs.ky.gov/agencies/dph/
Louisiana	www.ldh.la.gov
Maine	www.maine.gov/dhhs/
Maryland	https://health.maryland.gov
Massachusetts	www.mass.gov/orgs/department-of-public-health
Michigan	www.michigan.gov/mdhhs
Minnesota	www.health.state.mn.us
Mississippi	www.msdh.state.ms.us
Missouri	www.health.mo.gov
Montana	www.dphhs.mt.gov
Nebraska	www.dhhs.ne.gov

Nevada	*www.dpbh.nv.gov*
New Hampshire	*www.dhhs.nh.gov*
New Jersey	*www.nj.gov/health*
New Mexico	*www.nmhealth.org*
New York	*www.health.ny.gov*
North Carolina	*www.ncdhhs.gov*
North Dakota	*www.ndhealth.gov*
Ohio	*www.odh.ohio.gov*
Oklahoma	*www.ok.gov/health/*
Oregon	*www.public.health.oregon.gov*
Pennsylvania	*www.health.pa.gov*
Rhode Island	*https://health.ri.gov/*
South Carolina	*www.scdhec.gov*
South Dakota	*https://doh.sd.gov*
Tennessee	*www.tn.gov/health*
Texas	*www.dshs.state.tx.us*
Utah	*www.health.utah.gov*
Vermont	*www.healthvermont.gov*
Virginia	*www.vdh.virginia.gov*
Washington	*www.doh.wa.gov*
Washington, D.C.	*www.dchealth.dc.gov*
West Virginia	*www.dhhr.wv.gov*
Wisconsin	*www.dhs.wisconsin.gov*
Wyoming	*https://health.wyo.gov*
U.S. Virgin Islands	*https://doh.vi.gov*
Puerto Rico	*www.salud.gov.pr*