



Center for Clinical Standards and Quality/Quality, Safety & Oversight Group

Ref: QSO-23-07-REH

DATE: January 26, 2023

TO: State Survey Agency Directors

FROM: Director, Quality, Safety & Oversight Group (QSOG)

SUBJECT: Guidance for Rural Emergency Hospital Provisions, Conversion Process and Conditions of Participation

Memorandum Summary

- CMS is dedicated to improving access to health care in rural communities and addressing the issues which contribute to health inequities impacting these communities.
- The Consolidated Appropriations Act (CAA), 2021 established Rural Emergency Hospitals (REHs) as a new Medicare provider and allows REHs to participate in the Medicare program and receive payment for items and services furnished on or after January 1, 2023.
- CMS published a final rule establishing REHs as a new Medicare provider and codified the Conditions of Participation (CoP) that REHs must meet in order to participate in the Medicare and Medicaid programs along with REH payment policies, quality measures and enrollment policies.
- CMS is providing guidance regarding the REH enrollment and conversion process for eligible facilities, Frequently Asked Questions (FAQs), and a newly developed State Operations Manual Appendix (Appendix O) with survey procedures and CoP regulatory text. The interpretive guidance for REHs is pending and will be provided in a future release.
- The national survey database system has been updated to include the REH tags and corresponding regulatory text. CMS will release REH Basic Surveyor Training via the Quality Safety Education Portal (QSEP) website when available.

Background:

In response to rural hospital closures and in an effort to address barriers in access to health care for rural communities, the Consolidated Appropriations Act (CAA), 2021 ([CAA](#)) was signed into law on December 27, 2020, and established Rural Emergency Hospitals (REHs) as a new Medicare provider. Section 125 of the CAA added section 1861(kkk) to the Social Security Act (the Act) and sets forth the statutory authority for REHs.

The conversion of an eligible facility to an REH allows for the provision of emergency department services, observation care, and additional outpatient medical and health services, if elected by the REH, that do not exceed an annual per patient average length of stay of 24 hours. REHs are prohibited from providing inpatient services, except those furnished in a unit that is a distinct part licensed as a skilled nursing facility to furnish post-hospital extended care services. Effective January 1, 2023, this new provider type will promote equity in health care for those living in rural communities by facilitating access to needed services.

Additionally, since REHs will be providing emergency department services, these facilities must comply with the Emergency Medical Treatment and Labor Act (EMTALA) at section 1867 of the Social Security Act (the Act), the accompanying regulations in 42 CFR § 489.24 and the related requirements at 42 CFR § 489.20(l), (m), (q), and (r). EMTALA requires, among other things, Medicare-participating hospitals with emergency departments to offer a medical screening examination to any individual who comes to the emergency department and requests such an examination, and prohibits hospitals with emergency departments from refusing to examine or offer stabilizing treatment to individuals with an emergency medical condition (EMC). Please refer to SOM, Appendix V ([Appendix V](#)) for additional guidance related to the EMTALA requirements.

On November 23, 2022, CMS published a final rule ([CMS-1772-FC](#)) establishing REHs as a new Medicare provider effective January 1, 2023. The rule finalized the CoPs which REHs must meet in order to participate in the Medicare and Medicaid programs along with REH payment policies, quality measures and enrollment policies. CMS established the Conditions of Participation (CoPs) to ensure the health and safety of patients who will receive REH services, while taking into consideration the access and quality of care needs of an REH's patient population. The standards for REHs closely align with the current CoPs for Critical Access Hospitals (CAHs) in most cases, while accounting for the uniqueness of REHs and their statutory requirements. The REH CoPs are set forth at new Subpart E of 42 CFR Part 485 and establish a full range of health and safety standards specific to governance, services offered, staffing, physical environment, and emergency preparedness among other requirements. In most instances, the REH policies also closely align to the current hospital and Ambulatory Surgical Center (ASC) standards, such as the policies for outpatient service requirements and the Life Safety Code (LSC), respectively. A general overview of the new REH requirements include:

- REHs must have a clinician, a doctor of medicine (MD), doctor of osteopathy (DO), physician assistant (PA), nurse practitioner (NP) or clinical nurse specialist (CNS), with training or experience in emergency care on-call at all times and immediately available by phone or radio contact and available on-site within 30 or 60 minutes depending on if the facility is located in a frontier area.
- The REH emergency department must be staffed 24 hours per day and seven days per week by an individual or individuals competent in the skills needed to address emergency medical care, and the individual(s) must be able to receive patients and activate the appropriate medical resources to meet the care needed by the patient.

- REHs must develop, implement, and maintain an effective, ongoing, REH-wide, data-driven Quality Assessment and Performance Improvement (QAPI) program, and it must address outcome indicators related to staffing, among other things.
- The annual per-patient average length of stay cannot exceed 24 hours, in accordance with the statute, and the time calculation for this determination begins with the registration, check-in, or triage of the patient (whichever occurs first) and ends with the discharge of the patient from the REH (which occurs when the physician or other appropriate clinician has signed the discharge order or at the time the outpatient service is completed and documented in the medical record).
- REHs must have infection prevention and control and antibiotic stewardship programs that adhere to nationally recognized infection prevention and control guidelines and best practices for improving antibiotic use.

Discussion:

In response to the establishment of REHs as a new Medicare provider and the publication of CoPs, payment policies and enrollment policies in CMS-1772-FC, CMS is providing guidance regarding the enrollment and conversion process for eligible facilities interested in participating in the Medicare and Medicaid programs as an REH. The following sections provide an overview of the enrollment and conversion process.

Eligibility

The following facilities that were enrolled and certified to participate in Medicare as of December 27, 2020 are eligible to be an REH:

- CAHs; or,
- A subsection (d) hospital (as defined in section 1886(d)(1)(B) of the Act) with not more than 50 beds located in a county (or equivalent unit of local government) in a rural area (as defined in section 1886(d)(2)(D) of the Act) (referred to as rural hospital); or
- A subsection (d) hospital (as so defined) with not more than 50 beds that was treated as being located in a rural area pursuant to section 1886(d)(8)(E) of the Act (referred to as rural hospital).
- Facilities that were enrolled as CAHs or rural hospitals with not more than 50 beds as of December 27, 2020 and then subsequently closed after that date, would also be eligible to seek REH designation if they re-enroll in Medicare and meet all the CoPs and requirements for REHs.

Enrollment

As with all other providers and suppliers, REHs are required to enroll in Medicare to receive payments for services and items furnished to Medicare beneficiaries. The purpose of the provider enrollment process is to help confirm that providers and suppliers seeking to bill Medicare meet all applicable federal and state requirements. The final REH enrollment regulation at 42 CFR

§ 424.575 states that eligible facilities must submit a change of information application, rather than an initial enrollment application, to enroll as an REH. This regulation should expedite the conversion process and decrease provider burden. Prospective REH facilities should complete the Form CMS- 855A change of information application (see section 1) and submit the completed application to their designated Medicare Administrator Contractor (MAC) for review and approval. The MAC will review the change of information application and forward the recommendation of approval to the designated State Agency (SA).

For additional details pertaining to REH enrollment policies, refer to the [Medicare Program Integrity Manual, Chapter 10 Medicare Enrollment](#).

Additional Information

In addition to the Form CMS-855A change of information application, prospective REH facilities must submit additional information for conversion to an REH. This includes an action plan for initiating REH services. The action plan and additional information should be submitted to the SA as described below.

Action Plan

The action plan outlines the facility's plan for conversion to an REH and the initiation of REH specific services including the provision of emergency department services, observation care and other medical and health services elected by the REH. This should include details regarding staffing provisions and the number and type of qualified staff for the provision of REH services.

In addition, the action plan must include a detailed transition plan that lists the following:

- Specific services the facility will retain;
- Specific services the facility will modify;
- Specific services the facility will add; and
- Specific services the facility will discontinue.

Additionally, the facility must include a description of services that the facility intends to furnish on an outpatient basis if elected by the REH. The facility must also include information regarding how the facility intends to use the additional facility payment. This includes a description of the services that the additional facility payment would be supporting such as the operation and maintenance of the facility and furnishing of services (i.e., telehealth services, ambulance services etc.).

Eligible facilities may submit the action plan and additional information on letterhead or use the model template attached to this memo. The submission should be signed by the facility's legal representative/administrator. The SA will forward the action plan and information along with its recommendation for approval or denial to the designated CMS location for review and approval of the action plan components. The CMS location will make a final determination and notify the MAC once the enrollment package is complete and has been reviewed and approved.

The action plan and information must include all the required elements as specified. Missing or incomplete information may delay the conversion and enrollment process for eligible facilities applying to become an REH.

Also, in accordance with section 1861(kkk)(2)(A) of the Act, action plans will be available to the public and will eventually be posted on the CMS website. Additional information will be forthcoming once the process is finalized.

