CMS Manual System

Pub. 100-07 State Operations Provider Certification

Department of Health & Human Services (DHHS)
Centers for Medicare & Medicaid Services (CMS)

Transmittal-Advanced Copy 235 **Date: January 16, 2026**

SUBJECT: Revisions to the State Operations Manual (SOM) Appendix A - Hospitals.

I. SUMMARY OF CHANGES: This Transmittal includes revisions based on recent federal regulation changes via (CMS–3346–F; CMS–3334–F; CMS–3277–CN; CMS-1715-F) and is a follow-up to memo QSO 20-07 released on December 20, 2019. Revisions are being made to Appendix A to include the survey protocols, interpretive guidelines, and survey procedures for Psychiatric Hospitals. The Appendix A survey, Tasks 1 and 6, were also revised to remove references to Appendix T. The entirety of Appendix AA was transferred in a previous release to Appendix A, and now the interpretive guidance is being updated. In addition, several updates to the appendices have been made for technical correction and clarity. This transmittal will ensure that each of the appendices is updated with more substantive interpretive guidance to reflect the current regulatory language within the Medicare conditions. Besides updating the interpretive guidance for the federal regulation changes, Appendix A also includes updates to death in restraints or seclusion reporting, the Medicare Outpatient Observation Notice (MOON), Physical environment, and Prior to Surgery Procedures.

NEW/REVISED MATERIAL - EFFECTIVE DATE: January 16, 2026
IMPLEMENTATION DATE: January 16, 2026

The revision date and transmittal number apply to the red italicized material only. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (*N/A if manual not updated.*)
(R = REVISED, N = NEW, D = DELETED) – (*Only One Per Row.*)

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
R	Appendix A/Table of Contents
R	A/Survey Protocol/Task 1- Off Site Preparation
R	A/Survey Protocol/Task 6- Post Survey Activities
R	Appendix A/A-0020/§482.11 Condition of Participation: Compliance with Federal, State and Local Laws
R	Appendix A/A-0144/§482.13(c)(2) - The patient has the right to receive care in a safe setting
R	Appendix A/A-0213/§482.13(g)(1)(3)(i) Standard: Death Reporting Requirements: - Hospitals must report deaths associated with the use of seclusion or restraint.
R	Appendix A/A-0214//§482.13(g)(2)(3)(ii)(4) Standard: Death Reporting Requirements: [- Hospitals must report deaths associated with the use of seclusion or restraint.]

R	Appendix A/A-0263/§482.21 Condition of Participation: Quality Assessment and Performance Improvement Program
R	Appendix A/A-0273/ §§482.21(a), 482.21(b)(1), 482.21(b)(2)(i), & 482.21(b)(3) Data Collection and Analysis
R	Appendix A/A-0283/§§482.21(b)(2)(ii), 482.21(c)(1) & 482.21(c)(3) Quality Improvement Activities
R	Appendix A/A-0286/§§482.21(a)(1), 482.21(a)(2), 482.21(c)(2), & 482.21(e)(3) Patient Safety, Medical Errors & Adverse Events
R	Appendix A/A-0297/§482.21(d) Standard: Performance Improvement Projects.
R	Appendix A/A-0309/§482.21(e) Standard: Executive Responsibilities
R	Appendix A/A-0315/§482.21(e)(4) Standard: Executive Responsibilities
R	Appendix A/A-0320/§482.21(f) Standard: Unified and integrated QAPI program for multi-hospital systems.
R	Appendix A/A-0321/§482.21(f)(1) Standard: Unified and integrated QAPI program for multi-hospital systems.
R	Appendix A/A-0322/§482.21(f)(2) Standard: Unified and integrated QAPI program for multi-hospital systems.
R	A/A-0360/§482.22(c)(5)(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…
R	Appendix A/A-0361/§482.22(c)(5)(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…
R	Appendix A/A-0362/§482.22(c)(5)(v) The medical staff, if it chooses to develop and maintain a policy for the identification of specific patients to whom the assessment requirements…
R	Appendix A/A-0399/§482.23(b)(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:
R	Appendix A/A-0458/§482.24(c)(4) - All records must document the following, as appropriate: (i) Evidence of--
R	Appendix A/A-0461/§482.24(c)(4) - [All records must document the following, as appropriate:
R	Appendix A/A-0462/§482.24(c)(4) - [All records must document the following, as appropriate:
N	Appendix A/A-0470//§482.24(d)(1-4) Electronic Notifications
N	Appendix A/A-0471//§482.24(d)(5)
R	Appendix A/A-0700/§482.41 Condition of Participation: Physical Environment
R	Appendix A/A-0701/§482.41(a) Standard: Buildings
R	Appendix A/A-0702/ §482.41(a)(1)
R	Appendix A/A-0710
R	Appendix A/A-0713
R	Appendix A/A-0714

R	Appendix A/A-0715
R	Appendix A/A-0716
R	Appendix A/A-0717/§482.41(b)(8) When a sprinkler system is shut down for more than 10 hours, the hospital must:
R	Appendix A/A-0718/§482.41(b)(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.
R	Appendix A/A-0720/§482.41(c) Standard: Building Safety
R	Appendix A/A-0722
R	Appendix A/A-0723
R	Appendix A/A-0724
R	Appendix A/A-0725
R	Appendix A/A-0726
R	Appendix A/A-0747/§482.42 Condition of participation: Infection prevention and control and antibiotic stewardship programs.
R	Appendix A/A-0748/§482.42 (a) Standard: Infection prevention and control program organization and policies.
R	Appendix A/A-0749/§482.42 (a)(2) The hospital infection prevention and control program, as documented in its policies and procedures…
R	Appendix A/A-0750/§482.42(a)(3) The infection prevention and control program includes surveillance,
R	Appendix A/A-0751/§482.42(a)(4) The infection prevention and control program reflects the scope and complexity of the hospital services provided.
N	Appendix A/A-0760/§482.42(b) Standard: Antibiotic stewardship program organization and policies.
N	Appendix A/A-0761/§482.42(b)(2) The hospital-wide antibiotic stewardship program: (i) Demonstrates coordination among all components of the hospital responsible
N	Appendix A/A-0762/§482.42(b)(2)(ii) Documents the evidence-based use of antibiotics in all departments and services of the hospital; and
N	Appendix A/A-0763/§482.42(b)(2)(iii) Documents any improvements, including sustained improvements, in proper antibiotic use;
N	Appendix A/A-0764/§482.42(b)(3) The antibiotic stewardship program adheres to nationally recognized guidelines, as well as best practices, for improving antibiotic use; and
N	Appendix A/A-0765/§482.42 9(b)(4) The antibiotic stewardship program reflects the scope and complexity of the hospital services provided.
R	A/A-0770/§482.42(c) Standard: Leadership responsibilities
R	A/A-0771/§482.42(c)(1)(ii) All HAIs and other infectious diseases identified by the infection
R	Appendix A/A-0772/§482.42(c) Standard: Leadership responsibilities
R	Appendix A/A-0773/§482.42(c)(2)(ii) All documentation, written or electronic, of the infection prevention and control program and its surveillance, prevention, and control activities.

R	Appendix A/A-0774/§482.42(c)(2)(iii) Communication and collaboration with the hospital's QAPI program on infection prevention and control issues.
R	Appendix A/A-0775/§482.42(c)(2)(iv) Competency-based training and education of hospital personnel and staff
R	Appendix A/A-0776/§482.42(c)(2)(v) The prevention and control of HAIs, including auditing of adherence to infection prevention and control policies and procedures by hospital personnel.
R	Appendix A/A-0777/§482.42(c)(2)(vi) Communication and collaboration with the antibiotic stewardship program.
R	Appendix A/A-0778/§482.42(c) Standard: Leadership responsibilities (3) The leader(s) of the antibiotic stewardship program is responsible for:
R	Appendix A/A-0779/§482.42(c)(3)(ii) All documentation, written or electronic, of antibiotic stewardship program activities.
R	Appendix A/A-0780/§482.42(c)(3)(iii) Communication and collaboration with medical staff, nursing, and…
R	Appendix A/A-0781/§482.42(c)(3)(iv) Competency-based training and education of hospital personnel and staff…
R	Appendix A/A-0785/§482.42(d) Standard: Unified and integrated infection prevention and control and antibiotic stewardship programs for multi-hospital systems.
R	Appendix A/A-0786/§482.42(d)(1) The unified and integrated infection prevention and control and antibiotic stewardship programs are established in a manner…
R	Appendix A/A-0787/§482.42(d)(2) The unified and integrated infection prevention and control and antibiotic stewardship programs establish and implement policies and procedures to ensure…
R	Appendix A/A-0788/§482.42(d)(3) The unified and integrated infection prevention and control and antibiotic stewardship programs have mechanisms…
R	Appendix A/A-0789/§482.42(d)(4) A qualified individual (or individuals) with expertise in infection prevention…
R	Appendix A/A-0799/§482.43 Condition of Participation: Discharge Planning
R	Appendix A/A-0800/§482.43(a) Standard: Discharge Planning Process
R	Appendix A/A-0801/§482.43(a)(4) Standard: Discharge Planning Process
R	Appendix A/A-0802/§482.43(a)(6) Standard: Discharge Planning Process
R	Appendix A/A-0803/§482.43(a)(7) Standard: Discharge Planning Process
R	Appendix A/A-0804/§482.43(a)(8) Standard: Discharge Planning Process
R	Appendix A/A-0806/§482.43(a)(1) Standard: Discharge Planning Evaluation
R	Appendix A/A-0807/§482.43(a)(2) Standard: Discharge Planning Evaluation
R	Appendix A/A-0808/§482.43(a)(3) Standard: Discharge Planning Evaluation
R	Appendix A/A-0809/§482.43(a)(5) – Any discharge planning evaluation or discharge plan under this paragraph must be developed by or under the supervision of a registered nurse, social worker, or other appropriately qualified personnel.
R	Appendix A/A-0810/§482.43(b) Standard: Discharge of the patient and the provision and transmission of the patient's necessary medical information.
R	Appendix A/A-0811/§482.43(d) Standard: Requirements related to post-acute care services.

R	Appendix A/A-0812/§482.43(d)(1) – [The hospital must] include the discharge planning a list of HHA's, SNF's, IRF's, or LTCH's 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
R	Appendix A/A-0813/§482.43(d)(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 the post-discharge services and must, when possible, respect the patient's or the patient's representative 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 patients.
R	Appendix A/A-0814/§482.43(d)(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.
D	Appendix A/A-0823/§482.43(d)(6), §482.43(d)(7) & §482.43(d)(8) – [A-0823 relates to discharge planning]
N	Appendix A/A-0826//§482.43(c) Transfer protocols. Effective July 1, 2025, the hospital must have written policies and procedures for transferring patients under its care (inclusive of inpatient services) to the appropriate level of care (including to another hospital) as needed to meet the needs of the patient. The hospital must also provide annual training to relevant staff regarding the hospital policies and procedures for transferring patients under its care.
R	Appendix A/A-0953/§482.51(b)(1)(ii) - Prior to surgery or a procedure requiring anesthesia services and except in the case of emergencies:
R	Appendix A/A-0954/ §482.51(b)(1)(iii) - Prior to surgery or a procedure requiring anesthesia services and except in the case of emergencies:
N	Appendix A/A-1114/482.55 (c)Emergency services readiness. Effective July 1, 2025, in accordance with the complexity and scope of services offered, there must be adequate provisions and protocols to meet the emergency needs of patients.
N	Appendix A/A-1115/482.55 (c)(1) Protocols. Protocols must be consistent with nationally recognized and evidence-based guidelines for the care of patients with emergency conditions, including but not limited to patients with obstetrical emergencies, complications, and immediate post-delivery care.
N	Appendix A/A-1116/482.55 (c)(2),(c)(2)(i)(ii)(iii) Provisions. Provisions include equipment, supplies, and medication used in treating emergency cases. Such provisions must be kept at the hospital and be readily available for treating emergency cases to meet the needs of patients. The available provisions must include the following: (i)Drugs, blood and blood products, and biologicals commonly used in life saving procedures; (ii) Equipment and supplies commonly used in life-saving procedures; and (iii) each emergency services treatment areas must have call in system for each patient.

N	Appendix A/A-1117/482.55 (c)(3), (c)(3)(i)(ii)(iii)(iv) Staff training. Applicable staff, as identified by the hospital, must be trained annually on the protocols and provisions implemented pursuant to this section. (i) The governing body must identify and document which staff must complete such training. (ii) the hospital must document in the staff personnel records that the training was successfully completed. (iii) the hospital must be able to demonstrate staff knowledge on the topics implemented pursuant to this section
D	Appendix A/A-1568 §482.58(b)(4) Patient Activities (§483.24(c))
D	Appendix A/A-1570 §482.58(b)(5) Social Services (§483.40(d))
R	Appendix A/A-1572 §482.58(b)(6) Discharge planning (§483.20(e))
N	Appendix A/A-1572 §482.58(b)(6) Specialized rehabilitative services (§483.65)
R	Appendix A/A-1601/§482.60(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
R	Appendix A/A-1605/§482.60(b) Meet the Conditions of Participation specified in§§482.1 through 482.23 and §§482.25 through 482.57;
R	Appendix A/A-1610/§482.60(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
R	Appendix A/A-1615/§482.60(d) Meet the staffing requirements specified in §482.62.
R	Appendix A/A-1620/§482.61 Condition of Participation: Special Medical Record Requirements for Psychiatric Hospitals.
R	Appendix A/A-1621/§482.61(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.
R	Appendix A/A-1622/§482.61(a)(1) The identification data must include the patient's legal status.
R	Appendix A/A-1623/§482.61(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.
R	Appendix A/A-1624/§482.61(a)(3) The reasons for admission must be clearly documented as stated by the patient and/or others significantly involved.
R	Appendix A/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.
R	Appendix A/A-1626/§482.61(a)(5) When indicated, a complete neurological examination must be recorded at the time of the admission physical examination.
R	Appendix A/A-1630/§482.61(b) Standard: Psychiatric Evaluation. Each patient must receive a psychiatric evaluation that must--
R	Appendix A/A-1631/§482.61(b)(1) [Each patient must receive a psychiatric evaluation that must-] Be completed within 60 hours of admission;
R	Appendix A/A-1632/§482.61(b)(2) [Each patient must receive a psychiatric evaluation that must-] Include a medical history;

R	Appendix A/A-1633/§482.61(b)(3) [Each patient must receive a psychiatric evaluation that must-] Contain a record of mental status;
R	Appendix A/A-1634/§482.61(b)(4) [Each patient must receive a psychiatric evaluation that must-] Note the onset of illness and the circumstances leading to admission;
R	Appendix A/A-1635/§482.61(b)(5) [Each patient must receive a psychiatric evaluation that must-] Describe attitudes and behavior;
R	Appendix A/A-1636/§482.61(b)(6) [Each patient must receive a psychiatric evaluation that must-] Estimate intellectual functioning, memory functioning and orientation; and
R	Appendix A/A-1637/§482.61(b)(7) [Each patient must receive a psychiatric evaluation that must-] Include an inventory of the patient's assets in descriptive, not interpretive fashion.
R	Appendix A/A-1640/§482.61(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.
R	Appendix A/A-1641/§482.61(c)(1)(i) The written plan must include—A substantiated diagnosis;
R	Appendix A/A-1642/§482.61(c)(1)(ii) [The written plan must include—] Short-term and long range goals;
R	Appendix A/A-1643/§482.61(c)(1)(iii) [The written plan must include—] The specific treatment modalities utilized;
R	Appendix A/A-1644/§482.61(c)(1)(iv) [The written plan must include—] The responsibilities of each member of the treatment team; and
R	Appendix A/A-1645/§482.61(c)(1)(v) [The written plan must include—] Adequate documentation to justify the diagnosis and the treatment and rehabilitation activities carried out.
R	Appendix A/A-1650/§482.61(c)(2) The treatment received by the patient must be documented in such a way to assure that all active therapeutic efforts are included.
R	Appendix A/A-1655/§482.61(d) Standard: Recording Progress: Progress notes must be recorded by the physician(s), psychologists, or other licensed independent 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.
R	Appendix A/A-1660/§482.61(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…
R	Appendix A/A-1661/§482.61(d) …and must contain recommendations for revisions in the treatment plan as indicated…
R	Appendix A/A-1662/§482.61(d) …as well as [must contain] a precise assessment of the patient's progress in accordance with the original or revised treatment plan.
R	Appendix A/A-1670/§482.61(e) The record of each patient who has been discharged must have a discharge summary that includes a recapitulation of the patient's hospitalization and…

R	Appendix A/A-1671/§482.61(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…
R	Appendix A/A-1672/§482.61 (e) [The record of each patient who has been discharged must have a brief summary that includes] a brief summary of the patient's condition on discharge.
N	Appendix A/A-1673/§482.61(f)(1-4) Electronic Notifications
N	Appendix A/A-1674//§482.61(f)(5)
R	Appendix A/A-1680/§482.62 Condition of Participation: Special Staff Requirements for Psychiatric Hospitals. 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.
R	Appendix A/A-1685/§482.62(a)(1) Standard: Personnel. The hospital must employ or undertake to provide adequate numbers of qualified professional, technical, and consultative personnel to: (1) Evaluate Patients
R	Appendix A/A-1686/§482.62(a)(2) [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;
R	Appendix A/A-1687/§482.62(a)(3) [The hospital must employ or undertake to provide adequate numbers of qualified professional, technical, and consultative personnel to:] (3) Provide active treatment measures; and
R	Appendix A/A-1688/§482.62(a)(4) [The hospital must employ or undertake to provide adequate numbers of qualified professional, technical, and consultative personnel to:] (4) Engage in discharge planning;
R	Appendix A/A-1690/§482.62(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.
R	Appendix A/A-1691/§482.62(b) …The number and qualifications of doctors of medicine and osteopathy must be adequate to provide essential psychiatric services.
R	Appendix A/A-1692/§482.62(b)(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.
R	Appendix A/A-1693/§482.62(b)(2) The director must monitor and evaluate the quality and appropriateness of services and treatment provided by the medical staff.
R	Appendix A/A-1695/§482.62(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.

R	Appendix A/A-1700/§482.62(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.
R	Appendix A/A-1701/§482.62(d)(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…
R	Appendix A/A-1702/§482.62(d)(1) …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
R	Appendix A/A-1703/§482.62(d)(2) The staffing pattern must ensure the availability of a registered nurse 24 hours each day…
R	Appendix A/A-1704/§482.62(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.
R	Appendix A/A-1710/§482.62(e) Standard: Psychological Services. The hospital must provide or have available psychological services to meet the needs of the patients.
R	Appendix A/A-1715/§482.62(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.
R	Appendix A/A-1716/§482.62(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.
R	Appendix A/A-1717/§482.62(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.
R	Appendix A/A-1720/§482.62(g) Standard: Therapeutic Activities. The hospital must provide a therapeutic activities program.
R	Appendix A/A-1725/§482.62(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.
R	Appendix A/A-1726/§482.62(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.

III. FUNDING: No additional funding will be provided by CMS.
IV. ATTACHMENTS:

	Business Requirements
X	**Manual Instruction**
	Confidential Requirements
	One-Time Notification
	Recurring Update Notification

State Operations Manual
Appendix A - Survey Protocol, Regulations and Interpretive Guidelines for Hospitals and Psychiatric Hospitals
(Rev.)

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Hospital and Psychiatric Hospital Survey Protocol
(Rev. 235; Issued: 01-16-26; Effective: 01-16-26; Implantation:01-16-26)

Task 1 - Off-Site Survey Preparation

General Objective

The objective of this task is to analyze information about the provider in order to identify areas of potential concern to be investigated during the survey and to determine if those areas, or any special features of the provider (e.g., provider-based clinics, remote locations, satellites, specialty units, PPS-exempt units, services offered, etc.) require the addition of any specialty surveyors to the team. Information obtained about the provider will also allow the SA (or the RO for Federal teams) to determine survey team size and composition, and to develop a preliminary survey plan.

The type of provider information needed includes:

- Information from the provider file (to be updated on the survey using the Hospital/CAH Medicare Database Worksheet), such as the facility's ownership, the type(s) of services offered, any prospective payment system (PPS) exclusion(s), whether the facility is a provider of swing-bed services, and the number, type and location of any off-site locations;

- Previous Federal and state survey results for patterns, number, and nature of deficiencies, as well as the number, frequency, and types of complaint investigations and the findings;

- Information from CMS databases available to the SA and CMS. Note the exit date of the most recent survey;

- Waivers and variances, if they exist. Determine if there are any applicable survey directive(s) from the SA or the *CMS Locations (formerly known as the Regional Office)*; and

- Any additional information available about the facility (e.g., the hospital's Web site, any media reports about the hospital, etc.).

Off-Site Survey Preparation Team Meeting

The team should prepare for the survey offsite so they are ready to begin the survey immediately upon entering the facility. The team coordinator should arrange an off-site preparation meeting with as many team members as possible, including specialty surveyors. This meeting may be a conference call if necessary.

During the meeting, discuss at least the following:

- Information gathered by the team coordinator;

- Significant information from the CMS databases that are reviewed;

• Update and clarify information from the provider file so a surveyor can update the Medicare database using the "Hospital/CAH Medicare Database Worksheet," Exhibit 286;

• Layout of the facility (if available);

• Preliminary team member assignments;

• Date, location and time team members will meet to enter the facility;

• The time for the daily team meetings; and

• Potential date and time of the exit conference.

Gather copies of resources that may be needed. These may include:

• Medicare Hospital CoP and Interpretive Guidelines (Appendix A);

• Survey protocol and modules;

• Immediate Jeopardy (Appendix Q);

• Responsibilities of Medicare Participating Hospitals in Emergency Cases (Appendix V);

• Hospital/CAH Medicare Database Worksheet, Exhibit 286;

• Exhibit 287, Authorization by Deemed Provider/Supplier Selected for Accreditation Organization Validation Survey; and

• Worksheets for PPS exclusions.

Task 6 – Post-Survey Activities

General Objective

The general objective of this task is to complete the survey and certification requirements, in accordance with the regulations found at 42 CFR Part 488.

General Procedures

Each State agency and Federal *CMS Location* should follow the directives in the State Operations Manual. The procedures include:

- Timelines for completing each step of the process;

- Responsibilities of the team coordinator and other team members to complete the Form CMS-2567, "Statement of Deficiencies," following the "Principles of Documentation";
- Notification to the facility staff regarding survey results;
- Additional survey activities based on the survey results (e.g., revisit, forwarding documents to the *CMS Location* for further action/direction);
- Compilation of documents for the provider file;
- Authorization signed by Deemed Provider/Supplier Selected for Accreditation Organization Validation Survey is forwarded to *the CMS Location*; and
- Enter the information collected on the Hospital/CAH Medicare Database Worksheet into the Medicare database.

Plan of Correction

Regulations at 42 CFR 488.28(a) allow certification of providers with deficiencies at the Standard or Condition level "only if the facility has submitted an acceptable plan of Correction [POC] for achieving compliance within a reasonable period of time acceptable to the Secretary." Failure to submit a POC may result in termination of the provider agreement as authorized by 42 CFR 488.28(a) and §489.53(a)(1). After a POC is submitted, the surveying entity makes the determination of the appropriateness of the POC.

Regulations and Interpretive Guidelines

A-0020

(Rev. 235; Issued: 01-16-26; Effective: 01-16-26; Implantation:01-16-26)

§482.11 Condition of Participation: Compliance with Federal, State and Local Laws

Interpretive Guidelines §482.11

The hospital must ensure that all applicable Federal, State and local law requirements are met.

Medicare Outpatient Observation Notice (MOON)

On August 6, 2015, Congress enacted the Notice of Observation Treatment and Implication for Care Eligibility Act (NOTICE Act) Public Law 114-42, amending Section 1866(a)(1) of the Social Security Act (the Act) (42 U.S.C. 1395cc(a)(1)), by adding a new subparagraph (Y). The implementing regulations are located at §489.20(y).

The MOON informs all Medicare beneficiaries when they are outpatients receiving observation services and not inpatients of the hospital. The MOON must be delivered to a beneficiary who receives

observation services as an outpatient for more than 24 hours, and it must be delivered not later than 36 hours after observation services begin. The MOON must be delivered before 36 hours following initiation of observation services if the beneficiary is transferred, discharged, or admitted. The MOON may be delivered before a beneficiary receives 24 hours of observation services as an outpatient.

Hospitals must provide both the standardized written MOON, as well as oral notification. Oral notification must consist of an explanation of the standardized written MOON. The format of such oral notification is at the discretion of the hospital, and may include, but is not limited to, a video format. However, a staff person must always be available to answer questions related to the MOON, both in its written and oral delivery formats. Hospitals must use the OMB-approved MOON (CMS-10611).

The hospital must retain the original signed MOON in the beneficiary's medical record. Electronic notice retention is permitted. The notice and accompanying instructions may be found on the CMS website (link as of April 3, 2024 at).

A-0144

(Rev. 235; Issued: 01-16-26; Effective: 01-16-26; Implantation:01-16-26)

§482.13(c)(2) - The patient has the right to receive care in a safe setting.

Interpretive Guidelines §482.13(c)(2)

The intention of this requirement is to specify that each patient receives care in an environment that a reasonable person, similarly situated as the patient would consider to be safe. For example, hospital staff should follow current standards of practice for patient environmental safety, infection control, and security. The hospital must protect vulnerable patients, including newborns, children and *the elderly*. Additionally, this standard is intended to provide protection for the patient's emotional health and safety as well as his/her physical safety. Respect, dignity, and comfort *are* also components of an emotionally safe environment. To provide care in a safe setting, hospitals should also identify patients at risk for intentional harm to self or others, identify environmental safety risks for such patients, and provide *environmental safety* education and training for staff and volunteers.

Patients at risk of suicide (or other forms of self-harm), or who exhibit violent behaviors toward others, receive healthcare services in both inpatient and outpatient locations of hospitals. Although all risks cannot be eliminated, hospitals should be able to demonstrate how they identify patients at risk of self-harm or harm to others and the steps they are taking to minimize those risks in accordance with nationally recognized standards and guidelines. The potential risks include, but are not limited to, those from ligatures, sharps, harmful substances, access to medications, breakable windows, accessible light fixtures, plastic bags (for suffocation), oxygen tubing, bell cords, etc.

Hospitals should consider three main elements in ensuring patient safety related to ligature risks:

1. Patient Assessment

There are numerous models and versions of patient screening and assessment tools to identify the risk of harm to self or others. CMS does not endorse nor require the use of any particular

tool. The type of patient screening or assessment tool used to determine the risk of harm to self or others should be appropriate to the patient population served, care setting, and staff competency. Hospitals should implement a patient screening and risk assessment strategy that is appropriate to the patient population. For example, a patient screening and risk assessment strategy in a post-partum unit would most likely not be the same screening and risk assessment strategy utilized in the emergency department.

All patients in psychiatric hospitals and psychiatric units should be screened for suicidal ideation in order to ensure patient safety. In acute care hospitals, patients being evaluated and treated for behavioral health conditions as their primary reason for care should be screened for suicidal ideation. Hospital policy should address any other circumstances where suicidal screening is required.

Hospitals may find the recommendations and resources in the 2018 report, Recommended standard care for people with suicide risk: Making health care suicide safe, issued by the National Action Alliance for Suicide Prevention (Action Alliance), to be highly useful in developing the best practices for effective patient screening and assessment for those patients at risk for harm to themselves, as well as for improving the care of patients at risk of suicide.[1] *The Action Alliance is a public-private partnership working to advance*

[1] *National Action Alliance for Suicide Prevention: Transforming Health Systems Initiative Work Group. (2018). Recommended standard care for people with suicide risk: Making health care suicide safe. Washington, DC: the National Strategy for Suicide Prevention and reduce the suicide rate by twenty percent by 2025. Notably, the report advances two of the goals of the National Strategy for Suicide Prevention (National Strategy): (a) Promote suicide prevention as a core component of health care services, and (b) Promote and implement effective clinical and professional practices for assessing and treating those identified as being at risk for suicidal behaviors. (To download a copy of the National Strategy, please visit: www.actionallianceforsuicideprevention.org).*

2. Staffing/Monitoring

Hospitals should also provide the appropriate level of education and training to staff regarding the identification of patients at risk of harm to themselves or others, the identification of environmental patient safety risk factors, and mitigation strategies. Staff would include direct employees, volunteers, contractors, per diem staff, and any other individuals providing clinical care under arrangement. Hospitals have the flexibility to tailor the training to the services staff provide and the patient populations they serve. *CMS expects hospitals to provide education and training to all new staff initially upon orientation and whenever policies and procedures change. Additionally,* CMS recommends ongoing training at least every two years after initial training.

3. **Environmental Risk**

Just as all hospitals should implement a patient risk assessment strategy to ensure patient safety, all hospitals should implement an environmental risk assessment strategy to provide patient care

in a safe setting. Environmental risk assessment strategies may not be the same in all hospitals or hospital units. The hospital should implement environmental risk assessment strategies appropriate to the specific care environment and patient population. Risk assessments should be appropriate to each unit and should consider the possibility that the unit may sometimes care for patients at risk for the threat of harm to self or others.

Survey Procedures §482.13(c)(2)

- Review and analyze patient and staff incident and accident reports to identify any incidents or patterns of incidents concerning a safe environment. Expand your review if you suspect *more widespread or pervasive* problem*s* with safe environment *issues* in the hospital.

- *Observe patient care environments and other areas frequented by patients for unattended items such as utility or housekeeping carts that contain hazardous items that may pose a safety risk to patients, visitors and staff. Examples of these items could include cleaning agents, disinfectant solutions, mops, brooms, tools, etc.*

  - *Review policy and procedures and i*nterview staff in patient care areas to determine how the hospital train*s* staff *on assessment of the patient care environment upon hire, before providing patient care or working independently, and whenever policies and procedures are revised or updated.*
  - *Review policy and procedures and interview staff to identify processes to keep staff members current on meeting the needs of the patient population served,* to *identify risks in the care environment,* and if *risk is* found, how staff report those findings.

  - Review policy and procedures and interview staff to determine how the hospital defines *continuous visual observation or 1:1 monitoring* in which a staff member is assigned to observe only one patient at all times. The policy should *include the ability of the assigned staff member to immediately intervene when patient safety may be at risk.*

- Observe and interview staff at units where infants and children are inpatients. Are appropriate security protections (such as alarms, arm banding systems, etc.) in place? Are they functioning?

- Review policy and procedures on what the hospital does to curtail unwanted visitors, contaminated materials, or unsafe items that pose a safety risk to patients and staff.

- Access the hospital's security efforts to protect vulnerable patients including newborns, children, *the elderly,* and patients at risk of suicide or intentional harm to self or others. Is the hospital providing appropriate security to protect patients? Are appropriate security mechanisms in place and being followed to protect patients? Security mechanisms *should be* based on nationally recognized standards of practice.

- *Determine if the hospital has a policy for assessing and reassessing patients who have been identified as being at risk for suicide or harm to self or others, according to nationally accepted standards of practice. Review policies and interview staff to verify processes are established to*

protect these vulnerable patients and ensure care is provided in a safe setting.

A-0213

(Rev. 235; Issued: 01-16-26; Effective: 01-16-26; Implantation: 01-16-26)

§482.13(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 1 week after restraint or seclusion where it is reasonable to assume that use of restraint or placement in seclusion contributed directly or indirectly to 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….

Interpretive Guidelines §482.13(g)(1) & (3)(i)

The hospital must report to its CMS *Location within their region* each death that occurs:

- While a patient is in restraint or in seclusion, except when no seclusion has been used and the only restraint used was a soft, cloth-like two-point wrist restraints;
- Within 24 hours after the patient has been removed from restraint or seclusion, except when no seclusion has been used and the only restraint used was a soft, two-point wrist restraint; or,
- Within 1 week after use of restraint or seclusion where the death is known to the hospital and it is reasonable to assume that the use of restraint or seclusion contributed directly or indirectly to the patient's death, regardless of the type(s) of restraint used on the patient during this time.

- "Reasonable to assume" applies only to those deaths that occur on days 2-7 after restraint or seclusion has been discontinued.

- This criterion applies regardless of the type of restraint that was used on the patient. In other words, it applies to all uses of restraint or seclusion where the patient has died on days 2-7 after the restraint or seclusion was discontinued, and it is reasonable to assume the use of the restraint or seclusion contributed to the patient's death. In a case where only two-point soft wrist restraints were used and there was no seclusion, it may reasonably be presumed that the patient's death was not caused by the use of restraints.

- In cases involving death within one week after use of restraint or seclusion where the intervention may have contributed to the patient's death, it is possible that the patient's death might occur outside the hospital and that the hospital might not learn of the patient's death, or that there might be a delay in the hospital's learning of the patient's death.

See the guidance for §482.13(g)(2) for handling of deaths while a patient was in, or within 24 hours after removal of a soft, two-point wrist restraint, when no other restraint or seclusion was used.

Hospitals and/or Critical Access Hospital (CAH) Distinct Part Units (DPUs) must electronically submit the reports required under §482.13(g)(1) to the CMS *Locations within their regions* no later than close of the next business day following the day in which the hospital knows of the patient's death. *Hospitals and/or CAH DPUs must use the electronic Form CMS-10455, Report of a Hospital Death Associated with the Use of Restraint or Seclusion, which is accessed, completed, and submitted via the URL – https://restraintdeathreport.gov1.qualtrics.com/jfe/form/SV_5pXmjIw2WAzto8J. (Insert the URL into any browser and click to access, complete, and submit the Form CMS-10455.)*

The *electronic Form CMS-10455, Report of a Hospital Death Associated with the Use of Restraint or Seclusion,* include*s* basic identifying information related to the hospital, the patient's name, date of birth, date of death, name of attending physician/practitioner, primary diagnosis(es), cause of death (preliminary, in case a final, official cause of death is not yet available), and type(s) of restraint or seclusion used.

Hospitals must document in the patient's medical record the date and time each reportable death associated with the use of restraint or seclusion was reported to the*ir* CMS *Location within their r*egion.

After reviewing the submitted information, the *CMS Location* will determine whether an on-site investigation of the circumstances surrounding the patient's death is warranted and will direct the State Survey Agency to conduct a survey if applicable.

Survey Procedures §482.13(g)(1) & (3)(i):

- Does the hospital have restraint/seclusion death reporting policies and procedures that address responsibilities and systems for identifying restraint/seclusion-associated deaths reportable to CMS and for implementing the reporting and recordkeeping requirements?

- Can the hospital provide examples of restraint/seclusion-associated deaths that were reported to CMS?

    - If yes, review the report and medical records to determine whether:
        - the reports met the criteria for reporting to CMS;
        - were submitted timely to CMS;
        - were complete; and
        - the date and time the death reported to CMS was entered into the patient's medical record.

    - If no:
        - Ask the hospital how it ensures that there were no reportable restraint/seclusion-associated deaths.
        - If the hospital's system relies upon staff identification of reportable deaths, interview several applicable staff members to determine whether they are aware of the hospital's policy and know when and where to report internally a restraint/seclusion-associated death. Ask if there have been any patient deaths that meet the reporting requirements.

- Interview staff in various types of inpatient units, including a psychiatric unit if applicable, to determine whether they are aware of any patients who died while in restraints or seclusion or within one day of restraint or seclusion discontinuation, excluding cases involving only the use of two-point soft wrist restraints and no seclusion. If yes, check whether the hospital has any evidence that these cases were reported to CMS.

A-0214

(Rev. 235; Issued: 01-16-26; Effective: 01-16-26; Implantation: 01-16-26)

§482.13(g) Standard: Death Reporting Requirements: [- 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 is 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 not 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 attending physician or other licensed independent practitioner who is responsible for the care of the patient as specified under §482.12(c), medical record number, and primary diagnosis(es).
(iii) The information must be made available in either written or electronic form to CMS immediately upon request.

Interpretive Guidelines §482.13(g)(2), (3)(ii), & (4)

Hospitals must maintain an internal log or other type of tracking system for recording information on each death that occurs:

- While a patient is in only 2-point soft, cloth-like non-rigid wrist restraints and there is no use of seclusion; and
- Within 24 hours of the patient being removed from 2-point soft, cloth-like non-rigid wrist restraints where there was no use of any other type of restraint or seclusion.

Use of the log or tracking system is limited only to patient deaths meeting one of these two criteria. Examples of patient deaths associated with restraints that must still be reported to CMS include:

- Deaths occurring during or within 24 hours of discontinuation of 2-point soft, cloth-like non-rigid wrist restraints used in combination with any other restraint device or with seclusion; or

- Deaths associated with the use of other types of wrist restraints, such as 2-point rigid or leather wrist restraints.

These cases would not be included in this internal log or tracking system and would require reporting the death to CMS using *the electronic. Form CMS-10455, Report of a Hospital Death Associated with the Use of Restraint or Seclusion, at – https://restraintdeathreport.gov1.qualtrics.com/jfe/form/SV_5pXmjIw2WAzto8J.*

The two-point soft wrist restraint death report must be entered into the internal log or tracking system within 7 days of the patient's death.