Transfer Agreement

Under section 1861(kkk)(2) of the Act and at new 42 CFR § 485.538 *Condition of Participation: Agreements*, the REH is required to have a transfer agreement with at least one Medicare-certified hospital that is designated as a level I or level II trauma center. The agreement is intended to ensure an appropriate referral and transfer process is in place for patients requiring emergency care and continued care services beyond the capabilities of the REH. In order to document compliance, a copy of the transfer agreement should be submitted to the SA along with the action plan.

Attestation

An REH is required to meet the CoPs for Rural Emergency Hospitals set forth at new Subpart E of 42 CFR Part 485 (§ 485.500 - § 485.546). Other than the requirement that the REH submit its agreement with a nearby trauma center, eligible facilities converting to an REH may self-attest to meeting the REH CoPs and will not require an automatic on-site initial survey as eligible facilities are expected to be in full compliance with the existing CAH and hospital requirements at the time of the request for conversion. Additionally, the CAH and hospital CoPs closely align with the REH requirements (with the exception of rules regarding inpatient acute care services) and are consistent with REH requirements. Facilities that were eligible as of December 27, 2020, which subsequently closed and re-enrolled in Medicare would require an initial on-site survey by the SA. These facilities do not have to submit an attestation, as an on-site initial survey will be performed to determine the facility is operational and in compliance with the REH requirements.

Facilities may submit the attestation for compliance with the REH CoPs along with the action plan and copy of the transfer agreement to the SA. The attestation may be completed on facility letterhead or the model template provided in the attachment to this memo may be used. The attestation should be signed by the facility's legal representative or administrator. The SA will review the additional information for completeness and confirm compliance with any applicable state licensure requirements. Once complete, the SA will forward the additional information to the CMS location, along with a recommendation for certification or denial. The CMS location is responsible for making the final determination for certification of the REH.

Prior to making a final determination, the CMS location will confirm eligibility requirements, including bed count, based on the most recent cost report and rural status. Our criteria for determining an applicant's rural status will follow the guidance for CAHs in SOM Chapter 2, section 2256A, with the exception that REHs are not expected to meet any distance/mileage

requirements other than being located in a rural area or an area designated as rural. Once the information has been reviewed, confirmed and approved, the CMS location will complete the certification kit in the current survey database which includes upload of the action plan, attestation and copy of the transfer agreement. The CMS location will assign a CCN if approved and forward the approval or denial, as appropriate, along with the effective date to the MAC via the CMS-2007. The effective date will be based upon the date the application package was determined to be complete and approved by the CMS location for meeting all REH requirements. For facilities that require an on-site initial survey, the effective date will be based on current CMS policy, which is the exit day of survey if no deficiencies are cited, or in the alternative, if deficiencies are noted, the date an acceptable plan of correction was approved (see 42 CFR § 489.13).

As part of the enrollment package review, the SA and CMS location will review the materials provided and the survey history of the eligible provider. If any health or safety concerns are identified during the review, CMS maintains the discretion to perform an on-site survey at any time to further evaluate compliance with the REH requirements. Otherwise, the survey priorities for REHs will follow the annual Mission and Priority Document (MPD) released each fiscal year (FY).

The national survey database system has been updated to include the new REH tags and corresponding regulatory text.

Training: CMS will release REH Basic Surveyor Training via the Quality Safety Education Portal (QSEP) website when available.

For additional information related to the REH eligibility, enrollment, and conversion process, please see the attached FAQs.

For additional information related to the REH CoPs and survey process, please see the attached draft Appendix O, noting interpretive guidance will be forthcoming.

Contact:

For questions or concerns relating to this memorandum, please contact QSOG_REH@cms.hhs.gov.

Effective Date:

Immediately. Please communicate to all appropriate staff within 30 days.

/s/

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Attachment(s)- (1)Draft Appendix O, (2)REH FAQs, (3)Model Attestation Template, (4)Model Action Plan Template

Rural Emergency Hospitals Frequently Asked Questions (FAQs)

Q1. What is a Rural Emergency Hospital?

A1. The Consolidated Appropriations Act (CAA), 2021 ([Pub. L. 116-260](#)), was signed into law on December 27, 2020. In this legislation, Congress established a new rural Medicare provider type: Rural Emergency Hospitals (REHs). These providers will furnish emergency department services and observation care, and other specified outpatient medical and health services if elected by the REH, that do not exceed an annual per patient average length of stay of 24 hours.

Q2. What facilities are eligible to become a REH?

A2. Effective January 1, 2023, hospitals that were Critical Access Hospitals (CAHs) or rural hospitals (or one treated as such under section 1886(d)(8)(E) of the Social Security Act) with not more than 50 beds, participating in Medicare, as of December 27, 2020, may submit an enrollment application to convert to and enroll in Medicare as an REH. This includes eligible facilities that were CAHs or rural hospitals with not more than 50 beds as of the date of enactment of the CAA and then subsequently closed after that date. These facilities would be eligible to seek REH designation after the closure of the facility. However, prior to the conversion to an REH, these facilities must be re-enrolled in Medicare and meet all the requirements for REHs.

Q3. What services are REHs permitted to provide?

A3. REHs are eligible to furnish emergency department services, observation care and, if elected by the REH, other specified outpatient medical and health services that do not exceed an annual per patient average length of stay of 24 hours. CMS has defined “REH services” to include all covered outpatient department services (as defined in section 1833(t)(1)(B) of the Act (other than clause (ii) of such section)) when furnished by an REH. Such services could include radiology, laboratory, outpatient rehabilitation, surgical, maternal health, and behavioral health. The REH can provide additional medical and health services if the services align with the health care needs of the community served by the REH.

REHs are not eligible to provide inpatient services with the exception of post-hospital extended care services furnished in a distinct part unit licensed as a skilled-nursing facility (SNF).

Q4. What is the process for eligible facilities to convert to an REH?

A4. The complete process for eligible facilities to convert to an REH is outlined in the QSO-22-XX-REH memo. The memo is available on the CMS website at:

<https://www.cms.gov/medicare/provider-enrollment-and-certification/surveycertificationgeninfo/policy-and-memos-to-states-and-regions>.

Q5. Can eligible facilities that are in the midst of an enforcement action convert to an REH?

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A5. To convert to an REH, facilities must be in substantial compliance with all applicable health and safety standards and regulations at the time of conversion.

Q6. Can REHs relocate and maintain certification as an REH? If so, what is the process?

A6. Yes, but the REH must maintain rural status or continue to be located in an area that has been designated or reclassified as rural in accordance with 42 CFR §412.103. When an REH plans to relocate, it must update the CMS-855A form and submit it for reapproval.

Q7. Can REHs convert back to a CAH or hospital?

A7. REHs can convert back to a CAH or rural hospital. At that time, the CAH or rural hospital would be considered a new CAH or rural hospital, therefore, losing any grandfathered privileges. For example, if a CAH grandfathered as a necessary provider converts to an REH, it would lose its necessary provider designation and may not regain it if it reverts back to a CAH. Facilities would follow the existing enrollment and certification procedures for the initial certification of the elected provider type, including the completion of a new CMS-855A and any applicable fees.

Q8. What are the required elements for the action plan? Is a specific format or form required to be submitted for the facility action plan?

A8. The action plan outlines the facility's plan for conversion to an REH and the initiation of REH-specific services. The action plan should include the following elements:

- The provision of emergency department services, observation care and other medical and health services elected by the REH including details regarding staffing provisions and the number and type of qualified staff for the provision of REH services.
- A detailed transition plan that lists the specific services that the facility will retain, modify, add, and discontinue.
- A description of services that the facility intends to furnish on an outpatient basis, if elected.
- Information regarding how the facility intends to use the additional facility payment. This includes a description of the services that the additional facility payment would be supporting such as the operation and maintenance of the facility and furnishing of services (i.e. telehealth services, ambulance services etc.).

The facility may submit the action plan and additional information noted above on facility letterhead or use the model template provided as an attachment to the QSO-22-XX-REH memo. The plan should be signed by the facility's legal representative/administrator.

Q9. How do facilities submit the action plan?

A9. Section 1861(kkk)(4)(A)(i) of the Act requires that a hospital or CAH seeking REH conversion submit a detailed action plan at the time they submit their revised form CMS-855A. The action plan should be submitted to the state agency (SA). The SA will forward the action plan along with the recommendation for approval or denial of certification to the designated CMS location for review and approval of the action plan components. The CMS location will

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make a final determination and notify the MAC once the enrollment package is complete and has been reviewed and approved. The action plan must include all the required elements as specified.

Q10. When should the transfer agreement be submitted to CMS? Are there any required elements for the transfer agreement with a Medicare-certified hospital that is a level I or level II trauma center?

A10. A copy of the transfer agreement should be submitted to the SA along with the action plan. CMS requires that the Medicare-certified level I or level II trauma center meets certain licensure requirements, including being licensed as a hospital in a state that provides for the licensing of hospitals under state or applicable local law or approved by the agency of such state or locality responsible for licensing hospitals, as meeting standards established for licensing established by the agency of the state. The level I or level II trauma center may be located in a state other than the state where the REH is located. The level I or level II trauma center must be licensed or designated by the state or local government authority as a level I or level II trauma center or is verified by the American College of Surgeons as a level I or level II trauma center.