The death report log or tracking system entry must include:

- The patient's name;

- Patient's date of birth;
- Patient's date of death;
- Name of the attending physician or other licensed independent practitioner who is responsible for the care or the patient;
- Patient's medical record number; and
- Primary diagnosis(es).

Depending on the size and nature of the patient population the hospital serves and the types of services it provides, there will likely be variations in the frequency of restraint use as well as in the incidence of patient deaths. Surveyors should adjust their expectations for the volume of log or tracking system entries accordingly. For example, hospitals with intensive care units might be more likely to use both soft, 2-point wrist restraints and to have seriously ill patients who die as a result of their disease while such restraints are being used or within 24 hours after their discontinuance. On the other hand, a rehabilitation hospital would be expected to use such restraints less frequently, and to have patients who die less frequently while hospitalized.

The log or tracking system must be available in written, i.e., hard copy, or electronic form immediately upon CMS's request. CMS will specify the form in which the information is to be provided. Generally CMS would request access to the log or tracking system during an on-site survey by CMS staff or State surveyors acting on CMS's behalf when assessing compliance with restraint/seclusion requirements. However, CMS may also request that a copy of portions or the entire log or tracking system be provided, even though no survey is in progress.

Accreditation organizations conducting hospital inspections in accordance with a CMS-approved Medicare hospital accreditation program are also entitled to immediate access to the log or tracking system. The hospital is not required to make the contents of the log or tracking system available to any other outside parties, unless required to do so under other Federal or State law.

The hospital must document in the patient's medical record the date and time the death report entry was made into the log or tracking system.

Survey Procedures §482.13(g)(2), (3)(ii), & (4)

- Does the hospital have restraint/seclusion death reporting policies and procedures that address responsibilities and systems for identifying restraint/seclusion-associated deaths that must be recorded in an internal hospital log/tracking system, and for implementing the reporting and recordkeeping requirements?

- Ask the hospital how it ensures that each death that must be captured in the log/tracking system is identified and entered.

- Interview inpatient unit staff to determine whether they have had patients who die while 2-point soft wrist restraints are being used without seclusion or within 24 hours of their discontinuance. If yes, ask the hospital to demonstrate that it has recorded such deaths.

- If the hospital's log or tracking system relies upon staff identification of reportable deaths, interview several applicable staff members to determine whether they are aware of the hospital's policy and know when and where to report internally a restraint/seclusion-associated death.

- Review the log/tracking system for patient deaths associated with use of only 2-point soft wrist restraints to determine if:

    - Each entry was made within 7 days of the patient's death; and

    - Each entry contains all the information required under the regulation.

- Is the hospital able to make the log or tracking system available immediately on request?

- Review a sample of medical records of patients whose deaths were entered in the log or tracking system.

- Does the medical record indicate that only soft, 2-point wrist restraints were used?

- Is there documentation in the medical record of the entry into the log or tracking system?

REFER TO E-TAGS (Appendix Z)

§482.15 Condition of Participation. Emergency Preparedness

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, utilizing an all-hazards approach. The emergency preparedness program must include, but not be limited to, the following elements:

Interpretive Guidelines §482.15

The organization must comply with all Emergency Preparedness requirements under this condition. This condition consists of multiple standards. Please refer to State Operations Manual Appendix Z – Emergency Preparedness Requirements for All Providers and Suppliers Deficiencies will be cited as an E-Tag on the hospital 2567.

A-0263
(Rev. 235; Issued: 01-16-26; Effective: 01-16-26; Implantation:01-16-26)

§482.21 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.

Interpretive Guidelines §482.21

A hospital is required to have a quality assessment and performance improvement (QAPI) program that provides a mechanism to systematically examine the quality of care delivered and implement specific improvement projects on an ongoing basis for all of the services provided by the hospital. The hospital should also consider the complexity of those services when determining quality parameters of those services. Hospitals are expected to continuously study and improve their processes and service delivery and take a proactive approach to improve their performance and focus on improving patient outcomes and the prevention of medical errors.

CMS does not prescribe a particular QAPI program that all hospitals must use. Rather, each hospital is provided with the flexibility to develop its own program based on its unique needs, priorities, clinical programs, as well as its own considerations for the health equity needs of its patient population. Each hospital should have processes in place to continually identify opportunities for quality and safety improvements and to implement changes that lead to improved outcomes that are sustained over time.

The hospital is expected to provide evidence of continuous data collection, data analysis (with identified areas for improvement), and implementation of changes, including the ongoing monitoring of those changes to determine their effectiveness. In addition, there should be evidence that the governing body is engaged in the oversight of the QAPI program for all services provided by the hospital, including those provided under contract or arrangement.

The hospital-wide program should include all locations and services and departments of the hospital, whether on-campus or off-campus (i.e., other inpatient campuses, inpatient units located on another hospital's campus/buildings, off-campus EDs, etc.), covered under the hospital's Medicare provider agreement. While it is not expected that all departments and services be continuously engaged in large scale or resource-intensive QAPI projects, all departments and services (including those provided under arrangement or contract) should provide evidence that there is continuous monitoring of the quality and safety of the services provided and take corrective actions as necessary to ensure patient safety and to improve the quality of care provided.

For services under contract, in accordance with 42 CFR 482.12(e), the hospital's governing body must ensure that contractors provide services in a manner that allows the hospital to comply with all applicable Conditions of Participation and standards for the contracted services. Furthermore, the hospital must be able to demonstrate how it includes services provided under an arrangement or contract in its QAPI program. This may be done by providing evidence of the evaluation of contracted services and, when appropriate, conducting performance improvement activities or projects related to services under arrangement or contract.

Survey Process

Surveyors are not expected to judge the performance and quality measures used by a hospital. Instead, surveyors will evaluate the hospital's success in its efforts to improve performance and quality. The focus of the QAPI CoP assessment is to determine whether a hospital has an effective, ongoing system in place for identifying problematic events, policies, or practices, and is taking actions to remedy them and then following up on these remedial actions to determine if they were effective in improving performance and quality. The survey focus will also include whether improvements are sustained over time.

There may also be an evaluation of the QAPI program when surveyors identify non-compliance with other regulatory requirements. For example, a surveyor may observe deficiencies in infection control or medication administration practices. Citations should be made under the applicable portions of the infection control, nursing, or pharmacy CoPs. However, surveyors should also investigate the tracking of medical errors and adverse events related to healthcare-associated infections or medication errors, what type of analyses and actions have been taken to reduce future errors, and what follow-up evaluations are underway. If, during the course of the survey, such lapses in care and safety are found to be very serious or widespread, surveyors should investigate the effectiveness of the QAPI program related to the handling of medical errors and adverse events. If there is evidence that the hospital is taking effective actions through its QAPI program to correct such deficiencies, then a citation of QAPI CoP deficiencies generally would not be appropriate, despite the individual lapses surveyors might have observed for other regulatory requirements.

Surveyors should avoid using the hospital's own QAPI program data and analyses as evidence of violations of other CoPs unless there is evidence of current non-compliance with the regulatory requirements. However, surveyors may review additional records pertaining to the operation of the hospital, including medical error reports and peer review information when these documents are necessary to determine compliance with statutory and regulatory requirements. With rare exceptions, surveyors must not use the information they have gathered from QAPI program records as the basis for a deficiency citation under other CoPs. There may be cases where it might be appropriate to use QAPI program information as evidence of a deficiency, but these cases would be the exception rather than the rule. For example, a review of the QAPI program documents might show that a hospital identified three incidents of wrong-site surgery over twelve months, and another five near misses, but that no subsequent action was taken to analyze these incidents and implement any changes to its pre-surgical verification procedures. Here, the QAPI documents would suggest there is current noncompliance with the QAPI CoP since the hospital's QAPI program did not take any action to address the problems it had identified. In this circumstance, it would also be appropriate for surveyors to review the medical records for the incidents identified in the QAPI system to assess compliance with the surgical services CoP.

Surveyors should be aware of the sensitivity of the documents when reviewing QAPI program materials furnished by a hospital that relate to peer review or other analyses of adverse events. Surveyors must:

- *Avoid making copies of such information unless absolutely necessary to support a deficiency citation; and*

- *Avoid making notes that could identify particular events-- e.g., do not write: "root cause analysis of an adverse event in August, 20XX related to inadvertent disposal of an organ recovered from a living donor showed that primary causes were Y and Z and that the process for handling a recovered organ should be modified in XX manner. In December 20XX hospital made the following changes to its process…." Instead write: "confirmed that hospital conducted a root cause analysis of an adverse event related to the hospital's transplant program; reviewed analysis, which was systematic, detailed, and resulted in recommendations; confirmed the hospital implemented recommendations and is monitoring for effectiveness." Ensure that the recommendations resulted in improvements to processes, outcomes, etc., resulting in positive patient outcomes.*

Additionally, surveyors should:

- *Verify the hospital has a formal QAPI program by asking for a copy of the program documents.*

- *Review program documentation and verify the program is:*

    - *Based on, and reflects, the complexity of the hospital's organization and services*
        - *Is the size and complexity of the hospital reflected in the overall scope of the QAPI program?*
    - *Hospital-wide (including services under contract or arrangement)*
        - *Is there evidence that all hospital departments and services are included in the QAPI program?*
        - *Does the documentation include participation by all contracted services?*
            - *Do written contracts include QAPI requirements and roles and responsibilities of the contractor?*
    - *Data-driven (does the documentation indicate what data is used to make QAPI program decisions?)*
    - *Focused on quality indicators/measures related to improved health outcomes, as well as the prevention and reduction of medical errors (does the program focus on non-clinical measures such as employee satisfaction data as opposed to clinical measures such as infection control incidence rates and/or nationally recognized quality indicators?)*

- *Verify that the hospital enables surveyors to assess its compliance with the QAPI requirements by providing access to staff and program documentation as requested.*

If the surveyor requests information that the hospital asserts is protected from review, ask the hospital if it can provide alternative evidence of compliance that is not protected.

- *If the hospital produces alternative evidence, it is within the sole discretion of the surveyor to determine whether it provides sufficient evidence with which to assess compliance with the QAPI requirements.*

- *If the hospital cannot produce alternative evidence or if the alternative evidence is insufficient to determine compliance, a deficiency must be cited.*

A-0273

(Rev. 235; Issued: 01-16-26; Effective: 01-16-26; Implantation:01-16-26)

Data Collection & Analysis

§§482.21(a), 482.21(b)(1), 482.21(b)(2)(i), & 482.21(b)(3)

§482.21(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.

§482.21(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.

***Interpretive Guidance* §§482.21(a), 482.21(b)(1), 482.21(b)(2)(i), & 482.21(b)(3)**

Quality Indicators and Data Analysis

A QAPI program should include the continuous collection and analysis of quality indicators/data and corrective actions as appropriate to remedy processes, operations, and services that will improve patient outcomes. The quality indicator data should include patient care data such as adverse events and other data such as that received from Medicare quality reporting and performance programs. Examples of those measures may include, but not limited to, Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) data, maternal morbidity, sepsis, and safe opioid practices. The data gathered for quality indicators should be used to determine if the services provided by the hospital are effective toward delivering safe, quality care to the patients it serves. There may also be considerations for cultural competence as hospitals develop these measures. The hospital should demonstrate that the quality indicators it has selected, along with the associated data, are used to monitor quality and safety and to also identify opportunities for quality improvement.

An analysis of the data should demonstrate that the quality indicators used produce measurable improvement related to the specific quality indicator. For example, a medication error indicator included in the program must demonstrate a decrease in medication errors. The care process of proper hand hygiene (handwashing) must demonstrate increased staff compliance with hand hygiene standards of practice. A central line infection indicator must demonstrate a decrease in the incidence and prevalence of central line infections. Measurable improvement is evidenced by quantifiable data. For example, a hospital may have identified 10 medication errors in one month in its ICU. After analysis of the errors and implementation of medication administration changes, it tracks medication errors over the next 6 months. The 6 months of data show that there was only 1 medication error in the ICU over the entire 6 months. In this example, this is measurable improvement evidenced by data. CMS does not prescribe thresholds for acceptable improvement and expects hospitals to determine these thresholds in accordance with national standards of practice.

Additionally, a hospital is allowed to develop its own measures and indicators that are based on the scope and complexity of its their services, and on considerations for the health equity of its specific patient population. Under the QAPI CoP, a hospital is not required to use any specific set of measures or indicators.

Governing body responsibility for frequency and detail of data collection

The governing body is responsible for specifying the frequency and the detail of the data collection, which may include, but is not limited to, what data will be collected, what the data is intended to measure, in what areas of the hospital the data will be collected, and how frequently the various types of data will be collected. This does not mean that the governing body is expected to have a high degree of technical expertise in the area of quality data collection. However, the governing body must have information that describes the hospital's QAPI data collection program in sufficient detail so that the governing body is able to determine what program data requirements to approve.

There must be evidence that the governing body has had an active role in the development and ongoing planning of the frequency and detail of QAPI data collection. Such evidence may be documentation in the governing body meeting minutes that it has reviewed and approved the frequency and detail of the QAPI data collection program.

Survey Procedures §482.21(a)

- *Ask QAPI staff to provide a list of the quality indicators they are currently tracking.*
    - *Verify that this includes the tracking of adverse events.*
    - *Verify that the quality indicator data include patient care data, and other relevant data such as that received from Medicare quality reporting and performance programs, including, but not limited to, data related to hospital readmissions and hospital-acquired conditions.*
    - *Verify that the quality indicators are reflective of the hospital's patient population.*

- *Ask QAPI staff to provide evidence (measurement data) of measurable improvements in the quality indicators it has selected for its program.*
    - *Verify that improvements are ongoing (several data analyses showing improvement over time) and not just one-time events.*
    - *If the evaluation did not show improvements or sustained improvements, is there evidence that the hospital implemented a revised or new solution?*

Survey Procedures §482.21(b)

- *Ask to see evidence that the governing body has specified the frequency and detail of QAPI program data collection*
    - *Look at governing body meeting minutes.*
    - *Do QAPI program reviews include this information?*

- *Verify the hospital is using the data being collected to monitor the safety and quality of care.*
    - *Select a sample of data being collected and ask the governing body or other appropriate leadership to explain how the collection of the particular data is used to monitor quality and safety.*

- *Verify the hospital is using the data being collected to identify opportunities for improvement*
    - *Select a sample of data being collected and ask the governing body or other appropriate*

leadership to give examples of how the specific data has identified opportunities for improvement.

- *Ask to see documented evidence of the opportunities the hospital has identified for improvement based on the collection of data*

A-0283

(Rev. 235; Issued: 01-16-26; Effective: 01-16-26; Implantation: 01-16-26)

Quality Improvement Activities

§§482.21(b)(2)(ii), 482.21(c)(1) & 482.21(c)(3)
§482.21(b)(2) Standard: Program Data

The hospital must use the data collected to--…

(ii) Identify opportunities for improvement and changes that will lead to improvement.

***Interpretive Guidance* §§482.21(b)(2)(ii)**
As a component of the hospital's QAPI program, the hospital should utilize the data collected to identify opportunities of continuous and ongoing improvement as well as mechanisms for change to improve safety and quality of care for the patients it serves.

§482.21(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….

(3) 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.

***Interpretive Guidance* §§482.21(c)(1) & 482.21 (c)(3)**
Hospitals should evaluate their QAPI program data to ensure that they are considering the information below in establishing priority areas where it will undertake specific actions to improve its performance. The prioritization of quality of efforts should address the effect on health outcomes, patient safety, and quality of care. Hospitals should determine these areas based on the complexity of the services they provide.

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

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

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

- ***Incidence*** *refers to the rate or frequency at which an event being measured occurs within a specific timeframe.*

- ***Prevalence*** *refers to how widespread something is at a specific point in time in a particular place or population.*

- ***Severity*** *refers to the degree of seriousness or significance of an event or issue in a hospital.*

Survey Procedures §§482.21(b)(2)(ii), 482.21(c)(1) & 482.21(c)(3)

- *Ask to see a list of current or recent performance improvement activities.*

- *Ask the governing body or the leadership staff who oversee the QAPI program to provide evidence that its improvement activities are focused on high-risk, high-volume, or problem-prone areas. Does it have any data (either derived from its own QAPI data collection or public data) on incidence, prevalence, or severity to support its choices? Does it have evidence that the activities affect health outcomes through improving quality of care or patient safety?*

- *Ask the governing body or leadership staff who oversee the QAPI program to provide evidence of QAPI activities that were initiated based on data reported through the medical error/adverse event tracking system.*

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

A-0286

(Rev. 235; Issued: 01-16-26; Effective: 01-16-26; Implantation: 01-16-26)

Patient Safety, Medical Errors & Adverse Events

§§482.21(a)(1), 482.21(a)(2), 482.21(c)(2), & 482.21(e)(3)

§482.21(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… identify and reduce medical errors.

(2) The hospital must measure, analyze, and track…adverse patient events….

§482.21(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.

§482.21(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: …

(3) That clear expectations for safety are established.

Interpretive Guidance §§482.21(a)(1), 482.21(a)(2), 482.21(c)(2), & 482.21(e)(3)

Medical errors and adverse events

The reporting mechanism for medical errors and adverse events is at the discretion of the hospital. CMS does not specify the type of reporting mechanism to be used, but expects that the system will permit the hospital to track and analyze medical errors and adverse events in an effective and meaningful manner. As appropriate, hospitals should educate all hospital staff and contract staff on what is considered a medical error and an adverse event, as well as when and how to report these events.

CMS has adopted the following definition of an error from the Quality Interagency Coordination Task Force (QuIC) (68 FR 3435, 3436, January 24, 2003):

*"An **error** is defined as the failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim. Errors can include problems in practice, products, procedures, and systems."*

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

- *Medication administration errors - wrong medication, wrong dosage, wrong patient, etc.;*
- *Surgical errors - wrong patient, wrong site, retained instrument, etc.;*
- *Equipment failure – defibrillator without working batteries, IV pump that results in inadvertent dosing, alarms not working properly, etc.;*
- *Infection control errors – poor aseptic technique, incorrect processing of sterile instruments and equipment, incorrect isolation practices, lack of standard precautions, etc.;*
- *Blood transfusion-related errors – wrong patient, wrong blood product administered, etc.; and*
- *Diagnostic errors – misdiagnoses leading to incorrect choice of therapy, failure to use an indicated diagnostic test, misinterpretation of test results, failure to act properly on abnormal results.*

*Not every medical error results in harm to a patient; the error may be detected and addressed before a harmful effect can occur (a "**near miss**") or the consequence of the error may be minimal. From a patient safety perspective, a near miss is considered an error and much can be learned from the near miss in terms of system weaknesses that could, in the future, result in actual harm to patients. Therefore, hospitals must track and analyze errors that result in near misses, and focus on their prevention and reduction.*

While the regulation also specifically calls for measuring, analyzing, and tracking of adverse events, adverse events may or may not be preventable. A preventable adverse event is an injury caused by an error. Section 482.70 defines an adverse event as "an untoward, undesirable, and usually unanticipated event that causes death or serious injury, or the risk thereof."

Analysis of Causes of Medical Errors and Adverse Events

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

Implementing Improvement/Preventive Strategies

After the systemic analysis of the error or adverse event has led to the identification of the cause of the event, hospitals should develop and implement preventive actions to improve the quality and safety associated with the event or the error. Preventive actions include, but are not limited to, changes in policies and procedures, repairing or replacing equipment, staff education and training, etc. Where appropriate, the hospital should make all affected staff aware of the strategies and related actions it has implemented to correct and prevent specific errors and adverse events, and also provide applicable training. Hospitals should be able to provide evidence of the implemented changes, such as documented staff education and training, documentation of new or revised policies, evidence that equipment has been repaired or replaced, etc.

Evaluating Changes and Sustaining Improvement

The hospital should also have a method to assess whether the strategies and actions it has implemented resulted in improved outcomes and that those improved outcomes are sustained over time. This means the hospital should collect data that enables the hospital to determine whether indicators, related to a specific area targeted for change, actually demonstrated an improvement after implementation of the changes.

For example, the hospital should continue to periodically collect data on proper hand hygiene and then analyze the data to determine if the solution has resulted in sustained improvement in handwashing compliance. If the analysis of the periodic collection of handwashing data shows that the solution has not resulted in a sustained improvement over an appropriate period of time, a new or revised strategy/solution must be implemented, with subsequent data collection and monitoring to evaluate the effectiveness of the new solution.

Prospective hospitals applying for initial certification in Medicare

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

Survey Procedures

- *Ask to see evidence of the medical error/adverse event reporting system. Ask for a copy of the medical error and adverse event reporting policy. Ask for a demonstration of how to use the system and how the system is able to organize the reported data for meaningful analysis.*
    - *Can the system organize the data by type of error/adverse event?*
    - *Can the system organize the data by dates to show trends over time?*
    - *Can the system organize the data by shift, by unit where the error occurred, etc.?*

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

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

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

A-0297

(Rev. 235; Issued: 01-16-26; Effective: 01-16-26; Implantation: 01-16-26)

Performance Improvement Projects

§482.21(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 cooperative project, but its

own projects are required to be of comparable effort.

Interpretive Guidelines §482.21(d):

*Performance improvement **projects** are differentiated from performance improvement **activities** under 482.21(b)(2) in that performance improvement projects require a significant amount of up-front planning, include project objectives, and have a definitive beginning and end date (time-limited). Whereas performance improvement **activities** make up the continuous, ongoing functions of a hospital QAPI program, such as ongoing tracking of medical errors and adverse events, analysis of data, implementation of changes with associated education and training, continuous monitoring of quality and safety in all hospital departments and service areas, etc.*

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

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

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

Survey Procedures

- *Ask the hospital to provide a list of distinct performance improvement projects the hospital is currently conducting and has conducted within the last three years to verify the hospital is conducting annual QAPI projects.*

- *Ask to see the documentation of why each project was conducted and evidence to support the progress being made on each project.*

    - *Does the documentation include data to support "why" each project was conducted (e.g., medical error and adverse event reports indicated a need for improvement in a particular area)?*
    - *Does the documentation include evidence of ongoing monitoring of the project's progress, such as periodic data collection and analysis?*

- *Ask the Governing Body to explain how the selection (number and scope) of the specific projects is in alignment with the hospital's complexity and the scope of services it provides.*

    - *Consider the size of the facility and the intensity of its services, such as critical care services/units, complex surgeries, transplant services, maternal/child health services, and oncology services, including radiation and chemotherapy, etc.*

A-0309

(Rev. 235; Issued: 01-16-26; Effective: 01-16-26; Implantation: 01-16-26)

Executive Responsibilities

§482.21(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.

Interpretive Guidelines §482.21(e)(1), (2) & (5)

The hospital's leadership, meaning the hospital's governing body (or organized group or individual who assumes full legal authority and responsibility for operations of the hospital), medical staff, and administrative officials, are all responsible and accountable for the hospital's QAPI program. The medical staff may delegate this leadership responsibility and accountability for the QAPI program to the medical staff executive committee if it has such a committee. "Administrative officials" includes, at a minimum, the hospital's chief executive officer, chief operating officer, and the chief nurse executive (or equivalent), but would also include other executives in the hospital's administration.

Because the QAPI program is required to be a hospital-wide program, the governing body, medical staff, and administrative officials are responsible for the QAPI requirements at all locations of the hospital (onsite and off-site inpatient and outpatient services and departments) and with regard to all services provided directly by the hospital as well as those services provided under arrangement or contract. This means that the services at all locations of the hospital must be taken into consideration when developing, defining, implementing, and maintaining the QAPI program.

Together these hospital leaders are responsible for ensuring that the requirements identified in this standard, as well as in the other standards of this CoP, are met. Therefore, the hospital should be able to provide evidence that all such individuals are engaged in and fulfilling their QAPI responsibilities. While these leaders are not expected to be directly involved in the day-to-day activities of the hospital's QAPI program, they should be actively engaged in the oversight of the QAPI program through their periodic review of the program, including, but not limited to, the development of a plan to implement and maintain the QAPI program, the review of the progress of QAPI projects, the determination of annual QAPI projects, the evaluation of the effectiveness of improvement actions that the hospital has implemented, etc. Evidence may also include, but is not limited to, the establishment of a QAPI plan, QAPI meeting minutes with attendance rosters, signatures on annual QAPI project reviews and approvals, minutes from annual budget meetings that incorporate planning for QAPI resources, etc.

Additionally, this group of leaders is responsible for ensuring that clear expectations for safety are established and communicated hospital-wide. Establishing clear expectations for safety should, at a minimum, include, but not be not limited to, informing all staff of their specific roles and responsibilities in QAPI. Clear expectations for safety must also be set and communicated to those providing services under arrangements or contracts and should be documented in the contracts. It is expected that upon survey, all staff (including contractors) are able to articulate their roles and responsibilities in supporting the hospital's expectations for safety, such as what safety risks or breaches they are expected to report and how they would be expected to report them. Hospitals may communicate safety expectations through education and training, the use of posters that are constant reminders of safety requirements, staff newsletters, etc.

Contracted Services or Services Under Arrangement

When hospitals choose to provide services under an arrangement or through a contract instead of providing the services directly, it does not mean that the hospital is not responsible for the quality and safety of the services provided by the contractor. Instead, in accordance with 42

CFR 482.12(e)(1), the hospital's governing body must ensure that services performed under contract are provided in a safe and effective manner and, under 482.21, must ensure that services provided under contract or arrangement are included in the QAPI program. Therefore, the hospital must be able to demonstrate how it includes services provided under an arrangement or contract in its QAPI program, Evidence of this inclusion would include, but not be limited to, periodic assessment of contracted services, what resources the contractor has allocated to QAPI activities, how the contractor actively participates in QAPI activities, such as providing the governing body with periodic quality reports/data, attending QAPI planning meetings, and, when appropriate, conducting performance improvement projects. For example, a hospital that provides emergency services (and staffing) for its emergency department (ED) under contract or arrangement must demonstrate that it routinely receives quality data from the ED contractor, reviews the data, and takes necessary action based on the data. It is expected that the hospital must be able to provide evidence that the contracted services are included in the QAPI program in order to demonstrate compliance with the QAPI CoP.

Evidence of the executive leadership exercising its required QAPI program oversight would include:

- *budget or other documents that indicate the resources available to the QAPI program, and*
- *minutes of governing body meetings that show QAPI as a standing agenda item, and more specifically, that the executive leadership makes the required QAPI program decisions related to planning, data collection, and projects, conducts regular reviews of information on the performance of the QAPI program, and makes decisions based on that review for the overall direction and management of the program.*

Survey Procedures

- *Ask to see evidence that the governing body, hospital CEO, Medical Staff (or its executive committee), and other administrative officials are providing oversight in the QAPI program*
    - *Are there QAPI meeting minutes that document their attendance?*
    - *Do the Governing Body meeting agendas provide evidence that the QAPI program thas been addressed?*
    - *Do the governing body meeting minutes include evidence of QAPI discussions?*
    - *Are there documents such as annual QAPI program reviews that include their signatures?*

- *Ask to see evidence that the governing body, medical staff (or its executive committee), and administrative officials:*
    - *Approve the number of distinct QAPI projects to be conducted annually.*

- *Review the results of QAPI data collection, analyses, activities, and projects, and make decisions based on such review.*

- *For those services the hospital provides under arrangement or contract, ask to see evidence that the contractor is actively involved in the QAPI program:*

  - *Do the governing body, medical staff, and administrative officials periodically receive and review quality data from the contractor?*

  - *Is the contracted service involved in any current or past hospital QAPI projects?*

  - *Does the contract or agreement include the hospital's expectations regarding the contractor's roles and responsibilities regarding QAPI?*

  - *Does the data from the contractor demonstrate positive outcomes related to the services provided?*

A-0315

(Rev. 235; Issued: 01-16-26; Effective: 01-16-26; Implantation: 01-16-26)

Providing Adequate Resources

§482.21(e) Standard: Executive Responsibilities

[§482.21(e) 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.

Interpretive Guidelines §482.21(e)(4)

The resources dedicated to the QAPI program should be commensurate with the overall scope and complexity of the services provided by the hospital. The hospital's governing body, in collaboration with its administrative officials and medical staff, should allocate adequate resources to carry out the functions specified by the QAPI program CoP requirements. Adequate resources would mean that the hospital provides sufficient numbers of staff (including consultants, as needed), staff time, information systems, and education and training to support all elements of the QAPI programs' required activities and projects. In addition, adequate means that staff should be qualified to perform the QAPI functions to which they are assigned. Qualified also means staff have experience or training in the functions for which they are responsible. The hospital may choose to use qualified and experienced contractors for the day-

to-day technical aspects of the QAPI program, such as data collection and analysis. However, the hospital's governing body retains the responsibility for the ongoing management of the QAPI program, even when a contractor is used for those functions.

CMS does not prescribe a particular formula for determining whether the hospital has allocated adequate resources to its QAPI program. However, hospitals should be able to demonstrate inclusion of the QAPI program in its budget process and identify in detail the resources it dedicates to the QAPI program. This includes the resources that a contracted service has allocated to support QAPI functions. Additionally, the hospital must be able to provide evidence of the number of staff it has allocated to focus on the management and oversight of the day-to-day QAPI program functions.

Survey Procedures

- *Ask to see detailed evidence of the resources (staff, staff time, education, information systems, etc.) that are provided to support required QAPI functions.*

- *Ask to see evidence that staff are qualified to engage in their respective QAPI responsibilities.*
    - *Have all staff been educated and trained on how to report errors and adverse events?*
    - *Have staff that are required to conduct data collection and analysis received training or possess experience in these functions?*

- *For those services provided under contract, ask to see evidence that contracted services have been incorporated into the QAPI program and that there is governing body oversight of these services and the QAPI program.*

A-0320

(Rev. 235; Issued: 01-16-26; Effective: 01-16-26; Implantation: 01-16-26)

§482.21(f) Standard: Unified and integrated QAPI program 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 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:

Interpretive Guidelines §482.21(f)

The hospital must have a QAPI program for the entire hospital (including all campuses, provider-based locations, satellites, remote locations, etc.). In the case of a hospital system, it is permissible for the system to have a unified and integrated QAPI program (hereafter referred to as a "unified and integrated QAPI") for multiple, separately certified hospitals.

If the hospital uses a unified and integrated QAPI program that it shares with other hospitals that are part of a multi-hospital system, the system governing body is responsible and accountable for ensuring that each of its separately certified hospitals meets all of the requirements of §482.21. Thus, each separately certified hospital subject to the system's governing body must meet all of the QAPI program requirements as outlined in the regulations at §482.21.

Survey Procedures §482.21(f)

- *Surveyors assess the manner and degree of noncompliance with the standards within this condition to determine whether there is condition-level noncompliance.*

A-0321

(Rev. 235; Issued: 01-16-26; Effective: 01-16-26; Implantation: 01-16-26)

§482.21(f)(1) 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

Interpretive Guidelines §482.21(f)(1)

Although a hospital system has the flexibility to develop a unified and integrated QAPI program for all of the separately certified hospitals within its system, there must be evidence that the system wide program has taken into account the differences in patient populations and services offered that provide unique circumstances for each member hospital.

Survey Procedures §482.21(f)(1)

- *Review the QAPI program and identify unified and integrated QAPI elements. How these elements take into account the hospitals population and services offered?*

- *Identify the process for which the hospital's population and services are integrated into the QAPI program.*

A-0322

(Rev. 235; Issued: 01-16-26; Effective: 01-16-26; Implantation: 01-16-26)

§482.21(f)(2) 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.

Interpretive Guidelines §482.21(f)(2)

Each hospital must also demonstrate that the unified and integrated program has mechanisms in place to ensure that the needs and concerns of particular hospital(s) in the system are considered and addressed. This means that each hospital must be able to identify and address or communicate any hospital-specific QAPI issues in addition to any of the issues being addressed in the unified and integrated program of the system.

Survey Procedures §482.21(f)(2)

- *Review the QAPI program and identify unified and integrated QAPI elements and identify QAPI elements that are unique to the particular hospital.*
- *Identify the process for which these unique elements are integrated into the QAPI program*

A-0360

(Rev. 235; Issued: 01-16-26; Effective: 01-16-26; Implantation: 01-16-26)

[The bylaws must:]

§482.22(c)(5) - [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 1861(r) of the Act), an oral and maxillofacial surgeon, or other qualified licensed individual in accordance with State law and hospital policy.

Interpretive Guidelines §482.22(c)(5)(iii)

In lieu of the medical staff bylaws for history and physical requirements at §482.22(c)(5)(i) and (ii), a hospital and its medical staff are free to exercise their clinical judgment in determining whether to implement a policy for identifying, in accordance with §482.55(c)(5)(v), specific patients as not requiring a comprehensive history and physical or any update prior to specific outpatient surgery or a procedure requiring anesthesia. The option permits a pre-surgical

assessment for these patients when appropriate.

The assessment must be completed and documented in the medical record 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, after registration, but prior to surgery or a procedure requiring anesthesia services.

Survey Procedure §482.22(c)(5)(iii)

- *If the medical staff has opted to require a pre-surgical assessment for certain patients, review the written policy for identifying specific patients as not requiring a comprehensive history and physical prior to specific outpatient and surgical procedures.*

- *Review a sample of medical records of patients who had a pre-surgical assessment prior to outpatient surgeries or procedures for documentation that the assessments were completed and documented in the medical record 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, after registration, but prior to surgery or a procedure requiring anesthesia services.*

A-0361

(Rev. 235; Issued: 01-16-26; Effective: 01-16-26; Implantation: 01-16-26)

[The bylaws must:]

§482.22(c)(5) - [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.

Interpretive Guidelines §482.22(c)(5)(iv)

A hospital and medical staff have the flexibility of implementing a written policy for determining a less comprehensive assessment instead of a comprehensive history and physical to be performed for specific outpatients receiving specific surgeries or procedures.

If a hospital and medical staff choose not to develop a written policy to address the requirements at §482.22(c)(5)(iii), (iv), and (v), the medical staff will continue to adhere to medical staff policy requirements at §482.22(c)(5)(i) and (ii).

Survey Procedures §482.22(c)(5)(iv)

- *Review medical staff policies for history and physical requirements for patients receiving outpatient surgeries and procedures to determine if the hospital has exercised the option of an assessment in place of a comprehensive history and physical for specific outpatient surgeries.*

A-0362

(Rev. 235; Issued: 01-16-26; Effective: 01-16-26; Implantation: 01-16-26)

[The bylaws must:]

§482.22(c)(5) - [Include a requirement that --]

(iv) 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:

(v)

(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.

Interpretive Guidelines §482.22(c)(5)(v)

When the hospital and medical staff chooses to exercise the flexibility to perform a pre-surgical assessment, in lieu of the comprehensive history and physical (H&P) and updates, they are required to develop and maintain a written policy, approved by the governing body, that specifies those outpatients and surgeries and procedures for which this optional assessment would apply.

Policies must address certain patient characteristics that may necessitate the need for examination and testing prior to surgery. These factors include but are not limited to, the following:

- *patient age (considering the need for H&P based on pediatric, adult, or geriatric age differences),*
- *diagnosis,*
- *the type and number of procedures scheduled to be performed on the same surgery date,*
- *known comorbidities (e.g. cardiac or pulmonary disease), and*
- *planned anesthesia level (e.g. minimal sedation vs general anesthesia).*

Additionally, the written policy requires the consideration of and based on:

- *national standards and guidelines of practice for the assessment of specific types of patients prior to specific outpatient surgeries and procedures, and*
- *any applicable State and local health and safety laws.*

Survey Procedure §482.22(c)(5)(v)

- *Review a sample of medical records of patients receiving outpatient surgery to determine whether evidence exists that patients who did not receive a comprehensive history and physical prior to receiving outpatient surgeries and procedures met the criteria outlined in the medical staff policy.*

- *Review the hospital's policies and procedures regarding H&Ps to determine if they are consistent with the regulatory requirement.*

- *Is there documentation that the hospital has developed the H&P policies based on nationally recognized standards of practice and guidelines, and any applicable State and local health and safety laws?*

A-0399

(Rev. 235; Issued: 01-16-26; Effective: 01-16-26; Implantation: 01-16-26)

§482.23(b)(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

Interpretive Guidelines §482.23(b)(7)

The hospital must develop policies and procedures, when applicable, for outpatient departments that do not require a registered nurse to be physically present. For example, it would be necessary to have a nurse present in an outpatient surgery department, but it may not be necessary to have a registered nurse on-site at a hospital MRI facility that is outside of the hospital building.

When the hospital develops these policies and procedures, it must develop the criteria of the outpatient departments that do not require a registered nurse physically onsite, taking into account:

- *Types of services delivered by the department*

- *The general level of acuity of the patients receiving care in the department*
- *Established national standards of practice for the services being provided in the department*
- *Patient care and patient safety*
- *Response to patient emergency situations*

In addition to developing the policies and procedures for outpatient departments that do not have a registered nurse present under hospital policy, there must be alternative staffing plans for how the department will be staffed to deliver services to patients without the physical presence of a registered nurse. For example, in the event that a patient requires a one-time service that would require a registered nurse to be present, how would the outpatient department have a staffing alternative to accommodate the needs of the patient?

Once the policies and procedures have been developed, they must be approved by the director of nursing and must be reviewed at a minimum every 3 years.

Survey Procedures §482.23(b)(7)

- *Review outpatient policies and procedures to determine if criteria have been established for when a registered nurse is not required in the outpatient department*
- *Review the policies and procedures for evidence that the criteria were based on the following considerations:*
-
    - *Types of services delivered by the department*
    - *The general level of acuity of the patients receiving care in the department*
    - *Established national standards of practice for the services being provided in the department*
    - *Patient care and safety*
    - *Responsibilities to respond to patient emergency situations*

- *Review the policies and procedures to verify that approval from the director of nursing or designee is present and review is completed at a minimum of every 3 years.*
- *Review alternate staffing plans for the outpatient department when a registered nurse is not present.*

A-0458

(Rev. 235; Issued: 01-16-26; Effective: 01-16-26; Implantation: 01-16-26)

§482.24(c)(4) - All records must document the following, as appropriate:

(i) Evidence of--

(A) A medical history and physical examination 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 examination must be placed in the patient's medical record within 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia services.

Interpretive Guidelines §482.24(c)(4)(i)(A)

Except for those patients who are specified as not requiring a comprehensive history and physical for specific outpatient surgeries and procedures under §482.22(c)(4)(i)(C) (see 71 FR 68676), the medical record must include documentation that a medical history and physical examination (H&P) was completed and documented for each patient no more than 30 days prior to hospital admission or registration, or 24 hours after hospital admission or registration, but prior to surgery or a procedure requiring anesthesia services.

The purpose of an H&P is to determine whether there is anything in the patient's overall condition that would affect the planned course of the patient's treatment, such as an allergy to a medication that must be avoided, or a co-morbidity that requires certain additional interventions to reduce risk to the patient.

The H&P documentation must be placed in the medical record within 24 hours of admission or registration, but prior to surgery or a procedure requiring anesthesia services, including all inpatient, outpatient, or same-day surgeries or procedures. The H&P may be handwritten or transcribed. *For those patients that require an H&P, a*n H&P that is completed within 24 hours of the patient's admission or registration, but after surgery or a procedure requiring anesthesia, would not be in compliance.

Survey Procedures §482.24(c)(4)(i)(A)

- Review a sample of inpatient medical records for various types of patients and outpatient medical records for patients having same day surgery or a procedure requiring anesthesia, *except for those patients who are specified as not requiring a comprehensive history and physical for specific outpatient surgeries and procedures* to determine whether:

    - There is an H&P that was done no more than 30 days before or 24 hours after admission or registration, but, for all cases involving surgery or a procedure requiring anesthesia services, prior to the surgery or procedure, *except for those patients who are specified as not requiring a comprehensive history and physical for specific outpatient surgeries and procedures*;

    - The H&P documentation was placed in the medical record within 24 hours after admission or registration, but, for all cases involving surgery or a procedure requiring anesthesia services, prior to the surgery or procedure, *except for those patients who are specified as not requiring a comprehensive history and physical for specific outpatient surgeries and procedures*;

A-0461

(Rev. 235; Issued: 01-16-26; Effective: 01-16-26; Implantation: 01-16-26)

§482.24(c)(4) - [All records must document the following, as appropriate:

(i) Evidence of --]

(B) An updated examination of the patient, including any changes in the patient's condition, when the medical history and physical examination are completed within 30 days before admission or registration, and except as provided under paragraph (c)(4)(i)(C) of this section. Documentation of the updated examination must be placed in the patient's medical record within 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia services.

Interpretive Guidelines §482.24(c)(4)(i)(B)

When an H&P is completed within the 30 days before admission or registration, the hospital must ensure that an updated medical record entry documenting an examination for any changes in the patient's condition is placed in the patient's medical record within 24 hours after admission or registration, but, in all cases involving surgery or a procedure requiring anesthesia services, prior to the surgery or procedure, *except for those patients who are specified as not requiring a comprehensive history and physical for specific outpatient surgeries and procedures under §482.22(c)(4)(i)(C) (see 71 FR 68676).*

The update note must document an examination for any changes in the patient's condition since the time that the patient's H&P was performed that might be significant for the planned course of treatment. The physician, *oral and maxillofacial* surgeon, or qualified licensed individual uses his/her clinical judgment, based upon his/her assessment of the patient's condition and co-morbidities, if any, in relation to the patient's planned course of treatment to decide the extent of the update assessment needed as well as the information to be included in the update note in the patient's medical record.

If, upon examination, the licensed practitioner finds no change in the patient's condition since the H&P was completed, he/she may indicate in the patient's medical record that the H&P was reviewed, the patient was examined, and that "no change" has occurred in the patient's condition since the H&P was completed. (71 FR 68676) Such statements in the medical record would meet the requirement for documenting the H&P update.

Any changes in the patient's condition must be documented by the practitioner in the update note and placed in the patient's medical record within 24 hours of admission or registration, but prior to surgery or a procedure requiring anesthesia services, *except for those patients who are specified as not requiring a comprehensive H&P for specific outpatient surgeries and procedures*. Additionally, if the practitioner finds that the H&P done before admission is incomplete, inaccurate, or otherwise unacceptable, the practitioner reviewing the H&P, examining the patient, and completing the update

may disregard the existing H&P, and conduct and document in the medical record a new H&P within 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia.

Survey Procedures §482.24(c)(4)(i)(B)

- In the sample of medical records selected for review, look for cases where the medical history and physical examination was completed within 30 days before admission or registration, *except for those patients who are specified as not requiring a comprehensive history and physical for specific outpatient surgeries and procedures*.

- Determine whether an updated medical record entry documenting an examination for changes in the patient's condition was completed and documented in the patient's medical record within 24 hours after admission or registration, *except for those patients who are specified as not requiring a comprehensive history and physical for specific outpatient surgeries and procedures*.

- Determine whether, in all cases involving surgery or a procedure requiring anesthesia services, the update was completed and documented prior to the surgery or procedure, *except for those patients who are specified as not requiring a comprehensive history and physical for specific outpatient surgeries and procedures*.

A-0462

(Rev. 235; Issued: 01-16-26; Effective: 01-16-26; Implantation: 01-16-26)

§482.24(c)(4) - [All records must document the following, as appropriate:

(i) Evidence of --]

(C) 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.

Interpretive Guidelines §482.24(c)(4)(i)(C)

The medical record must provide evidence of a pre-surgical assessment, in lieu of a comprehensive history and physical, that has been completed after registration, but prior to surgery or a procedure requiring anesthesia services for patients that are receiving specific outpatient surgeries and procedures.

The pre-surgical assessment must be determined by the medical staff policy in place that addresses specific patient characteristics that may not necessitate the need for a comprehensive H&P or updated H&P prior to surgery. These factors include, but are not limited to, the following:

- *patient age (considering the need for H&Ps based on pediatric, adult, or geriatric age differences),*
- *diagnosis,*
- *the type and number of procedures scheduled to be performed on the same surgery date,*
- *known comorbidities (e.g. cardiac or pulmonary disease), and*
- *planned anesthesia level (e.g. minimal sedation vs general anesthesia).*

Additionally, the written policy would require the consideration of national standards and guidelines of practice for the assessment of specific types of patients prior to specific outpatient surgeries and procedures and in accordance with State and local laws.

Survey Procedures §482.24(c)(4)(i)(C)

- *Review a sample of medical records of patients receiving outpatient surgery to determine whether evidence exists that pre-surgical assessments and updates have been completed and documented after registration, but prior to surgery or a procedure requiring anesthesia services.*

- *Review the hospital's policies and procedures regarding pre-surgical assessments and updates to determine if they are consistent with the regulatory requirements.*

A-0470
(Rev. 235; Issued 01-16-26; Effective Date 06-30-20; Implementation Date 04-30-21)

§482.24 Condition of Participation*: Medical Records.*

(d) Standard: Electronic notifications. If the hospital utilizes an electronic medical records system or other electronic administrative system, which is conformant with the content exchange standard at 45 CFR 170.205(d)(2), then the hospital must demonstrate that—

> *(1) The system's notification capacity is fully operational and the hospital uses it in accordance with all State and Federal statutes and regulations applicable to the hospital's exchange of patient health information.*
> *(2) The system sends notifications that must include at least patient name, treating practitioner name, and sending institution name.*
>
> *(3) To the extent permissible under applicable federal and state law and regulations, and not inconsistent with the patient's expressed privacy preferences, the system sends notifications directly, or through an intermediary that facilitates exchange of health information, at the time of:*

(i) The patient's registration in the hospital's emergency department (if applicable).

(ii) The patient's admission to the hospital's inpatient services (if applicable).

(4) To the extent permissible under applicable federal and state law and regulations, and not inconsistent with the patient's expressed privacy preferences, the system sends notifications directly, or through an intermediary that facilitates exchange of health information, either immediately prior to, or at the time of:

(i) The patient's discharge or transfer from the hospital's emergency department (if applicable).

(ii) The patient's discharge or transfer from the hospital's inpatient services (if applicable).

Interpretive Guidance §482.24(d)(1-4):

A hospital with an electronic health records system or electronic patient registration systems, which are conformant with the content exchange standard HL7 2.5.1 at 45 CFR 170.205(d)(2), are expected to use these systems to their full capacity to facilitate the notification of patient admission, discharge, and transfer information in accordance with state and federal law. Upon the consent of patient or the patient representative, at a minimum, the information exchange must include the name of the patient, the practitioner responsible for the treatment of the patient, and the name of the institution providing care to the patient. A patient or patient representative does have the right to privacy and not permit the hospital to share this information through this exchange. A patient's refusal should be documented.
These requirements are applicable to all patients regardless of inpatient or outpatient status. There may be instances of multiple admission notifications for one patient. For example, a patient that enters through the emergency department (ED) are not admitted as an inpatient, but the hospital would be responsible for sending a notification of the patient's ED visit; and once the patient is admitted as an inpatient, another notification would be sent as the patient has changed their admission status.

Transfer notifications would be applicable for any patients who may be transferring to another facility for additional needs or changes in level of care.

Discharge notifications would be applicable for all patient discharges from either inpatient or outpatient admissions.

For hospitals that do not have such electronic medical records system or other electronic administrative system, which is conformant with the content exchange standard HL7 2.5.1 at 45 CFR 170.205(d)(2), they are not required to be in compliance with this standard.

A-0471
(Rev. 235; Issued 01-16-26; Effective Date 06-30-20; Implementation Date 04-30-21)

§482.24 Condition of Participation: Medical Records.

(d) Standard: Electronic notifications. If the hospital utilizes an electronic medical records system or other electronic administrative system, which is conformant with the content exchange standard at 45 CFR 170.205(d)(2), then the hospital must demonstrate that—

> *(5) The hospital has made a reasonable effort to ensure that the system sends the notifications to all applicable post-acute care services providers and suppliers, as well as to any of the following practitioners and entities, which need to receive notification of the patient's status for treatment, care coordination, or quality improvement purposes:*
>
> > *(i) The patient's established primary care practitioner;*
> >
> > *(ii) The patient's established primary care practice group or entity; or*
> >
> > *(iii) Other practitioner, or other practice group or entity, identified by the patient as the practitioner, or practice group or entity, primarily responsible for his or her care*

***Interpretive Guidance §482.24(d)(5)**:*

The hospital is expected to make every attempt to send notifications of the patient's status to all applicable post-acute providers and suppliers, in addition to the patient's primary care practitioner, primary care group, or other practitioner or group that is identified by the patient that may be responsible for the patient's care. For example, patient may request that these admission, discharge, and transfer notifications be sent to a specialist responsible for their care, that is not their primary care provider. This requirement does not limit the hospital's ability to notify additional entities based on hospital policy, such as ACO attribution lists.

A-0700
(Rev. 235; Issued: 01-16-26; Effective: 01-16-26; Implantation: 01-16-26)

§482.41 Condition of Participation: Physical Environment

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.

Interpretive Guidelines §482.41

This CoP applies to all locations of the hospital, all campuses, all satellites, all provider-based activities, and all inpatient and outpatient locations.

The hospital's Facility Maintenance and hospital departments or services responsible for the hospital's buildings and equipment (both facility equipment and patient care equipment) must be incorporated into the hospital's QAPI program and be in compliance with the QAPI requirements.

Survey Procedures §482.41

The Physical Environment CoP *standards are typically assessed as part of the health and safety survey*. Each surveyor should assess the hospital's compliance with the Physical Environment CoP *during the course of the survey*. The Life Safety Code *(LSC)* survey *is typically* conducted separately by *surveyors trained to assess LSC requirements. There is a separate survey form (Form CMS-2786) used to evaluate compliance with the LSC.*

A-0701

(Rev. 235; Issued: 01-16-26; Effective: 01-16-26; Implantation: 01-16-26)

§482.41(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 assured.

Interpretive Guidelines §482.41(a)

The hospital must ensure that the condition of the physical plant and overall hospital environment is developed and maintained in a manner to ensure the safety and well-being of patients. This includes ensuring that routine and preventive maintenance and testing activities are performed as necessary, in accordance with Federal and State laws, regulations, and guidelines and manufacturer's recommendations, by establishing maintenance schedules and conducting ongoing maintenance inspections to identify areas or equipment in need of repair. The routine and preventive maintenance and testing activities should be incorporated into the hospital's QAPI plan.

The hospital must be constructed and maintained to ensure risks are minimized for patients as well as for employees and visitors. Hospitals are expected to demonstrate how they are addressing important safety features in accordance with nationally recognized standards. *Important safety features* should be addressed when applicable*, including but not limited to the following:*

Accessibility

- The hospital must ensure all buildings at all locations of the certified hospital meet State and Federal accessibility standards (e.g. Office of Civil Rights requirements). The requirements apply to the interior and exterior of all buildings.

Age-related safety *considerations*

- Hospitals are expected to address safety hazards and risks related to age-related factors. Healthcare provided to neonatal, pediatric, and geriatric patients must be in accordance with nationally recognized standards. Age-related risks may include *factors* such as security of inpatient and outpatient locations, access to medications, cleaning supplies and other hazardous materials, furniture and other medical equipment, and increased *risk* of falls.

Security

- To minimize the risk of unauthorized access to or inappropriate departure from secured healthcare units, hospitals must demonstrate security features in accordance with nationally recognized standards to ensure the safety of vulnerable patients. This includes, but is not limited to, patients such as newborn (e.g. infant abduction), pediatric, behavioral health, those with diminished capacity and dementia/Alzheimer's.

  Access to non-clinical rooms identified as hazardous locations must be secured to prevent patient and visitor entry. Examples include electrical rooms and heat, ventilation, air conditioning (HVAC) rooms.

Ligature risk

- The presence of unmitigated ligature risks in a psychiatric hospital or a psychiatric unit of a hospital *may be* an immediate jeopardy situation. *Please refer to Appendix Q for guidance on the determination of immediate jeopardy.* Ligature risk findings must be referred to the health and safety surveyors for further evaluation and possible citation under Patients' Rights.

Weather-related exterior issues

- Although hospitals cannot address all weather-related issues, they are expected to address potential safety hazards specific to weather on both the exterior and interior locations in accordance of nationally recognized standards. Areas of risk include driveways, garages, entry points, walkways, etc.

Survey Procedures §482.41(a)

- Verify that the condition of the hospital is maintained in a manner to assure the safety and well-being of patients (e.g., condition of ceilings, walls, and floors, presence of patient hazards, etc.).

- Review the hospital's routine and preventive maintenance schedules to determine that ongoing maintenance inspections are performed and that necessary repairs are completed.

- Review a copy of the most recent environmental risk assessment to determine if the

hospital has identified any accessibility, age-related, security, suicide and/or weather related risks or concerns. If environmental safety concerns have been identified in this assessment, what plans have been implemented by the hospital to ensure patient/staff safety?

- Refer any potential power strip use deficiencies to Life Safety Code surveyors.

- Communicate findings with health and safety surveyors as appropriate. *Patient safety issues related to the presence of ligature risks resulting in an unsafe setting, including but not limited to the presence of unmitigated ligature risks in a psychiatric hospital or a psychiatric unit, must be cited at the appropriate CoP, such as under Patient Rights §482.13(c)(2), Physical Environment §482.41(a), Nursing Services, QAPI, etc. For example, in follow-up to a suicide by hanging it was determined there was lack of screening and assessment of a patient at risk as well as hazards in the physical environment (presence of drop ceilings or ligature points in unmonitored areas), surveyors may consider citing Physical Environment in addition to Patient Rights.*

NOTE: Life Safety Code waivers are not permissible for ligature risk findings since ligature risks are a Patient Rights issue, even though they may also be a Physical Environment issue.

A-0702

(Rev. 235; Issued: 01-16-26; Effective: 01-16-26; Implantation: 01-16-26)

§482.41(a)(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.

Interpretive Guidelines §482.41(a)(1)

The hospital must comply with the applicable provisions of the 2012 edition of the National Fire Protection Amendments (NFPA) LSC and mandatory references, such as, Health Care Facilities Code and National Electric Code, which contain requirements for emergency lighting and emergency power. In locations not required to have emergency power and lighting by the LSC or its applicable references, battery lamps and flashlights must be readily available.

Survey Procedures §482.41(a)(1)

LSC surveyors will assess the NFPA requirements for emergency power and lighting. However, health and safety surveyors should also assess whether emergency power and lighting are observed in operating, recovery, intensive care, emergency rooms, and stairwells.

A-0710

(Rev. 235; Issued: 01-16-26; Effective: 01-16-26; Implantation: 01-16-26)

§482.41(b)

(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.

Interpretive Guidelines §482.41(b)(1)–(3)

Medicare-participating hospitals must comply with the *2012 edition of the LSC and Tentative Interim Amendments 12-1 through 12-4* for all patient care locations*, including* locations such as emergency departments, outpatient care locations, etc.

Outpatient surgical departments of a hospital that meet the LSC definition of an Ambulatory Health Care Occupancy (AHCO) must meet the AHCO chapters requirements, regardless of the number of patients served. The LSC would permit a reduction in the level of fire protection to that of a Business Occupancy at facilities providing services simultaneously to less than four patients who are incapable of self-preservation. However, considering the complexity and elevated risk associated with surgical procedures performed in hospitals outpatient surgical departments and because such departments are comparable to ASCs (see 42 CFR 416.44), CMS requires that the minimum level of fire protection afforded by the AHCO requirements be maintained, regardless of the number of patients being served by the department.

Corridor doors and doors to rooms containing flammable or combustible materials must be provided with hardware that has a latch to keep the door in a closed position. Roller latches, which will release by pushing on the door, are prohibited on such doors.

As part of its survey Plan of Correction, a hospital may request a waiver of specific LSC provisions that would result in unreasonable hardship on the hospital and would not adversely affect the health and safety of patients. The State survey agency (SAs) or CMS approved Accreditation Organizations (AO) may recommend approval of waivers requested by providers,

but only CMS locations may grant approval of waivers. Therefore, all LSC and HCFC waiver requests recommended for approval by SAs and AO, must be forwarded to the CMS location for adjudication. There is no authority for either the State or the CMS location to grant waivers of Board and Care Occupancy provisions.. Deficiencies must be corrected as part of the survey plan of correction within the timeframe established by CMS.

The LSC requirements do not apply in a State if CMS finds that a fire and safety code imposed by State law adequately protects patients in a hospital. Surveyors should refer to Chapter 2, section 2470E for guidance.

Survey Procedures §482.41(b)(1) - (3)

The Physical Environment CoP standards are typically reviewed by one surveyor as part of the health and safety survey. However, each surveyor should assess the hospital's compliance with the Physical Environment CoP during the course of their survey. The LSC survey is typically conducted separately by surveyors trained to assess LSC requirements. There is a separate survey form (Form CMS-2786) used by the *State agency (SA) LSC surveyors* to evaluate compliance with the *LSC*.

As part of a survey Plan of Correction, hospitals may request waivers of specific LSC provisions that would result in unreasonable hardship on a hospital and that would have no adverse effect on the health and safety of patients. Any request for a LSC waiver should be included when submitting the survey plan of correction. The State survey agency (SAs) or CMS approved Accreditation Organizations (AO) may recommend approval of waivers requested by providers, but only CMS locations may grant approval of waivers. Therefore, all LSC and HCFC waiver requests recommended for approval by SAs and AO, must be forwarded to the CMS location for adjudication. There is no authority for either the State or the CMS location to grant waivers of Board and Care Occupancy provisions.

Life safety fire requirements that are specifically noted in the regulation that are not specific provisions of the LSC are not subject to the LSC waiver allowance. These deficiencies must be corrected as part of the survey plan of correction within a reasonable period of time established by CMS.

A-0713

(Rev. 235; Issued: 01-16-26; Effective: 01-16-26; Implantation: 01-16-26)

§482.41(b)(4) - The hospital must have procedures for the proper routine storage and prompt disposal of trash.

Interpretive Guidelines §482.41(b)(4)

The term trash refers to common garbage as well as bio*logical, medical, and other* hazardous waste*s*. The storage and disposal of trash must be in accordance with Federal, State, and local laws and regulations (*e.g., Environmental Protection Agency*, *Occupational Safety & Health Administration*, *Centers for Disease Control and Prevention*, *Department of Transportation*

(DOT), State environmental, health and safety regulations). *This may include the disposal of some medications.* The Conditions of Participation for Radiology and Nuclear Medicine Services (§482.26(b)(1), tag A-0536) address handling and storage of radioactive materials.

Survey Procedures §482.41(b)(4)

Verify that the hospital has developed and implemented policies for the proper storage and disposal of trash. Verify through observation that staff adhere to these policies and that the hospital has *appropriate storage areas,* signage, *containers, and documentation.*

A-0714

(Rev. 235; Issued: 01-16-26; Effective: 01-16-26; Implantation: 01-16-26)

§482.41(b)(*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 fire fighting authorities.

Survey Procedures §482.41(b)(*5*)

- Review the hospital's written fire control plans to verify they contain the required provisions of the *LSC and* State law.

- Verify that hospital staff reported all fires as required to State officials.

- Interview staff throughout the facility to verify their knowledge of their responsibilities during a fire (this is usually done during the LSC survey, but health surveyors may also verify staff knowledge).

A-0715

(Rev. 235; Issued: 01-16-26; Effective: 01-16-26; Implantation: 01-16-26)

§482.41(b)(*6*) - The hospital must maintain written evidence of regular inspection and approval by State or local fire control agencies.

Survey Procedures §482.41(b)(6)

Examine copies of *reports* from State and local fire control agencies *and verify the facility has written evidence of regular inspections and maintains necessary approvals required by the State or local fire authorities.*

A-0716

(Rev. 235; Issued: 01-16-26; Effective: 01-16-26; Implantation: 01-16-26)

§482.41(b)(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.

Interpretive Guidelines, 482.41(b)(*7*):

*Alcohol-based hand rub (*ABHR*)* dispensers are a common infection control method. Healthcare-acquired infections are of increasing concern, and many such infections are transmitted because health care workers do not wash their hands or do so improperly or inadequately. An important aspect of getting health care workers to use ABHR dispensers is their accessibility. The American Hospital Association commissioned a study to determine the safest method to place ABHR dispensers in corridors. As a result of this study, the *LSC was amended to permit their use under certain conditions in patient care rooms and egress corridors.*

In addition, CMS requires that ABHR dispensers be installed in a manner that protects against inappropriate access by persons who may not comprehend the associated risks of misusing ABHR solutions, which are both toxic and flammable (e.g., children, individuals with intellectual disabilities, psychiatric patients, etc.). In order to avoid dangerous situations, a facility must take appropriate precautions to secure ABHR dispensers from inappropriate access. This means facilities could choose not to install ABHR dispensers in locations where vulnerable populations exist, or a facility may choose to install ABHR dispensers only in areas that can be easily and frequently monitored, such as in view of a nurse's station or areas that are continuously monitored with a security camera, or not install them at all in other areas. It is up to the hospital to decide how best to secure ABHR dispensers against inappropriate access.

Regular maintenance *of ABHR dispensers* is seen as a crucial step in making sure that dispensers *do not leak contents, which would allow inappropriate access*. Hospitals are expected to maintain ABHR dispensers in accordance with manufacturers' guidelines. If the manufacturer does not have specific maintenance requirements, the facility is expected to develop its own policies and procedures *to maintain all ABHR dispensers*.

Survey Procedures §482.41(b)(*7*):

- *Determine whether ABHR dispensers are adequately protected against inappropriate access.*

- Determine whether the hospital maintains the ABHR dispensers in accordance with the manufacturer's guidelines, or, if there are no manufacturer's guidelines, that the hospital has adopted policies and procedures to ensure that the dispensers *are maintained*.

A-0717

(Rev. 235; Issued: 01-16-26; Effective: 01-16-26; Implantation: 01-16-26)

§482.41(b)(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.

Interpretive Guidelines §482.41(b)(8):

A building sprinkler system is a significant fire protection feature. Therefore, when a sprinkler system is out of service for more than 10 hours in a 24-hour period, this regulation and the LSC requires either an evacuation of the building or portion of the building affected by the system outage, or the establishment of a fire watch until the sprinkler system has been returned to service.

A fire watch consists of trained personnel who continuously patrol the affected areas until the sprinkler system has been restored. The personnel must have access to fire extinguishers and the ability to quickly notify the fire department. Fire watch personnel lookout for fire and other hazardous situations. They also ensure that fire protection features of the building (e.g., extinguishers, means of egress, alarm systems) are available and functioning. The fire department should be notified any time the building sprinkler system is out of service.

Survey Procedures §482.41(b)(8):

The LSC surveyors will assess the sprinkler system during the LSC survey, but health surveyors should also assess the status of the sprinkler system at the time of the health survey. Part of this assessment includes determining if the sprinkler system has been out of service for more than 10 hours, and if so, to confirm that an evacuation or a fire watch was in effect until the system is back in service.

A-0718

(Rev. 235; Issued: 01-16-26; Effective: 01-16-26; Implantation: 01-16-26)

§482.41(b)(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.

Interpretive Guidelines §482.41(b)(9):

Every patient sleeping room shall have an outside window or door. Rooms intended for less than 24 hours occupancy (e.g., recovery, delivery, emergency care, nursery, etc.) do not require outside windows or doors. Windows in atrium walls are considered outside windows for the purpose of this requirement.

In buildings constructed after July 5, 2016, the maximum allowable sill height is 36 inches above the floor, except in special nursing areas (e.g., recovery rooms, intensive care units, coronary care units, etc.) where the sill height can be up to 60 inches.

Survey Procedures §482.41(b)(9):

Identify patient sleeping rooms intended to be occupied for more than 24 hours. Confirm these rooms have an outside window or outside door. If the building was constructed after July 5, 2016, confirm the outside window sill is 36 inches or less above the floor. In newly constructed special nursing areas, confirm the outside window is 60 inches or less above the floor.

A-0720

(Rev. 235; Issued: 01-16-26; Effective: 01-16-26; Implantation: 01-16-26)

§482.41(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 Health Care Facilities Code (NFPA 99 and Tentative Interim Amendments TIA 12–2, TIA 12–3, TIA 12–4, TIA 12–5 and TIA 12–6).

(1) Chapters 7, 8, 12, and 13 of the adopted Health Care Facilities Code do not apply to a hospital.

(2) If application of the Health Care Facilities Code required under paragraph (c) of this section would result in unreasonable hardship for the hospital, CMS may waive specific provisions of the Health Care Facilities Code, but only if the waiver does not adversely affect the health and safety of patients.

Interpretive Guidelines §482.41(c)(1), (2):

Medicare-participating hospitals must comply with the 2012 edition of the NFPA 99 - Health Care Facilities Code (HCFC) and Tentative Interim Amendments 12-2 through 12-6 for all inpatient and outpatient care locations. This includes locations such as emergency departments, surgical departments, intensive care units, observation units, etc. Chapters 7, 8, 12 and 13 of the HCFC were not adopted by CMS and therefore do not apply to hospitals. In addition, the hospital must be in compliance with the referenced publications in the HCFC.

Hospitals may request a waiver of specific HCFC provisions that would result in unreasonable hardship if applied and would not adversely affect the health and safety of patients. HCFC

waivers may be recommended by the State survey agency or AO, but only the CMS RO may grant those waivers for Medicare or Medicaid-participating hospitals.

Survey Procedures §482.41(c)(1), (2):

There is a separate survey form (Form CMS-2786) used by the SA LSC surveyors to evaluate compliance with the HCFC.

As part of its survey Plan of Correction, a hospital may request a waiver of specific HCFC provisions that would result in unreasonable hardship on a facility and that would have no adverse effect on the health and safety of patients. The State survey agency (SAs) or CMS approved Accreditation Organizations (AO) may recommend approval of waivers requested by providers, but only CMS locations may grant approval of waivers. Therefore, all LSC and HCFC waiver requests recommended for approval by SAs and AO, must be forwarded to the CMS location for adjudication. There is no authority for either the State or the CMS location to grant waivers of Board and Care Occupancy provisions.

A-0722

(Rev. 235; Issued: 01-16-26; Effective: 01-16-26; Implantation: 01-16-26)

§482.41(d) Standard: Facilities

The hospital must maintain adequate facilities for its services.

Interpretive Guidelines §482.41(d)

Adequate facilities means the hospital has facilities that are:

- Designed and maintained in accordance with Federal, State and local laws, regulations and guidelines; and

- Designed and maintained to reflect the scope and complexity of the services it offers in accordance with accepted standards of practice.

Survey Procedures §482.41(d)

- Observe the facility layout and determine if the patient's needs are met. Toilets, sinks, specialized equipment, etc. should be accessible.

- Review the facility's water supply and distribution system to ensure that the water quality is acceptable for its intended use (drinking water, irrigation water, lab water, etc.). Review the facility water quality monitoring and, as appropriate, treatment system.

A-0723

(Rev. 235; Issued: 01-16-26; Effective: 01-16-26; Implantation: 01-16-26)

§482.41(d)(1) - Diagnostic and therapeutic facilities must be located for the safety of patients.

Interpretive Guidelines §482.41(d)(1)

Diagnostic and therapeutic facilities must be in rooms or areas specifically designed for the purpose intended. Facilities must be designed and maintained to ensure the safety of patients and to minimize the risk of harm, e.g. unintended exposure to radiation.

Survey Procedures §482.41(d)(1)

Determine whether x-ray, physical therapy, and other specialized services are provided in areas appropriate for the services provided for the safety of patients. When specialized services are provided outside of designated locations (e.g. at the bedside), ensure the safety of patients, visitors and staff is maintained.

A-0724

(Rev. 235; Issued: 01-16-26; Effective: 01-16-26; Implantation: 01-16-26)

§482.41(d)(2) - Facilities, supplies, and equipment must be maintained to ensure an acceptable level of safety and quality.

Interpretive Guidelines §482.41(d)(2)

Facilities

The hospital must ensure that the condition of the physical plant and overall hospital environment is developed and maintained in a manner that provides an acceptable level of safety and well-being of patients, staff and visitors.

Supplies

The hospital must ensure that supplies are maintained to provide an acceptable level of safety and quality for patients. Among other things, this means that the hospital identifies the supplies required to meet its patients' needs for both day-to-day operations as well as those supplies that are likely to be needed in likely emergency situations, such as mass casualty events resulting from natural disasters, mass trauma, disease outbreaks, etc. Further, the hospital must make adequate provisions to ensure the availability of those supplies when needed.

Supplies must be stored in such a manner to ensure their safety (e.g., protection against theft or damage, contamination, or deterioration), as well as that the storage practices do not violate fire codes or otherwise endanger patients (e.g., storage of flammables, blocking passageways,

storage of contaminated or dangerous materials, safe storage practices for poisons, etc.).

Equipment

In order to ensure an acceptable level of safety and quality, the hospital must identify the equipment required to meet its patients' needs for both day-to-day operations and in a likely emergency/disaster situation, such as mass casualty events resulting from natural disasters, mass trauma, disease outbreaks, internal disasters, etc. In addition, the hospital must make adequate provisions to ensure the availability and reliability of equipment needed for its operations and services. Equipment includes both facility equipment, which supports the physical environment of the hospital (e.g., elevators, generators, air handlers, medical gas systems, air compressors and vacuum systems, etc.) and medical equipment, which are devices intended to be used for diagnostic, therapeutic or monitoring care provided to a patient by the hospital (e.g., IV infusion equipment, ventilators, laboratory equipment, surgical devices, etc.).

All equipment should be inspected and tested for performance and safety before initial use and after major repairs or upgrades.

All equipment must be inspected, tested, and maintained to ensure its safety, availability, and reliability. Equipment maintenance activities may be conducted using hospital personnel, contracted services, or through a combination of hospital personnel and contracted services. Individual(s) responsible for overseeing the development, implementation, and management of equipment maintenance programs and activities must be qualified. The hospital should maintain records of hospital personnel qualifications and be able to demonstrate how it ensures all personnel, including contracted personnel, are qualified.

All equipment maintenance policies, procedures, and programs, as well as specific equipment maintenance inventories, activities, and schedules, fall under the purview of the hospital's clinical maintenance personnel, safety department personnel or other personnel who have been assigned responsibility for equipment maintenance by hospital leadership.

As mentioned in S&C memo 14-7 regarding equipment maintenance, hospitals comply with this regulation when they follow the manufacturer-recommended maintenance activities and schedule. Hospitals may choose to perform maintenance more frequently than the manufacturer recommends, but should use the manufacturer-recommended maintenance activities in such cases. When equipment is maintained in accordance with the manufacturer's recommendations, the hospital must maintain documentation of those recommendations and the hospital's associated maintenance activity for the affected equipment.

Alternate Equipment Management (AEM) Program

A hospital may, under certain conditions, use equipment maintenance activities and frequencies that differ from those recommended by the manufacturer. Hospitals that choose to employ alternate maintenance activities and/or schedules should develop, implement, and maintain a documented AEM program to minimize risks to patients and others in the hospital associated with the use of facility or medical equipment. An AEM program must be based on generally

accepted standards of practice for facility or medical equipment maintenance. An example of guidelines for a medical equipment medical equipment maintenance program may be found in the American National Standards Institute/ Association for the Advancement of Medical Instrumentation document: ANSI/AAMI EQ 56:2024, Recommended Practice for a Medical Equipment Management Program. Likewise, an example of guidelines for physical plant equipment may be found in the American Society for Healthcare Engineering (ASHE) 2014 document: Maintenance Management for Health Care Facilities. There may be similar documents issued by other nationally recognized organizations which hospitals might choose to reference.

Decision to Place Equipment in an AEM Program

The determination of whether it is safe to perform facility or medical equipment maintenance without following the equipment manufacturer recommendations should be made by qualified personnel, regardless of whether they are hospital employees or contractors.

In the case of medical equipment, a clinical or biomedical technician or engineer would be considered qualified. Highly specialized or complex equipment may require specialized knowledge or training in order for personnel to be considered qualified to make a decision to place such equipment in an AEM program.

In the case of facility equipment, a Healthcare Facility Management professional (facility manager, director of facilities, vice president of facilities) would be considered qualified.

The hospital must maintain records of the qualifications of hospital personnel who make decisions on placing equipment in an AEM program and must be able to demonstrate how they assure contracted personnel making such decisions are qualified.

In determining whether or not to include equipment in an AEM program, and which maintenance strategies to use in developing maintenance activities and frequencies for particular equipment, the hospital takes into account the typical health and safety risks associated with the equipment's use. Note that the risk may vary for the same type of equipment, depending on the patient care setting within the hospital where it is used.

A hospital should identify any equipment in its AEM program which is "critical equipment," i.e., biomedical or physical plant equipment for which there is a risk of serious injury or death to a patient or staff person should the equipment fail. Surveyors must focus their review of a hospital's AEM program on critical equipment and the hospital's documentation of the factors and evidence it considered in developing an AEM strategy for that equipment.

Factors for a hospital to consider when evaluating the risks associated with a particular type of equipment may include, but are not limited to:

- *How the equipment is used and the likely consequences of equipment failure or malfunction - would failure or malfunction of the equipment hospital-wide or in a particular setting be likely to cause harm to a patient or a staff person?*

- *How serious is the harm likely to be? For example, a slightly miscalibrated scale in an adult internal medicine outpatient clinic might not present significant risk of harm. However, a miscalibrated scale in a neonatal intensive care unit could have very serious consequences for patient care.*

- *How widespread is the harm likely to be? For example, are many patients exposed to the equipment, resulting in harm due to failure impacting more patients or staff? If harm would be widespread, even if the harm to each affected individual is not serious, this would be a cause for concern.*

- *Information, if available, on the manufacturer's equipment maintenance recommendations, including the rationale for the manufacturer's recommendations;*

- *Maintenance requirements of the equipment:*

  - *Are they simple or complex?*

  - *Are the manufacturer's instructions and procedures available in the hospital, and if so can the hospital explain how and why it is modifying the manufacturer's instructions?*

  - *If the manufacturer's instructions are not available in the hospital, how does the hospital assess whether the AEM uses appropriate maintenance strategies?*

  - *How readily can the hospital validate the effectiveness of AEM methods for particular equipment? For example, can the hospital explain how it ensures there is no reduction in the quality of the performance of biomedical equipment subjected to alternate maintenance methods?*

- *The timely availability of alternate devices or backup systems in the event of equipment failure or malfunction; and*

- *Incident history of identical or very similar equipment – is there documented evidence, based on the experience of the hospital (or its third party contractor), or on evidence publicly reported by credible sources outside the hospital, which:*

  - *Provides the number, frequency and nature of previous failures and service requests?*

  - *Indicates use of an AEM strategy does not result in degraded performance of the equipment?*

Generally multiple factors are considered since different types of equipment present different combinations of severity of potential harm and likelihood of failure. The hospital should be able to demonstrate to a surveyor the factors it considered in its risk assessment for equipment placed in its AEM program.