Q11. Will the REH need to have an initial survey conducted? What information is required for self-attestation, and is there a specific format or form for submission? How often will REHs be surveyed?

A11. Eligible facilities that are existing CAHs and hospitals converting to an REH may attest to meeting the REH CoPs and will not require an automatic on-site initial survey as eligible facilities are expected to be in full compliance with the existing CAH and hospital requirements (as applicable) at the time of the request for conversion. Facilities that were eligible as of December 27, 2020, that subsequently closed and re-enrolled in Medicare would require an initial on-site survey by the SA. These facilities do not have to submit an attestation, as an on-site initial survey will be performed to determine the facility is operational and in compliance with the REH requirements.

For existing CAHs and hospitals, the attestation allowing the facility to submit a general statement of compliance with the REH requirements and provisions of care may be completed on facility letterhead or the model template provided in memo QSO-22-XX-REH may be used. Subsequent REH surveys will be conducted as outlined in the annual Mission and Priority Document.

Q12. Are REHs eligible to be deemed by a CMS-approved accreditation organization?

A12. Yes, REHs are eligible to be deemed by Accrediting Organizations that have a Medicare-approved program for REHs. As of January 2023, there are not yet any CMS-approved Accrediting Organizations for REHs.

Q13. How are licensed beds determined or counted?

A13. The bed count will be determined by calculating the number of available bed days during the most recent cost reporting period divided by the number of days in the most recent cost reporting period. We use this methodology to determine if Medicare-dependent small rural

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hospitals meet the required bed count for that program. We believe this is an appropriate methodology for determining if a rural hospital meets the bed count requirement to seek REH designation, as this is a known and existing methodology for small rural hospitals seeking to determine bed count for eligibility in Medicare programs.

State Operations Manual

Appendix O – Survey Protocol, Regulations and Interpretive Guidelines for Rural Emergency Hospitals

(Rev.)

Part I Survey Protocol

Introduction

Regulatory & Policy Reference

Tasks in the Survey Protocol

Survey Team

Task 1 – Off-Site Survey Preparation

Task 2 – Entrance Activities

Task 3 – Information Gathering/Investigation

Task 4 – Preliminary Decision Making and Analysis of Findings

Task 5 – Exit Conference

Task 6 – Post-Survey Activities

Part II Regulations and Interpretive Guidelines for Rural Emergency Hospitals

§485.500 Basis & Scope

§485.502 Definitions

§485.504 Basic Requirements

§485.506 Designation and Certification of REHs

§485.508 Compliance with Federal, State and Local Laws and Regulations

§485.510 Governing Body and Organizational Structure of the REH

§485.514 Provision of Services

§485.516 Emergency Services

§485.518 Laboratory Services

§485.520 Radiologic Services

§485.522 Pharmaceutical Services

§485.524 Additional Outpatient Medical and Health Services

§485.526 Infection Prevention and Control and Antibiotic Stewardship Programs

§485.528 Staffing and Staff Responsibilities

§485.530 Nursing Services

§485.532 Discharge Planning

§485.534 Patient Rights

§485.536 Quality Assessment and Performance Improvement Program

§485.538 Agreements

§485.540 Medical Records

§485.542 Emergency Preparedness

§485.544 Physical Environment

§485.546 Skilled Nursing Facility Distinct Part Unit

Survey Protocol

Introduction

Rural Emergency Hospitals (REHs) are required to be in compliance with the Federal requirements set forth in the Medicare Conditions of Participation (CoP) in order to participate in Medicare and be eligible to receive Medicare/Medicaid payment. The goal of a REH survey is to determine if the REH is in compliance with the CoPs set forth at 42 CFR Part 485, Subpart E.

Certification of REH compliance with the CoPs is accomplished through observations, interviews, and document/record reviews. The survey process focuses on a REH's performance of organizational and patient-focused functions and processes as well as the safety of the environment of care within the REH. The REH survey is the means used to assess compliance with Federal health, safety, and quality standards that will assure that the patients receive safe, quality care and services within an environment that is safe.

Regulatory & Policy Reference

- The Medicare CoPs for REHs are found at 42 CFR Part 485, Subpart E.
- Survey authority and compliance regulations can be found at 42 CFR Part 488 Subpart A.
- If an individual or entity (REH) refuses, upon reasonable request, to allow immediate access to either a State Survey Agency (SA) or CMS surveyor, the Office of Inspector General (OIG) may exclude the REH from participation in the Medicare and Medicaid programs in accordance with 42 CFR 1001.1301. See State Operations Manual (SOM) section 2708.
- If an REH fails to grant immediate access upon a reasonable request to an SA or other CMS-authorized entity for the purpose of determining, in accordance with 42 CFR 488.3, whether the REH meets the applicable CoP, CMS may terminate the REH Medicare provider agreement in accordance with 42 CFR 489.53(a)(18).
- If a REH refuses to permit copying of any records or other information by, or on behalf of, CMS, as necessary to determine or verify compliance with participation requirements, CMS may terminate the REH's Medicare provider agreement in accordance with 42 CFR 489.53(a)(13).
- The CMS SOM provides CMS instructions and processes regarding survey and certification activities.

Surveyors assess REH compliance with the applicable CoPs for all services, areas and locations in which the provider receives reimbursement for patient care services billed under its CMS

Certification Number (CCN), as well as certain entities that provide services to the REH on a contractual basis. These areas include all emergency, observation and outpatient services including practice locations, buildings and facilities (including, but not limited to, generators, electrical rooms, food services, HVAC, supply areas, sterilization areas, etc.).

Although the survey generally occurs during daytime working hours (Monday through Friday), surveyors may conduct the survey at other times. These survey hours may include weekends and times outside of daytime (Monday through Friday) working hours. When the survey begins at times outside of normal work times, the survey team modifies the survey, if needed, in recognition of patients' activities and the staff available.

All REH surveys are unannounced. Do not provide REHs with advance notice of the survey. The SAs and CMS may not make any communications or requests to a REH that would amount to advance notice of a survey (with the exception of providing resurvey timeframes as stated in the SOM). See [SOM Chapter 2 section 2700A](#) for information regarding unannounced surveys

Tasks in the Survey Protocol

Listed below, and discussed in this document, are the tasks that comprise the survey protocol for REH surveys.

Task 1 Off-Site Survey Preparation

Task 2 Entrance Activities

Task 3 Information Gathering/ Investigation

Task 4 Preliminary Decision Making and Analysis of Findings

Task 5 Exit Conference

Task 6 Post-Survey Activities

Survey Team

- **Size and Composition** - The SA (or the CMS Location for Federal teams) decides the composition and size of the team. In general, a suggested survey team for a full survey of a REH would include 1-2 surveyors who will be at the facility for one or more days. Each survey team should include at least one RN with hospital or CAH survey experience, as well as other surveyors who have the expertise needed to determine whether the REH is in compliance with the CoPs. Survey team size and composition are normally based on the following factors:
 - Size of the facility to be surveyed, based on average daily census;
 - Complexity of services offered, including outpatient services;
 - Type of survey to be conducted;

- Whether the facility has special care units or off-site clinics or locations;
 - Whether the facility has a historical pattern of serious deficiencies or complaints;
 - Whether new surveyors are to accompany a team as part of their training.
- **Qualifications for REH Surveyors** - Minimum qualifications. Surveys must be conducted by individuals who meet minimum qualifications prescribed by CMS. In addition, before any State or Federal surveyor may serve on a REH survey team (except as a trainee), he/she must have successfully completed the relevant CMS-sponsored basic REH surveyor training courses and any associated prerequisites. New surveyors may accompany the team as part of their training prior to completing the basic training courses.
- **Team Coordinator** - Surveyors conduct the survey under the leadership of a Team Coordinator. The SA (or the RO for Federal teams) should designate the Team Coordinator. The Team Coordinator is responsible for assuring that all survey preparation and survey activities are completed within the specified timeframes and in a manner consistent with this protocol, SOM, and SA procedures. Responsibilities of the Team Coordinator include:
- Scheduling the date and time of survey activities;
 - Acting as the spokesperson for the team;
 - Assigning staff to areas of the REH or tasks for the survey;
 - Facilitating time management;
 - Encouraging and facilitating on-going communication among team members;
 - Evaluating team progress;
 - Coordinating daily team meetings;
 - Coordinating any ongoing discussions with REH leadership (as determined appropriate by the circumstances and SA/RO policy) and providing on-going feedback, as appropriate, to REH leadership on the status of the survey;
 - Coordinating Task 2 Entrance Conference;
 - Facilitating Task 4 Preliminary Decision Making;
 - Coordinating Task 5 Exit Conference;
 - Ensuring that all survey team activities are conducted in accordance with CMS procedures;
 - Ensuring that the team completes all applicable forms prescribed by CMS, including Form CMS-2567.

Task 1 – Off-Site Survey Preparation

General Objectives

The objective of this task is to analyze information about the REH in order to identify areas of potential concern to be investigated during the survey. Information obtained about the REH will

also allow the SA (or the CMS location for Federal teams) to determine survey team size and composition, and to develop a preliminary survey plan. The type of REH information needed includes:

- 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.
- Review the initial action plan in the CMS survey database for information regarding services offered by the REH, existence of a Skilled Nursing Facility (SNF) Distinct Part Unit (DPU), the number, type and location of off-site locations, number and category of personnel.
- Waivers and variances, if they exist. Determine if there are any applicable survey directive(s) from the SA or the CMS location; and
- Any additional information available about the REH (e.g. the REH's Web site, any media reports about the REH, etc.).

Note: Since REHs are a newly formed provider beginning January 1, 2023, previous survey results of the facility as an eligible CAH or rural hospital may be reviewed to determine patterns and trends of compliance to inform the REH pre-survey process.

Off-Site Survey Preparation Team Meeting

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

During the meeting, discuss the following at a minimum.

- Information gathered by the Team Coordinator
- Significant information gathered from the CMS database;
- Review information submitted in initial action plan provided by REH;
- Layout of REH (if available);
- Preliminary team member assignments;
- Date, location and time team members will meet to enter the REH;
- The time for the daily team meetings; and
- Potential date and time of the exit conference.

Gather copies of or have access to resources that may be needed. These may include:

- REH regulations and interpretive guidelines (Appendix O)
- Survey protocols or modules
- Immediate Jeopardy (Appendix Q)
- Responsibilities of Medicare Participating Hospitals in Emergency Cases (Appendix V)

TASK 2 – Entrance Activities

General Objectives

The objectives of this task are to explain the survey process to the REH and obtain the information needed to conduct the survey.

General Procedures

Arrival

The entire survey team should enter the facility together. Upon arrival, surveyors should present their identification. The Team Coordinator should announce to the Administrator, or whoever is in charge, that a survey is being conducted. If the Administrator (or person in charge) is not on site or available (e.g., if the survey begins outside normal daytime, Monday – Friday working hours), ask that they be notified that a survey is being conducted. Do not delay the survey because the Administrator or other staff is/are not on site or available.

Entrance Conference

The entrance conference sets the tone for the entire survey. Be prepared and courteous, and make requests, not demands. The entrance conference should be informative, concise, and brief; it should not utilize a significant amount of time. Conduct the entrance conference with administrative staff available at the time of entrance (do not delay the survey to wait for additional management staff to arrive). During the entrance conference, the Team Coordinator should address the following:

- Explain the purpose and scope of the survey;
- Briefly explain the survey process;
- Introduce survey team members, including any additional surveyors who may join the team at a later time. Discuss the general area that each will be responsible for, and the various documents that they may request;
- Clarify that all REH areas and locations, departments, and patient care settings under the REH CCN may be surveyed, including any contracted patient care activities or patient services;
- Explain that all interviews will be conducted privately with patients, staff, and visitors, unless requested otherwise by the interviewee;

- Discuss and determine how the REH will ensure that surveyors are able to obtain the photocopies of material, records, and other information as they are needed;
 - Explain that surveyors will need to have access to one or more copying machines so they can personally make copies as needed;
 - If the REH uses electronic medical records or uses electronic documents for its policies, procedures, or other activities, explain that surveyors will need access to one or more printers so they can personally print documents as needed;
 - Explain that if the REH wishes, surveyors will make the REH an additional copy of every document that surveyors copy;
- Obtain the names, locations, and telephone numbers of key staff to whom questions should be addressed;
- Explain that the survey team will not be providing the REH with a list of all patients, staff, or visitors interviewed or records reviewed during the survey;
- Discuss the approximate time, location, and possible attendees of any meetings to be held during the survey. The Team Coordinator should coordinate any meetings with facility leadership; and
- Propose a date and time for the exit conference.

During the entrance conference, the Team Coordinator will arrange with the REH administrator, or available REH administrative/supervisory staff if the administrator is unavailable, to obtain the following:

- A location (e.g., conference room) where the team may meet privately during the survey;
- A telephone for team communications, preferably in the team meeting location;
- A list of department heads with their locations and telephone numbers;
- A copy of the REH's organizational chart;
- The names and addresses of all off-site locations operating under the same CCN;
- The REH's infection control plan;
- A list of employees;
- A list of current patients receiving care in the REH
- The medical staff bylaws and rules and regulations;
- A list of contracted services; and
- A copy of the REH's floor plan, indicating the location of patient care and treatment areas.
- The Team Coordinator will inform the REH that this is not an all-inclusive list and other documents/manuals may be requested throughout the survey depending on potential issues that may be identified.

During the entrance conference the Team Coordinator will inquire whether the REH wishes to have REH personnel accompany surveyors during their survey activities. The Team Coordinator

must explain that this is allowed as long as the REH personnel do not interfere or delay the survey. For example:

- When a patient or another REH staff person is interviewed, the accompanying REH staff must not provide the answers or interject information.
- The surveyor will inform the accompanying REH staff when an interview with a patient, patient family member, or REH staff person is confidential and they cannot be present.
- When the surveyor is to go to another unit, department or survey location and the REH guide is not present, the surveyor is never to delay while waiting for the arrival of the REH staff person. The survey must be conducted whether or not those personnel are present.
- The REH personnel must never be allowed to be present during discussions of findings. If a REH staff person enters the conference area during discussions, the discussions must stop until the REH staff person departs.

Surveying REHs with electronic health records (EHR) and other documents, such as, policies, procedures, or data related to compliance efforts.

During the entrance conference surveyors will establish with the REH the process they will follow in order to have unrestricted access to the medical record. Inform the REH as to whether the team will use one or a combination of the following:

- Surveyors will directly access the REH's EHR or other electronic documents. If this is the case, inform the REH that it must provide surveyor(s) with passcodes that will provide sufficient system access permissions that ensure the surveyor's ability to retrieve complete medical records, including, when requested, information from built-in audit features that enable identification of the date, time, and author for entries or changes made to the record. Inform the REH that the surveyor(s) must have sufficient access to review any REH documents needed to evaluate the REH's compliance with the CoPs (for example policies, procedures, schedules, Infection Control information, etc.) Whenever possible, the REH must provide surveyors electronic access to records in a read-only format or other secure format to avoid any inadvertent changes to the record. The provider is solely responsible for ensuring that all necessary back up of data and security measures are in place.
- Surveyors will utilize staff, such as nurses assigned to patient care units to review medical records, or Infection Control staff to review those activities. If this is the case, inform the REH that staff will be requested to access and display medical records for review by the surveyor. In other situations, the surveyor may request REH staff to access policies, procedures, Infection Control information, committee minutes, etc.
- Surveyors will request that experienced REH EHR users with appropriate system permissions be assigned as "navigators" to assist surveyors with retrieval of medical record information and other electronically stored information as needed for evaluation of the REH's compliance. If this is the case, an EHR navigator would assist a surveyor in

retrieving medical records and other electronically stored information that the surveyor has identified as needed to evaluate compliance. The navigator is expected to have sufficient system access permissions that ensure the navigator's ability to retrieve electronically stored REH records such as policies, committee minutes, and complete medical records. In addition, when requested, information from built-in audit features that enable identification of the date, time and author of entries or changes made to the record.

In REHs that use hybrid mixes of electronic and paper medical record systems, REH staff are expected to know which portions of the medical record are not captured in the EHR, to inform the surveyor of this, and to be able to retrieve those paper-based portions of the records as well.

Note: If a REH declines to provide the requested means of access to the surveyor when requested, the surveyor will first remind the REH that failure to provide access to records may, in accordance with 42 CFR 489.53(a)(5), be grounds for terminating the Medicare provider agreement. In a situation where the survey team requests a method of access other than surveyor direct access, and the REH offers to furnish only direct surveyor access to the EHR system, the SA must determine whether it is willing and able to continue the survey with the surveyor directly accessing the EHR system.

Arrange an interview with a member of the administrative staff to update and clarify information from the provider file.

REH Tours

Guided tours of the REH are not encouraged and should be avoided. A tour of a REH could consume several man-hours of allocated survey time and resources that are needed to conduct the survey.

Initial On-Site Team Meeting

After the conclusion of the Entrance Conference, the team will meet in order to evaluate information gathered and modify surveyor assignments, as necessary. The team should not delay the continuation of the survey process waiting for information from the provider, and should adjust survey activities as necessary. During the initial on-site team meeting, team members should:

- Review the scope of services;
- Identify all locations to be surveyed, including all off-site locations;
- Adjust surveyor assignments, as necessary, based on new information;
- Discuss issues such as change of ownership, sentinel events, construction activities, and disasters, if they have been reported;
- Discuss any issues that have been observed or reported while surveyors have been at the REH facility;

- Make an initial patient sample selection (the patient list may not be available immediately after the entrance conference, therefore the team may delay completing the initial patient sample selection a few hours as meets the needs of the survey team); and
- Set the next meeting time and date.