Equipment not Eligible for Placement in the AEM Program:

Some equipment may not be eligible for placement in the AEM program, for one or more of the following reasons:

- *Other Federal law (for example, regulations promulgated by another Federal agency) or State law may require that facility or medical equipment maintenance, inspection and testing be performed strictly in accordance with the manufacturer's recommendations, or may establish other, more stringent maintenance requirements. In these instances, the hospital must comply with these other Federal or State requirements, but State surveyors conducting Federal surveys assess compliance only with the hospital Conditions of Participation (CoPs).*

- *Other CoPs require adherence to manufacturer's recommendations and/or set specific standards which preclude their inclusion in an AEM program. For example:*

    - *The National Fire Protection Association LSC requirements incorporated by reference at 42 CFR 482.41(b) has some provisions that are pertinent to equipment maintenance, and compliance with these requirements are assessed on Federal surveys. Further, §482.41(b)(7) requires that hospitals may install ABHRs if they are installed in a manner that adequately protects against inappropriate access. Hospitals should be following the manufacturer's maintenance guidelines when using ABHRs. Compliance with these requirements is assessed on Federal surveys.*

    - *Imaging/radiologic equipment, whether used for diagnostic or therapeutic purposes, is governed by 42 CFR 482.26(b)(2) and must be maintained per manufacturer's recommendations.*

- *The equipment is a medical laser device. It should be noted that for medical lasers the U.S. Food and Drug Administration requires manufacturers to provide a schedule of maintenance and adequate instructions for service adjustments and service procedures to purchasers and, at cost, to any other parties requesting them.*

- *New equipment for which sufficient maintenance history, either based on the hospital's own or its contractor's records, or available publicly from nationally recognized sources, is not available to support a risk-based determination should not be immediately included in the AEM program. New equipment should be maintained in accordance with manufacturer recommendations until a sufficient amount of maintenance history has been acquired to determine whether the alteration of maintenance activities or frequencies would be safe. If a hospital later transitions the equipment to a risk-based maintenance regimen different than the manufacturers' recommendations, the hospital should maintain evidence that it has first*

evaluated the maintenance track record, risks, and tested the alternate regimen.

Alternative Maintenance Frequencies or Activities

Maintenance strategies are various methodologies used for determining the most efficient and effective maintenance activities and frequencies. Manufacturers' recommendations may be based on one or more such strategies. A hospital may also use one or more maintenance strategies for its AEM program in order to determine the appropriate maintenance, inspection, and testing activities and frequencies, based upon the nature of the equipment and the level of risk it presents to patient or staff health and safety. The risk to patient health and safety that is considered in developing alternative maintenance strategies must be explained and documented in the AEM program.

In developing AEM maintenance strategies hospitals may rely upon information from a variety of sources, including, but not limited to: manufacturer recommendations and other materials, nationally recognized expert associations, and/or the hospital's (or its third party contractor's) own experience. Maintenance strategies may be applied to groups or to individual pieces of equipment.

The hospital is expected to adhere strictly to the AEM activities or strategies it has developed.

Background Information on Types of Maintenance Strategies

- ***Preventive Maintenance (Time-based Maintenance)** – a maintenance strategy where maintenance activities are performed at scheduled time intervals to minimize equipment degradation and reduce instances where there is a loss of performance. Most preventive maintenance is "interval-based maintenance" performed at fixed time intervals (e.g., annual or semi-annual), but may also be "metered maintenance" performed according to metered usage of the equipment (e.g., hours of operation). In either case, the primary focus of preventive maintenance is reliability, not optimization of cost-effectiveness. Maintenance is performed systematically, regardless of whether or not it is needed at the time. Example: Replacing a battery every year, after a set number of uses or after running for a set number of hours, regardless.*

- ***Predictive Maintenance (Condition-based Maintenance)** – a maintenance strategy that involves periodic or continuous equipment condition monitoring to detect the onset of equipment degradation. This information is used to predict future maintenance requirements and to schedule maintenance at a time just before equipment experiences a loss of performance. Example: Replacing a battery one year after the manufacturer's recommended replacement interval, based on historical monitoring that has determined the battery capacity does not tend to fall below the required performance threshold before this extended time.*

- ***Reactive Maintenance (Corrective, Breakdown or Run-to-Failure Maintenance)** – a maintenance strategy based upon a "run it until it breaks" philosophy, where maintenance or replacement is performed only after equipment fails or experiences a problem. This*

strategy may be acceptable for equipment that is disposable or low cost and presents little or no risk to health and safety if it fails. Example: Replacing a battery after equipment failure when the equipment has little negative health and safety consequences associated with a failure and there is a replacement readily available in supply.

- ***Reliability-Centered Maintenance*** *– a maintenance strategy that not only considers equipment condition, but also considers other factors unique to individual pieces of equipment, such as equipment function, consequences of equipment failure, and the operational environment. Maintenance is performed to optimize reliability and cost effectiveness. Example: Replacing a battery in an ambulance defibrillator more frequently than the same model used at a nursing station, since the one in the ambulance is used more frequently and is charged by an unstable power supply.*

Maintenance Tools

Tools (e.g., hand tools, test equipment, software, etc.) necessary for performing equipment maintenance must be available and maintained to ensure that measurements are reliable. Tools used for maintenance are not required to be those specifically recommended by the manufacturer, but tools utilized must be capable of providing results equivalent to those required by the equipment manufacturer.

AEM Program Documentation

For each type of equipment subject to the AEM program, there should be documentation indicating:

- *The pertinent types and level of risks to patient or staff health and safety;*
- *Alternate maintenance activities, and the maintenance strategy and any other rationale used to determine those activities; the differences from the manufacturer's recommended maintenance activities are made explicit, unless the hospital is unable to obtain the manufacturer's maintenance recommendations, due to the age of the equipment or the manufacturer's restricting the availability of its recommendations;*
- *Alternate maintenance frequencies to be used, if any, and the maintenance strategy and any other rationale used to determine those frequencies. For equipment identified as presenting a very low risk to patient or staff safety, it could be acceptable to not set a particular frequency but instead indicate a less specific approach, for example, an interval range, such as "every 12 – 24 months." It could also be acceptable to employ periodic "departmental sweeps" for such very low risk equipment, where equipment functioning is sampled and operators are polled about its functionality.*
- *The date when AEM program maintenance activities were performed and, if applicable, further actions required/taken; and*
- *Documentation of any equipment failures (not including failures due to operator error),*

including whether there was resulting harm to an individual. (Note: equipment failure that is due to operator error and which results in an adverse event or near miss must be documented in accordance with the QAPI CoP, as part of the hospital's required tracking of patient safety-related incidents. However, there is no requirement to include operator failures in equipment maintenance documentation.)

When the hospital has multiple identical equipment items, the documentation may be generic to that type of equipment, except that documentation of maintenance activities performed must be specific to each item of equipment.

Evaluating Safety and Effectiveness of the AEM Program

The hospital must have policies and procedures which address the effectiveness of its AEM program. In evaluating the effectiveness of the AEM program the hospital should address factors including, but not limited to:

- *How equipment is evaluated to ensure there is no degradation of performance, particularly for equipment where such degradation may not be readily apparent to staff using the equipment, e.g., miscalibration.*

- *How incidents of equipment malfunction are investigated, including:*

    - *whether or not the malfunction could have been prevented, and what steps will be taken to prevent future malfunctions; and*

    - *how a determination is made whether or not the malfunction resulted from the use of an AEM strategy;*

- *The process for the removal from service of equipment determined to be unsafe or no longer suitable for its intended application; and*

- *The use of performance data to determine if modifications in the AEM program procedures are required.*

Equipment Inventory

All hospital facility and medical equipment, regardless of whether it is leased or owned, and regardless of whether it is maintained according to manufacturer recommendations or is in an AEM program, is expected to be listed in an inventory which includes a record of maintenance activities. For low cost/low risk equipment, such as housekeeping cleaning equipment, it is acceptable for the inventory to indicate under one item the number of such pieces of equipment in the hospital, e.g., "15 vacuum cleaners for cleaning patient rooms and common areas."

If the hospital is using an AEM program, the equipment managed through that program must be readily separately identifiable as subject to AEM. Critical equipment, whether in an AEM program or not, must also be readily identified as such.

To facilitate effective management, a well-designed equipment inventory contains the following information listed below for all equipment included. However, hospitals have the flexibility to demonstrate how alternative means they use are effective in enabling them to manage their equipment.

- *A unique identification number;*
- *The equipment manufacturer;*
- *The equipment model number;*
- *The equipment serial number;*
- *A description of the equipment;*
- *The location of the equipment (for equipment generally kept in a fixed location);*
- *The identity of the department considered to "own" the equipment;*
- *Identification of the service provider;*
- *The acceptance date; and*
- *Any additional information the hospital believes may be useful for proper management of the equipment.*

Survey Procedures §482.41(d)(2)

Interview personnel in charge of facility, supplies and equipment maintenance:

- *Determine if supplies are maintained in such a manner as to ensure an acceptable level of safety and quality.*
- *Determine if supplies are stored as recommended by the manufacturer.*
- *Determine if supplies are stored in such a manner as not to endanger patient safety.*
- *Determine if the hospital has identified supplies and equipment that are likely to be needed in emergency situation.*
- *Determine if the hospital has made adequate provisions to ensure the availability of those supplies and equipment when needed.*

Concerning facility and medical equipment:

- *Interview equipment users when surveying the various units/departments of the hospital to determine if equipment failures are occurring and causing problems for patient health or safety.*

- *Determine if there is a complete inventory of equipment required to meet patient needs, regardless of ownership.*

    - *Is critical equipment readily identified?*

    - *If the hospital employs an AEM program, is equipment in this program readily identified?*

- *Determine if the hospital has documentation of the qualifications (e.g., training certificates, certifications, degrees, etc.) of hospital personnel responsible for the AEM program (if one is being used by the hospital) as well as for those performing maintenance.*

- *Determine if the hospital is able to demonstrate how it assures contractors use qualified personnel.*

***If the hospital is following the manufacturer-recommended equipment maintenance activities and frequencies**:*

In addition to reviewing maintenance records on equipment observed while inspecting various hospital locations for multiple compliance assessment purposes, select a sample of equipment from the hospital's equipment inventory to determine whether the hospital is following the manufacturer's recommendations. Critical equipment which poses a higher risk to patient safety if it were to fail, such as ventilators, defibrillators, robotic surgery devices, etc. should make up the sample majority.

For the sample selected, determine if:

- *The hospital has available manufacturer's recommendations (e.g., manufacturer's operation and maintenance manual, standards, studies, guidance, recall information, service records, etc.)*

- *Maintenance is being performed in accordance with manufacturer's recommendations*

***If a hospital is using an AEM for some equipment**:*

- *Does the hospital's inventory include equipment, for example, any diagnostic imaging or therapeutic radiologic equipment, which is not eligible for AEM?*

- *Determine if the hospital's development of alternate maintenance activities and frequencies for equipment in the AEM program as well as AEM activities are being performed by qualified personnel.*

- *Verify the hospital has documented maintenance activities and frequencies for all equipment included in the AEM program.*

- *Verify the hospital is evaluating the safety and effectiveness of the AEM program.*

- *If there is equipment on the inventory the hospital has identified as having such a very low level of risk that it has determined it can use a broad interval range or departmental "sweeps," ask the hospital for the evidence used to make this determination. Does it seem reasonable?*

Select a sample of equipment in the AEM program. The majority of the sample must include critical equipment that poses a higher risk to patient safety if it were to fail, such as ventilators, defibrillators, robotic surgery devices, etc. For the sample selected:

- *Ask the responsible personnel to explain how the decision was made to place the equipment in an AEM program. Does the methodology used consider risk factors and make use of available evidence?*

- *Ask the responsible personnel to describe the methodology for applying maintenance strategies and determining alternative maintenance activities or frequencies for the sampled equipment. Can they readily provide an explanation and point to sources of information they relied upon?*

- *Determine if maintenance is being performed in accordance with the maintenance activities and frequencies defined in the AEM program.*

- *Verify the hospital is evaluating the safety and effectiveness of the AEM maintenance activities for this equipment and taking corrective actions when needed.*

A-0725

(Rev. 235; Issued: 01-16-26; Effective: 01-16-26; Implantation: 01-16-26)

§482.41(d)(3) - The extent and complexity of facilities must be determined by the services offered.

Interpretive Guidelines §482.41(d)(3)

Physical facilities must be large enough, numerous enough, appropriately designed and equipped, and of appropriate complexity to provide the services offered in accordance with Federal and State laws, regulations and guidelines and accepted standards of practice for that location or service.

Survey Procedures §482.41(d)(3)

Verify through observation that the physical facilities are large enough and properly equipped for

the scope of services provided and the number of patients served.

A-0726

(Rev. 235; Issued: 01-16-26; Effective: 01-16-26; Implantation: 01-16-26)

§482.41(d)(4) - There must be proper ventilation, light, and temperature controls in pharmaceutical, food preparation, and other appropriate areas.

Interpretive Guidelines §482.41(d)(4)

There must be proper ventilation in at least the following areas:

- *Areas using ethylene oxide, nitrous oxide, gluteraldehydes, xylene, pentamidine, or other potentially hazardous substances;*
- *Locations where oxygen is transferred from one container to another;*
- *Isolation rooms and reverse isolation rooms (both must be in compliance with Federal and State laws, regulations, and guidelines such as OSHA, CDC, NIH, etc.);*
- *Pharmaceutical preparation areas (hoods, cabinets, etc.);*
- *Food preparation areas;*
- *Laboratory locations; and*
- *Operating rooms.*

There must be adequate lighting in all the patient care areas, and food and medication preparation areas.

Temperature, humidity and airflow must be maintained within acceptable standards to inhibit microbial growth, reduce risk of infection, control odor, and promote patient comfort. In operating rooms and associated ancillary rooms (e.g., pre-op, post-op, storage, sterilization, etc.), ventilation standards may permit the reduction of relative humidity levels as low as 20%, but hospitals must consider sterile supply and medical equipment manufacturer instructions for use regarding required humidity levels prior to any humidity level adjustment. Failure to maintain manufacturer required humidity levels may void sterile packaging and result in medical equipment malfunction or failure.

In addition, ventilation standards typically require hospital operating rooms to maintain the upper range of RH at 60 percent or less, as excessive humidity is conducive to microbial growth and again may compromise the integrity of supplies and medical equipment. Hospitals must maintain records that demonstrate they are maintaining the required temperature, humidity, and airflow levels.

Each operating room should have separate temperature control. Acceptable standards such as from the Association of Operating Room Nurses (AORN) or the Facilities Guidelines Institute (FGI) should be incorporated into hospital policy.

The hospital must ensure that an appropriate number of refrigerators and/or heating devices are provided and ensure that food and pharmaceuticals are stored properly and in accordance with nationally accepted guidelines (food) and manufacturer's recommendations (pharmaceuticals).

Survey Procedures §482.41(d)(4)

- *Verify that all food and medication preparation areas are well lighted.*
- *Verify that the hospital is in compliance with ventilation requirements for patients with contagious airborne diseases, such as tuberculosis, patients receiving treatments with hazardous chemical, surgical areas, and other areas where hazardous materials are stored.*
- *Verify that food products are stored under appropriate conditions (e.g., time, temperature, packaging, location) based on a nationally-accepted source such as the United States Department of Agriculture, the Food and Drug Administration, or other nationally-recognized standard.*
- *Verify that pharmaceuticals are stored at temperatures recommended by the product manufacturer.*
- *Review monitoring records for temperature to ensure that appropriate levels are maintained.*
- *Review temperature, humidity and airflow maintenance records for operating rooms and associated ancillary rooms to ensure acceptable parameters are being maintained. If monitoring determined temperature, humidity or airflow levels were not within acceptable parameters, confirm corrective actions were performed in a timely manner to achieve acceptable levels.*

A-0747

(Rev. 235; Issued: 01-16-26; Effective: 01-16-26; Implantation: 01-16-26)

§482.42 Condition of Participation: Infection Prevention and Control and Antibiotic Stewardship Programs

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.

Interpretive Guidelines §482.42

The hospital must have an active infection control program throughout the hospital for the surveillance, prevention, and control of Healthcare Associated Infections (HAIs) and other infectious diseases and a program for the optimization of antibiotic use through stewardship. These hospital-wide programs must include, at a minimum, a system for preventing, identifying, reporting (as applicable), investigating, and controlling infections and communicable diseases for all patients, staff, and visitors and a system for improving antibiotic use for patients.

The programs are based on the individual hospital's assessment while demonstrating adherence to nationally recognized infection prevention and control standards of practice, 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. The hospital should have written standards, policies, and procedures and issues identified in the infection control program must be addressed more broadly through the hospital QAPI program.

Survey Procedures §482.42

- *Review policies and procedures of the infection control program for evidence that the hospital has an active, hospital-wide program for surveillance, prevention, and control of health associated infections and other infectious diseases based on national standards of practice and best practices.*

- *Review the antibiotic stewardship program for evidence that the hospital has an active hospital-wide program for the optimization of antibiotic use through stewardship based on national standards of practice and best practices.*

- *Review the infection control program for evidence that the hospital is working collaboratively between infection control and hospital QAPI when infection control issues are identified.*

- *Review the antibiotic stewardship program for evidence that the hospital is working collaboratively between antibiotic stewardship and hospital QAPI when antibiotic use issues are identified.*

A-0748

(Rev. 235; Issued: 01-16-26; Effective: 01-16-26; Implantation: 01-16-26)

§482.42(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;

Interpretive Guidelines §482.42(a)(1)

Individuals responsible for the hospital infection prevention and control program are often referred to as "hospital epidemiologists (HEs)," "infection control professionals (ICPs)" and/or "infection preventionists." CDC has defined "infection control professional" as "a person whose primary training is in either nursing, medical technology, microbiology, or epidemiology and who has acquired specialized training in infection control."

The hospital must designate an individual or group of individuals as its *infection preventionist(s)/infection control professional(s). The individual(s) must be appointed by the hospital governing body based on the recommendations of the medical staff leadership and nursing leadership. The hospital should ensure high-level hospital clinical leadership, specifically leadership from the medical staff and the nursing service, are involved in the process of selecting the infection preventionist(s)/ infection control professional(s). This high-level participation promotes a hospital-wide culture of safety and quality in which input across the hospital is solicited and acted upon.*

In designating infection preventionist(s)/infection control professional(s), hospitals should assure that the individuals so designated are qualified through education, training, experience, or certification in infection prevention and control.

CMS does not specify either the number of infection preventionist(s)/infection control professional(s) to be designated or the number of infection preventionist(s)/infection control professional(s) hours that must be devoted to the infection prevention and control programs. However, resources must be adequate to accomplish the tasks required for the infection prevention and control program. In hospitals with more than one infection preventionist(s)/infection control professional(s), the staff members should work as an integrated team to ensure the functions of an infection prevention and control program are covered. A prudent hospital would consider patient census, characteristics of the patient population, and complexity of the healthcare services it offers in determining the size and scope of the resources it commits to infection prevention and control.

Survey Procedures §482.42(a)

- *Determine whether an infection preventionist(s)/infection control professional(s) was appointed by the governing body based on recommendations of the medical staff leadership and nursing leadership and has the responsibility for the infection prevention and control program.*

- *Review the personnel file of the infection preventionist(s)/infection control professional(s) to determine whether he/she is qualified through professional education, training, experience, or certification to oversee the infection prevention and control program.*

- *Review the criteria the hospital used to determine the resources necessary to operate effectively and ensure the resource allocation matches the determined needs.*

A-0749

(Rev. 235; Issued: 01-16-26; Effective: 01-16-26; Implantation: 01-16-26)

§482.42(a)(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;

Interpretive Guidelines §482.42(a)(2)

The hospital infection prevention program must establish policies and procedures for implementing methods of preventing and controlling the transmission of infection in the broader sense, to include not only the hospital but between the hospital and other institutions or settings. The development of such policies and procedures will require hospitals focus efforts to prevent and control infections not just between patients and personnel, but also between individuals across the entire hospital setting (for example, among patients, personnel, and visitors) as well as between the hospital and other healthcare institutions and settings and between patients and the healthcare environment. It is expected that hospitals consider the impact of their outpatient facilities on their inpatient units with the development and implementation of a hospital wide infection control and prevention program policies.

We believe this section reflects current best practices that are in place in most hospitals. The reality is that patients move between settings with great frequency and carry organisms with them, hence it is imperative that hospitals approach multi-drug resistant organism control from the broader perspective in order to protect their patients and staff. A concrete example of this already being part of current practice is that hospitals are already required to track both hospital- and community-onset cases of CDI and MRSA, because research has shown that community onset cases of these pathogens can impact hospitals. Hospitals should consider how they can partner with facilities with whom they frequently share patients (e.g. nursing homes) to establish ways to share information on patients who harbor potentially transmissible pathogens. Likewise, the role of the environment is being increasingly recognized as an important source of infections and this change simply reflects this data and best practices. There are many good examples of

hospitals working on preventing the spread of infection between healthcare environments. This update also fits with the clarification that these CoPs apply to both a hospital's inpatient and outpatient locations.

Survey Procedures §482.42(a)(2)

- *Review the hospital policies and procedures for infection control and prevention to provide evidence that the hospital is following policies and procedures that employ the methods for preventing and controlling the transmission of infections within the hospital and between the hospital and other healthcare settings.*

- *Determine whether the infection control program is being applied throughout the hospital to both inpatient and outpatient settings.*

A-0750

(Rev. 235; Issued: 01-16-26; Effective: 01-16-26; Implantation: 01-16-26)

§482.42(a)(3) The infection prevention and control program includes 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

Interpretive Guidelines §482.42(a)(3)

The hospital must provide and maintain a clean and sanitary environment to avoid sources and transmission of infections and communicable diseases. All areas of the hospital must be clean and sanitary. This includes all hospital departments and off-site locations. The infection prevention and control program should include appropriate monitoring of housekeeping, maintenance (including repair, renovation and construction activities), and other activities to ensure that the hospital maintains a sanitary environment. Examples of areas to monitor would include the hospital's: onsite laundry facilities, food storage, preparation, serving and dish rooms, refrigerators, ice machines, air handlers, autoclave rooms, venting systems, inpatient rooms, treatment areas, labs, waste handling, surgical areas, supply storage, equipment cleaning, etc.

CMS expects Medicare certified hospitals 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. An industry standard calling for the development and implementation of water management programs in large or complex building water systems to reduce the risk of legionellosis was published by American Society of Heating, Refrigerating, and Air Conditioning Engineers (ASHRAE). The CDC and its partners developed a toolkit to facilitate implementation of this ASHRAE Standard (https://www.cdc.gov/legionella/maintenance/wmp-toolkit.html). Environmental, clinical, and epidemiologic considerations for healthcare facilities are described in this toolkit.

To ensure that water is not the source of infections, hospitals should consider implementing a water management program that considers the ASHRAE industry standard and the CDC toolkit. A documented water management program includes a hospital 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 hospital water system. In addition, the water management program should specify testing protocols and acceptable ranges for control measures, and document the results of testing and corrective actions taken when control limits are not maintained.

The hospital must conduct surveillance on a hospital-wide basis in order to identify infectious risks or communicable disease problems at any particular location. This does not imply all areas and locations of the hospital at all times, but it does mean that the hospital must have reliable sampling or other mechanisms in place to permit identifying and monitoring infections and communicable diseases occurring throughout the hospital's various locations or departments. The hospital must document its surveillance activities, including the measures selected for monitoring, and collection and analysis methods. Surveillance activities should be conducted in accordance with recognized infection control surveillance practices, such as those set forth by the CDC's National Healthcare Safety Network (NHSN).

The hospital should know how to recognize and contain infectious disease outbreaks. An outbreak is the occurrence of more cases than expected in a given area or among a specific group of people over a particular period of time. In the event of an outbreak of an infectious disease, hospitals should have policies and procedures in place to address the appropriate steps to diagnose and manage cases, implement appropriate precautions, and prevent further transmission of the disease as well as documentation of follow-up activity in response and comply with state and local public health authority requirements for identification, reporting, and containing communicable diseases and outbreaks.

Survey Procedures §485.42(a)(3)

- *Observe the hospital for the sanitary condition of their environments of care, noting the cleanliness of patient rooms, floors, horizontal surfaces, patient equipment, air inlets, mechanical rooms, food service activities, treatment and procedure areas, surgical areas, central supply, storage areas, medication preparation etc.*

- *Review policies and procedures of the infection control program for evidence that the program has a mechanism for surveillance to identify the transmission of infection and also address transmission of infections that have been reported by public health authorities. Ensure there is a process in place for reporting to public health authorities when the transmission of infections occur.*

- *Review any water management program documentation, if a water management program has been implemented, for the hospital risk assessment, and water quality monitoring.*

- *Review policies and procedures for the detection, investigation and control of outbreaks.*

A-0751

(Rev. 235; Issued: 01-16-26; Effective: 01-16-26; Implantation: 01-16-26)

§482.42(a)(4) The infection prevention and control program reflects the scope and complexity of the hospital services provided.

Interpretive Guidelines §482.42(a)(4)

All hospitals are required to have an infection prevention and control program. The program should reflect the scope of services offered throughout the organization. The hospital is expected to demonstrate how its infection prevention and control program adequately represents the services provided to the community it serves. In addition, the hospital program should have mechanisms in place for assessment and reevaluation of the infection prevention and control program to ensure it responds to changes in the hospital environment on an ongoing basis.

Survey Procedures §482.42(a)(4)

- *Determine whether the infection control and prevention program is hospital-wide and program-specific in gathering and assessing infection and communicable disease data and in taking steps to reduce the risks of infections.*

- *Review the hospital infection control and prevention program for evidence of the parameters of the active surveillance program to determine whether it is consistent with infection control standards of practice and is suitable to the scope and complexity of the hospital's services.*

A-0760

(Rev. 235; Issued: 01-16-26; Effective: 01-16-26; Implantation: 01-16-26)

§482.42(b)(1) Standard: Antibiotic stewardship program organization and policies. The hospital must demonstrate that:

(1) An individual (or individuals), who is qualified through education, training, or experience in infectious diseases and/or antibiotic stewardship, is appointed by the governing body as the leader(s) of the antibiotic stewardship program and that the appointment is based on the recommendations of medical staff leadership and pharmacy leadership;

Interpretive Guidelines §482.42(b)(1)

Antibiotic stewardship, has long been recognized as one of the special challenges that facilities must meet in order to address the problems of infectious disease treatment, medication safety and multidrug-resistant organisms in hospitals.

The hospital must designate an individual or group of individuals as its antibiotic stewardship program leaders. Ideally, an antibiotic stewardship program is jointly led by a physician and

pharmacist. The individual(s) must be appointed by the hospital's governing body based on the recommendations of the medical staff leadership and pharmacy leadership. The hospital must ensure high-level hospital clinical leadership, specifically leadership from the medical staff and the pharmacy service, are involved in the process of selecting the antibiotic stewardship leaders. This high-level participation promotes a hospital-wide culture of safety and quality in which input across the hospital is solicited and acted upon.

In designating antibiotic stewardship leaders, hospitals must ensure that the individuals so designated are qualified through education, training, experience, or certification in antibiotic stewardship. Training and/or certification may be obtained through organizations such as the specialty boards in adult or pediatric infectious diseases offered for physicians by the American Board of Internal Medicine (for internists), the American Board of Pediatrics (for pediatricians), and the Society for Infectious Disease Pharmacists (for pharmacists)

Antibiotic stewardship staff should maintain their qualifications through ongoing education and training, which can be demonstrated by participation in antibiotic stewardship courses, or in local and national meetings organized by recognized professional societies. Organizations that provide ongoing training and education include the Society for Healthcare Epidemiology of America (SHEA), and the Infectious Diseases Society of America (IDSA) and the Society for Infectious Disease Pharmacists (SIDP).

CMS does not specify either the number of antibiotic stewardship staff to be designated or the number of antibiotic stewardship hours that must be devoted to the antibiotic stewardship programs. However, resources must be adequate to accomplish the tasks required for the antibiotic stewardship program. In hospitals with more than one antibiotic stewardship staff member, the staff members should work as an integrated team to ensure the functions of an antibiotic stewardship program are covered. A prudent hospital would consider patient census, characteristics of the patient population, and complexity of the healthcare services it offers in determining the size and scope of the resources it commits to antibiotic stewardship. SHEA has studies and recommendations on resource allocation that hospitals may find useful.

The antibiotic stewardship staff must develop and implement policies governing the optimal use of antibiotics. Antibiotic stewardship policies should address the roles and responsibilities for antibiotic stewardship and use within the hospital; how the various hospital committees and departments interface with the antibiotic stewardship program; and how to optimize antibiotic use.

Survey Procedures §482.42(b)(1)

- *Determine whether the antibiotic stewardship leadership and staff was/were appointed by the governing body based on recommendations of the medical staff leadership and pharmacy leadership and has the responsibility for the antibiotic stewardship program.*

- *Review the personnel file of the antibiotic stewardship staff to determine whether he/she/they is/are qualified through ongoing education, training, experience, or certification to oversee the antibiotic stewardship program.*

- *Determine whether the antibiotic stewardship staff have developed and implemented hospital antibiotic stewardship policies.*

- *Review the criteria the hospital used to determine the resources necessary to operate effectively and ensure the resource allocation matches the determined needs.*

A-0761
(Rev. 235; Issued: 01-16-26; Effective: 01-16-26; Implantation: 01-16-26)

§482.42(b)(2) The hospital-wide antibiotic stewardship program:
(i) Demonstrates coordination among all components of the hospital responsible for antibiotic use and resistance, including, but not limited to, the infection prevention and control program, the QAPI program, the medical staff, nursing services, and pharmacy services;

Interpretive Guidelines §482.42(b)(2)(i)

Hospitals must develop and implement appropriate antibiotic stewardship interventions to address issues identified through their assessment activities and then monitor the effectiveness of interventions through further data collection and analysis. Hospitals should improve their internal coordination among all components responsible for antibiotic use and reducing the development of resistance, including, but not limited to, the antibiotic stewardship programs, the infection prevention and control program, the QAPI program, the medical staff, nursing services, laboratory services, and pharmacy services. Hospitals must promote evidence-based use of antibiotics, to reduce the incidence of adverse consequences of inappropriate antibiotic use including, but not limited to, treatment failures, C. difficile infections (CDIs), and growth of antibiotic resistance in the hospital overall.

The hospital must implement and maintain an active and hospital-wide antibiotic stewardship program as an effective means to improve hospital antibiotic-prescribing practices and thereby curb patient risks for adverse drug events, treatment failures, and potentially life-threatening, antibiotic-resistant infections, including CDIs. A robust antibiotic stewardship program must be coordinated with the hospital's overall infection prevention and control program to address healthcare-acquired infections and antibiotic resistance.

Survey Procedures §485.640(b)(2)(i)

- *Review the hospital's antibiotic stewardship policies and procedures for evidence that the hospital has a process in place for coordination among all components of the hospital responsible for antibiotic use and resistance, including, but not limited to, the antibiotic stewardship program, the infection prevention and control program, the QAPI program, the medical staff, nursing services, and pharmacy services.*

A-0762
(Rev. 235; Issued: 01-16-26; Effective: 01-16-26; Implantation: 01-16-26)

[§482.42(b)(2) The hospital-wide antibiotic stewardship program:]
(ii) Documents the evidence-based use of antibiotics in all departments and services of the hospital; and

Interpretive Guidelines §482.42(b)(2)(ii)

Hospitals must promote evidence-based use of antibiotics to reduce the incidence of adverse consequences of inappropriate antibiotic use, including, but not limited to, adverse drug events, CDIs, and growth of antibiotic resistance in the hospital overall.

Survey Procedures §485.640(b)(2)(ii)

- *Verify that the hospital's antibiotic use is consistent with its documented evidence-based hospital-wide antibiotic stewardship program recommendations.*

A-0763
(Rev. 235; Issued: 01-16-26; Effective: 01-16-26; Implantation: 01-16-26)

[§482.42(b)(2) The hospital-wide antibiotic stewardship program:]
(iii) Documents improvements, including sustained improvements, in proper antibiotic use, such as through reductions in CDI and antibiotic resistance in all departments and services of the hospital;

Interpretive Guidelines §482.42(b)(2)(iii)

The hospital must provide documentation of improvements and the sustained improvement toward the proper use of antibiotics through the implementation of the hospital wide antibiotic stewardship program. It is expected that the hospital will reduce patient risk for adverse drug events and potentially life-threatening, antibiotic-resistant infections, including CDIs. The antibiotic stewardship program should be updated with any advancing evidence-based improvements in antibiotic-prescribing practices.

Survey Procedures §485.640(b)(2)(iii)

- *Review documentation of improvements and/or sustainment of improvements using the evidence-based hospital-wide antibiotic stewardship program recommendations.*

A-0764
(Rev. 235; Issued: 01-16-26; Effective: 01-16-26; Implantation: 01-16-26)

§482.42(b)(3) The antibiotic stewardship program adheres to nationally recognized guidelines, as well as best practices, for improving antibiotic use; and

Interpretive Guidelines §482.42(b)(3)

Hospitals must implement and maintain an active and hospital-wide antibiotic stewardship program consistent with nationally recognized standards for improving antibiotic use. Optimizing the use of antibiotics is critical to effectively treat infections, protect patients from harms caused by unnecessary antibiotic use, and combat antibiotic resistance.

For example, the Centers for Disease Control and Prevention (CDC) provides "Core Elements of Antibiotic Stewardship" at https://www.cdc.gov/antibiotic-use/core-elements/index.html. CDC's Core Elements of Antibiotic Stewardship offer providers and facilities a set of key principles to guide efforts to improve antibiotic use and, therefore, advance patient safety and improve outcomes. There is no "one size fits all" approach to optimize antibiotic use for all settings. The complexity of medical decision-making surrounding antibiotic use and the variability in hospital size and types of care in U.S. healthcare settings require flexible programs and activities.

Examples of other organizations that promulgate nationally recognized antibiotic stewardship guidelines and/or recommendations include and are not limited to: the Society for Healthcare Epidemiology of America (SHEA), and the Infectious Diseases Society of America (IDSA), the American Society for Health System Pharmacists (ASHP) and the Society for Infectious Disease Pharmacists (SIDP).

Survey Procedures §482.42(b)(3)

- *Verify evidence that nationally recognized standards have been implemented for their evidence-based hospital-wide antibiotic stewardship program.*

- *Verify that core elements of best practices have been included within the hospital-wide antibiotic stewardship program that may include: hospital leadership commitment, accountability, pharmacy expertise, tracking, reporting, education, and appropriate interventions or actions being taken to improve antibiotic use to reduce adverse events, prevent emergence of resistance, and ensure better outcomes for patients in this setting.*

A-0765

(Rev. 235; Issued: 01-16-26; Effective: 01-16-26; Implantation: 01-16-26)

§482.42(b)(4) The antibiotic stewardship program reflects the scope and complexity of the hospital services provided.

Interpretive Guidelines §482.42(b)(4)

Hospitals must implement and maintain an active and hospital-wide antibiotic stewardship

program that reflects the scope and complexity of the hospital services provided.

Survey Procedures §485.640(b)(4)

- *Review the parameters of the antibiotic stewardship program to determine whether it is suitable for the scope and complexity of the hospital's services.*

A-0770

(Rev. 235; Issued: 01-16-26; Effective: 01-16-26; Implantation: 01-16-26)

§482.42(c)(1) 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.

Interpretive Guidelines §482.42(c)(1)(i)

The hospital's governing body must ensure that an infection prevention and control program is in place and operational for the monitoring and prevention of healthcare-associated infections and the transmission of pathogens, and an antibiotic stewardship program is in place and operational for the monitoring and improvement of antibiotic use. The development and implementation of both the infection control and antibiotic stewardship programs should include leadership support and accountability via the participation of the medical director, pharmacy director, nursing and administrative leadership, and individuals with designated responsibility for the infection control program and the antibiotic stewardship program; however the governing body or responsible individual is responsible to demonstrate the implementation, success, and sustainability of such activities.

Hospital policies should address the roles and responsibilities for infection prevention and control within the hospital; how the various hospital committees and departments interface with the infection prevention and control program; how to prevent infectious/communicable diseases; and how to report infectious/communicable diseases to the infection prevention and control program.

Likewise, hospital policies should address the roles and responsibilities for antibiotic stewardship within the hospital; how the various hospital committees and departments interface with the antibiotic stewardship program; and how to monitor and improve antibiotic use.