Sample Size and Selection

To select the patient sample, review the patient list provided by the facility and select patients who represent a cross section of the patient population and services, to include contracted services (e.g. emergency services, observation care etc.) provided. The sample should include emergency department visits including observation patients, outpatients and closed records of discharged patients. Open records should include information about care already provided by all services and departments. The anticipated discharge date should be used to assist in determining which patients will be in the REH long enough for the surveyor to contact the patient during the course of the survey. Patient logs (ED, OB, OR, etc.) in conjunction with the patient list provided by the facility, provide a good source to use when selecting patients for the sample. If the team finds it necessary during the survey to remove a patient from the sample (e.g., the patient refused to participate in an interview), replace this patient with another who fits a similar profile. Make the substitution as early in the survey as possible.

Whenever possible and appropriate, surveyors should interview patients that are in the facility during the time of the survey to assess the facility's compliance with the CoPs. Therefore, open patient records should be selected whenever possible. Open records allow the surveyor to conduct a patient-focused survey and allow the surveyor to compare the medical record with patient observations and interviews. There are situations where closed records will be needed to assess compliance and there may be other situations where there are not adequate numbers of open records to assess compliance. The selected patient records should reflect the scope of services provided by the facility. The sample needs to be no fewer than 20 patient records, provided that number is adequate to determine compliance. Additionally, ensure the sample of records is representative of the services provided by the REH including both the additional outpatient and health services offered (i.e. behavioral health, radiology, laboratory, surgical and maternal health) and emergency services in order to determine compliance with the applicable CoPs for the REH.

Note:

- Open records are medical records of patients who are currently receiving services in the REH.
- Closed records are medical records of patients who have been discharged, transferred, or are deceased.

Give each patient in the sample a unique identifier. Appropriate identifiable information should be kept on a separate identifier list. Do not use medical record numbers, Social Security numbers, care unit or billing record numbers to identify patients. To conduct an initial survey of a REH there must be enough patients currently in the REH and patient records (open and closed)

for surveyors to determine whether the REH can demonstrate compliance with all the applicable CoPs. The number of current and discharged patients and outpatients in relation to the complexity of care provided to patients and the length of stay of those patients needs to be large enough for surveyors to evaluate the manner and degree to which the REH satisfies all the standards within each CoP. Utilize the same sample size and selection methods as previously discussed. If a complaint is being investigated during the survey, patients who have been identified as part of a complaint should be added to the sample. Issues or concerns identified in complaints may be a focus of concern when selecting sample patients.

TASK 3 – Information Gathering & Investigation

General Objective

The objective of this task is to determine the REH's compliance with the Medicare CoPs through observations, interviews, and documentation review.

Guiding Principles

- Focus attention on actual and potential patient outcomes, as well as required processes.
- Assess the care and services provided, including the appropriateness of the care and services within the context of the regulations.
- Visit patient care settings, including observation units, outpatient clinics, anesthetizing locations, emergency departments, imaging, rehabilitation, etc.
- Observe the actual provision of care and services to patients and the effects of that care, in order to assess whether the care provided meets the needs of the individual patient.
- Use the interpretive guidelines and other published CMS policy statements to guide the survey.
- Use Appendix Q for guidance if Immediate Jeopardy is suspected.

General Procedures

During the Survey

- Visit as many patient care settings as possible, including all on campus and off campus patient care locations that bill for services under the REH's CCN. Because the REH's compliance with the requirements is being assessed, all patient care locations should be part of the total REH survey. A surveyor should observe what activities are taking place and assess the CoP that represent the scope and complexity of the patient care services located at each location, as well as, any other CoP that apply to those locations. Observation of the care environment must include assessing for safety risks in the patient care setting. The depth of assessment of the CoPs will be determined by what the

surveyor observes at each location. The surveyor expands the survey activities as necessary.

- On any Medicare survey, contracted patient care activities or patient services (such as dietary services, treatment services, diagnostic services, etc.) located on the REH campus or at REH provider-based locations should be included in the survey.
- The SA and surveyors have discretion whether to allow, or to refuse to allow, facility personnel to accompany the surveyors during a survey. Sometimes facility personnel may be helpful and may answer questions or point out concerns to the survey team. Conversely, facility personnel may sometimes hinder the surveyor, and argue about observed problems. Surveyors should decide whether to allow facility personnel to accompany them based on the circumstances at the time of the survey.
- If more than one surveyor, the team must meet at least daily in order to assess the status of the survey, to discuss each surveyor's findings, progress of completion of assigned tasks, areas of concern, and to identify areas for additional investigations. All issues must be discussed at the next available team meeting. Surveyors must not withhold their findings or areas of concern while individually attempting to make a final conclusion or while attempting to obtain conclusive evidence. The team meetings should include a briefing/update by each surveyor to the entire team that addresses findings and areas of concern that have been identified. It is important to note that team meetings are not to be individual briefings to the Team Coordinator; rather they must be briefings to the entire team so that the entire team is aware of all findings and the entire team can discuss how the presented findings are impacting their own findings. If areas of concern are identified in the discussion, the team should coordinate efforts to obtain additional information. Additional team meetings can be called at any time during the survey to discuss crucial problems or issues. The format for the daily team meetings is:
 - In an organized manner, each surveyor, in turn, will report their compliance concerns and identified or potential deficient practices to the entire team,
 - Other team members will add any of their own observations related to the issues brought up.
 - The Team Coordinator and other team members will suggest other ideas as to where to look or other survey methods to evaluate identified concerns.
- The Team Coordinator will maintain organized notes of the discussions for future follow-up.
 - **Note:** As needed, members of the team may participate by conference calls. This method works well when surveyors are in different areas or locations of the REH.
- All significant issues or significant adverse events must be brought to the Team Coordinator's attention immediately.

- Maintain open and ongoing dialogue with the REH staff throughout the survey process. Informal discussions with REH staff may be held in order to inform them of survey findings. This affords REH staff the opportunity to present additional information or to offer explanations concerning identified issues. Survey information must not be discussed unless the investigation process and data collection for the specific concerns is completed. Regular meetings with REH leadership are not encouraged, but a meeting may be needed when a problem conducting the survey has arisen and the Team Coordinator needs to explain procedures to REH leadership. Additionally, REH leadership may request a meeting with the Team Coordinator to address any concerns with the survey. If meetings with REH leadership are held, the Team Coordinator must be the spokesperson for the team.
- Surveyors should always maintain a professional working relationship with REH staff.
- Surveyors need to respect patient privacy and maintain patient confidentiality at all times during the survey.
- Surveyors should maintain their role as representatives of a regulatory agency. Although non-consultative information may be provided upon request, the surveyor is not a consultant.

Patient Review

A comprehensive review of care and services received by each patient in the sample should be part of the survey. A comprehensive review includes observations of care/services provided to the patient, patient and/or family interview(s), staff interview(s), and medical record review. After obtaining the patient's permission, observe each sample patient receiving treatments (e.g., intravenous therapy and wound dressing changes) and observe the care provided in a variety of treatment settings, as necessary, to determine if patient needs are met.

Observations

Observations provide first-hand knowledge of REH practice and the provision of care and services to emergency department patients, observation patients and outpatients. The regulations and interpretive guidelines offer guidance for conducting observations. Observation of the care environment provides valuable information about how the care delivery system works and how REH departments work together to provide care. Surveyors are encouraged to make observations, complete interviews, and review records and policies/procedures by stationing themselves as physically close to patient care as possible. While completing a chart review, for instance, it may be possible to also observe the environment and the patients, staff interactions with patients, safety hazards, and infection control practices. When conducting observations, particular attention should be given to the following:

- Patient care, including treatments and therapies in all patient care settings;
- Staff member activities, equipment, documentation, building structure, sounds and smells;

- People, care, activities, processes, documentation, policies, equipment, etc., that are present that should not be present, as well as, those that are not present that should be present;
- Integration of all services, such that the REH is functioning as one integrated whole;
- Whether quality assurance (QA) is a REH-wide activity, incorporating every service and activity of the provider and whether every facility department and activity reports to, and receives reports from, the REH's central organized body managing the facility-wide QA program;
- Storage, security, and confidentiality of medical records; and
- Environmental risks. Examples may include, but are not limited to, unattended cleaning carts, unattended hazardous cleaning solutions, unlocked medications, and ligature risks in areas where psychiatric patients may have care provided.

A surveyor should take complete notes of all observations and should document: the date and time of the observation(s); location; patient identifiers, individuals present during the observation, and the activity being observed (e.g., therapy, treatment modality, etc.).

A surveyor should have observations verified by the patient, family, REH staff, other survey team member(s), or by another mechanism. For example, when finding an outdated medication in the pharmacy, ask the pharmacist to verify that the drug is outdated. In addition, a surveyor should integrate the data from observations with data gathered through interviews and document reviews.

A surveyor must not touch or examine patients by themselves. However, in certain circumstances, it is permissible and necessary to determine the physical condition of patients. Whenever a surveyor views it necessary to determine the physical condition of the patient, the surveyor must request that a staff member examine the patient in the surveyor's presence. The health and dignity of the patient is always of paramount concern. Additionally, if the surveyor believes that blankets or clothing are hiding bedsores, bruises, or incontinence, and with the patient's permission, they may remove the coverings and decide based on observation.

In all situations, surveyors must obtain the patient's (or authorized representative's) permission prior to making any examination. The health and dignity of the patient is always of paramount concern. A surveyor must respect the patient's right to refuse to be examined.

Interviews

Interviews provide a method to collect information, and to verify and validate information obtained through observations. Informal interviews should be conducted throughout the duration of the survey. Use the information obtained from interviews to determine what additional observations, interviews, and record reviews are necessary.

When conducting interviews, observe the following:

- Maintain detailed documentation of each interview conducted. Document the interview date, time, and location; the full name and title of the person interviewed; and key points made and/or topics discussed. To the extent possible, document quotes from the interviewee.
- Interviews with REH staff should be brief. Use a few well-phrased questions to elicit the desired information. For example, to determine if a staff member is aware of disaster procedures and his/her role in such events, simply ask, “If you smelled smoke, what would you do?”
- When interviewing staff, begin your interviews with staff that work most closely with the patient.
- Conduct patient interviews regarding their knowledge of their plan of care, the implementation of the plan, and the quality of the services received. Other topics for patient or family interview may include advanced directives and the REH’s grievance/complaint procedure.
- Interviews with patients must be conducted in privacy and with the patient’s prior permission.
- Use open-ended questions during your interview.
- Validate all information obtained.
- Telephone interviews may be conducted if necessary, but a preference should be made for in-person interviews.
- Integrate the data from interviews with data gathered through observations and document reviews.

Staff interviews should gather information about the staff’s knowledge of the patient’s needs, plan of care, and progress toward goals. Problems or concerns identified during a patient or family interview should be addressed in the staff interview in order to validate the patient’s perception, or to gather additional information.

Patient interviews should include questions specific to the patient’s condition, reason for admission, quality of care received, and the patient’s knowledge of their plan of care. For instance, a surgical patient should be questioned about the process for preparation for surgery, the patient’s knowledge of and consent for the procedure, pre-operative patient teaching, post-operative patient goals and discharge plan.

Document Review

Document review focuses on a REH’s compliance with the CoPs. When conducting a document review, document the source and date of the information obtained. When making document copies, identify the original date of the document and indicate the date and time

the copies were made. Once a document review is completed, integrate the data obtained with data gathered through observations and interviews to decide if the REH is in compliance with the CoPs. Documents reviewed may be both written and electronic and include the following:

- Patient's clinical records, to validate information gained during the interviews, as well as for evidence of notice of rights, advanced directives, discharge planning instructions, and patient teaching. This review will provide a broad picture of the patient's care. Plans of care and discharge plans should be initiated immediately upon admission, and be modified, as patient care needs change. The record review for that patient who has undergone surgery would include a review of the pre-surgical assessment, informed consent, operative report, and pre-, inter-, and postoperative anesthesia notes. Although team members may have a specific area assigned during the survey, the team should avoid duplication of efforts during review of medical records and each surveyor should review the record as a whole instead of targeting the assigned area of concern. Surveyors should use open patient records rather than closed records, whenever practical.
- Closed medical records may be used to determine past practice, and the scope or frequency of a deficient practice. Closed records should also be reviewed to provide information about services that are not being provided by the REH at the time of the survey. For example, if there are no obstetrical patients in the facility at the time of the survey, review closed OB records to determine care practices, or to evaluate past activities that cannot be evaluated using open records. In the review of closed clinical records, review all selected medical records for an integrated plan of care, timelines of implementation of the plan of care, and the patient responses to the interventions.
- Personnel files to determine if staff members have the appropriate qualifications including educational requirements, have had the necessary training required, and are licensed, if it is required (the sample selection, both numbers and types of personnel files to be reviewed, will be based on individual CoPs and issues being investigated);
- Privileging files to determine if the REH complies with CMS requirements and State law, as well as, follows its own written policies for medical staff privileges and credentialing;
- Maintenance records to determine if equipment is periodically examined and to determine if it is in good working order and if environmental requirements have been met;
- Staffing documents to determine if adequate numbers and types of staff are provided according to the number and acuity of patients;
- Policy and procedure manuals. When reviewing policy and procedure manuals, verify with the person in charge of an area that the policy and procedure manuals are current;

- Contracts, if applicable, to what requirements are provided under arrangements or agreements.

Electronic Documents Including EHR

Electronic access to records will not eliminate the need for a surveyor to print a paper copy or to request a paper copy of certain parts of certain records. However, the surveyor shall make reasonable efforts to avoid, where possible, the printing of entire records. It is neither expected nor advisable to ask that all requested records be printed out for the surveyor to review. Surveyors will request print-outs or screen shots selectively, based on their preliminary survey findings. The surveyor should print or request a paper copy of only those parts of records that are needed to support findings of noncompliance.

The goal of the surveyor's observation of how the EHR is used by REH staff is to determine whether staff can enter into and retrieve the information necessary for their patient's care in a timely fashion.

- Healthcare staff must be able to demonstrate their ability to access parts of the record necessary for the provision of care for their patients.
- The focus of the review is determining staff competence in using the EHR system as opposed to the surveyor's ability to navigate the system.

Surveyors must investigate what happens when the computer is unavailable or offline, whether planned or unplanned. Some examples might include:

- How to register, admit, transfer, move, or discharge patients;
- How to order, determine, and record medications and administration of medications;
- How to order, determine, and record treatments; and
- How to obtain laboratory reports and other testing results.

Photocopies

Surveyors must make photocopies of all documents needed to support survey findings. Photocopies support survey findings, and therefore in order to ensure accurate copies of the documents needed, the survey team must either make their own copies or hand carry the material to the copy machine where they directly observe hospital staff make the requested copies and then take immediate possession of the copies. If requested by the REH, the surveyor should make the REH a copy of all items photocopied. All photocopies need to be dated and timed as to when photocopied, and identified such as "REH IV management policy-12/05/22 page 3" or "Patient # 6, progress note – 12/05/22."

Task 4 - Preliminary Decision Making and Analysis of Findings

General Objectives

The general objectives of this task are to integrate findings, review and analyze all information collected from observations, interviews, and record reviews, and to determine whether or not the REH meets the CoPs found at 42 CFR Part 485, Subpart E. The team's preliminary decision-making and analysis of findings assist it in preparing the exit conference report. Based on the team's decisions, additional activities may need to be initiated.

General Procedures

Preparation

Prior to beginning this Task, each team member should review his/her notes, worksheets, records, observations, interviews, and document reviews to assure that all investigations are complete and organized for presentation to the team.

Discussion Meeting

Prior to the preliminary decision-making meeting all members of the team should review their findings and concerns regarding the REH's compliance and be prepared to present their findings during the meeting. Each team member should be familiar with the team's findings as discussed during the daily team meetings. The preliminary decision-making meeting is not organized or conducted in the same manner as daily team meetings. The meeting will be conducted as a team.

- The entire survey team that is at the REH must be present. Additionally:
 - Survey team members who are off-site must join the meeting by conference call.
 - Survey team members who have already departed the survey should join the meeting by conference call when possible.
- The Team Coordinator will sequentially discuss the regulations in order as they appear in the regulations, CoP, Standard, or Tag, depending on what issues have been identified during the survey.
- Surveyors will share their findings, evaluate the evidence, and make team decisions regarding compliance with each requirement when that requirement is discussed.
 - Team discussion is to include the official interpretation of the regulation as put forth in the interpretive guidelines for each regulation (**Note:** citations of non-compliance must be based on non-compliance with regulation; citations of non-compliance cannot be based on noncompliance with the interpretive guidelines),
 - The discussion must address potential outcomes (**Note:** actual adverse outcomes are not needed to identify or cite a deficient practice),

- The Team Coordinator must verify with the team whether all evidence has been collected to support any citations (this must be done at the time each requirement is discussed). If not, the Team Coordinator must direct someone to collect that evidence prior to the exit conference,
- The Team Coordinator must take accurate notes for later reference and to assist him/her in preparation for the exit conference.

Decisions about deficiencies are to be team decisions, with each member having input. The team should document their decisions, the substance of the evidence, and the numbers of patients impacted, in order to identify the extent of REH's noncompliance. The team must ensure that their findings are supported by adequate documentation of observations, interviews, and document reviews, and includes any needed evidence such as photocopies. Any additional documentation or evidence needed to support identified noncompliance should be gathered prior to the exit conference but at a minimum prior to exiting the REH.