Survey Procedures §485.640(c)(1)(i)

- *Review the hospital policies and governing body meeting minutes for a record of support for the infection control and antibiotic stewardship programs.*

- *Verify that the hospital policies are being followed for the tracking of all infection surveillance, prevention and control, and the monitoring of hospital antibiotic use activities.*

A-0771

(Rev. 235; Issued: 01-16-26; Effective: 01-16-26; Implantation: 01-16-26)

[§482.42(c)(1) The governing body must ensure all of the following:]
(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.

Interpretive Guidelines §482.42(c)(1)(ii)

Hospitals are required to coordinate internally among all components responsible for infection control and antibiotic stewardship, including, but not limited to, the infection prevention and control program, the antibiotic stewardship program, the QAPI program, the medical staff, nursing services, laboratory services, and pharmacy services.

The hospital's governing body, the medical staff, and the director of nursing must ensure that the hospital-wide Quality Assessment and Performance Improvement (QAPI) program and staff in-service training programs address problems identified through the infection prevention and control program and the antibiotic stewardship program. To reflect the importance of infection control and antibiotic stewardship, the regulations specifically require that the hospital's QAPI and training programs must be involved in addressing problems identified by the infection control program and antibiotic stewardship program and hold the leadership jointly responsible for linking the infection control program and antibiotic stewardship program with the QAPI and training programs. These hospital leaders are also held explicitly responsible for implementing successful corrective action plans. In order to accomplish this, hospital leaders must monitor adherence to corrective action plans, as well as assess the effectiveness of actions taken, with implementation of revised corrective actions as needed.

Education on the principles and practices for preventing infections and the transmission of infectious agents and the appropriate use of antibiotics within the hospital should be provided to anyone who has an opportunity for contact with patients or medical equipment or prescribing, preparing or administering antibiotics, e.g., nursing and medical staff; pharmacy staff, therapists and technicians, such as those involved in respiratory, physical, and occupational therapy and radiology and cardiology services; phlebotomists; housekeeping and maintenance staff; volunteers; and all students and trainees in healthcare professions.

Survey Procedures §482.42(c)(1)(ii)

- *Confirm that the hospital's infection control program and antibiotic stewardship program are being coordinated with their QAPI leadership, medical staff, nursing services, and pharmacy services.*

- *Determine whether the hospital's QAPI program and staff in-service training programs address problems identified by the infection control officer(s) and antibiotic stewardship staff.*

- *Determine whether infection control and antibiotic use problems identified are reported to the hospital's leadership. Verify that hospital leadership takes steps to ensure that corrective actions are implemented and successful.*

A-0772

(Rev. 235; Issued: 01-16-26; Effective: 01-16-26; Implantation: 01-16-26)

§482.42(c)(2) Standard: Leadership responsibilities

(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.

Interpretive Guidelines §482.42(c)(2)(i)

Hospitals must implement and maintain an active and hospital-wide infection control program consistent with nationally recognized standards for preventing infections and the transmission of pathogens. The infection preventionist(s) and/or infection control professional(s) is responsible for the development and implementation of hospital-wide infection surveillance, prevention, and control policies and procedures that adhere to nationally recognized guidelines.

Hospitals have the flexibility to adopt the approaches that best fit their infection prevention and control needs. CMS does not discourage innovative methodologies or approaches; however, it does expect to see the hospitals engaging in these sorts of innovative practices while also having an adequate program rooted in the traditional evidence-based model. There are ample recognized evidence-based approaches for hospitals to follow in order to adhere to nationally recognized guidelines without impeding any hospital's ability to otherwise make progress in infection prevention and control.

Survey Procedures §482.42(c)(2)(i)

- *Verify that the hospital's infection prevention and control program, including its hospital-wide infection surveillance, prevention, and control policies and procedures, is consistent with nationally recognized standards.*

A-0773

(Rev. 235; Issued: 01-16-26; Effective: 01-16-26; Implantation: 01-16-26)

[§482.42(c)(2) The infection preventionist(s)/infection control professional(s) is responsible

for:]
(ii) All documentation, written or electronic, of the infection prevention and control program and its surveillance, prevention, and control activities.

Interpretive Guidelines §482.42(c)(2)(ii)

The hospital's infection preventionist(s) and/or infection control professional(s) is responsible for all documentation, written or electronic, of the prevention and control program, and its surveillance, prevention, and control activities. ''Documentation'' encompasses both collecting and maintaining pertinent information in a systematic fashion.

When considering priority activities, the infection preventionist(s) and/or infection control professional(s) can review the HHS Action Plan to Prevent Healthcare-Associated Infections (HHS. ''HHS Action Plan to Prevent Healthcare-Associated Infections. 2025'') https://health.gov/hcq/prevent-hai-action-plan.asp.

Survey Procedures §482.42(c)(2)(ii)

- *Verify that the hospital's infection preventionist(s) and/or infection control professional(s) are documenting, in written or electronic form, the prevention and control program, and its surveillance, prevention, and control activities.*

A-0774

(Rev. 235; Issued: 01-16-26; Effective: 01-16-26; Implantation: 01-16-26)

[§482.42(c)(2) The infection preventionist(s)/infection control professional(s) is responsible for:]
(iii) Communication and collaboration with the hospital's QAPI program on infection prevention and control issues.

Interpretive Guidelines §482.42(c)(2)(iii)

The hospital's infection preventionist(s) and/or infection control professional(s) must communicate and collaborate with the hospital's QAPI program on all infection prevention and control issues. Such issues include all concerns, including ones that are emerging and ones that are already problematic. This communication and collaboration are intended to foster and enhance a proactive culture around a hospital's infection prevention and control programs.

Survey Procedures §485.640(c)(2)(iii)

- *Verify that the hospital's infection preventionist(s) and/or infection control professional(s) are communicating and collaborating with the hospital's QAPI program on all infection prevention and control issues.*

A-0775

(Rev. 235; Issued: 01-16-26; Effective: 01-16-26; Implantation: 01-16-26)

[§482.42(c)(2) The infection preventionist(s)/infection control professional(s) is responsible for:]
(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.

Interpretive *Guidelines §482.42(c)(2)(iv)*

The hospital's infection preventionist(s) and/or infection control professional(s) must take an active role in the competency-based training and education of hospital personnel and staff, including medical staff, and, as applicable, personnel providing contracted services in the hospital. This training and education must include the practical applications of infection prevention and control guidelines, policies, and procedures.

Survey Procedures §482.42(c)(2)(iv)

- *Review the hospital's policies and procedures on training and educating staff.*
- *Confirm that the hospital's infection preventionist(s) and/or infection control professional(s) training and education of hospital personnel and staff is competency-based.*
- *Verify that training on the practical applications of infection prevention and control guidelines is occurring by reviewing the staff records on completed competencies.*

A-0776

(Rev. 235; Issued: 01-16-26; Effective: 01-16-26; Implantation: 01-16-26)

[§482.42(c)(2) The infection preventionist(s)/infection control professional(s) is responsible for:]
(v) The prevention and control of HAIs, including auditing of adherence to infection prevention and control policies and procedures by hospital personnel.

Interpretive Guidelines §482.42(c)(2)(v)

The hospital's infection preventionist(s) and/or infection control professional(s) are responsible for preventing and controlling healthcare-acquired infections, and transmission of pathogens, including auditing of adherence to infection prevention and control policies and procedures by hospital personnel.

Survey Procedures §482.42(c)(2)(v)

- *Verify that the hospital's infection preventionist(s) and/or infection control professional(s) have an active role in auditing the adherence to infection prevention and control policies and procedures by hospital personnel.*

A-0777

(Rev. 235; Issued: 01-16-26; Effective: 01-16-26; Implantation: 01-16-26)

[§482.42(c)(2) The infection preventionist(s)/infection control professional(s) is responsible for:]
(vi) Communication and collaboration with the antibiotic stewardship program.

Interpretive Guidelines §482.42(c)(2)(vi)

The hospital's infection preventionist(s) and/or infection control professional(s) is responsible for communication and collaboration with the antibiotic stewardship program. Collaboration between the hospital's infection prevention and control and antibiotic stewardship programs provides the optimal approach to reducing healthcare acquired infections and antibiotic resistance.

Survey Procedures §482.42(c)(2)(vi)

- *Verify that the hospital's infection preventionist(s) and/or infection control professional(s) are communicating and collaborating with the antibiotic stewardship program.*

A-0778

(Rev. 235; Issued: 01-16-26; Effective: 01-16-26; Implantation: 01-16-26)

§482.42(c)(3) Standard: Leadership responsibilities

(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.

Interpretive Guidelines §482.42(c)(3)(i)

The hospital's designated antibiotic stewardship program leader, similar to the responsibilities of the hospital's designated infection preventionist(s) and/or infection control professional(s), ensures the appropriate antibiotic use for reducing adverse drug events, treatment failures, and antibiotic resistance, including deadly C. difficile infections. The antibiotic stewardship program must have dedicated and expert leadership responsible and accountable for its success,

whose responsibilities include the development and implementation of a hospital-wide antibiotic stewardship program, based on nationally recognized guidelines, to monitor and improve the use of antibiotics.

Survey Procedures §482.42(c)(3)(i)

- *Verify that the hospital's designated antibiotic stewardship program leader develops and implements the hospital-wide antibiotic stewardship program, based on nationally recognized guidelines, to monitor and improve the use of antibiotics.*

A-0779

(Rev. 235; Issued: 01-16-26; Effective: 01-16-26; Implantation: 01-16-26)

[§482.42(c)(3) The leader(s) of the antibiotic stewardship program is responsible for:]
(ii) All documentation, written or electronic, of antibiotic stewardship program activities.

Interpretive Guidelines §482.42(c)(3)(ii)

The hospital's designated antibiotic stewardship program leader is responsible for documentation, written or electronic, of antibiotic stewardship program activities and antibiotic-use issues.

Survey Procedures §482.42(c)(3)(ii)

- *Verify that the hospital's designated antibiotic stewardship program leader documents the hospital's antibiotic stewardship program activities and antibiotic use issues*

A-0780

(Rev. 235; Issued: 01-16-26; Effective: 01-16-26; Implantation: 01-16-26)

[§482.42(c)(3) The leader(s) of the antibiotic stewardship program is responsible for:]
(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.

Interpretive Guidelines §482.42(c)(3)(iii)

The hospital's designated antibiotic stewardship program leader is responsible for communication and collaboration with medical staff, nursing, and pharmacy leadership, as well as the hospital's infection prevention and control and QAPI programs on antibiotic use issues.

Survey Procedures §485.640(c)(3)(iii)

- *Verify that the hospital's designated antibiotic stewardship program leader*

communicates and collaborates with medical staff, nursing, and pharmacy leadership, as well as the hospital's infection prevention and control and QAPI programs

A-0781

(Rev. 235; Issued: 01-16-26; Effective: 01-16-26; Implantation: 01-16-26)

[§482.42(c)(3) The leader(s) of the antibiotic stewardship program is responsible for:]

(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.

Interpretive Guidelines §482.42(c)(3)(iv)

The hospital's designated antibiotic stewardship program leader is responsible for 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.

Survey Procedures §482.42(c)(3)(iv)

- *Verify that the hospital's designated antibiotic stewardship program leader provides 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.*

A-0785

(Rev. 235; Issued: 01-16-26; Effective: 01-16-26; Implantation: 01-16-26)

§482.42(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:

Interpretive Guidelines §482.42(d)

The hospital must have an infection prevention and control program and an antibiotic stewardship program for the entire hospital (including all campuses, provider-based locations, satellites, remote locations, etc.). In the case of a hospital system, it is permissible for the system to have unified and integrated infection prevention and control and antibiotic stewardship programs (hereafter referred to as a "unified infection prevention and control and antibiotic stewardship") for multiple, separately certified hospitals.

If the hospital uses a unified and integrated program that it shares with other hospitals that are part of a multi-hospital system, this does not change the requirement that each separately certified hospital is held responsible and accountable to the system's governing body for meeting all of the requirements of an infection prevention and control program and antibiotic stewardship program as outlined in the regulations at §482.42.

Survey Procedures §482.42(d)

- *Surveyors assess the manner and degree of noncompliance with the standards within this condition to determine whether there is condition-level noncompliance.*

A-0786

(Rev. 235; Issued: 01-16-26; Effective: 01-16-26; Implantation: 01-16-26)

§482.42(d)(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;

Interpretive Guidelines §482.42(d)(1)

Although a hospital system has the flexibility to develop a unified and integrated infection prevention and control program and antibiotic stewardship program for all of the separately certified hospitals within its system, there must be evidence that the system-wide programs have taken in to account the significant differences in patient populations and services offered that provide unique circumstances for each member hospital.

Survey Procedures §482.42(d)(1)

- *Review the infection prevention and control program and antibiotic stewardship program and identify unified infection prevention and control and antibiotic stewardship policies and activities and how these take into account the hospital's population and services offered.*

- *Identify the process by which the hospitals' population and services are integrated into the infection prevention and control and antibiotic stewardship programs.*

A-0787

(Rev. 235; Issued: 01-16-26; Effective: 01-16-26; Implantation: 01-16-26)

§482.42(d)(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;

Interpretive Guidelines §482.42(d)(2)

The unified infection prevention and control and antibiotic stewardship programs must develop and implement policies and procedures for each certified hospital to address the needs and concerns of each hospital separately. The practice and location of the hospital must be given consideration when developing these policies and procedures.

Survey Procedures §482.42(d)(2)

- *Review the infection prevention and control and antibiotic stewardship programs and identify unified infection prevention and control and antibiotic stewardship policies and procedures and identify how each separately certified hospital's unique needs and areas of concern have been considered in the development of those policies and procedures.*

A-0788

(Rev. 235; Issued: 01-16-26; Effective: 01-16-26; Implantation: 01-16-26)

§482.42(d)(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; and

Interpretive Guidelines §482.42(d)(3)

Each hospital must also demonstrate that the unified and integrated programs have mechanisms in place to ensure that issues localized to particular hospitals in the system are also considered and addressed. Therefore, each hospital should be able to identify and address QAPI issues, particularly specific to their hospital in addition to any of the issues being addressed in the unified and integrated programs.

Survey Procedures §482.42(d)(2)

- *Review the QAPI program and identify unified QAPI elements and QAPI elements that are unique to the particular hospital.*

- *Identify the process for which these unique elements are integrated into the QAPI program.*

A-0789

(Rev. 235; Issued: 01-16-26; Effective: 01-16-26; Implantation: 01-16-26)

§482.42(d)(4) A qualified individual (or individuals) with expertise in infection prevention and control and in antibiotic stewardship 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.

Interpretive Guidelines §482.42(d)(4)

The hospital must designate an individual or group of individuals with expertise in infection prevention and control and antibiotic stewardship. This individual or group of individuals are responsible for communicating, implementing, and maintaining the policies and procedures governing infection prevention and control and antibiotic stewardship. They are directed by the unified infection prevention and control and antibiotic stewardship programs. Additionally, they are responsible for providing education and training on the practical applications of infection prevention and antibiotic stewardship to hospital staff.

Survey Procedures §482.42(d)(4)

- *Review governing body policies for evidence that a qualified individual(s) has/have been designated as responsible for communicating with the unified infection prevention program and antibiotic stewardship program, for implementing and maintaining policies and procedures governing the infection prevention and control and antibiotic stewardship programs, and training of hospital staff.*

- *Review documentation that the designated individual(s) communicate(s) with the unified program leadership related to issues with infection prevention and antibiotic stewardship.*

- *Review hospital training documents related to education in infection prevention and antibiotic stewardship as evidence of training of hospital staff.*

- *ram leader develops and implements the hospital-wide antibiotic stewardship program, based on nationally recognized guidelines, to monitor and improve the use of antibiotics.*

A-0799

(Rev. 235; Issued: 01-16-26; Effective: 01-16-26; Implantation: 01-16-26)

§482.43 Condition of Participation: Discharge Planning

The hospital must have in effect a discharge planning process that focuses on the patient goals and treatment preferences and includes the patient and his or her caregivers/support person(s) 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 a preventable hospital readmissions.

Interpretive Guidelines §482.43

Hospital discharge planning is a process that involves hospital staff, patients, and his or her caregivers or support person(s) in determining the appropriate post-hospital discharge plan for the patient. It includes identifying patient needs for a safe transition from the hospital to his/her discharge destination, identifying patient and caregiver preferences and goals for care and treatment beyond their hospital stay, and should be inclusive of measures to prevent avoidable hospital readmissions.

Hospitals must actively involve patients and their caregivers/ support person(s) throughout the discharge planning process. The patient and his or her caregiver, and support person participate in the development and implementation of his/her plan of care and discharge planning for post-discharge care.

The hospital should specify in writing its discharge planning policies and procedures. The policies and procedures for the discharge planning process must address all of the requirements of 42 CFR 482.43. The hospital must take steps to ensure that its discharge planning policies and procedures are implemented consistently.

Survey Procedures §482.43

- *Verify that the discharge plan involves hospital staff, patients, and their caregivers/ support person(s) in determining the appropriate post-hospital discharge plan for the patient.*

- *Verify that the discharge plan documents the patient's goals for care and treatment preferences.*

- *Verify that the discharge plan includes a safe transition from the hospital to discharge destination.*

A-0800

(Rev. 235; Issued: 01-16-26; Effective: 01-16-26; Implantation: 01-16-26)

§482.43(a) Standard: Discharge Planning Process

(a) 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.

Interpretive Guidelines §482.43(a)

The discharge planning process is expected to begin in the early stages in the hospitalization of the patient. Identifying upon admission of the patient those patients who are likely to suffer adverse health consequences upon discharge without adequate discharge planning would allow sufficient time to complete discharge planning evaluations and develop appropriate discharge plans that support the discharge needs, goals, and preferences of the patient and their caregivers. The hospital's discharge planning policies and procedures must document the criteria and screening process it uses to identify patients likely to need discharge planning, including the evidence or basis for the criteria and process. They should also identify which staff are responsible for carrying out the evaluation to identify patients likely to need discharge planning.

However, no noncompliance deficiency citations will be made if the identification of patients likely to need discharge planning is completed at least 48 hours in advance of the patient's discharge and there is no evidence that (1) the patient's discharge was delayed due to the hospital's failure to complete an appropriate discharge planning evaluation on a timely basis, or (2) the patient was placed unnecessarily in a setting other than that from which he/she was admitted primarily due to a delay in discharge planning. For example, a delay in identification of a patient in need of discharge planning might result in discharging the patient to a nursing facility, because such placements can be arranged comparatively quickly, when the patient preferred to return home, and could have been supported in the home environment with arrangement of appropriate community services.

If the patient's hospital stay is for less than 48 hours, hospitals must nevertheless ensure that they are timely screened so that, if needed, the discharge planning process is completed before the patient's discharge.

For patients that may not have been initially identified as in need of a discharge plan, there may be changes in the patient's condition that may warrant development of a discharge plan. The hospital's discharge planning policies and procedures must address how the staff responsible for discharge planning will be made aware of changes in a patient's condition that require a discharge planning evaluation.

In the event that a patient is transferred to another hospital, any pertinent information concerning the identification of the patient's post-hospital needs should be in the patient's medical record that is transferred with the patient. The receiving hospital then becomes responsible for the discharge planning process for the patient.

Survey Procedures §482.43(a)

- *Identify the hospital's discharge planning policies and procedures.*

- *Verify that patients are timely screened so that the discharge planning process is completed before the patient's discharge and to avoid unnecessary delays in discharge.*

A-0801

(Rev. 235; Issued: 01-16-26; Effective: 01-16-26; Implantation: 01-16-26)

§482.43(a)(4) Standard: Discharge Planning Process

(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.

Interpretive Guidelines §482.43(a)(4)

Hospitals must evaluate a patient's discharge planning needs and develop and initially implement a discharge plan upon request of the patient's physician, regardless of whether the patient meets the hospital's screening criteria for an evaluation.

Survey Procedures §482.43(a)(4)

- *Review medical records to determine if the discharge plan has been developed and implemented when requested by a physician.*
- *Review hospital policy for how the hospital will develop and implement a discharge plan when a patient does not meet the screening criteria for evaluation but is otherwise requested by a physician.*

A-0802

(Rev. 235; Issued: 01-16-26; Effective: 01-16-26; Implantation: 01-16-26)

§482.43(a)(6) Standard: Discharge Planning Process

(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.

Interpretive Guidelines §482.43(a)(6)

Hospitals must have in place either a routine reassessment of all plans or a process for triggering a reassessment of the patient's post-discharge needs, capabilities and discharge plan when significant changes in the patient's condition or available supports occur. Significant changes may include, but is not limited to, an increase or decreased need for post hospital services and additional specific medication therapy or treatments. These changes may not only change the discharge plan but may alter the availability of resources to meet the patient's discharge needs.

There should be documentation in the patient's medical record of the re-evaluations and modifications to the discharge plan at the time the changes are made to the plan.

Survey Procedures §482.43(a)(6)

- *Verify that the hospital has a discharge planning process in place to regularly reevaluate the patient's condition to identify any required modifications to the discharge plan and to update the discharge plan as needed.*

A-0803

(Rev. 235; Issued: 01-16-26; Effective: 01-16-26; Implantation: 01-16-26)

§482.43(a)(7) Standard: Discharge Planning Process

(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 admitted within 30 days of a previous admission, to ensure that the plans are responsive to the patient post-discharge needs.

Interpretive Guidelines §482.43(a)(7)

Hospitals must provide evidence of an ongoing review of their discharge planning process to evaluate whether the patient's discharge plans are meeting the discharge needs of the patient. The ongoing review must include a representative sample of discharge plans, including patients that have been readmitted to the hospital within 30 days of the previous discharge. This requirement is important because an effective discharge plan should prevent avoidable hospital readmissions.

Additionally, this ongoing assessment must be on a periodic basis as determined by hospital policy.

Survey Procedures §482.43(a)(7)

- *Verify that the hospital reviews a representative sample of patient discharge plans at regular intervals of time, as per hospital policy, including those patients who were readmitted within 30 days of a previous admission.*

A-0804

(Rev. 235; Issued: 01-16-26; Effective: 01-16-26; Implantation: 01-16-26)

§482.43(a)(8) Standard: Discharge Planning Process

(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 on measures. The hospital must ensure that the post-acute care data on quality measures and data on resource measures is relevant and applicable to the patient's goals and treatment preferences.

Interpretive Guidelines §482.43(a)(8)

Hospitals are required to provide patients, families, and/or the patient's representative with information and resources for post-acute care providers that are relevant and applicable to the patient's treatment goals of care and preferences. The manner in which this information is provided should be based upon the needs of the individual(s) making decisions about post-acute care.

Data on quality and resource use measures should include data currently available and publicly reported at the appropriate reading level and should contain items that are relevant to patient goals and treatment preferences. Such data allows individuals to make an informed decision about the choice of the post-acute care providers. The resources available include, but are not limited to, those on the CMS.gov website.

Search the internet for the following Medicare certified providers:

- *Home Health Agencies (HHAs): Medicare.gov Home Health Compare, https://www.medicare.gov/homehealthcompare/search.html;*

- *Skilled Nursing Facilities, (SNF): Medicare.gov Nursing Home Compare, https://www.medicare.gov/nursinghomecompare/search.html;*

- *Inpatient Rehabilitation Facilities (IRF): Medicare.gov Inpatient Rehabilitation Facilities Compare, https://www.medicare.gov/inpatientrehabilitationfacilitycompare/; and*

- *Long Term Care Hospitals (LTCHs): Medicare.gov Long Term care Hospital Compare, https://www.medicare.gov/longtermcarehospitalcompare/.*

The hospital will need to provide evidence that this information was provided and the manner in which the information was delivered to the patient, family, and/or patient representative.

Survey Procedures §482.43(a)(8)

- *Review the policy for how data on quality measures and data on resource use on measures is provided to patients.*
- *Review the documentation that the hospital has provided this information to patient, family, and/or patient representative.*
- *Review medical records to ensure that the post-acute care data on quality measures and data on resource measures is relevant and applicable to the patient's goals and treatment preferences.*

A-0806

(Rev. 235; Issued: 01-16-26; Effective: 01-16-26; Implantation: 01-16-26)

§482.43(a)(1) Standard: Discharge Planning Process

(1) Any discharge planning evaluation must be made in a timely basis to ensure the appropriate arrangements for post-hospital care will be made before discharge and to avoid unnecessary delays in discharge.

Interpretive Guidelines §482.43(a)(1)

After a patient has been identified as needing a discharge planning evaluation, or after a request for an evaluation has been made by the physician, patient and/or patient's representative, the evaluation must be completed timely. This means there must be sufficient time after completion to allow arrangements for post-hospital care to be made, without having to delay the patient's discharge in order to do so, and without unnecessarily transferring the patient to a different setting than that from which he/she was admitted primarily due to the delay in making appropriate arrangements. Acute care hospital inpatients frequently have short lengths of stay, which necessitates prompt attention to patients' discharge planning needs in acute care hospitals. Failure to complete the evaluation in a timely manner could make it more difficult to implement the patient's final discharge plan, and/or may cause an unnecessary delay in the patient's discharge from the hospital.

There may be citations if the hospital does not identify patients likely to need discharge planning at least 48 hours in advance of the patient's discharge, and there is evidence that: (1) the patient's discharge was delayed due to the hospital's failure to complete an appropriate discharge planning evaluation on a timely basis; or (2) that the patient was placed unnecessarily in a setting other than that from which he/she was admitted primarily due to a delay in discharge planning. For example, a delay in identification of a patient in need of discharge planning might result in discharging the patient to a nursing facility, because such placements can be arranged comparatively quickly, when the patient preferred to return home, and could have been supported in the home environment with the arrangement of appropriate community services.

If the patient's stay is for less than 48 hours, hospitals must nevertheless ensure that they are screened so that, if needed, the discharge planning process is completed before the patient's discharge.

For patients that may not have been initially identified as in need of a discharge plan, there may be changes in the patient's condition that warrant development of a discharge plan. The hospital's discharge planning policies and procedures must address how the staff responsible for discharge planning will be made aware of changes in a patient's condition that require a discharge planning evaluation.

Survey Procedures *§482.43(a)(1)*

- *Identify the hospital's discharge planning policies and procedures.*

- *Verify that patients are screened so that the discharge planning process is completed before the patient's discharge.*

A-0807

(Rev. 235; Issued: 01-16-26; Effective: 01-16-26; Implantation: 01-16-26)

§482.43(a)(2) Standard: Discharge Planning Evaluation

(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.

Interpretive Guidelines §482.43(a)(2)

As a component of the discharge planning evaluation, it is required that the evaluation include an assessment of the patient's likely need for any appropriate healthcare, non-healthcare, and community-based services provided following discharge from the hospital. Once the services needed by the patient following discharge have been identified, it is required that the hospital determine if the necessary services are available and accessible by the patient.

If neither the patient nor the patient's family or informal caregiver(s) are able to address all of the required care needs, then the evaluation must determine whether there are community-based services that are available to meet the patient's needs while allowing the patient to continue living at home.

Such health care services may include, but are not limited to:

- *Home health, attendant care, and other community-based services;*
- *Hospice or palliative care;*
- *Respiratory therapy;*
- *Rehabilitation services (PT, OT, Speech, etc.);*
- *End Stage Renal Dialysis services;*
- *Pharmaceuticals and related supplies;*
- *Substance use and behavioral health services;*
- *Nutritional consultation/supplemental diets; and/or*
- *Medical equipment and related supplies.*

However, services may also include those that are not traditional health care services, but which may be essential to a patient's ongoing ability to live in the community, including, but not limited to:

• Home and physical environment modifications;
• Transportation services;
• Meal services; and/or
• Household services, such as housekeeping, shopping, etc.

Some of the information related to needed services will emerge from the required evaluation of the patient's ability to receive care in the home, either as self-care or provided by someone else. All patients, even those with a high capability for self-care, are likely to require some follow-up ambulatory health care services, e.g., a post-discharge appointment with their surgeon, specialist or primary care physician, or a series of appointments for physical or occupational therapy. Some patients might have more complex care needs which nevertheless may still be met in the home setting, depending on the specific clinical needs and the services available in the patient's community.

Hospitals are expected to have knowledge of the capabilities and capacities of not only long term care facilities, but also of the various types of service providers in the area where most of the patients it serves receive post-hospital care, in order to develop a discharge plan that not only meets the patient's needs but also can be implemented.

Once the determination has been made that services will be necessary post-discharge, the team must then determine the availability of those services or identify comparable substitutions. Included in the evaluation is coordination with insurers and other payors, including the State Medicaid agency, as necessary to ensure resources prescribed are approved and available.

Survey Procedures §482.43(a)(2)

- *Verify that the discharge planning evaluations assess patients' likely needs for any appropriate healthcare, non-healthcare, and community-based services provided following discharge from the hospital.*

- *Assess whether the hospital has the knowledge of the capabilities, capacities, and the various types of service providers in the area where most of the patients it services receive post care.*

A-0808

(Rev. 235; Issued: 01-16-26; Effective: 01-16-26; Implantation: 01-16-26)

§482.43(a)(3) Standard: Discharge Planning Evaluation

(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).

Interpretive Guidelines §482.43(a)(3)

The medical record must demonstrate evidence of the discharge planning evaluation and provide evidence of how the evaluation was used in developing an appropriate discharge plan.

Additionally, there must be evidence in the medical record that the evaluation and the established discharge plan have been discussed with the patient and/or the patient's representative. The hospital is required to arrange for the initial implementation of the discharge plan. This includes providing in-hospital education/training to the patient for self-care or to the patient's family or other support person(s) who will be providing care in the patient's home. It also includes arranging:

- *Transfers to rehabilitation hospitals, long term care hospitals, or long term care facilities;*
- *Referrals to home health or hospice agencies;*
- *Referral for follow-up with physicians/practitioners, occupational or physical therapists, behavioral health and/or substance abuse treatment, etc.;*
- *Referral to medical equipment suppliers; and*
- *Referrals to pertinent community resources that may be able to assist with financial, transportation, meal preparation, or other post-discharge needs.*

The discharge planning process is a collaborative one that must include the participation of the patient and the patient's informal caregiver or representative, when applicable. In addition, other family or support persons who will be providing care to the patient after discharge need to be engaged in the process. Keeping the patient, and, when applicable, the patient's representative and other support persons informed throughout the development of the plan is essential for its success. Providing them with information on post-discharge options, what to expect after discharge and, as applicable, instruction and training in how to provide care is essential. The patient needs clear instructions regarding what to do when concerns, issues, or problems arise, including who to call and when they should seek emergency assistance.

Survey Procedures §482.43(a)(3)

- *Verify that patient medical records have documented discharge planning evaluations and evidence of how the evaluation was used in developing an appropriate discharge plan.*

- *Verify that the discharge plan has been discussed with the patient and/or the patient's representative.*

A-0809

(Rev. 235; Issued: 01-16-26; Effective: 01-16-26; Implantation: 01-16-26)

§482.43(a)(5) – Any discharge planning evaluation or discharge plan under this paragraph must be developed by or under the supervision of a registered nurse, social worker, or other appropriately qualified personnel.

Interpretive Guidelines §482.43(a)(5)

The patient's discharge planning evaluation must be developed by a registered nurse, social

worker, or other appropriately qualified personnel, or by a person who is supervised by such personnel. State law governs the qualifications required to be considered a registered nurse or a social worker. The hospital's written discharge planning policies and procedures must specify the qualifications for personnel other than registered nurses or social workers who develop or supervise the development of the evaluation.

The qualifications should include such factors as previous experience in discharge planning, knowledge of clinical and social factors that affect the patient's functional status at discharge, knowledge of community resources to meet post-discharge clinical and social needs, and assessment skills. All personnel performing or supervising discharge planning evaluations, including registered nurses and social workers, should have knowledge of clinical, social, insurance/financial and physical factors that must be considered when evaluating how a patient's expected post-discharge care needs can be met. It is acceptable for a hospital to include new staff who may not have had previous discharge planning experience, but who are being trained to perform discharge planning duties and whose work is reviewed by qualified personnel.

Survey Procedures §482.43(a)(5)

- *Verify that patient discharge planning evaluations and discharge plans are developed by, supervised by, and/or reviewed by qualified personnel.*

A-0810

(Rev. 235; Issued: 01-16-26; Effective: 01-16-26; Implantation: 01-16-26)

§482.43(b) Standard: Discharge of the patient and the provision and transmission of the patient's necessary medical information.

(b) 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.

Interpretive Guidelines §482.43(b)

For all patients being discharged, referred, or transferred from the hospital, the hospital must provide at the time of discharge all of the patient's medical information that is pertinent and appropriate to post hospital providers and suppliers, facilities, agencies and outpatient providers and practitioners. Post hospital providers, suppliers, and practitioners include but are not limited to skilled nursing facilities, nursing facilities, home health agencies, hospice agencies, mental health agencies, dialysis centers, suppliers of durable medical equipment, suppliers of physical and occupational therapy, physician offices, etc. which offer post-acute care services that address the patient's post-hospital needs identified in the patient's discharge

planning evaluation. They may also include other hospitals to which a patient is transferred for follow-up care, such as rehabilitation hospitals, long term care hospitals, or even other short-term acute care hospitals.

The necessary medical information will be related to the patient's current course of illness and treatment, goals of post-hospital care, and patient treatment preferences. The goal of providing this information is to assist the post hospital providers with medical information that will allow for a safe transition from acute care settings.

The "medical information" that is necessary for the transfer or referral may include, but is not limited to:

- *Brief reason for hospitalization and patient history (or, if hospital policy requires a discharge summary for certain types of outpatient services, the reason for the encounter) and principal diagnosis;*
- *Brief description of hospital course of treatment;*
- *Patient's condition at discharge, including cognitive, functional, and behavioral status and social supports needed (including any mental health or substance treatment supports);*
- *Medication list (reconciled to identify changes made during the patient's hospitalization) including prescription and over-the-counter medications and herbal. (Note, an actual list of medications needs to be included in the discharge information, not just a referral to an electronic list available somewhere else in the medical record.);*
- *List of allergies (including food as well as drug allergies) and drug interactions;*
- *Pending laboratory work and test results, if applicable, including information on how the results will be furnished.*

For patients discharged home:

- *Brief description of care instructions reflecting training provided to patient and/or caregiver(s);*
- *If applicable, list of all follow-up appointments with practitioners with which the patient has an established relationship and which were scheduled prior to discharge, including who the appointment is with, date and time.*
- *If applicable, referrals to potential primary care providers, such as health clinics, if available, for patients with no established relationship with a practitioner.*
- *Additional post-acute or community health service referrals;*

For transfer to other facilities, necessary medical information also includes, but is not limited to, a copy of the patient's advance directive, if the patient has one; and contact information for the hospital and nursing staff with knowledge of the patient in the event the receiving facility needs to communicate regarding patient care needs.

Survey Procedures §482.43(b)

- *Verify that all necessary medical information pertaining to the patient's current course of*

illness and treatment, post-discharge goals of care, and treatment preferences were provided 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 at the time of the patient's discharge.

A-0812
(Rev. 235; Issued: 01-16-26; Effective: 01-16-26; Implantation: 01-16-26)

§482.43(d) Standard: Requirements related to post-acute care services.

(d) For those patients discharged to 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:

A-0813
(Rev. 235; Issued: 01-16-26; Effective: 01-16-26; Implantation: 01-16-26)

§482.43(d)(1) – The hospital must include the discharge planning 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.

(i) The 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.

(ii) For patients enrolled in managed care organizations, the hospital must make the patient aware of the need to verify with their managed care organization which practitioners, providers or certified suppliers are in the network of the patient's managed care organization, it must share this with the patient or the patient's representative.

(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.

Interpretive Guidelines §482.43(d)(1)

The hospital must include a list of Medicare-participating HHAs, SNFs, IRFs, or LTCHs in the discharge plan for those patients for whom the plan indicates home health or post-hospital extended care services are required and that are available to the patient. The list must be based on the geographic area in which the patient resides for HHA services, or in the geographic area requested by the patient for other post-acute care services. Hospitals have the flexibility either to develop their own lists or to print a list of post-acute care providers and home health agencies in the applicable geographic areas from the CMS websites.

For home health agencies, the list must consist of Medicare-participating HHAs that have requested the hospital to be listed and that serve the geographic area where the patient lives. Hospitals may expect the HHA to define its geographic service area when it submits its request to be listed.

The list must only be provided to the patient when post-acute care services are identified through the discharge planning evaluation. The list provided to the patient should be appropriate for the care and services needed.

There must be documentation in the patient's medical record that the list was provided to the patient and/or the patient's representative.

If the patient is enrolled in a managed care insurance program that utilizes a network of exclusive or preferred providers, the hospital should make reasonable attempts, based on information from the insurer, to identify HHAs and SNFs that participate in the insurer's network of providers.

Survey Procedures §482.43(d)(1)

- *Review a sample of cases of patients discharged to HHAs, SNFs, IRFs, and LTCHs to determine if, when applicable, the hospital provided the patient with lists of Medicare-participating providers. In making this determination:*

    - *Is there documentation of a list of multiple HHAs or SNFs being provided (including electronically) to the patient? If not, is there documentation for an acceptable rationale for providing only one option, e.g., the patient's home is included in the service area of only one Medicare-participating HHA that requested to be included on hospital lists, or there is only one Medicare-participating SNF in the area preferred by the patient?*

    - *Ask to see examples of lists of HHAs and SNFs provided to patients prior to discharge.*

    - *Interview staff members involved with the discharge planning process. Ask them to describe how patient preferences are taken into account in the selection of post-hospital HHA or SNF services.*

A-0814

(Rev. 235; Issued: 01-16-26; Effective: 01-16-26; Implantation: 01-16-26)

§482.43(d)(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 the post-discharge services and must, when possible, respect the

patient's or the patient's representative 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 patients.

Interpretive Guidelines §482.43(d)(2)

During the discharge planning process, the hospital must inform the patient of his/her freedom to choose among Medicare-participating post-hospital providers and must not direct the patient to specific provider(s) or otherwise limit which qualified providers the patient may choose among.

When the patient or the patient's family has expressed a preference, the hospital must attempt to arrange post-hospital care, as applicable, which meets these preferences. If the hospital is unable to make the preferred arrangement, e.g., if there is no bed available in the preferred SNF, IRF or LTCH, it must document the reason the patient's preference could not be fulfilled and must explain that reason to the patient.

Survey Procedures §482.43(d)(2)

- *Ask the hospital to identify current patients for whom HHA or SNF services are planned. Interview the patient or the patient's family to ask them:*
    - *Were they presented with a list of HHAs or SNFs, as applicable, to choose from?*
    - *Did the hospital emphasize the patient's freedom of choice?*
    - *Did the hospital arrange for their referral/transfer to an HHA or SNF reflecting their preferences? If not, did the hospital explain why their choice was not feasible*?

A-0815

(Rev. 235; Issued: 01-16-26; Effective: 01-16-26; Implantation: 01-16-26)

§482.43(d)(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.

Interpretive Guidelines §482.43(d)(3)

If the hospital has a disclosable financial interest in an HHA or SNF on a patient's list, or an HHA or SNF on the list has a disclosable financial interest in the hospital, these facts must also be stated on the list provided to the patient. Hospitals are expected to identify for the surveyor whether there are such disclosable financial interests, as described in part 420, subpart C, between the hospital and any specific HHAs or SNFs to which they refer/transfer patients.

Survey Procedures §482.43(d)(3)

- *Ask the hospital if it has any disclosable financial interests in any HHA or SNF on its lists, or if an HHA or SNF has a disclosable financial interest in the hospital. If yes, is this stated clearly on the lists?*

- *If applicable, were patients made aware of disclosable financial interests?*

A-0826

(Rev. 235; Issued: 01-16-26; Effective: 01-16-26; Implantation: 01-16-26)

§482.43(c)Standard: Transfer protocols. Effective July 1, 2025, the hospital must have written policies and procedures for transferring patients under its care (inclusive of inpatient services) to the appropriate level of care (including to another hospital) as needed to meet the needs of the patient. The hospital must also provide annual training to relevant staff regarding the hospital policies and procedures for transferring patients under its care.

Interpretive Guidance §482.43(c):
Guidance Pending
Survey Procedures §482.43(c):
Guidance Pending

A-0953

(Rev. 235; Issued: 01-16-26; Effective: 01-16-26; Implantation: 01-16-26)

§482.51(b)(1)(ii) - Prior to surgery or a procedure requiring anesthesia services and except in the case of emergencies:

(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.

Interpretive Guidelines §482.51(b)(1)(ii)

- *There must be an updated history and physical examination (H&P), including any change in patient condition, documented in the medical record within 24 hours of admission or registration to the hospital when the H&P was completed within 30 days of admission or registration. This update is required for every patient prior to any surgery or a procedure requiring anesthesia services, except in emergencies and except for those patients who are specified as not requiring a comprehensive history and physical for specific outpatient surgeries and procedures pursuant to §482.51(b)(1)(iii).*

- *The updated H&P must be conducted in accordance with the requirements of 42 CFR 482.22(c)(5), except for those patients who are specified as not requiring a comprehensive history and physical for specific outpatient surgeries and procedures.*

Survey Procedures §482.51(b)(1)(ii)

- Review a sample of open and closed medical records of patients (both inpatient and outpatient) who have had surgery or a procedure requiring anesthesia.

- Determine whether an *updated* H&P was conducted*, including any change in patient condition,* and documented in a timely manner, *except for those patients who are specified as not requiring a comprehensive history and physical for specific outpatient surgeries and procedures*.

- Determine whether the H&P *update* was conducted in accordance with the requirements of 42 CFR 482.22(c)(5) *except for those patients who are specified as not requiring a comprehensive history and physical for specific outpatient surgeries and procedures*.

- Determine whether the records of patients who did not have a timely H&P update indicate that the surgery or procedure was conducted on an emergency basis *except for those patients who are specified as not requiring a comprehensive history and physical for specific outpatient surgeries and procedures*.

A-0954

(Rev. 235; Issued: 01-16-26; Effective: 01-16-26; Implantation: 01-16-26)

§482.51(b)(1)(iii) - Prior to surgery or a procedure requiring anesthesia services and except in the case of emergencies:

(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.

Interpretive Guidelines §482.51(b)(1)(iii)

A pre-surgical assessment must be completed and documented after registration for any outpatient surgery or procedure requiring anesthesia, and except for emergencies, when it is

determined by the medical staff policy in place that addresses specific patient characteristics that may not necessitate the need for a comprehensive medical H&P examination and testing, or updated examination, prior to surgery. Patient specific considerations that may be used in determining the necessity for a pre-surgical assessment may include but are not limited to, the following:

- *patient age (considering the need for H&Ps based on pediatric, adult, or geriatric age differences),*
- *diagnosis,*
- *the type and number of procedures scheduled to be performed on the same surgery date,*
- *known comorbidities (e.g. cardiac or pulmonary disease), and*
- *planned anesthesia level (e.g. minimal sedation vs general anesthesia).*

Additionally, the policy should require the consideration of national standards and guidelines of practice for the assessment of specific types of patients prior to specific outpatient surgeries and procedures and in accordance with State and local laws.

Survey Procedures §482.51(b)(1)(iii)

- *Review a sample of medical records of patients receiving outpatient surgery to determine whether evidence exists that pre-surgical assessments and updates have been completed and documented after registration, but prior to surgery or a procedure requiring anesthesia services except in the case of emergencies.*

- *Review the hospital's policies and procedures regarding pre-surgical assessments for outpatient surgical or procedural services and updates to determine if they are consistent with the regulatory requirement.*

A-1114

(Rev. 235; Issued: 01-16-26; Effective: 01-16-26; Implantation: 01-16-26)

§482.55(c) Standard: Emergency services readiness. Effective July 1, 2025, in accordance with the complexity and scope of services offered, there must be adequate provisions and protocols to meet the emergency needs of patients.

Interpretive Guidance §482.55(c):
Guidance Pending

Survey Procedure §482.55(c):
Guidance Pending

A-1115

(Rev. 235; Issued: 01-16-26; Effective: 01-16-26; Implantation: 01-16-26)

§482.55(c)(1) Protocols must be consistent with nationally recognized and evidence-based guidelines for the care of patients with emergency conditions, including but not limited to patients with obstetrical emergencies, complications, and immediate post-delivery care.

Interpretive Guidance §482.55(c)(1):
Guidance Pending

Survey Procedures §482.55(c)(1):
Guidance Pending

A-1116

(Rev. 235; Issued: 01-16-26; Effective: 01-16-26; Implantation: 01-16-26)

§482.55 (c)(2),(c)(2)(i)(ii)(iii) Provisions. Provisions include equipment, supplies, and medication used in treating emergency cases. Such provisions must be kept at the hospital and be readily available for treating emergency cases to meet the needs of patients. The available provisions must include the following: (i)Drugs, blood and blood products, and biologicals commonly used in life saving procedures; (ii) Equipment and supplies commonly used in life-saving procedures; and (iii) each emergency services treatment areas must have call in system for each patient.

Interpretive Guidance §482.55 (c)(2), (c)(2)(i)(ii)(iii):
Guidance Pending

Survey Procedures §482.55 (c)(2), (c)(2)(i)(ii)(iii):
Guidance Pending

A-1117

(Rev. 235; Issued: 01-16-26; Effective: 01-16-26; Implantation: 01-16-26)

§482.55 (c)(3), (c)(3)(i)(ii)(iii)(iv) Staff training. Applicable staff, as identified by the hospital, must be trained annually on the protocols and provisions implemented pursuant to this section. (i) The governing body must identify and document which staff must complete such training. (ii) the hospital must document in the staff personnel records that the training was successfully completed. (iii) the hospital must be able to demonstrate staff knowledge on the topics implemented pursuant to this section.

Interpretive Guidance §482.55 (c)(3), (c)(3)(i)(ii)(iii)(iv):
Guidance Pending

Survey Procedures §482.55 (c)(3), (c)(3)(i)(ii)(iii)(iv):
Guidance Pending

A-1572
(Rev. 235; Issued: 01-16-26; Effective: 01-16-26; Implantation: 01-16-26)

§482.58(b)(6) Specialized rehabilitative services (§483.65)

§483.65 Specialized rehabilitative services

(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(f), 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.

(b) Qualifications. Specialized rehabilitative services must be provided under the written order of a physician by qualified personnel.

Interpretive Guidelines §482.58(b)(6)

Refer to §483.65(a)(b) (Tags F-0825 and F-0826) in Appendix PP of the State Operations Manual (SOM) for interpretive guidelines

Survey Procedures §482.58(b)(6)

Refer to §483.65(a)(b) (Tags F-0825 and F-0826) in Appendix PP of the SOM for survey procedures

Psychiatric Hospital Survey Module

Introduction

Under section 1861(f)(1) of the Social Security Act (the Act), a psychiatric hospital is an institution that is primarily engaged in providing, by or under the supervision of a physician, psychiatric services for the diagnosis and treatment of mentally ill persons. A psychiatric hospital is a type of hospital, and is required to be in compliance with the Federal requirements at 42 CFR part 482, including the special requirements for psychiatric hospitals which are the following:

- *42 CFR 482.60 -- Special provisions applying to psychiatric hospitals;*
- *42 CFR 482.61 -- Special medical record requirements for psychiatric hospitals; and*
- *42 CFR 482.62 -- Special staff requirements for psychiatric hospitals*

The focus of the psychiatric hospital survey is on the "outcome" experienced by the patient, and the overall process and implementation of care provided to achieve a favorable outcome. The survey process includes seven (7) tasks. When these tasks are viewed in total, they give a clear indication of how the provider is meeting or not meeting the requirements. The seven tasks are:

- *Task 1 - Representative sample of patients -- selection methodology;*
- *Task 2 - Record review of individuals in the sample;*
- *Task 3 - Other record reviews;*
- *Task 4 - Direct patient observation;*
- *Task 5 - Interviews;*
- *Task 6 - Visit to each area of the hospital serving certified patients; and*
- *Task 7 - Team assessment of compliance.*

Psychiatric hospital requirements at 42 CFR §§482.60-482.62 do ***not*** *apply in the following settings:*

Psychiatric Residential Treatment Facilities (PRTF) are not psychiatric hospitals. They are non-hospital, inpatient settings that treat children, adolescents and individuals under the age of 21 with psychiatric disorders. The psychiatric hospital requirements do not apply in PRTFs.

Inpatient Prospective Payment System (IPPS)-excluded psychiatric distinct part units located in hospitals or critical access hospitals (CAHs) are not psychiatric hospitals and are not subject to the psychiatric hospital special conditions at §§482.60-62. Facilities with inpatient psychiatric units must meet the payment requirements at 42 CFR part 412 and must attest to meeting the necessary requirements that make them exempt from receiving payments under the IPPS. These units must submit Form CMS-437 to attest that they meet the requirements for IPPS exempt status prior to being placed into excluded status. CMS accepts this attestation and does not survey to the IPPS-excluded psychiatric unit for compliance with the psychiatric hospital special conditions.

Rehabilitation Hospital Survey Module

When conducting a full survey of an accredited or non-accredited rehabilitation hospital, conduct a survey of the hospital's compliance with rehabilitation hospital excluded requirements using the survey methods in this module.

Surveys of the PPS excluded rehabilitation hospital requirements utilizing these methods will count as annual validation compliance surveys of the hospital's self-attestation of compliance with the excluded requirements.

Background

The term "exclusion" is a reimbursement term. Patient care in a PPS excluded rehabilitation hospital is reimbursed at the PPS rehabilitation hospital excluded rate rather than at the hospital PPS rate. In order for a hospital to receive the excluded rate for rehabilitation care provided, the hospital must comply with the excluded requirements found at 42 CFR 412.

A PPS excluded rehabilitation hospital is regulated by both the hospital CoP at 42 CFR 482 (also found in Appendix A of the SOM) and the PPS excluded rehabilitation hospital requirements at 42 CFR 412.

Regulatory Authority and Requirements for PPS Excluded Rehabilitation Hospitals

- 42 CFR 482-Conditions of Participation for Hospitals;
- 42 CFR 412.22-Excluded hospitals and hospital units ; and
  42 CFR 412.23-Excluded hospitals: Classifications.

Activities Conducted Prior to a Rehabilitation Hospital Survey

- Contact the *CMS Location* to determine if the hospital has approval for a PPS excluded rehabilitation hospital.
- Contact the *CMS Location* to determine the hospital's cost reporting period.
- Do not conduct the survey of the PPS excluded rehabilitation hospital requirements within 90 days of the end of the hospital's cost reporting period.
- Identify any satellite locations of the hospital.
- Verify with the *CMS Location* that the hospital is in compliance with the inpatient population percent rule, and that each satellite, if any, is independently in compliance with the inpatient population percent rule.
- Review the "Rehabilitation Hospital Criteria Worksheet," Form CMS-437B.

Survey Tool

"Rehabilitation Hospital Criteria Worksheet," Form CMS-437B.

Survey Procedures for Determining Compliance with the PPS Excluded Rehabilitation Hospital Requirements

- Survey activities to determine hospital compliance with the PPS excluded rehabilitation hospital requirements should be conducted concurrently with the full survey of the hospital's compliance with the hospital CoP.
- Using the "Rehabilitation Hospital Criteria Worksheet," Form CMS-437B, verify whether the requirements have been met by checking the appropriate box marked "YES" or "NO." Under the column "Explanatory Statement," document specifics about the findings. Additional findings can be documented in a narrative note that should be attached to the worksheet.
- Select a minimum of two current inpatients for the patient sample.
- Select additional patients (open or closed records) as needed to determine compliance with the excluded rehabilitation hospital requirements.

- The selected patients should be included in the patient sample used for the full hospital survey.
- Identify if the rehabilitation hospital has remote locations, satellites, or other provider based locations. Record the location, name, address and telephone number for every remote location, satellite, or provider based location on the Hospital/CAH Medicare Database Worksheet for updating the Medicare database.

Exit Conference

- Inform the hospital of findings of noncompliance with the excluded rehabilitation hospital requirements.
- Inform the hospital that the SA will forward the completed Form CMS-437B to the hospital at the same time as the completed Form CMS-2567.

Post Survey Activities

- Do not include the survey findings for the PPS excluded rehabilitation hospital requirements on the Form CMS-2567.
- If there are PPS excluded hospital requirements that have not been met, notify the *CMS Location*. Document survey findings of the PPS excluded rehabilitation hospital requirements on the CMS 437B. Submit the completed Form CMS-437B to the *CMS Location* within the same time frame as the completion of the Form CMS-2567 and at least 60 days prior to the end of the hospital's cost reporting period.
- Follow the requirements in the SOM for post-survey activities.

Inpatient Rehabilitation Unit Survey Module

When conducting a full survey of an accredited or non-accredited hospital that has a PPS excluded rehabilitation unit, conduct a survey of the rehabilitation unit using the survey methods in this module to assess the hospital's compliance with the excluded rehabilitation unit requirements.

Surveys of the PPS excluded rehabilitation unit requirements utilizing these methods will count as annual validation compliance surveys of the hospital's self-attestation of compliance with the excluded requirements.

Background

The PPS excluded rehabilitation unit is part of the hospital and is included as part of the overall hospital survey. The term "exclusion" is a reimbursement term. Patient care in a PPS excluded rehabilitation unit is reimbursed at the PPS excluded rehabilitation unit rate rather than the hospital PPS rate. In order for a hospital to receive the excluded rate for rehabilitation care provided in its excluded unit, the unit must comply with the excluded rehabilitation unit requirements found at 42 CFR 412.

A PPS excluded rehabilitation unit is regulated by both the hospital CoP at 42 CFR 482 (also found in Appendix A of the SOM) and the PPS excluded rehabilitation unit requirements at 42 CFR 412.

Requirements for PPS Excluded Rehabilitation Units

- 42 CFR 482-Conditions of Participation for Hospitals;
- 42 CFR 412.25-Excluded hospital units: Common Requirements;
- 42 CFR 412.29-Excluded rehabilitation units: Additional Requirements; and
- State Operations Manual, Chapter 3, §3100.

Activities Conducted Prior to Rehabilitation Unit Survey

- Contact the *CMS Location* to determine if the hospital has approval for a PPS excluded rehabilitation unit.
- Contact the *CMS Location* to determine the unit's cost-reporting period.
- Do not conduct the survey of the PPS excluded rehabilitation unit requirements within 90 days of the end of the hospital's cost reporting period.
- Verify with the *CMS Location* that the hospital is in compliance with the inpatient population percent rule for the unit and that each rehabilitation unit satellite, if any, is independently in compliance with the inpatient population percent rule.
- If possible, establish the location or locations of the rehabilitation unit. Determine if the unit has a satellite or satellites in other locations. Determination or verification of this information may have to wait until the survey team is onsite.
- Review the "Rehabilitation Unit Criteria Worksheet," Form CMS-437A.

Survey Tool

The "Rehabilitation Unit Criteria Worksheet," Form CMS-437A.

Survey Procedures for Determining Compliance with the PPS Excluded Rehabilitation Unit Requirements

- Survey activities to determine hospital compliance with the PPS excluded rehabilitation unit requirements should be conducted concurrently with the full survey of the hospital's compliance with the hospital CoP.
- Using the "Rehabilitation Hospital Criteria Worksheet," Form CMS-437A, verify whether the requirements have been met by checking the appropriate box marked "YES" or "NO." Under the column "Explanatory Statement," document specifics about the findings. Additional findings can be documented in a narrative note that should be attached to the worksheet.
- Select 10 percent of the unit's average daily census or a minimum of two current patients for the patient sample.
- The selected patients should be included in the patient sample used for the full hospital survey.

- Select additional patients (open or closed records) as needed to determine compliance with the excluded rehabilitation unit requirements.
- If there are no patients on the unit at the time the survey is conducted, review closed patient records of unit patients treated within six months of the survey.
- Identify if the rehabilitation unit has a satellite or satellites. Record the location, name, address and telephone number for every satellite on the Hospital/CAH Medicare Database Worksheet for updating the Medicare database.

Exit Conference

- Inform the hospital of findings of noncompliance with the excluded rehabilitation unit requirements.
- Inform the hospital that the SA will forward the completed Form CMS-437A to the hospital at the same time as the completed Form CMS-2567.

Post Survey Activities

- Do not include the survey findings for the PPS excluded rehabilitation unit requirements on the Form CMS-2567.
- If there are PPS excluded unit requirements that have not been met, notify the *CMS Location*. Document survey finding of the PPS rehabilitation unit requirements on the CMS-437A. Submit the completed Form CMS-437A to the *CMS Location* within the same time frame as the completion of the Form CMS-2567 and at least 60 days prior to the end of the hospital's cost reporting period.
- Follow the requirements in the SOM for post-survey activities.

Hospital Swing-Bed Survey Module

When conducting a full survey of an accredited or unaccredited hospital that has swing-bed approval, conduct a survey of the hospital swing-bed requirements found at 42 CFR 482.66.

Background

Swing-bed patients are hospital patients who are situated in the hospital but for whom the hospital is receiving reimbursement for skilled nursing services, as opposed to acute-care reimbursement. The reference to swing-bed is a patient care and reimbursement status and has no relationship to geographic location in the facility. The patient may be in acute-care status one day and change to swing-bed status the next day. The patient doesn't need to change location in the hospital when the reimbursement status changes, but moving to a different location is allowed. A 3-day qualifying stay for the same spell of illness in any hospital or critical access hospital (CAH) is required prior to admission to swing-bed status. The 3-day qualifying stay does not need to be from the same facility as the swing-bed admission.

Regulatory Authority and Requirements for Hospital Providers of Extended Care Services ("Swing-beds")

Hospital swing-bed care is regulated by the hospital *swing-bed* requirements at 42 CFR 482.66. The swing-bed survey requirements are referenced in the Medicare Nursing Home requirements at 42 CFR Part 483.

Section 1883 of the Act authorizes payment under Medicare for post-hospital SNF services provided by any hospital that meets certain requirements. By regulation, the Secretary has specified these requirements at 42 CFR 482.66:

- The hospital has a Medicare provider agreement;
- The facility has fewer than 100 hospital beds, excluding beds for newborns and beds in intensive care type inpatient units;
- The hospital is located in a rural area. This includes all areas not delineated as "urbanized" areas by the Census Bureau, based on the most recent census;
- The hospital does not have in effect a 24-hour nursing waiver granted under 42 CFR §488.54(c);
- The hospital has not had a swing-bed approval terminated within the two years previous to application; and
- The hospital meets the swing-bed CoP on Resident Rights; Admission, Transfer, and Discharge Rights; Resident Behavior and Facility Practices; Social Services; Discharge Planning; Specialized Rehabilitative Services; and Dental Services.

Activities Conducted Prior to Swing-Bed Survey

Prior to conducting the swing-bed survey, verify the following:

- The hospital continues to be located in a rural census tract;
- The hospital does not have a 24-hour nursing waiver in place; and
- The hospital's swing-bed approval is in effect and has not been terminated within the two previous years.

Survey Procedures

In conducting the survey, verify that the hospital has fewer than 100 hospital beds, excluding beds for newborns and beds in intensive care units. A hospital licensed for more than 100 beds may be eligible for swing-bed approval if it utilizes and staffs for fewer than 100 beds. Count the staffed beds in each nursing unit. Do not count beds in recovery rooms, intensive care units, operating rooms, newborn nurseries or stretchers in emergency departments.

Assess the hospital's compliance with the swing-bed requirements at 42 CFR 482.66.–Swing-bed requirements apply to any patient discharged from the hospital and admitted to a swing-bed for skilled nursing services. The requirements for acute-care hospitals also apply.

If swing-bed patients are present during the on-site inspection, conduct an open record review and an environmental assessment. Include patient interviews and observations of care and services. However, if no swing-bed patients are present during the on-site inspection, review two closed records for compliance with swing-bed requirements. In all cases, review policies, procedures, and contracted services to assure that the hospital has the capability to provide the services needed.

It is important for surveyors to maintain on-going documentation of their findings during the course of the survey for later reference.

Exit Conference

Any findings of noncompliance may be discussed during the time of the hospital exit conference.

Post-Survey Activities

The findings for swing-bed deficiencies must be documented on *the same* Form CMS-2567 *as the* hospital survey.

Part II Interpretive Guidelines – Psychiatric Hospitals

A-1600

(Rev. 235; Issued: 01-16-26; Effective: 01-16-26; Implantation: 01-16-26)

§482.60 Condition of Participation: Special Provisions Applying to Psychiatric Hospitals

Psychiatric hospitals must—

Interpretive Guidelines §482.60

A psychiatric hospital is defined in section 1861(f) of the Act as a hospital that is primarily engaged in providing, by or under the supervision of a physician, psychiatric services for the diagnosis and treatment of mentally ill persons and:

- *Satisfies all of the requirements in sections 1861(e)(3) through (9) of the Act, including that the hospital:*
    - *Has bylaws in effect with respect to its staff of physicians;*
    - *Has a requirement that every patient with respect to whom payment may be made under this title must be under the care of a physician except that a patient receiving qualified psychologist services may be under the care of a clinical psychologist with respect to such services to the extent permitted under State law;*

- *Provides 24-hour nursing services rendered or supervised by a professional registered nurse, and has a licensed practical nurse or registered professional nurse on duty at all times;*
- *Has in effect a hospital utilization review plan and has in place a discharge planning process that meets the requirements of sections 1861(k) and (ee) of the Act, respectively;*
- *In the case of an institution in any State in which State or applicable local law provides for licensing of hospitals, meets the standards established for such licensing;*
- *Has in effect an overall plan and budget consistent with section 1861(z);*
- *Meets other such requirements as the Secretary finds necessary in the interest of the health and safety of individuals who are furnished services in the institution;*

- *Maintains clinical records on all patients and as the Secretary finds to be necessary to determine the degree and intensity of the treatment provided to individuals entitled to hospital insurance benefits under Medicare part A;*
- *Meets such staffing requirements as the Secretary finds necessary for the institution to carry out an active program of treatment for the individuals who are furnished services in the institution; and*
- *In the case of an institution which satisfies the requirements at section 1861(f)(1)-(2) and contains a distinct part which also satisfies the requirements at section 1861(f)(3)-(4), the distinct part shall be considered to be a "psychiatric hospital".*

- *All patients in a psychiatric hospital must be receiving active treatment for their psychiatric conditions. The active treatment requirement in psychiatric hospitals applies to all patients regardless of the population served, acute or long-term focus, or length of stay. Psychiatric hospitals do not provide residential treatment.*

Additionally, psychiatric hospitals are required to meet the hospital CoPs at §482.1 through §482.23 and §482.25 through §482.57, as well as the special CoPs for psychiatric hospitals at §482.60, §482.61 and §482.62. The special conditions of participation for psychiatric hospitals only apply to psychiatric hospitals. They do ***not*** *apply to psychiatric units of hospitals or critical access hospitals (CAHs), or Inpatient Prospective Payment System (IPPS)-excluded psychiatric units in hospitals or distinct part psychiatric units of CAHs.*

If the psychiatric hospital provides any outpatient services, the services must comply with the hospital outpatient services CoP at §482.54 (Tags A-1076 through A-1081). The hospital outpatient services CoP at §482.54 requires that all outpatient services "must be organized and integrated with inpatient services." If the psychiatric hospital chooses to provide outpatient psychiatric services, those services must be provided by or under the supervision of a medical doctor or doctor of osteopathy (MD/DO).

Emergency services are optional services in hospitals, including psychiatric hospitals. Psychiatric hospitals that provide emergency services are required to comply with the Emergency Services CoP at §482.55, Tag A-0092, as well as the Emergency Medical Treatment and Labor Act (EMTALA) requirements at §489.24 and the EMTALA-related requirements at

§489.20. Psychiatric hospitals may choose to offer emergency services, which must be provided in a "dedicated emergency department," as defined at §489.24(b) and referenced in Tag A-0094. In the psychiatric hospital setting, emergency services may be provided in an intake or assessment unit if the unit meets the listed requirements in §489.24(b).

A-1601

(Rev. 235; Issued: 01-16-26; Effective: 01-16-26; Implantation: 01-16-26)

§482.60(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.

Interpretive Guidelines §482.60(a)

Medicare-certified psychiatric hospitals must be primarily engaged in providing psychiatric care for the diagnosis and treatment of mentally ill persons. The psychiatric services must be provided by or under the supervision of a MD or DO.

Survey Procedures §482.60(a)

- *Interview members of the governing body or medical staff to ensure the psychiatric hospital is supervised by a MD or DO.*
- *Interview staff to determine supervisory authority.*
- *Interview staff and review medical records of current and past patients to determine if the psychiatric hospital is primarily engaged in providing psychiatric services for diagnosing and treating mentally ill persons.*

A-1605

(Rev. 235; Issued: 01-16-26; Effective: 01-16-26; Implantation: 01-16-26)

§482.60(b) Meet the Conditions of Participation specified in §§482.1 through 482.23 and §§482.25 through 482.57;

Interpretive Guidelines §482.60(b)

The psychiatric hospital must meet the Conditions of Participation for Hospitals (CoPs) §§482.1 through 482.23 and §§482.25 through 482.57.

Note: The hospital CoP for Medical Records at §482.24 does not apply to psychiatric hospitals. The psychiatric hospital CoP at §482.61 addresses the special medical records requirements for psychiatric hospitals. See §482.61 for more comprehensive details related to the special medical record requirements for psychiatric hospitals.

Note: Psychiatric hospitals are not permitted to provide "Swing-Bed" Services as regulated at 42 CFR §482.58.

Survey Procedures §482.60(b)

- *Follow the survey procedures for §§ 482.1 through 482.23 and §§ 482.25 through 482.57 as addressed in the applicable parts of this Appendix.*

A-1610

(Rev. 235; Issued: 01-16-26; Effective: 01-16-26; Implantation: 01-16-26)

§482.60(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

Interpretive Guidelines §482.60(c)

Refer to interpretive guidelines under §482.61 for details on the clinical record requirements for psychiatric hospitals.

A-1615

(Rev. 235; Issued: 01-16-26; Effective: 01-16-26; Implantation: 01-16-26)

§482.60(d) Meet the staffing requirements specified in §482.62.

Interpretive Guidelines §482.60(d)

Refer to interpretive guidelines under §482.62 for detail on the special staff requirements for psychiatric hospitals.

A-1620

(Rev. 235; Issued: 01-16-26; Effective: 01-16-26; Implantation: 01-16-26)

§482.61 Condition of Participation: Special Medical Record Requirements for Psychiatric Hospitals

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.

Interpretive Guidelines §482.61

All psychiatric hospitals must maintain written medical records. Those medical records must be written and maintained in a manner that will allow surveyors to evaluate the degree and intensity of treatment provided to individuals who are furnished services in the hospital. The degree and intensity of treatment is determined by the number and type of the therapeutic engagements, and the duration of treatments over a period of time.

The psychiatric hospital ensures that all medical records accurately and completely document the need for admission, all orders, test results, evaluations, care plans, treatment plans, treatments, treatment goals, interventions, care provided and the patient's responses to those treatments, interventions and care. The structure and content of the individual patient's record is expected to be a complete and accurate representation of the patient's actual experience while receiving care in the psychiatric hospital.

In order for surveyors to evaluate the degree and intensity of treatment provided to each patient, all entries in the medical records should be:

- ***Accurately written**. The psychiatric hospital must ensure that all medical records accurately and completely document all orders, test results, evaluations, care plans, treatments, interventions, care provided and the patient's response to those treatments, interventions and care.*

- ***Complete**. A medical record is considered complete if it contains sufficient information to identify the patient; support the diagnosis/condition; justify the care, treatment, and services; document the course and results of care, treatment, and services; and promote continuity of care among providers.*

Survey Procedures §482.61

- *Review a sample of patient records and verify that the degree of severity of mental illness is documented in the medical records.*

- *Verify that the intensity of the treatment is documented in the medical records.*

- *Verify that records are accurate and complete.*

- *Verify that the patient's response to treatments and interventions is documented in the patient's medical record.*

- *Determine whether all medical record entries are legible. Are they clearly written in such a way that they are not likely to be misread or misinterpreted?*

§482.61(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.

Interpretive Guidelines §482.61(a)

Medical records for inpatients and outpatients must be organized in such a manner that all psychiatric components of the record reflect the condition of the patient. This includes the history of findings and the treatment provided for the psychiatric condition for which the patient is hospitalized or receiving treatment. The psychiatric components of the record include, but are not limited to:

- *Psychiatric diagnosis*
- *Psychiatric evaluation*
- *Psychiatric treatment plan*
- *Psychiatric history*
- *Progress notes*

The psychiatric components of the medical record aid in the diagnosis, treatment and management of a patient's psychiatric condition.

Survey Procedures §482.61(a)

- *Review a sample of patient records and verify that the psychiatric components of the record are present and available to those staff involved in the treatment and care of the patient.*
- *Verify that the components of the records include the history of findings and treatment for all psychiatric conditions for which the patient is hospitalized or receiving treatment.*

A-1622

(Rev. 235; Issued: 01-16-26; Effective: 01-16-26; Implantation: 01-16-26)

§482.61(a)(1) The identification data must include the patient's legal status.

Interpretive Guidelines §482.61(a)(1)

The patient's legal status when admitted to a psychiatric hospital may be classified as voluntary, involuntary or committed by court. The legal status must be documented in the patient's medical

record. If the admission and treatment is involuntary or committed by court, the medical record must contain documentation required by state law or from the court.

***Survey Procedure* §482.61(a)(1):**

- *Review a sample of medical records to verify that the patient's legal status is accurately documented.*
- *Review a sample of medical records to verify that documentation required by state law or court order is present. If the inpatient admission or outpatient treatment is involuntary, verify documentation that the psychiatric hospital has submitted a court hearing notification.*

- If evaluation and recertification is required by the State, determine that the legal documentation supporting *the patient's legal* status is present. Changes in *the patient's* legal status *are* recorded with the date *and time* of *the* change*, and the person determining the change in status is present and is properly identified in the record.*

A-*1623*

(Rev. 235; Issued: 01-16-26; Effective: 01-16-26; Implantation: 01-16-26)

§482.61(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.

Interpretive Guidelines §482.61(a)(2)

Every psychiatric patient must have an admission or provisional psychiatric diagnosis documented utilizing the most current edition of the American Psychiatric Association's Diagnostic and Statistical Manual (DSM) or the approved International Classification of Diseases (ICD) nomenclature. This diagnosis is made and documented on each patient at the time of the inpatient admission order is entered into the medical record. A provisional diagnosis is determined by the admitting psychiatrist, physician, or licensed independent practitioner, based on the patient's medical and psychiatric condition, and information gathered at the time of admission. The admitting psychiatrist, physician or licensed independent practitioner issues a provisional diagnosis when he/she first evaluates the patient to form the basis of the initial treatment until further tests, assessments, and information are available to determine a final diagnosis. Provisional in this sense means existing until being permanently replaced. The final diagnosis may differ from the provisional diagnosis if subsequent evaluation and observation support a change.

If a diagnosis is absent, there must be justification for its absence. For example, if a patient was psychotic on admission and was not accompanied by family or significant others.

Intercurrent (other than psychiatric) diagnoses are diseases that occur during the course of another disease and must be documented when they are made. Intercurrent diagnoses may also

be identified as co-morbidities. Attention should be paid to physical examination notes, including known medical conditions, allergies, recent exposure to infections, illness, or substance abuse. In addition, attention should be paid to available laboratory or test reports that identify abnormal findings to see that these are reflected by an appropriate diagnosis.

These diagnoses may be found in a variety of locations in the medical record, e.g., the identification/face sheet, the findings of admission physical examination, the psychiatric evaluation, the admission workup, or the physician's progress notes. Diagnostic categories should include physical illness when present.

Survey Procedures §482.61(a)(2)

- *Review the sample of patient records and verify that a provisional or admitting diagnosis is present; verify the diagnosis was made at the time of the inpatient admission.*

- *Review the medical records to verify intercurrent diagnoses are documented to include known medical conditions or co-morbidities as well as the psychiatric diagnosis.*

A-1624

(Rev. 235; Issued: 01-16-26; Effective: 01-16-26; Implantation: 01-16-26)

§482.61(a)(3) The reasons for admission must be clearly documented as stated by the patient and/or others significantly involved.

Interpretive Guidelines §482.61(a)(3)

The medical record must provide clear documentation of what caused the patient to come to the hospital. The medical record must include the statements and reason(s) for admission, given in the patient's own words and/or given as a statement by a family member, patient's care provider, and/or other individual with knowledge of the patient's condition. The identity of the individual providing the statement or information must be documented. The patient's response to the admission should also be documented in the medical record.

Survey Procedures §482.61(a)(3)

- *Review the sample of patient records and verify that each medical record contains the reason(s) for admission as stated by the patient and/or others significantly involved.*
    - *If the patient is unable to speak or verbalize the reason(s) for the admission, does the documentation include statements from family members, caregivers, or others who are significantly involved in the care of the patient?*

- *Review the medical records for the patient's response to the admission.*

A-1625

(Rev. 235; Issued: 01-16-26; Effective: 01-16-26; Implantation: 01-16-26)

§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.