Determining the Severity of Deficiencies

The regulations at 42 CFR 488.26 states, "The decision as to whether there is compliance with a particular requirement, condition of participation, or condition for coverage depends upon the manner and degree to which the provider or supplier satisfies the various standards within each condition." When noncompliance with a condition of participation is noted, the determination of whether a lack of compliance is at the standard- or condition-level depends upon the degree (how severe, how dangerous, how critical, etc.) and manner (how prevalent, how many, how pervasive, how often, etc.) of the lack of compliance. The cited level of noncompliance is determined by the interrelationship between the degree and manner of the noncompliance.

A deficiency at the condition level may be due to noncompliance in a single standard or several standards, or parts of standards within the condition, or because of noncompliance with a single part (tag) representing a severe or critical health or safety breach. Even a seemingly small breach in critical actions or at critical times can kill or severely injure a patient, and represents a critical or severe health or safety threat.

A deficiency is at the standard level when there is noncompliance with any single requirement or several requirements within a particular standard that are not of such character as to substantially limit a facility's capacity to furnish adequate care, or which would not jeopardize or adversely affect the health or safety of patients if the deficient practice recurred.

On a complaint investigation where the REH states that it has corrected the deficient practice/issue (noncompliance) that is the basis of the complaint, issues for the survey team to consider would include:

- Is the corrective action superficial or inadequate, or is the corrective action adequate and systemic?
- Is the deficient practice still present?
- Has the REH implemented the corrective intervention(s) or action(s)?

- Has the REH taken a quality improvement approach to the corrective action to ensure monitoring, tracking and sustainability?
- Have the REH's corrective actions made it unlikely for the deficient practice to recur?

The survey team uses their judgment to determine if any action(s) taken by the REH prior to the survey is sufficient to correct the noncompliance and to prevent the deficient practice from continuing or recurring. If the deficient practice is corrected prior to the survey, do not cite noncompliance. However, if the noncompliance with any requirements is noted during the survey, even when the REH corrects the noncompliance during the survey, cite noncompliance.

All identified noncompliance must be cited even when corrected on site during the survey. Identified non-compliance must be cited at either Immediate Jeopardy, Condition-level or Standard-level. Citing noncompliance at the appropriate level is important to the integrity of the survey process. Citing too high a level is unfair to the REH. Citing noncompliance at a level below the noted degree and manner of the noncompliance does not ensure that the REH will develop acceptable plans of correction and implement corrective actions, does not depict whether the care provided adversely affects the health and safety of patients, and whether continued deficient practices may lead to adverse patient outcomes such as injury or death.

Gathering Additional Information

If it is determined that the survey team needs additional information to determine the REH's compliance or noncompliance, the Team Coordinator should decide the best way to conduct the additional review.

Task 5 - Exit Conference

General Objective

The general objective of this task is to inform the REH staff of the team's preliminary findings.

Prior to the Exit Conference

- The Team Coordinator is responsible for organization of the presentation of the exit.
- The team determines who will present the findings.
- If the team feels it may encounter a problem during the exit, they should contact their immediate supervisor.

Discontinuation of an Exit Conference

It is CMS general policy to conduct an exit conference at the conclusion of each survey. However, there are some situations that justify refusal to continue or to conduct an exit conference. For example:

- If the provider is represented by counsel (all participants in the exit conference should identify themselves), surveyors may refuse to conduct the conference if the lawyer tries to turn it into an evidentiary hearing; or
- Any time the provider creates an environment that is hostile, intimidating, or inconsistent with the informal and preliminary nature of an exit conference, surveyors may refuse to conduct or continue the conference. Under such circumstances, it is suggested that the Team Coordinator stop the exit conference and call the State agency for further direction.

Recording the Exit Conference

If the REH wishes to audio record the conference, it must provide two tapes and tape recorders, recording the meeting simultaneously. In order for this to occur, the REH must be able to supply a copy of the recording, or transmit a copy in a format the survey team can utilize (or if the survey team has the capability to record the discussion, the team can use its own recording device for its purposes).

General Principles

The following general principles apply when conducting an exit conference:

- The REH's leadership determines which REH staff will attend the exit conference.
- The identity of an individual patient or staff member must not be revealed in discussing survey results. Identity includes not just the name of an individual patient or staff member, but also includes any references by which identity might be deduced.
- Because of the ongoing dialogue between surveyors and REH staff during the survey, there should be few instances in which the REH is unaware of surveyor concerns or has not had an opportunity to present additional information prior to the exit conference.

Exit Conference Structure

The following discusses the sequence of events in conducting an exit conference.

- **Introductory Remarks**
 - Thank everyone for cooperation during the survey.
 - Introduce all team members, mentioning any that have concluded their portion of the survey and have left the REH.
 - Briefly mention the reason for the survey.
 - Explain that the exit conference is an informal meeting to discuss preliminary findings.
 - Indicate that official findings are presented in writing on the Form CMS-2567.

- **Ground Rules**
 - Explain how the team will conduct the exit conference and any ground rules.
 - Ground rules may include waiting until the surveyor finishes discussing each deficiency before accepting comments from REH staff.
 - State that the REH staff will have an opportunity to present new information or evidence of compliance after the exit conference for consideration after the survey
- **Presentation of Findings**
 - Avoid referring to data tag numbers.
 - Present the preliminary findings of noncompliance, explaining why the findings are a violation. If the provider asks for the regulatory basis, provide it.
 - Refrain from making any general comments (e.g., “Overall the REH did well”). Stick to the facts. Do not rank findings. Treat requirements as equal as possible.
 - Refrain from making global statements, such as, “The REH does not have any Condition level citations”, or “The REH only has lower level citations”. Except in citations of Immediate Jeopardy, the survey team does not discuss citation levels for individual citations or for the overall survey.
 - Do not identify unmet requirements as condition- or standard-level. Avoid statements such as, “the condition was not met” or “the standard was not met.” It is better to state, “the requirement is not met.”
 - If immediate jeopardy was identified, explain the significance and the need for immediate correction. Follow instructions in Appendix Q.
 - Assure that all findings are discussed at the exit conference.
- **Closure**
 - Explain that a statement of deficiencies (Form CMS-2567) will be mailed within 10 business days to the REH.
 - Explain that the Form CMS-2567 is the document disclosed to the public about the REH’s deficiencies and what is being done to remedy them. The Form CMS-2567 is made public no later than 90 calendar days following completion of the survey. It documents specific deficiencies cited, the REH’s plans for correction and timeframes, and it provides an opportunity for the REH to refute survey findings and furnish documentation that requirements are met.

- Inform the REH that a written plan of correction (POC) must be submitted to the survey agency within 10 business days following receipt of the written statement of deficiencies.
- Explain the required characteristics of a plan of correction. The characteristics of an acceptable POC include:
 - Separately addressing each citation;
 - A Quality Assessment and Performance Improvement (QAPI) methodology for each citation and address improvements in the hospital's systems in order to prevent the likelihood of the cited deficient practice from recurring;
 - A procedure for implementing each corrective action taken;
 - A procedure for monitoring the corrective actions taken for each citation Providing the identity or position of the person who will monitor the corrective action and the frequency of monitoring;
 - Dates each corrective action for each citation was/will be completed;
 - The administrator or appropriate individual must sign and date the Form CMS-2567 before returning it to the survey agency.
- The submitted plan of correction must meet the approval of the State agency, or in some cases the CMS Location for it to be acceptable.

All team members should leave the REH together immediately following the exit conference. If the REH staff provides further information for review, the Team Coordinator should decide the best way to conduct the further review. It is usually prudent for at least two individuals to remain.

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 CMS Location should follow 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, using the Principles of Documentation as reference;
- 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); and
- Compilation of documents for the provider file.

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 provider or supplier has submitted an acceptable plan of correction for achieving compliance within a reasonable period of time acceptable to CMS.” 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 for REHs

(Rev.)

§485.500 Basis and Scope

(Rev.)

Section 1861(kkk) of the Act requires the Secretary to establish the conditions REHs must meet in order to participate in the Medicare program and which are considered necessary to ensure the health and safety of patients receiving services at these entities.

§485.502 Definitions

(Rev.)

As used in this subpart, *rural emergency hospital or REH* means an entity that operates for the purpose of providing emergency department services, observation care, and other outpatient medical and health services specified by the Secretary in which the annual per patient average length of stay does not exceed 24 hours. The time calculation for determining the length of stay of a patient receiving REH services begins with the registration, check-in or triage of the patient (whichever occurs first) and ends with the discharge of the patient from the REH. The discharge occurs when the physician or other appropriate clinician has signed the discharge order, or at the time the outpatient service is completed and documented in the medical record. The entity must not provide inpatient services, except those furnished in a unit that is a distinct part licensed as a skilled nursing facility to furnish post-hospital extended care services.

O-100

§485.504 Basic Requirements

(Rev.)