Interpretive Guidelines §482.61(a)(4)

The purpose of the *social services (social work)* assessment is to determine the current baseline social functioning (strengths and deficits) of the patient, from which treatment interventions and discharge plans can be formulated. *The social services documentation must provide an assessment of home plans, family attitudes (including supportive and non-supportive attitudes), community resource contacts, and a social history. Home plans may include assessing the patient's pre-hospitalization residence, family members or other supportive co-inhabitants, and expected discharge location (including if the patients is homeless).*

A psychosocial history/assessment may be completed on all patients. *A psychosocial assessment is an evaluation of an individual's mental health and social well-being, and as such, a comprehensive psychosocial history would address, at a minimum, the following three key components: factual and historical information, social history, and conclusions and recommendations based on the factual, social, and historical information. Hospitals may use accepted standard of practice, such as the American Psychological Association (APA), for determining the full content of its psychosocial assessments.*

Survey Procedures §482.61(a)(4)

- *Review a sample of medical records and verify that a social service assessment was completed.*
- *Verify that the social service assessment contains:*
    - *A description of home plans (which may include a description of household members, pre-hospital residence or homelessness, and expected discharge location, etc.);*
    - *A description of family attitudes;*
    - *A social history for the patient; and,*
    - *A list of community resource contacts.*
- *Review reports of interviews, which indicate whether the patient participated in the assessment and collection of data for treatment and discharge planning. If the record indicates a lack of patient participation, check to see that the staff documented reason(s) for the lack of patient participation.*

- *If the record indicates that someone other than the patient provided information for the social services assessment, verify the identity of the individual and his/her relationship with the patient is documented.*

- *Interview the social worker or individual in charge of performing the social services assessment to verify that the patient, the patient's family member, and/or patient representative was involved in constructing the patient's discharge plan.*

- *Verify that initial recommendations for community resource contacts have been documented.*

- *For patients who were determined as incapable of managing their care or making self-care decisions, verify that a representative is appropriately appointed and identified in the record to help the patient with making discharge-planning decisions. Check the record to verify that appropriate documentation is in place for individuals who have power of attorney to make treatment decisions for the patient.*

A-1626

(Rev. 235; Issued: 01-16-26; Effective: 01-16-26; Implantation: 01-16-26)

§482.61(a)(5) When indicated, a complete neurological examination must be recorded at the time of the admission physical examination.

Interpretive Guidelines §482.61(a)(5)

The Hospital CoPs, Tag A-0358 Hospital standard §482.22(c)(5)(i), requires that a medical history and physical 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. 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. Any concerns related to the medical history and physical examination requirements should be cited under Tag A-0358. The examining practitioner makes a determination, in accordance with State law and hospital policy, as to whether a neurological examination is warranted. If the findings of the medical history and physical examination indicate the need for a neurological examination, it must be completed at the same time the admission physical examination is being conducted and must be documented in the medical record.

Survey Procedures §482.61(a)(5)

- *Review the sample of patient records and verify that, when the history and physical examination indicates, a neurological examination was completed and documented at the time the admission history and physical examination was completed.*

- *If no neurological examination is present in the medical record, is there documentation from the practitioner who completed the history and physical examination that states a neurological examination was not indicated?*

- *Verify that neurological function screening/examination was done (when indicated) and recorded at the time of the admission physical examination, and that a complete, comprehensive neurological exam was ordered, completed and recorded in the medical record in a timely manner.*

A-1630

(Rev. 235; Issued: 01-16-26; Effective: 01-16-26; Implantation: 01-16-26)

§482.61(b) Standard: Psychiatric Evaluation. Each patient must receive a psychiatric evaluation that must--

Interpretive Guidelines §482.61(b)

The psychiatric evaluation is done for the purpose of determining the patient's diagnosis and treatment. Therefore, it must contain the necessary information to justify the diagnosis and planned treatment.

Survey Procedures §482.61(b)

- *Review the hospital policies and procedures for completing the psychiatric evaluations. If utilized, verify non-physician practitioners are privileged to complete part or all of the psychiatric evaluation.*

- *Review the sample of patient records and verify that a psychiatric evaluation has been completed and documented in the medical record for the patients.*

- *If there is a change in psychiatric diagnosis or if a new diagnosis is added, verify that the change in diagnosis is supported by documentation of the patient's condition or the current symptoms the patient exhibits. The rationale for changing the diagnosis must be documented.*

A-1631

(Rev. 235; Issued: 01-16-26; Effective: 01-16-26; Implantation: 01-16-26)

§482.61(b)(1) ***[Each patient must receive a psychiatric evaluation that must--] Be completed within 60 hours of admission;***

Survey Procedures §482.61(b)(1)

- *Review a sample of open and closed records to verify the psychiatric evaluation was completed within 60 hours of admission.*

- *Review hospital policy to ensure that psychiatric evaluations are required to be completed within 60 hours of admission.*

A-1632

(Rev. 235; Issued: 01-16-26; Effective: 01-16-26; Implantation: 01-16-26)

§482.61(b)(2) [Each patient must receive a psychiatric evaluation that must--] Include a medical history;

Interpretive Guidelines §482.61(b)(2)

In addition to the psychiatric diagnosis and history, the psychiatric evaluation must include the patient's non-psychiatric medical history, including physiological problems, physical and intellectual disabilities, and the recommended treatment. The purpose of a medical history is to determine whether there is anything in the patient's overall condition that would affect the planned course of the patient's treatment, such as a medication allergy, or a new or existing co-morbid condition that requires additional interventions to reduce risk to the patient.

The medical history is a collection of medical information that physicians or other practitioners obtained from assessing a patient or by asking specific questions, either of the patient or of other individuals who know the patient and can give suitable information about the patient's health condition, present illness or history of past illness. The medical history will guide the treatment team in formulating the patient's medical diagnosis and providing the medical treatment the patient needs while receiving psychiatric care. See Medical Staff CoP at §482.22(c)(5)(i) for more comprehensive details for H&P requirements.

Survey Procedures §482.61(b)(2)

- *Review the sample of patient records and verify that the psychiatric evaluation includes a medical history which would include such notations as medication allergies, co-morbid conditions, other intellectual challenges, etc.*

A-1633

(Rev. 235; Issued: 01-16-26; Effective: 01-16-26; Implantation: 01-16-26)

§482.61(b)(3) [Each patient must receive a psychiatric evaluation that must--] Contain a record of mental status;

Interpretive Guidelines §482.61(b)(3)

The purpose of the mental status examination is to obtain evidence of symptoms and signs of mental disorders, including danger to self and/or others, that are present at the time of the interview. (Practice Guidelines for the Psychiatric Evaluation of Adults Third Edition 2016, released by the American Psychological Association). The mental status examination describes the appearance and behavior, emotional response, verbalization, thought content, and cognition of the patient as reported by the patient and observed by the examiner at the time of the examination.

Survey Procedure §482.61(b)(3)

- *Review the sample of patient records and verify that the patient's mental status is described in the psychiatric evaluation and documented in the medical record. Ensure the mental status describes such specific examples as the patient's appearance and behavior, emotional response to interventions and other situations, verbalization ability, cognition, etc.*

- *Interview patients and family members or others significantly involved with the patient to determine if patient's mental status is accurately reflected in the record.*

A-1634

(Rev. 235; Issued: 01-16-26; Effective: 01-16-26; Implantation: 01-16-26)

§482.61(b)(4) ***[Each patient must receive a psychiatric evaluation that must--] Note the onset of illness and the circumstances leading to admission;***

Interpretive Guidelines §482.61(b)(4)

For those patients that are admitted to the hospital as well as those being treated in the outpatient setting, the practitioner completing the psychiatric evaluation must note the onset of the patient's illness and all relevant circumstances that lead to the present admission or outpatient visit. The onset of illness and precipitating circumstances must be clearly documented in the medical record as a component of the psychiatric evaluation. The identified problem should be related to the patient's need for hospital admission and treatment, or related to the patient's need for outpatient treatment in the case of the outpatient setting. The psychiatric evaluation includes a history of present illness, including onset, precipitating factors and reason for the current admission, signs and symptoms, course of the illness and treatment(s), and the results of any treatment(s) received.

Survey Procedures §482.61(b)(4)

- *Review the sample of patient records and verify each contains information regarding the onset of the patient's illness and the precipitating circumstances that lead to the current admission or outpatient visit.*

- *Review the sample of medical records to verify that identified problems are documented and are indicated as related to the patient's need for admission and treatment or outpatient treatment.*

A-1635

(Rev. 235; Issued: 01-16-26; Effective: 01-16-26; Implantation: 01-16-26)

§482.61(b)(5) ***[Each patient must receive a psychiatric evaluation that must--] Describe attitudes and behavior;***

Interpretive Guidelines §482.61(b)(5)

The medical record should describe behavior(s) that require a change in order for the patient to function in a less restrictive setting. This may also include behavioral or relationship difficulties with significant others which require active treatment in order to facilitate a successful discharge.

Survey Procedures §482.61(b)(5)

- *Review the Psychiatric Evaluations in the sample of medical records and verify that they contain a description of the patient's attitudes and behaviors.*

- *Interview patients and family members or others significantly involved with the patient to determine the patient's attitudes and behavior are accurately reflected in the record.*

A-1636

(Rev. 235; Issued: 01-16-26; Effective: 01-16-26; Implantation: 01-16-26)

§482.61(b)(6) ***[Each patient must receive a psychiatric evaluation that must--] Estimate intellectual functioning, memory functioning and orientation; and***

Interpretive Guidelines §482.61(b)(6)

Mental status exam should include an estimate of the patient's intellectual functioning, the memory functioning and the patient's orientation. Refer to §482.61(b)(3) Tag A1633 for more comprehensive details for this requirement.

Survey Procedures §482.61(b)(6)

- *Review the sample of medical records to verify specifics of the patient's mental status exam are recorded; such as, the patient's appearance and behavior, emotional response to interventions and other situations, verbalization ability, cognition, etc.*

A-1637

(Rev. 235; Issued: 01-16-26; Effective: 01-16-26; Implantation: 01-16-26)

§482.61(b)(7) ***[Each patient must receive a psychiatric evaluation that must--] Include an inventory of the patient's assets in descriptive, not interpretive, fashion.***

Interpretive Guidelines §482.61(b)(7)*:*

Although the term "strength" is often used interchangeably with "assets," only the assets that describe personal factors on which to base the treatment plan or which are useful in therapy represent personal strengths. Strengths are personal attributes, i.e., knowledge, interests, skills, aptitudes, personal experiences, education, talents and employment status, which may be useful in developing a meaningful treatment plan.

Survey Procedures §482.61(b)(7)

- *Review the sample of medical records to verify the psychiatric evaluation includes an inventory of the patient's assets in descriptive form as personal attributes and not in an interpretive fashion.*
- *Interview patients and family members or others significantly involved with the patient to determine the patient's strengths as personal attributes such as, the patient's personal interests, skills, talents, etc. are included in the record.*

A-1640

(Rev. 235; Issued: 01-16-26; Effective: 01-16-26; Implantation: 01-16-26)

§482.61 (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.

Interpretive Guidelines §482.61 (c)(1)

The comprehensive treatment plan is an outline of the identified disabilities that will be treated during hospitalization. The treatment plan must include an inventory of the patient's strengths and disabilities. The inventory is derived from the psychiatric evaluation, assessment and diagnostic data which have been collected by various disciplines that comprise the total treatment team. In collaboration with the patient, the treatment team develops the individualized, comprehensive treatment plan. The hospital must have a policy for staff to follow in the development of the treatment plan.

NOTE: *A disability in this context is any psychiatric, bio-psychosocial problem requiring treatment/intervention. In this guidance, the terms disability and problem are used interchangeably. In assessing the patient's ability to comply and respond to the treatment, the treatment plan must take into consideration the patient's strengths that can be utilized in*

treatment, as well as weaknesses/disabilities that may negatively influence the patient's treatment. (See also §482.61(b)(7) Tag A1637.)

Survey Procedures §482.61(c)(1)

- *Review the sample of medical records and verify they contain a comprehensive treatment plan.*
- *Review the treatment plan to determine that it is individualized and the patient's particular strengths and psychiatric disabilities are documented.*
- *Interview staff. Ask staff to describe how they develop treatment plans and comply with the hospital's policy for treatment plan development.*
- *Interview patients, family members and caregivers. Verify that the patients, and their family members or other supportive caregivers, participated in the development of the treatment plans.*

A-1641

(Rev. 235; Issued: 01-16-26; Effective: 01-16-26; Implantation: 01-16-26)

§482.61(c)(1)(i) The written plan must include—A substantiated diagnosis;

Interpretive Guidelines §482.61(c)(1)(i)

The substantiated diagnosis serves as the basis for psychiatric treatment interventions. A substantiated diagnosis is the psychiatric diagnosis identified by the qualified practitioner and agreed upon by the treatment team to be the primary focus upon which treatment planning will be based.

Data to substantiate the psychiatric diagnosis may be found in, but is not limited to, the psychiatric evaluation, the medical history and physical examination, laboratory tests, medical and other psychological consults, assessments done by disciplines involved in patient evaluations and information supplied from other sources such as community agencies and significant others.

Survey Procedures §482.61(c)(1)(i)

- *Review the sample of medical records to verify the substantiated psychiatric diagnosis is documented and the psychiatric diagnosis matches the specific problems listed in the individualized, comprehensive treatment plan.*
- *Verify identified physical problems and other health conditions are included as a part of the substantiated psychiatric diagnosis if they require treatment, or interfere with treatment during the patient's hospitalization.*

- *When a psychiatric evaluation results in a new diagnosis or additional psychiatric diagnosis, verify that the treatment or intervention recommendation is added to the comprehensive treatment plan. Review the treatment plan to verify that the diagnosis is addressed.*

A-1642

(Rev. 235; Issued: 01-16-26; Effective: 01-16-26; Implantation: 01-16-26)

§482.61(c)(1)(ii) [The written plan must include—] Short-term and long-range goals;

Interpretive Guidelines §482.61(c)(1)(ii)

Based on the problems identified for treatment, short-term and long-range treatment goals are developed. Whether the use of short-term or a combination of short-term and long-range treatment goals is appropriate is dependent on the patient and the length of hospital stay or outpatient treatment.

Short-term and long-range goals include specific dates for expected achievement. As goals are achieved, the treatment plan should be revised. When a goal is modified, changed or discontinued without achievement, the individualized, comprehensive treatment plan should be reviewed and updated as needed.

In crisis intervention and short-term treatment there may be only one timeframe for treatment goals. As the length of the hospital stay increases or the outpatient treatment period extends (often because of the long-term chronic nature of the patient's illness), both long-range and short-term treatment goals are needed.

The long-range treatment goal is achieved through the development of a series of short-term treatment goals, (i.e., smaller, logical sequential steps which, when followed and met, will result in reaching the long-range goal). Both the short-term and long-range goals must be stated as expected behavioral outcomes for the patient. Treatment goals must be related to the problems identified in the documented diagnosis, assessment and evaluation, and in the individualized, comprehensive treatment plan. Goals must be written as observable, measurable patient outcomes to be achieved. Discharge criteria such as ability to independently complete activities of daily living, ability to complete self-care, full cognitive function, etc. may be included as long-range goals if they include the short-term logical and sequential steps to achieve them.

Survey Procedures §482.61(c)(1)(ii)

- *Review the sample of medical records to verify the treatment plans contain short-term and long-range goals and:*
    - *Reflect the diagnosis, assessment and evaluation for which the patient is being treated.*

- *Both short and long-range goals should have specific dates for expected achievement.*

- *The goals are stated as expected behavioral outcomes for the patient.*

- *Goals are written in a way that allows for changes in the patient's behavior to be measured.*

A-1643

(Rev. 235; Issued: 01-16-26; Effective: 01-16-26; Implantation: 01-16-26)

§482.61(c)(1)(iii) [The written plan must include—] The specific treatment modalities utilized;

Interpretive Guidelines §482.61(c)(1)(iii)

This requirement refers to all of the planned treatment modalities used to treat the patient during hospitalization or in the outpatient setting which includes outside community and professional resources. Having identified the problems requiring treatment, and defining the outcome goals to be achieved, appropriate treatment approaches must be identified.

Modalities are methods of therapeutic approach that are adopted in implementing all of the active treatment interventions provided to the patient by various staff. There must be enough specificity in the treatment modality to ensure consistent implementation across staff.

A daily schedule of unit activities does not, in itself, constitute planned modalities of treatment. It is expected that when a patient receives various specific treatment interventions, the treatment interventions are a part of the individualized treatment plan goals, with a specific purpose and focus for that patient.

In addressing treatment modalities, it is required that they be specific to the patient. For example, simply "naming" modalities (e.g., individual therapy, group therapy, occupational therapy, and/or medication education) is not acceptable. The focus of the treatment must be included.

Simply "stating" modality approaches (e.g., "set limits," "encourage socialization," "discharge planning as needed") is not acceptable. Modality approaches must be specifically described in order to assure consistency of approach.

Survey Procedures §482.61(c)(1)(iii)

- *Review a sample of patient records and verify that the treatment plan documents the specific treatment modalities to be used.*

- *Observe the staff during treatment intervention to determine that staff are following the individualized, specific treatment intervention modalities that are contained in the treatment plan.*

- *Review the treatment plan to verify that:*

    - *Individualized, specific treatment modalities are included in the plan.*

    - *The observed treatment methods, approaches and interventions from all appropriate disciplines are included in the plan.*

- *Interview staff to determine if modalities are determined for specific needs of individual patients.*

- *Interview patients and family members or others significantly involved with the patient to determine if the patient is offered specific, individualized treatment modalities.*

- *Verify that the interventions or treatments, such as medication therapy, documented in the patient's treatment plan are supported by the psychiatric evaluation or other comprehensive assessment. Any change in treatment must be justified by assessment of the patient's response to the treatment or a documented change in the patient's condition.*

A-1644

(Rev. 235; Issued: 01-16-26; Effective: 01-16-26; Implantation: 01-16-26)

§482.61(c)(1)(iv) ***[The written plan must include—] The responsibilities of each member of the treatment team; and***

Interpretive Guidelines §482.61(c)(1)(iv)

There is no "correct" number of staff who comprise the treatment team. The disciplines involved in the patient's treatment depend upon the problems to be treated, the short-term and long-range goals, and the treatment approaches and modalities used to achieve these goals.

The intent of the regulation is to ensure that each individual on the treatment team who is primarily responsible for ensuring compliance with particular aspects of the patient's individualized treatment program is identified. Identification of the staff should be recorded in a manner that includes the title and discipline of the individual.

The patient, as well as family/significant others, should be aware of the staff responsible for various aspects of treatment.

Survey Procedures §482.61(c)(1)(iv)

- *Review a sample of medical records and verify that the individualized treatment plan includes the responsibilities of each member of the treatment team.*

- *Review a sample of medical records and verify treatment and interventions include the discipline assigned to take responsibility for the treatment and that the treatment is being completed by an individual either by name and title or by their title within that discipline.*

A-1645

(Rev. 235; Issued: 01-16-26; Effective: 01-16-26; Implantation: 01-16-26)

§482.61(c)(1)(v) ***[The written plan must include—] Adequate documentation to justify the diagnosis and the treatment and rehabilitation activities carried out.***

Interpretive Guidelines §482.61(c)(1)(v)

All psychiatric hospitals must provide documentation with sufficient frequency to justify the patient's diagnosis, and the treatment and rehabilitative activities that are carried out. The content of the notes must indicate the reason(s) for the treatment provided, the rehabilitative activities provided, and the patient's response to the treatment and rehabilitative activity. Additionally, the progress and treatment notes should reflect the goals of the individualized treatment plan. The numbers, types, frequency, and content of progress and treatment notes completed by appropriate qualified personnel may be evidence of adequate documentation.

Survey Procedures §482.61(c)(1)(v)

- *Review the sample of medical records to determine if there is adequate documentation in progress and treatment notes to justify the patient's diagnosis and the treatment and rehabilitative activities that were carried out; Refer to §482.61(d), Tag A1660, for minimum frequency requirements.*

- *Verify the appropriate qualified personnel completed the progress and treatment notes.*

- *Verify that the patient's participation and responses to the treatment and rehabilitative activities are documented.*

A-1650

(Rev. 235; Issued: 01-16-26; Effective: 01-16-26; Implantation: 01-16-26)

§482.61(c)(2) The treatment received by the patient must be documented in such a way to assure that all active therapeutic efforts are included.

Interpretive Guidelines §482.61(c)(2)

Active treatment is an essential requirement for psychiatric care. Active treatment is a clinical process involving ongoing assessment, diagnosis, intervention, evaluation of care and treatment, and planning for discharge and aftercare, under the direction of a psychiatrist.

All aspects of treatment and therapeutic efforts, to which the hospital has committed itself, based upon the patient's assessment, evaluation and plan of care, must be documented in the medical record. It is the hospital's responsibility to provide those treatment modalities with sufficient frequency and intensity to assure that the patient achieves his/her optimal level of functioning.

The medical record must contain evidence that the patient's rights are being addressed and protected during therapeutic efforts. Refer to §482.13(a), Standard: Notice of Rights, Tags A0116 through A0217.

Clarification of the types of notes found in the medical record.

Treatment notes are recordings in the medical record that indicate provision of, and a patient's response to, a specific modality. This modality may be drug therapy, individual, family, marital, or group therapy, art therapy, recreational therapy, and any specialized therapy ordered by the physician or other practitioners acting within their scope of practice and hospital policy to write orders in the medical record.

A combined treatment and progress note may be written.

Progress notes are recordings in the medical record that are written by persons directly responsible for the care and active treatment of the patient. Progress notes give a chronological picture of how the patient is progressing toward the accomplishment of the individual goals in the treatment plan.

Survey Procedures §482.61(c)(2)

- *Review a sample of medical records and verify staff members are recording their interventions and therapeutic efforts in such a way that the interventions and therapeutic efforts are included.*

- *Verify documentation of treatment progress is written as an objective description of observed or monitored behaviors of the patient in response to the treatment modalities, including medication.*

- *Interview the patient, family member or others significantly involved with the patient, and the staff to determine if a patient is actively involved in assigned treatment.*

- *If the patient is not actively involved in the assigned treatment, review the documentation to determine if the reason has been documented. Refer to §482.61(c)(1)(v), Tag A1645.*

- *Review the progress notes to determine if progress or lack thereof has been documented.*

- *Verify that all treatment team members document their observations and interventions so that the information is available and accessible to the entire team.*

A-1655

(Rev. 235; Issued: 01-16-26; Effective: 01-16-26; Implantation: 01-16-26)

§482.61(d) Standard: Recording Progress. Progress notes must be recorded by the physician(s), psychologists, or other licensed independent 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.

Interpretive Guidelines §482.61(d)

Progress notes must be recorded by the doctor of medicine or osteopathy, psychologists, or other licensed independent practitioners 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.

- ***Doctor of medicine or osteopathy (MD/DO)****: Progress notes must be recorded by the physician(s), psychologist(s), or other licensed independent practitioner(s) responsible for the care of the patients as specified in §482.12(c).*

- ***Nurses:*** *Nursing progress notes documentation must be current and should give a clear picture of the patient's needs and the patient's response to nursing interventions. Nursing progress notes must follow hospital policy and nationally recognized standards of practice.*

- ***Social workers:*** *Those who are significantly involved in active treatment modalities/interventions must provide current documentation of every therapeutic engagement and intervention, and the patient's response to the treatment. Social work progress notes must follow hospital policy and nationally recognized standards of practice.*

- ***Staff from other disciplines****, e.g., rehabilitative therapy, recreational therapy, group therapy, and psychology: Those who are significantly involved in active treatment modalities/interventions must provide current documentation of every therapeutic engagement and intervention, and the patient's response to the treatment. Progress notes documented by individual disciplines must follow hospital policy and nationally recognized standards of practice.*

Survey Procedures §482.61(d)

- *Verify that Medicare patients are under the care of a MD/DO, psychologist(s), or other licensed independent practitioners responsible for the care of the patient.*

Review a sample of medical records and verify that physicians, nurses, social workers, and other care providers who are significantly involved in active treatment modalities/interventions are documenting the patient's progress toward achieving the individualized treatment goals.

- *Do the progress notes provide a clear picture of the patient's progress or lack thereof? Do the physicians, nurses, social workers, and other care providers make recommendations for further care?*

A-1660

(Rev. 235; Issued: 01-16-26; Effective: 01-16-26; Implantation: 01-16-26)

§482.61(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…

Interpretive Guidelines §482.61(d)

Progress notes must be written to document the patient's condition and the subsequent changes during treatment. Progress notes must be recorded at least weekly for the first 2 months and at least once a month thereafter. When patients progress more rapidly or if the patient experiences a significant change in condition, progress notes may be written more frequently as determined by the patient's status.

A significant change can include the need for increased observation by staff, seclusion and restraint episodes, self-harm episodes, assaultive behaviors, elopements, decline in medical status, falls and injuries, treatment refusal, transfer to another facility, and other adverse events.

Survey Procedures §482.61(d)

- *Review a sample of medical records. Review the progress notes in the patient's medical record to ensure that the progress notes were recorded at least weekly for the first 2 months and at least once a month thereafter.*

- *Verify that changes, variations and updates in the treatment modalities are documented in the progress notes and the documentation shows the rationale for any sudden change or termination of treatment. Refer to §482.61(c)(1)(v) and §482.61(c)(2) for additional clarification on documentation of treatment.*

A-1661

(Rev. 235; Issued: 01-16-26; Effective: 01-16-26; Implantation: 01-16-26)

§482.61(d) …and must contain recommendations for revisions in the treatment plan as indicated…

Interpretive Guidelines §482.61(d)

Documentation of treatment progress should identify the objective efforts the patient is making toward accomplishing the target goal of the individualized treatment plan, and they must contain recommendation(s) for updating the treatment plan as indicated.

When updating or revising the treatment plan, documentation indicates the reason for the revisions and reflects the acuity of the illness of the patient. The acuity of the illness of the patient and the length of hospital admission or treatment for outpatients, determines the expected frequency of the treatment plan revision(s). If the patient is more acutely ill, the surveyor should see an increase in the frequency of documentation describing the patient's illness, treatment, and interventions, and the patient's progress and changes to the treatment plan, if appropriate.

Survey Procedures §482.61(d)

- *Review the sample of medical records and verify that changes in the patient's condition are reflected in the progress notes and recommendations for revisions to the current treatment plan are included.*

A-1662

(Rev. 235; Issued: 01-16-26; Effective: 01-16-26; Implantation: 01-16-26)

§482.61(d) …as well as [must contain] a precise assessment of the patient's progress in accordance with the original or revised treatment plan.

Interpretive Guidelines §482.61(d)

The progress notes must contain, in clear objective terms, an evaluation of the patient's progress in accordance with the comprehensive, individualized treatment plan.

Survey Procedures §482.61(d)

- *Review the sample of medical records and verify that the progress notes give a clear picture of the patient's progress, or lack thereof, during the course of the hospitalization or outpatient visits.*

- *Assure that the progress notes are related to the goals of the comprehensive, individualized treatment plan, and track treatment interventions from admission through discharge, if the patient is discharged from the hospital.*

- *If the patient is being treated in the outpatient setting, ensure each individual visit notes progress as related to the individualized treatment plan.*

A-1670

(Rev. 235; Issued: 01-16-26; Effective: 01-16-26; Implantation: 01-16-26)

§482.61(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…

Interpretive Guidelines §482.61(e)

The medical records, of all patients who have received psychiatric hospital treatment, must contain a discharge summary. A discharge summary must include a recapitulation of the patient's hospitalization, which is a summary of the circumstances and rationale for admission, and a synopsis of accomplishments achieved as reflected through the treatment plan. This summary includes the reason(s) for admission, treatment, goals achieved during hospitalization, a baseline of the psychiatric, physical and social functioning of the patient at the time of discharge, and evidence of the patient, family, and/or significant other's response to the treatment interventions.

The MD/DO or other qualified practitioner, as determined by hospital policy and State law, with admitting privileges and who admits the patient, is responsible for the patient during the patient's stay in the hospital. This responsibility includes developing and entering the discharge summary into the patient medical record. The discharge summary includes the patient's response to the treatment and rehabilitative activity, and discusses the outcome of the hospitalization, the disposition of the patient, and provisions for follow-up care. Refer to §482.22 for additional guidance related to medical staff responsibilities and governing bylaws.

At the request of the responsible MD/DOs, a different MD/DO, psychologist, or other qualified practitioner who works with the patient's MD/DO, and who is covering for the patient's MD/DO, and who is knowledgeable about the patient's condition, the patient's care during the hospitalization, and the patient's discharge plans, may write the discharge summary.

In accordance with hospital policy and 42 CFR §482.12(c)(1)(i), the MD/DO may delegate writing the discharge summary to other qualified health care personnel such as nurse practitioners and MD/DO assistants to the extent recognized under State law.

Whether delegated or non-delegated, we would expect the person who writes the discharge summary to authenticate, date, and time their entry.

Survey Procedures §482.61(e)

- *Review a sample of medical records of discharged patients to verify that all records contain a discharge summary.*

- *Verify the discharge summary includes (1) the outcome of the treatment and procedures; (2) the disposition of the case; and (3) provisions for follow-up care.*

A-1671

(Rev. 235; Issued: 01-16-26; Effective: 01-16-26; Implantation: 01-16-26)

§482.61(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…

Interpretive Guidelines §482.61(e)

The discharge summary must include recommendations for follow-up or aftercare, that should include any post-hospital appointments, plans for post-hospital care, and describe how post-hospital patient care needs are to be met.

The summary should identify the recommended outpatient and community mental health resources in the geographical area where the patient is being discharged, and the coordinated services to be provided by the aftercare facilities to ensure effective continuity of care.

The patient's discharge planning process should identify and attempt to address potential problems after discharge and suggested means for intervention, (e.g., accessibility and availability of community resources and support systems, including transportation, and special problems related to the patient's functional ability to participate in aftercare planning such as homelessness and lack of family/significant other support systems).

The discharge summary should contain a discussion related to recommendations to the next treatment provider for patient-specific issues/problems that may arise after hospitalization.

Examples of what should be included in in the discharge summary regarding follow up or aftercare include, but are not limited to the following:

- *A description of arrangements for treatment and other community resources for the provision of follow-up services;*

- *A plan outlining follow-up psychiatric care, medical/physical treatment and the medication regimen as applicable;*

- *A description of community housing/living arrangement(s) available in the community/area where the patient is being discharged to;*

- *A description of the recommended and/or actual planned involvement of family and significant others with the patient after discharge; and*

- *A list of discharge medications including dosage, frequency and quantity.*

Survey Procedures §482.61(e)

- *Review a sample of medical records and verify the discharge summary follow up care recommendations were included in the discharge summary.*

- *Review the discharge plan to verify that it identifies appropriate aftercare for follow-up treatment.*

- *Verify that discharge related documents are made available to the patient, patient's representative, community treatment source and/or any other aftercare service provider, as appropriate, who may need the record for continuity of care.*

- *Verify that the aftercare plan was communicated to the post-hospital treatment entity, when indicated.*

- *Review the discharge summary to determine if it contains a plan for follow-up psychiatric care, medical/physical treatment and the medication regimen as applicable.*

A-1672

(Rev. 235; Issued: 01-16-26; Effective: 01-16-26; Implantation: 01-16-26)

§482.61(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.

Interpretive Guidelines §482.61(e)

The discharge summary must contain information about the condition of the patient at time of discharge. The condition should address both the patient's psychiatric state and medical status, if applicable.

Survey Procedures §482.61(e)

- *Review a sample of medical records and verify the discharge summary contains information on the status of the patient's condition on the day of discharge.*

A-1673

(Rev. 235; Issued 01-16-26; Effective Date 06-30-20; Implementation Date 04-30-21)

§482.61 Condition of participation: *Special medical records requirements for psychiatric hospitals.*

(f) Standard: Electronic notifications. If the hospital utilizes an electronic medical records system or other electronic administrative system, which is conformant with the content exchange standard at 45 CFR 170.205(d)(2), then the hospital must demonstrate that –

(1) The system's notification capacity is fully operational and the hospital uses it in accordance with all State and Federal statutes and regulations applicable to the hospital's exchange of patient health information.

(2) The system sends notifications that must include at least patient name, treating practitioner name, and sending institution name.

(3) To the extent permissible under applicable federal and state law and regulations, and not inconsistent with the patient's expressed privacy preferences, the system sends notifications directly, or through an intermediary that facilitates exchange of health information, at the time of:

(i) The patient's registration in the hospital's emergency department (if applicable).

(ii) The patient's admission to the hospital's inpatient services (if applicable).

(4) To the extent permissible under applicable federal and state law and regulations, and not inconsistent with the patient's expressed privacy preferences, the system sends notifications directly, or through an intermediary that facilitates exchange of health information, either immediately prior to, or at the time of:

(i)The patient's discharge or transfer from the hospital's emergency department (if applicable).

(ii) The patient's discharge or transfer from the hospital's inpatient services (if applicable).

Interpretive Guidance §482.61(f)(1-4):

A psychiatric hospital with an electronic health records system or electronic patient registration systems, which are conformant with the content exchange standard HL7 2.5.1 at 45 CFR 170.205(d)(2), are expected to use these systems to their full capacity to facilitate the notification of patient admission, discharge, and transfer information in accordance with state and federal law. Upon the consent of patient or the patient representative, at a minimum, the information exchange must include the name of the patient, the practitioner responsible for the treatment of the patient, and the name of the institution providing care to the patient. A patient or patient

representative does have the right to privacy and not permit the hospital to share this information through this exchange. A patient's refusal should be documented.
These requirements are applicable to all patients regardless of inpatient or outpatient status. There may be instances of multiple admission notifications for one patient. For example, a patient that enters through the emergency department (ED) are not admitted as an inpatient, but the hospital would be responsible for sending a notification of the patient's ED visit; and once the patient is admitted as an inpatient, another notification would be sent as the patient has changed their admission status.

Transfer notifications would be applicable for any patients who may be transferring to another facility for additional needs or changes in level of care.

Discharge notifications would be applicable for all patient discharges from either inpatient or outpatient admissions.

For psychiatric hospitals that do not have such electronic health records system or electronic patient registration systems which are conformant with the content exchange standard HL7 2.5.1 at 45 CFR 170.205(d)(2), they are not required to be in compliance with this standard.

A-1674
(Rev. 235; Issued 01-16-26; Effective Date 06-30-20; Implementation Date 04-30-21)

§482.61 Condition of participation: Special medical records requirements for psychiatric hospitals.

(f) Standard: Electronic notifications. If the hospital utilizes an electronic medical records system or other electronic administrative system, which is conformant with the content exchange standard at 45 CFR 170.205(d)(2), then the hospital must demonstrate that –

(5) The hospital has made a reasonable effort to ensure that the system sends the notifications to all applicable post-acute care services providers and suppliers, as well as to any of the following practitioners and entities, which need to receive notification of the patient's status for treatment, care coordination, or quality improvement purposes:

(i) The patient's established primary care practitioner;

(ii) The patient's established primary care practice group or entity; or

(iii) Other practitioner, or other practice group or entity, identified by the patient as the practitioner, or practice group or entity, primarily responsible for his or her care.

Interpretive Guidance §482.61(f)(5):

The psychiatric hospital is expected to make every attempt to send notifications to post-acute providers and suppliers, in addition to the patient's primary care practitioner, primary care group, or practitioner or group that is identified by the patient that may be responsible for the patient's care. For example, a patient may request that these admission, discharge, and transfer notifications be sent to a specialist responsible for their care, that is not their primary care provider. This requirement does not limit the hospital's ability to notify additional entities based on hospital policy, such as ACO attribution lists.

A-1680

(Rev. 235; Issued: 01-16-26; Effective: 01-16-26; Implantation: 01-16-26)

§482.62 Condition of Participation: Special Staff Requirements for Psychiatric Hospitals

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.

Interpretive Guidelines §482.62

The purpose of this Condition of Participation is to ensure that the psychiatric hospital is adequately staffed with qualified mental health professionals and supportive staff to carry out an intensive and comprehensive active treatment program and to protect and promote the physical and mental health of the patients.

Adequate numbers are defined to mean the numbers, types, and utilization of staff with qualifications to evaluate, plan, implement and document active treatment.

An RN should make all patient care assignments. The director of psychiatric nursing services and the hospital ensures that nursing personnel with the appropriate education, experience, licensure, competence and specialized qualifications are assigned to provide nursing care for each patient in accordance with the individual needs of each patient.

The regulatory text of this condition of participation regarding special staff requirements for psychiatric hospitals is duplicated in standard (a) of the condition, Tag A-1685. This means non-compliance with the requirements may be cited at either the standard or condition level, based on the manner and degree of non-compliance. Substantial non-compliance with the requirements listed in the condition of participation would warrant a Condition-level citation.

Survey Procedures §482.62

Assess the adequacy of the Special Staffing Condition by:

- *Observing patients in a variety of settings, including both structured and unstructured, to determine if there is adequate staff available to implement the patients' individualized treatment plans.*

- *Interviewing staff to determine if the number, type, and utilization of staff available is appropriate to the volume and acuity of patients in order to evaluate patients, formulate written, individualized comprehensive treatment plans, provide active treatment measures and engage in discharge planning.*

- *Observing structure of units to ensure adequate programming is provided by various interdisciplinary staff, i.e., therapeutic groups, social work therapy, recreational therapy, or occupational therapy.*

- *Review the nursing assignments. Verify that the assignments take into consideration the complexity of patient's care needs and the competence and specialized qualifications of the nursing staff.*

- *Interview patients, family members and others involved with the patient to determine if staffing appears adequate for the proper care and treatment of the patient to meet the needs as documented in the medical record.*

- *Review incident logs to determine if staffing may have played a part in any recorded incidents.*

- *Review observation logs to ensure rounds are being conducted in real time, and if not, determine if lack of staff may be contributing to this failure.*

- *If necessary, review video monitoring to determine if rounds are being conducted and recorded in real time. If not, determine if lack of staff may be contributing to this failure.*

A-1685

(Rev. 235; Issued: 01-16-26; Effective: 01-16-26; Implantation: 01-16-26)

§482.62(a)(1) Standard: Personnel. The hospital must employ or undertake to provide adequate numbers of qualified professional, technical, and consultative personnel to:

(1) Evaluate Patients

Interpretive Guidelines §482.62(a)(1)

The hospital must have sufficient professional, technical, and consultative staff with appropriate qualifications to assure the needs of all psychiatric patients are met. Staff must be knowledgeable of clinical symptoms of mental illness to provide clinical evaluations of patients, so that the ensuing and ongoing treatment is based on appropriate documented information.

Survey Procedures §482.62(a)(1)

- *Review a sample of medical records for discipline-specific evaluations of patients (for example, admission assessment, nursing assessment, social service evaluation, physical therapy evaluation, etc.)*

- *Is there evidence to support the hospital has adequate staffing to evaluate patients?*

- *Interview professional staff, technical staff, and consultative staff regarding services provided, schedules, and availability of staff throughout the day and week to determine that the number and type of staff available is appropriate to the volume and types of treatments furnished. If needed, review staffing and on-call schedules.*

- *Review a sample of personnel files for professional, technical, and consultative staff to determine that the personnel meet the qualifications specified by the hospital policy, consistent with state law, to perform discipline-specific evaluations.*

A-1686

(Rev. 235; Issued: 01-16-26; Effective: 01-16-26; Implantation: 01-16-26)

§482.62(a)(2) [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;

Interpretive Guidelines §482.62(a)(2)

Each patient must have an individualized, comprehensive treatment plan that considers specific goals, interventions, and treatment necessary to meet their psychological and medical needs.

Formulation of a comprehensive treatment plan generally involves a multidisciplinary team approach to select treatment modalities, specific types of treatment and the treatment setting based on the patient's diagnosis and multidisciplinary assessments. This team approach is essential to communicating the effectiveness of identified interventions and treatment. Staffing must be sufficient so that members of the patient's multidisciplinary treatment team are able to contribute their respective data for consideration in the formulation, review, and evaluation of the individualized, comprehensive treatment plan.

Survey Procedures §482.62(a)(2)

- *Review a sample of medical records and verify there is an individualized, comprehensive treatment plan that addresses the specific psychiatric needs of each patient.*

- *Review the individualized, comprehensive psychiatric treatment plan to ensure it is, in fact, individualized and comprehensive.*

- *If the treatment plans are absent, lacking information, or reveal delayed implementation to the extent that they are not useful to the treatment team for the purpose of planning individualized treatment:*
    - *Verify there is sufficient interdisciplinary staff participation at the treatment team meeting, to assure formulation of a comprehensive treatment plan that meets the patient's individualized needs.*

    - *Interview staff to determine what issues prevent staff members from attending treatment meetings, and if those issues are related to inadequate staffing.*

A-1687

(Rev. 235; Issued: 01-16-26; Effective: 01-16-26; Implantation: 01-16-26)

§482.62(a)(3) [The hospital must employ or undertake to provide adequate numbers of qualified professional, technical, and consultative personnel to:]

(3) Provide active treatment measures; and

Interpretive Guidelines §482.62(a)(3)

Active treatment occurs when the patient receives treatment interventions that are delivered under the direction of a physician, and which are specific to patient strengths, disabilities, and problems identified in the treatment plan. Staff, in accordance with nationally recognized standards of professional practice, furnish treatment interventions and other services. Although the active treatment process must be identifiable in documentation, it must be first and foremost observable and evident in daily practice.

Treatment interventions need to be individualized, in that the patient receives assistance with resolving or improving the problems/circumstances that led to hospitalization. Treatment intervention(s) must target/address the unique needs of individual patients. If active treatment measures are not provided, this could indicate a lack of adequate staff.

Survey Procedures §482.62(a)(3)

- *Determine through observation, interviews and record reviews that patients receive active treatment measures. Do the treatment measures match the treatment plan?*

- *Verify the hospital's distribution of staff is consistent with particular patient needs, and an adequate number of staff with an appropriately skilled staffing mix is sufficient to carry out the therapeutic activities of patients' individualized, comprehensive treatment plans.*

- *Review a sample of medical records and verify in the individualized, comprehensive treatment plan that the patient is receiving psychiatric treatment or psychiatric therapy that is relevant to the identified problems that brought the patient to the hospital.*

- *Verify if staff absences and/or vacancies are preventing the patient from receiving active treatment.*

    - *Determine if the patient's inability to attend therapeutic activities off the patient care unit (if occurring) is because there is no staff to escort them.*

    - *Determine if therapeutic groups are available on the patient care unit for patients who are not able to go off the unit.*

- *Observe treatment activities to ensure active treatment sessions or therapeutic activities are provided at discrete time intervals and according to the treatment scheduled.*

- *Verify through record review that active treatment is implemented as the patient's needs emerge during the course of the day.*

A-1688

(Rev. 235; Issued: 01-16-26; Effective: 01-16-26; Implantation: 01-16-26)

§482.62(a)(4) [The hospital must employ or undertake to provide adequate numbers of qualified professional, technical, and consultative personnel to:]

(4) **Engage in discharge planning.**

Interpretive Guidelines §482.62(a)(4)

Discharge planning focuses on safe, post hospital care for patients. An effective discharge transition into follow-up after care and the reduction of preventable readmissions is more likely to occur when the patients and their family/support person(s), together with relevant qualified professional and supportive staff caring for the patient, actively participate in the discharge planning process.

Additionally, psychiatric hospitals must comply with the hospital CoP requirements for discharge planning at §482.43 and section 1861(ee) of the Act on which the CoP is based. In general, the discharge planning requirements usually provide for a four-stage discharge planning process. Depending on the patient, the discharge planning may include all or some of the below:

• Screening all inpatients to determine which ones are at risk of adverse health consequences post-discharge if they lack discharge planning;

• Evaluation of the post-discharge needs of inpatients identified in the early stage of hospitalization, or of inpatients who request an evaluation, or whose physician requests one;

• Development of a discharge plan, if requested by the patient's physician; and

• Initiating the implementation of the discharge plan prior to the discharge of an inpatient.

The policies and procedures must address all of the requirements of 42 CFR 482.43(a) –(c). The hospital must take steps to assure that its discharge planning policies and procedures are implemented consistently.

Although CMS does not specify the number of staff required for discharge planning, resources must be adequate to accomplish the tasks required for appropriate discharge planning in accordance with the requirements at §482.43.

Survey Procedures §482.62(a)(4)

- *Review the hospital's written policies and procedures for discharge planning.*
- *Are staff aware of how, when, and whom to notify of changes in the patient's clinical condition that might warrant a change in the discharge planning process?*
- *Is there evidence of discharge planning evaluation activities?*
- *Review a sample of cases to determine if the discharge planning evaluation documents the patient's goals and preferences for post-discharge placement and care.*
- *Confirm during medical record review and staff interviews that relevant disciplines have participated in the discharge planning process.*
- *Are the results of the discharge planning evaluation documented in the medical record?*
- *Ask staff about any discharge planning delays. If delays are identified, ask staff about adequate staffing to complete necessary tasks.*

A-1690

(Rev. 235; Issued: 01-16-26; Effective: 01-16-26; Implantation: 01-16-26)

§482.62(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…

Interpretive Guidelines §482.62(b)

All psychiatric care provided in the psychiatric hospital must be under the supervision of a single clinical director, service chief, or equivalent. The individual must be a licensed MD or DO who is a psychiatrist.

Inpatient psychiatric services provide intensive diagnostic evaluation, emergent treatment, treatment to stabilize individuals in crisis, and long-term chronic treatment. The following functions are examples of psychiatric services under the supervision of the clinical director, service chief, or equivalent:

- *Admission interviews,*
- *Assessments and evaluations,*
- *Psychiatric and medical work-ups,*
- *Treatment team leadership,*
- *Medication management,*
- *On-call provision of emergency psychiatric and medical treatment,*
- *Provision of individual, group and family therapies,*
- *Provision of clinical supervision to other professionals and paraprofessionals,*
- *Provision of medical and psychiatric educational workshops and conferences for all staff, and*
- *Provision of consultation to staff for clinical and/or administrative matters.*

The hospital must demonstrate how their selection for medical director, service chief, or equivalent is qualified to provide the leadership required for an intensive treatment program, following nationally recognized standards of practice.

Survey Procedure §482.62(b)

- *Verify that a single MD/DO who is a psychiatrist is responsible for supervising inpatient psychiatric services.*
    - *Review the credentialing file of the clinical director to verify qualifications and the leadership exhibited for the scope of psychiatric treatment programs needed by patients.*
- *Request and review evidence to verify that the clinical director plays an integral part in supervising the planning, evaluation, and revision of policies, procedures, and activities*

that affect the safety, quality, and compliance related to inpatient psychiatric treatment or services.

- *Review medical staff meeting documents, QAPI, and related committee notes to verify the supervision and leadership activities of the clinical director.*

A-1691

(Rev. 235; Issued: 01-16-26; Effective: 01-16-26; Implantation: 01-16-26)

§482.62(b) … The number and qualifications of doctors of medicine and osteopathy must be adequate to provide essential psychiatric services.

Interpretive Guidelines §482.62(b)

The hospital must ensure that it has adequate numbers of full-time, part-time, or consulting MD/DOs with the appropriate qualifications to provide essential psychiatric services to each patient at all times.

Factors to consider the adequacy of physician coverage includes, but is not limited to, the following list:

- *Average daily census;*
- *Types of psychiatric and behavioral health conditions specific to the patient population;*
- *Ages of the hospital's patient population (pediatric vs adult psychiatric services);*
- *Whether the hospital's patients are violent or non-violent;*
- *Whether the hospital's MD/DOs have the proper qualifications to address the modalities of care provided by the hospital;*
- *The ability of the hospital to ensure physician coverage on evening, nights and weekends;*
- *The ability of the hospital to employ physicians with the appropriate qualifications to participate in treatment planning; and*
- *Availability of physicians to consult with multi-disciplinary staff regarding treatment issues.*

Survey Procedures §482.62(b)

- *Review a sample of medical records and interview staff to verify patients are under the supervision of a psychiatrist.*

- *Based on census and services provided by the hospital, is there evidence of adequate qualified MD/DO staff to provide essential psychiatric services?*

- *Interview RNs, SWs, and other disciplines about physician/psychiatrist presence, accessibility and availability to participate in the provision of patient care.*

- *Review patient records for evidence of ongoing consultation and evaluation by physician staff.*

A-1692

(Rev. 235; Issued: 01-16-26; Effective: 01-16-26; Implantation: 01-16-26)

§482.62(b)(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.

Interpretive Guidelines §482.62(b)(1)

A physician is qualified to take the examination for board certification upon successful completion of a psychiatric residency program approved by the American Board of Psychiatry and Neurology and/or the American Osteopathic Board of Psychiatry and Neurology.

Evidence that the physician meets the requirements for the position of clinical director includes:

- *Certification by the American Board of Psychiatry and Neurology and/or certification by the American Osteopathic Board of Neurology and Psychiatry or;*

- *If no certification, evidence that the physician is board-certification eligible:*

    - *To be admitted to the American Board Examinations, the following conditions must be met:*

    - *License without restrictions,*

    - *Graduation from an approved medical school.*

    - *A successful completion of an approved residency-training program.*

Survey Procedures §482.62(b)(1)

Review the clinical director's personnel (credentialing) file for evidence that the director is board certified or eligible for board certification. Additionally, look for evidence of

completion of a psychiatric residency program approved by the American Board of Psychiatry and Neurology and/or the American Osteopathic Board of Psychiatry.

A-1693

(Rev. 235; Issued: 01-16-26; Effective: 01-16-26; Implantation: 01-16-26)

§482.62(b)(2) The director must monitor and evaluate the quality and appropriateness of services and treatment provided by the medical staff.

Interpretive Guidelines §482.62(b)(2)

Services and treatment prescribed to patients must be in accordance with appropriate and acceptable standards of practice. *The clinical director must show evidence of direct involvement in monitoring and evaluating the quality and appropriateness of all clinical services and treatment. Oversight and involvement may include:*

- *Participating in the credentialing and privileging process which includes recommendations to the governing body,*
- *Ongoing review of medical staff performance,*
- *Reviewing clinical outcomes,*
- *Being involved in peer review process, and*
- *Collaborating with other disciplines to identify and discuss issues related to the medical staff.*

Additionally, oversight and monitoring may include:

- *Attending clinical rounds with the medical staff,*
- *Performing medical record reviews, and*
- *Observing the provision of care by medical staff.*

The clinical director and hospital's governing body must approve policies and procedures that establish a system for overseeing and evaluating the quality of the clinical services provided by the medical staff. Policies include the process, criteria and frequency for evaluating the medical staff performance in providing clinical services. Evaluations should take place at regular intervals specified in the hospital's policy.

Additionally, in states that allow psychologists and other licensed practitioners to have admitting privileges, it is still the responsibility of the clinical director to oversee the quality of the

patient's treatment. In cases where someone other than a psychiatrist admits a patient, §482.60 requires a physician to be responsible for the patient's care.

There are a variety ways for monitoring and improving the quality of care provided within the psychiatric hospital. In accordance with 42 CFR §482.21, the hospital's Governing Body must ensure that the quality assessment and performance improvement (QAPI) program reflects the complexity of the hospital's organization and services. The director of psychiatric services should choose specific indicators related to improved health outcomes and the prevention and reduction of medical errors to be included in the overall QAPI program.

Survey Procedures §482.62 (b)(2)

- *Interview the clinical director and ask him/her to describe their role and involvement in the credentialing and privileging process.*
- *Ask the clinical director to describe the process for ongoing review of the medical staff.*
- *What mechanisms are used to monitor and evaluate the work of the medical staff?*
- *Is there evidence that the clinical director spends sufficient time at the hospital monitoring the provision of care by the medical staff?*
- *Interview the clinical director to determine how he/she addresses problems or concerns related to the psychiatric services. Interview staff and patients to determine the effectiveness of clinical director's interventions.*
- *Review medical staff meeting minutes and/or Governing Body meeting minutes to verify the clinical director's involvement in oversight and evaluation of the medical staff.*
- *Review the mechanisms utilized, as reported by the clinical director, to ensure the quality and appropriateness of psychiatric services and treatment are monitored.*

A-1695

(Rev. 235; Issued: 01-16-26; Effective: 01-16-26; Implantation: 01-16-26)

§482.62(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.

Interpretive Guidelines §482.62(c)

All psychiatric hospitals must have the ability to address medical and surgical conditions of psychiatric patients. The hospital must have MDs or DOs and other appropriate professional personnel available to provide diagnostic and treatment services to address comorbidities and concurrent medical and surgical conditions. The hospital is required to provide care and treatment of necessary medical conditions in addition to psychiatric care.

It is not uncommon for psychiatric patients to experience minor injuries or illnesses during hospitalization. The hospital must have qualified professionals who can assess and provide initial, stabilizing treatment for any minor injuries or illnesses.

All psychiatric hospitals, like other Medicare participating hospitals, must have the ability to address emergencies that occur on the hospital's campus, as required by §482.12(f). The hospital must have qualified personnel and equipment to address such emergencies.

If the medical or emergency condition of a patient exceeds the hospital capabilities, the hospital must provide an appropriate transfer of the patient to a hospital that can provide the services needed. See §482.12(f)(2), Tag A-0093, interpretive guidelines for referral when appropriate.

Survey Procedures §482.62(c)

- *Interview staff to determine how the hospital meets the medical/surgical/diagnostic needs of its patients.*

- *Interview patients who have required medical/surgical/diagnostic needs to determine adequacy and quality of treatment.*

- *Review the medical, surgical, and diagnostic services provided by the hospital during the interview with the clinical director. If the medical and surgical services are provided by outside sources or another hospital, discuss the contract or agreement with the clinical director to determine the kind and extent of services provided.*

- *Ask the clinical director for copies of the agreements to verify the hospital has agreements in place.*

- *Review medical records to verify if medical, surgical and diagnostic services are provided timely and appropriately.*

- *Interview hospital staff at various locations. Ask them to describe how they respond to emergencies and minor injuries or illnesses.*

- *For medical and surgical diagnostic and treatment services that are beyond the capabilities of the hospital, verify the hospital has an agreement with an outside source of these services to ensure they are immediately available or with a local Medicare participating hospital for transferring patients.*

A-1700

(Rev. 235; Issued: 01-16-26; Effective: 01-16-26; Implantation: 01-16-26)

§482.62(d) Standard: Nursing Services. The hospital must have a qualified director of psychiatric nursing services. In addition to the director of nursing, there must be adequate numbers of registered nurses, licensed practical nurses, and mental health workers to provide nursing care necessary under each patient's active treatment program and to maintain progress notes on each patient.

Interpretive Guidelines §482.62(d)

***NOTE**: Psychiatric hospitals must additionally comply with the Nursing Services CoP at 42 CFR §482.23.*

There can be only one Director of Nursing Services for the entire hospital. Therefore, the director of psychiatric nursing services required at §482.62(d) must be the same person as the director of nursing that is required at §482.23(a).

The organized department of nursing in a psychiatric hospital must have sufficient nursing staff (including RNs, licensed practical nurses (LPNs), nursing assistants (NAs), and mental health aides) with the appropriate qualifications to ensure the nursing needs of all patients are met, to ensure the provision of nursing care necessary under each patient's active treatment program, and to maintain progress notes on each patient. Additionally, sufficient numbers, qualifications, and training of nursing staff, must be considered when taking into account the number of patients, acuity of patients, and layout of the hospital.

The progress notes are kept current by documenting assessments of the patient's needs, the care provided to the patient, and the patient's response to these nursing interventions.

Survey Procedures §482.62(d)

- *Determine if the hospital has one designated director of psychiatric nursing services who is the same person as the director of nursing services in any other parts of the hospital.*
- *Review staffing schedules and staffing assignments to determine if the staffing numbers are adequate to meet the nursing care demands, taking into consideration the following:*
    - *Number of patients,*
    - *Patient acuity,*
    - *Availability of RNs, LPNs, NAs, and mental health aides.*

- *Review a sample of medical records and verify that nursing care identified in the patient's active treatment program is being provided and documented.*

- *Verify that progress notes contain nursing documentation of:*

    - *Assessments,*

    - *Procedures,*

    - *Treatments, and*

    - *Other interventions received while hospitalized.*

A-1701

(Rev. 235; Issued: 01-16-26; Effective: 01-16-26; Implantation: 01-16-26)

§482.62(d)(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…

Interpretive Guidelines §482.62(d)(1)

The psychiatric hospital director of nursing (DON) may have other titles such as chief nursing officer or vice president of nursing. The DON must be a registered nurse who has a master's Degree in psychiatric or mental health nursing (or its equivalent). If the DON does not have a master's Degree in Psychiatric Nursing, the hospital must demonstrate how their selection for DON meets the requirements based on:

- *Specialized education,*

- *Psychiatric hospital experience in the care of the mentally ill, or*

- *On-going training in psychiatric nursing in support of the leadership role.*

Survey Procedures §482.62(d)(1)

- *Determine if there is a qualified DON providing the required leadership and supervision for the psychiatric hospital nursing services.*

- *Review the personnel file of the DON to look for evidence of current nursing licensure and the preferred master's degree in psychiatric or mental health nursing or its equivalent from a school of nursing accredited by the National League for Nursing,*

- *If the DON does not have a master's degree, review the criteria (job description) utilized by the hospital to support their selection of a qualified DON. The evidence should include documentation of education, training, and experience in the care of the mentally ill.*

A-1702

(Rev. 235; Issued: 01-16-26; Effective: 01-16-26; Implantation: 01-16-26)

§482.62(d)(1) …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.

Interpretive Guidelines §482.62(d)(1)

The DON is not required to formulate individual treatment plans or directly provide skilled nursing care and therapy but must be able to demonstrate competency in these skills. The DON is expected to be responsible for ensuring that the nursing staff demonstrate the competency to participate in interdisciplinary formulation of individualized treatment plans and to provide skilled nursing care and therapy; and to ensure the staff actually provide these services. Staff may demonstrate competence through direct observation of skills or through appropriate documentation of competencies.

The hospital must provide sufficient documented evidence (based on nationally recognized standards of practice) that the DON possesses the current competence to fulfill the requirements of this standard.

Sufficient documentation could include evidence of current:

- *Professional certification in psychiatric-mental health nursing,*
- *Training in the formulation of individual treatment plans, or*
- *Continuing education in psychiatric nursing care and therapy.*

Evidence that might demonstrate the DON's competence to direct, monitor and evaluate the nursing care furnished should include at a minimum:

- *Having measures in place to monitor and evaluate the nursing care furnished by nursing staff as part of a quality improvement program,*
- *Assisting with the development and review of nursing service policies and procedures,*
- *Approving nursing service policies and procedures, and*

- *Ensuring the provision of ongoing in-services and continuing education programs for psychiatric nurses and mental health care staff.*

Survey Procedures §482.62(d)(1)

- *Review the personnel file of the DON to assess for evidence of current training:*
    - *Professional certification in psychiatric-mental health nursing,*
    - *In interdisciplinary formulation of individual treatment plans, or*
    - *In skilled psychiatric nursing care and therapy.*
- *Determine if the DON has a mechanism in place to monitor and evaluate the nursing care furnished by nursing staff as part of a quality improvement program or another program which would evaluate care.*
- *Determine if the DON is assisting with the development and review of nursing service policies and procedures.*
- *Determine if the DON is approving the nursing service policies and procedures.*
- *Determine if the DON is ensuring the on-going and continuing education for psychiatric nurses and mental health care staff.*

A-1703

(Rev. 235; Issued: 01-16-26; Effective: 01-16-26; Implantation: 01-16-26)

§482.62(d)(2) The staffing pattern must ensure the availability of a registered nurse 24 hours each day…

Interpretive Guidelines §482.62(d)(2)

There must be an RN immediately available 24 hours each day, 7 days a week.

Refer to §482.23 Tag A-0385 for more comprehensive details for this requirement.

Survey Procedures §482.62(d)(2)

- *Interview the Director of Nursing Service. Request the following items:*

- *Organizational chart(s) for nursing services for all locations where the hospital provides nursing services;*
- *Job or position descriptions for all nursing personnel including the director's position description.*

- *Select at least one patient from every inpatient care unit. Observe the nursing care in progress to determine the adequacy of staffing and to assess who is providing care to ensure the delivery of care is provided by staff who are functioning within their scope of practice. Other sources of information to use in the evaluation of the nursing services are: nursing care plans, medical records, patients, family members, accident and investigative reports, staffing schedules, nursing policies and procedures, and QAPI activities and reports.*
- *Interview patients and family members or significant others involved in the patient's care for information relative to the delivery of nursing services.*
- *Interview staff to determine adequacy of nursing staffing. Determine if there is immediate availability of an RN 24 hours a day.*

A-1704

(Rev. 235; Issued: 01-16-26; Effective: 01-16-26; Implantation: 01-16-26)

§482.62(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.

Interpretive Guidelines §482.62(d)(2)

In addition to meeting the requirements of this standard, the requirements at §482.23(b)(1) must also be met. The interpretive guidelines for that regulation at Tag A-0393 state, "The hospital must provide nursing services 24 hours a day, 7 days a week. An LPN can provide nursing services if an RN, who is immediately available for the bedside care of those patients, supervises that care."

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

There must be an RN physically present on the premises and on duty at all times. Every inpatient unit/department/location within the hospital-wide nursing service must have adequate numbers of RNs physically present at each location to ensure the availability of an RN for the bedside care of any patient. An RN would not be considered immediately available if the RN was working on more than one unit, building, or floor in another building at the same time.

Staffing schedules must be reviewed and revised as necessary to meet the patient care needs and to make adjustments for nursing staff absenteeism.

The evaluation of sufficient numbers and levels of RNs, LPNs, NAs, and mental health aides is based on the patient characteristics as seen in structured observations of patients in the sample and other patients in the hospital, patient interviews, and as evidenced in medical records and other data related to patients (e.g. incident reports, seclusion/restraint reports). Patient care assignments should be appropriate to the skills and qualifications of the nursing personnel providing patient care.

Survey Procedure §482.62(d)(2)

- *Determine that there are written staffing schedules which correlate to the number and acuity of patients. Verify that there is supervision of personnel performance and nursing care for each department or nursing unit. To determine if there are adequate numbers of nurses to provide nursing care to all patients as needed, take into consideration:*
    - *Physical layout and size of the hospital;*
    - *Number of patients;*
    - *Acuity of illness and nursing needs;*
    - *Availability of NAs and mental health workers and other resources for nurses;*
    - *Training and experience of personnel.*
- *Observe the staffing available, interview patients/patients' representatives, and review medical records to determine if each patient's nursing needs were addressed. There must be sufficient numbers, types and qualifications of supervisory and staff nursing personnel to respond to the appropriate nursing needs and care of the patient population.*
    - *Does the nursing staff have the appropriate qualifications for the tasks they are required to perform?*
- *Review medical records to determine if nursing care under the patient's individualized comprehensive treatment plan is being provided.*

A-1710

(Rev. 235; Issued: 01-16-26; Effective: 01-16-26; Implantation: 01-16-26)

§482.62(e) Standard: Psychological Services. The hospital must provide or have available psychological services to meet the needs of the patients.

Interpretive Guidelines §482.62(e)

The hospital can choose which psychological services it will provide; however, it must offer enough psychological services, by volume and type, to ensure that the hospital meets the needs of its patients.

Psychological (or psychiatric) services may include the following:

- *Psychological testing,*
- *Neuropsychological testing interpretation and reporting,*
- *Individual psychotherapy,*
- *Family psychotherapy which includes the patient,*
- *Group psychotherapy,*
- *Health & behavior intervention – individual, group, family with patient, family without patient, and/or*
- *Participation in multidisciplinary treatment conferences.*

The number and types of mental health professionals (i.e., psychiatrists, psychologists, clinical social workers, psychiatric nurse practitioners etc.), whether full-time, part-time or consulting, must be adequate to provide necessary psychological/psychiatric services to inpatients and outpatients.

Survey Procedures §482.62(e)

- *During interview with the clinical director, ask how psychological service staffing needs are determined.*
    - *How many of the various types of mental health professionasl are on staff and staffed each shift?*
    - *Do the psychological services' staff participate in interdisciplinary treatment planning?*
    - *If additional resources are needed, what plans are in place to secure those services?*
- *Ask the clinical director to describe the types of psychological services and programs that are provided and how they meet the needs of the patient population.*
- *Review the psychological services staffing; is there sufficient staff to address each patient's psychological needs? Do the psychological services staff have the appropriate qualifications for the task they are asked to perform?*

A-1715

(Rev. 235; Issued: 01-16-26; Effective: 01-16-26; Implantation: 01-16-26)

§482.62(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.

Interpretive Guidelines §482.62(f)

The social services director is responsible for the social services activities within the hospital. He/she manages and assigns responsibilities to staff and implements social service policies. Additionally, the social services director must provide mechanisms for monitoring and evaluating social services activities. The hospital's social services policies and procedures must clearly delineate the role of the director.

Hospital policies and procedures for social services must be consistent with accepted standards of practice based on guidelines or recommendations issued by nationally recognized organizations with expertise in social work. This applies to social services furnished to inpatients and outpatients. Examples of such organizations include, but are not limited to:

- *National Association of Social Workers (NASW) (http://www.naswdc.org/), or*
- *American Board of Examiners in Clinical Social Work (https://abecsw.org/).*

The NASW provides a comprehensive list of roles and responsibilities for social services personnel in health care settings.

In accordance with §482.62(a)(4) and §482.43, psychiatric hospitals must have qualified staff who engage in discharge planning. Social services personnel are key in supporting psychiatric treatment plans by identifying current and future needs and facilitating discharge planning and transitions of care.

Survey Procedures §482.62(f)

- *Ask the director to describe how he/she determines the social service needs of the patient population served.*
- *During interviews, ask the director of social services to demonstrate or provide evidence of how he/she monitors and evaluates quality and appropriateness of services furnished to patients.*
    - *Ask the director how he/she periodically audits the quality and appropriateness of services furnished to patients. Is there a policy for auditing the services*

furnished? How is information gathered through the auditing process shared with social services staff? Is there an established quality improvement program to monitor these services?

- *Ask the social services director how he/she delegates responsibility within the department.*
- *Determine if the director of social services is involved with the development of and approval of the social services policies and procedures.*
- *Ask the director of social services as well as social services staff to demonstrate how the social services, furnished to patients, are consistent with nationally recognized standards of practice. Is there documentation that the hospital has developed social services policies and procedures based on accepted standards of practice?*
- *Review a sample of records to determine if social services are furnished to both inpatients and outpatients.*
- *Ask social services staff to provide copies of social service patient care policies.*
- *Ask social services staff to demonstrate how they provide social services to patients in accordance with the hospital's policies and procedures.*
- *Review a sample of medical records to verify that social services staff have provided treatment in accordance with the patients' individualized, comprehensive treatment plans.*
- *Interview patients to determine social services staff is providing adequate treatment which is individualized and comprehensive.*
- *Observe treatment team meetings. As referenced in §482.12(c), social services should play an active role in the treatment team and participate in the meetings.*

A-1716

(Rev. 235; Issued: 01-16-26; Effective: 01-16-26; Implantation: 01-16-26)

§482.62(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.

Interpretive Guidelines §482.62(f)(1)

The director of the social work department or service must have a master's degree in social work (MSW) from an accredited school of social work or must be qualified by education and

experience in the social services needs of the mentally ill. Qualifications are determined by a combination of education, experience, specialized training, state licensure, and maintaining professional standards of practice. As of 2017, the Council on Social Work Education (CSWE) is the only organization that accredits MSW programs. A MSW from a school of social work that is not accredited by CSWE will not meet the MSW requirement. The exact requirements as per CSWE can be found on their website at https://www.cswe.org/.

CMS expects hospitals to demonstrate how the director of social services meets the requirements of this standard.

Survey Procedures §482.62(f)(1)

- *Review personnel record for the Director of Social Work to determine whether he/she has a MSW from an accredited school of social work or is qualified by education and experience in the social services needs of the mentally ill.*

- *If the director of social services does not have a MSW from an accredited school of social work, determine if there is another social service professional on staff with a MSW from an accredited school of social work.*

A-1717

(Rev. 235; Issued: 01-16-26; Effective: 01-16-26; Implantation: 01-16-26)

§482.62(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.

Interpretive Guidelines §482.62(f)(2)

Social services contact with the patient, family, patient representative and significant others should occur during admission or as soon as possible after the admission. A high-risk psychosocial case finding should result in supporting information from patient, patient representative, and/or any other reputable source being available for early integration into the patient's treatment plan and subsequent social service action as indicated. The treatment team should consider, for possible inclusion into the patient's treatment plan, the anticipated social services role and expected interventions as recommended in the psychosocial assessment. Treatment and discharge planning activities as well as liaison/follow-up efforts should be based upon the goals, including discharge goals, and staff responsibilities specified in the treatment plan.

Communicating appropriate information to healthcare providers and community resources outside the psychiatric hospital assists in providing continuity of care, provision of a safe discharge, and the provision of community care.

Survey Procedures §482.62(f)(2)

- *Review the hospital's policy to determine the role(s) of social services staff.*

- *Review medical records to verify when the social worker had contact with patient, patient representative and significant others; e.g., occurred during admission or soon after admission.*

- *Observe treatment plan meetings to assess how social workers participate in the development of a discharge plan.*

- *Interview social work staff and ask them to describe discharge planning processes including how patients are provided options for continuity of care after discharge.*

- *Interview patients and ask them to describe how social services staff are working with them to plan their discharge; verify the patient is involved in the discharge planning decision making through interviewing the patient and medical record documentation. As per A-1624, the patient and/or significant other must be involved in admission of the patient which includes care all the way through discharge.*

- *Review medical record documentation to verify social services participation in the assessment, development and implementation of the discharge plan including the arrangement of follow-up care.*

- *Ask social worker to provide documentation of how they develop mechanisms for exchange of appropriate information with organizations outside the hospital.*

- *Verify through interviews and reviews of a sample of medical records the extent to which social work staff prepare patients for post-hospitalization treatment and outpatient services.*

- *Determine whether social work staff act as the liaison between the patient and community resource providers.*

- *Review a sample of medical records to verify documentation that social work staff provided appropriate information to sources outside the hospital who will provide aftercare, such as post-hospital patient service providers, community agencies, the patient, family members, and anyone else significantly involved with the patient who will provide care after hospitalization.*

A-1720

(Rev. 235; Issued: 01-16-26; Effective: 01-16-26; Implantation: 01-16-26)

§482.62(g) Standard: Therapeutic Activities. The hospital must provide a therapeutic activities program.

Interpretive Guidelines §482.62(g)

Therapeutic activities refer to any endeavor, other than routine activities of daily living (ADLs), in which the patient participates that is intended to enhance, restore, and maintain optimal levels of physical, psychosocial, cognitive and emotional functioning. These include, but are not limited to, activities that promote self-esteem, pleasure, comfort, education, creativity, success, and independence.

The hospital is responsible for ensuring consistent availability and provision of individualized therapeutic activities to inpatients and outpatients. The therapeutic activities provided must be appropriate to the patient's diagnosis and physical condition, based on the patient's identified needs, appropriate to the setting, and follow nationally recognized standards of practice.

Types of therapies that may be used to restore, maintain and optimize physical and psychosocial functioning may include, but are not limited to, Tai Chi, Yoga, dance therapy, music therapy, exercise, etc.

The selection of individualized therapeutic activities should be based on the patient's needs and interests, and goals set in the patient's treatment plan after an assessment by the therapeutic activities personnel.

Survey Procedures §482.62(g)

- *Verify that the hospital has a therapeutic activities program,*
- *Ask the hospital leadership to identify the person responsible for the direction of the therapeutic activities program,*
- *Ask the person responsible for directing therapeutic activities:*
    - *To describe how patients are informed of therapeutic activities available,*
    - *To describe the types of therapeutic activities offered, and*
    - *To describe how the activities are appropriate to meet the needs and interests of the patient.*
- *Ask the staff providing therapeutic activities to describe how the activities are selected and made available to each patient,*
- *Verify there are mechanisms in place to provide therapeutic activities during periods when certain activities are not available at the facility, yet needed,*

- *Interview patients. Ask if they were provided options for therapeutic activities.*

A-1725

(Rev. 235; Issued: 01-16-26; Effective: 01-16-26; Implantation: 01-16-26)

§482.62(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.

Interpretive Guidelines §482.62(g)(1)

The hospital is responsible for ensuring consistent availability and provision of individualized therapeutic activities and rehabilitative services based on patient needs.

The selection of individualized therapeutic and rehabilitative staff modalities should be based on patient need and goals set in the patient's treatment plan. Rehabilitative services may include educational, occupational, recreational, physical, art, dance, music, speech therapies, and vocational rehabilitation evaluation and counseling. There are other disciplines that also serve patients. Consultants include but are not limited to the following: educational instructors, registered occupational therapist/certified occupational therapy assistant, certified therapeutic recreation specialist, certified therapeutic recreation assistant, speech-language pathologist has certificate of clinical competence, registered and certified music therapist, registered art therapist, and registered physical therapist. The qualified vocational specialist may perform duties of a rehabilitation counselor, vocational evaluator, or work adjustment specialist.

A-1726

(Rev. 235; Issued: 01-16-26; Effective: 01-16-26; Implantation: 01-16-26)

§482.62(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.

Interpretive Guidelines §482.62(g)(2)

The psychiatric hospital must provide adequate numbers of qualified staff (therapists, support personnel, and consultants) to carry out all therapeutic activities and to meet the individual needs of its patients. For staff to be considered qualified, they must meet training, education, licensure, certification and experience requirements in accordance with state scope of practice laws, hospital policy, and nationally recognized standards.

Adequate numbers means the hospital has enough qualified therapists, support personnel and consultants to ensure each patient's active treatment program provides therapeutic activities that meet the patient's needs and are implemented as ordered.

The hospital is expected to have written criteria for determining whether each therapist, support personnel, or consultant is qualified for the therapeutic activities each provides.

The types of staff to support and provide therapeutic activities may include occupational therapists, recreation specialists, speech-language pathologists, music therapists, art therapists, physical therapists, vocational specialists and assistants. These disciplines serve to meet the needs of various types of psychiatric patient populations served such as child, adolescent, adult and geriatric.

Survey Procedures §482.62(g)(2)

- *Review the hospital's written criteria for determining qualification of therapeutic staff.*
- *Review personnel files to verify the qualifications of the therapeutic activities staff are documented.*
- *Review a sample of medical records to determine if patient care that is to be provided by therapeutic activity staff is being provided as ordered.*
- *Is there evidence to support that the hospital has adequate staffing to provide therapeutic activities to each patient?*
- *Interview therapeutic activities staff regarding activities provided and the availability of staff throughout the day and week to determine that the numbers and types of staff available is appropriate to provide therapeutic activities consistent with each patient's treatment plan.*
- *Ask staff to describe how they determine the therapeutic needs of patients and how they are meeting those needs.*
- *Interview patients and family members or significant others to determine if the therapeutic needs of the patients are being met.*