Participation as an REH is limited to facilities that—

- (a) Meet the definition in § 485.502.**
- (b) Have in effect a provider agreement as defined at § 489.3 of this chapter to provide services.**
- (c) Meet the conditions of participation set out in this subpart.**

O-102

(Rev.)

§485.506 Designation and certification of REHs

CMS certifies a facility as an REH if the facility was, as of December 27, 2020—

(a) A critical access hospital; or

(b) A hospital as defined in section 1886(d)(1)(B) of the Act with not more than 50 beds located in a county (or equivalent unit of local government) that is considered rural (as defined in section 1881(d)(2)(D) of the Act); or

(c) A hospital as defined in section 1881(d)(1)(B) of the Act with not more than 50 beds that was treated as being located in a rural area that has had an active reclassification from urban to rural status as specified in § 412.103 of this chapter as of December 27, 2020.

O-110

(Rev.)

§485.508 Compliance with Federal, state, and local laws and regulations.

(a) The REH must be in compliance with applicable Federal laws related to the health and safety of patients.

(b) The REH must be located in a state that provides for the licensing of such hospitals under state or applicable local law; and is

(1) Licensed in the state as an REH; or

(2) Approved as meeting standards for licensing established by the agency of the state or locality responsible for licensing hospitals.

(c) The REH must assure that personnel are licensed or meet other applicable standards that are required by state or local laws to provide services within the applicable scope of practice.

Interpretive Guidelines §485.508(a)-(c)

Guidance is pending and will be updated in future release.

O-140

(Rev.)

§485.510 Governing body and organizational structure of the REH

There must be an effective governing body, or responsible individual or individuals, that is legally responsible for the conduct of the REH. If an REH does not have an organized governing body, the person or persons legally responsible for the conduct of the REH must carry out the functions specified in this subpart that pertain to the governing body.

Interpretive Guidance §485.510

Guidance is pending and will be updated in future release

O-142

(Rev.)

§485.510(a) Standard: Medical Staff. The governing body must:

(1) Determine, in accordance with state law, which categories of practitioners are eligible candidates for appointment to the medical staff.

Interpretive Guidelines §485.510(a)(1)

Guidance is pending and will be updated in future release

O-144

(Rev.)

§485.510(a) Standard: Medical Staff. The governing body must:

(2) Appoint members of the medical staff after considering the recommendations of the existing members of the medical staff.

Interpretive Guidelines §485.510(a)(2)

Guidance is pending and will be updated in future release

O-146

(Rev.)

§485.510(a) Standard: Medical Staff. The governing body must:

(3) Ensure that the medical staff has bylaws.

Interpretive Guidelines §485.510(a)(3)

Guidance is pending and will be updated in future release

O-148

(Rev.)

§485.510(a) Standard: Medical Staff. The governing body must:

(4) Approve medical staff bylaws and other medical staff rules and regulations.

Interpretive Guidelines §485.510(a)(4)

Guidance is pending and will be updated in future release

O-150

(Rev.)

§485.510(a) Standard: Medical Staff. The governing body must:

(5) Ensure that the medical staff is accountable to the governing body for the quality of care provided to patients.

Interpretive Guidelines §485.510(a)(5)

Guidance is pending and will be updated in future release

O-152

(Rev.)

§485.510(a) Standard: Medical Staff. The governing body must:

(6) Ensure the criteria for selection are individual character, competence, training, experience, and judgment.

Interpretive Guidelines §485.510(a)(6)

Guidance is pending and will be updated in future release

O-154

(Rev.)

§485.510(a) Standard: Medical Staff. The governing body must:

(a)(6)(i) Members of the medical staff must be legally and professionally qualified for the positions to which they are appointed and for the performance of privileges granted. The REH grants privileges in accordance with recommendations from qualified medical personnel.

Interpretive Guidelines §485.510(a)(6)(i)

Guidance is pending and will be updated in future release

O-156

(Rev.)

§485.510(a) Standard: Medical Staff. The governing body must:

(a)(6)(ii) Medical staff privileges must be periodically reappraised by the REH. The scope of procedures performed in the REH must be periodically reviewed and amended as appropriate.

Interpretive Guidelines §485.510(a)(6)(ii)

Guidance is pending and will be updated in future release

O-158

(Rev.)

§485.510(a) Standard: Medical Staff. The governing body must:

(a)(6)(iii) If the REH assigns patient care responsibilities to practitioners other than physicians, it must have established policies and procedures, approved by the governing body, for overseeing and evaluating their clinical activities.

Interpretive Guidelines §485.510(a)(6)(iii)

Guidance is pending and will be updated in future release

O-160

(Rev.)

§485.510(a) Standard: Medical Staff. The governing body must:

(7) Ensure that under no circumstances is the accordance of staff membership or professional privileges in the REH dependent solely upon certification, fellowship, or membership in a specialty body or society.

Interpretive Guidelines §485.510(a)(7)

Guidance is pending and will be updated in future release

O-162

(Rev.)

§485.510(a) Standard: Medical Staff. The governing body must:

(8) Ensure that, when telemedicine services are furnished to the REH's patients through an agreement with a distant-site hospital, the agreement is written and that it specifies that it is the responsibility of the governing body of the distant-site hospital to meet the requirements in paragraphs (a)(1) through (7) of this section with regard to the distant-site hospital's physicians and practitioners providing telemedicine services. The governing body of the REH whose patients are receiving the telemedicine services may, in accordance

with § 485.512(a)(3), grant privileges based on its medical staff recommendations that rely on information provided by the distant-site hospital.

Interpretive Guidelines §485.510(a)(8)

Guidance is pending and will be updated in future release

O-164

(Rev.)

§485.510(a) Standard: Medical Staff. The governing body must:

(9) Ensure that when telemedicine services are furnished to the REH's patients through an agreement with a distant-site telemedicine entity, the written agreement specifies that the distant-site telemedicine entity is a contractor of services to the REH and as such, in accordance with paragraph (b) of this section, furnishes the contracted services in a manner that permits the REH to comply with all applicable conditions of participation for the contracted services, including, but not limited to, the requirements in paragraphs (a)(1) through (7) of this section with regard to the distant-site telemedicine entity's physicians and practitioners providing telemedicine services. The governing body of the REH whose patients are receiving the telemedicine services may, in accordance with § 485.512(a)(4), grant privileges to physicians and practitioners employed by the distant-site telemedicine entity based on such REH's medical staff recommendations; such staff recommendations may rely on information provided by the distant-site telemedicine entity.

Interpretive Guidelines §485.510(a)(9)

Guidance is pending and will be updated in future release

O-166

(Rev.)

§485.510(a) Standard: Medical Staff. The governing body must:

(10) Consult directly with the individual assigned the responsibility for the organization and conduct of the REH's medical staff, or their designee. At a minimum, this direct consultation must occur periodically throughout the fiscal or calendar year and include discussion of matters related to the quality of medical care provided to patients of the REH. For a multi-facility system, including a multi-hospital or multi-REH system, using a single governing body, the single multi-facility or multi-REH system governing body must consult directly with the individual responsible for the organized medical staff (or their designee) of each hospital or REH within its system in addition to the other requirements of this paragraph (a).

Interpretive Guidelines §485.510(a)(10)

Guidance is pending and will be updated in future release

O-168

(Rev.)

§485.510(b) Standard: Contracted Services

(b) The governing body must be responsible for services furnished in the REH whether or not they are furnished under contracts. The governing body must ensure that a contractor of services (including one for shared services and joint ventures) furnishes services that permit the REH to comply with all applicable conditions of participation and standards for the contracted services.

Interpretive Guidelines §485.510(b)

Guidance is pending and will be updated in future release

O-170

(Rev.)

§485.510(b) Standard: Contracted Services

(1) The governing body must ensure that the services performed under a contract are provided in a safe and effective manner.

Interpretive Guidelines §485.510(b)(1)

Guidance is pending and will be updated in future release

O-172

(Rev.)

§485.510(b) Standard: Contracted Services

(2) The REH must maintain a list of all contracted services, including the scope and nature of the services provided.

Interpretive Guidelines §485.510(b)(2)

Guidance is pending and will be updated in future release

O-180

(Rev.)

§485.512 Medical Staff

The REH must have an organized medical staff that operates under bylaws approved by the governing body, and which is responsible for the quality of medical care provided to patients by the REH.

Interpretive Guidelines §485.512

Guidance is pending and will be updated in future release

O-182

(Rev.)

§485.512(a) Standard: Eligibility and process for appointment to medical staff

(a) The medical staff must be composed of doctors of medicine or osteopathy. In accordance with state law, including scope-of-practice laws, the medical staff may also include other categories of physicians (as listed at § 482.12(c)(1) of this chapter and non-physician practitioners who are determined to be eligible for appointment by the governing body.

Interpretive Guidelines §485.512(a)

Guidance is pending and will be updated in future release

O-184

(Rev.)

§485.512(a) Standard: Eligibility and process for appointment to medical staff

(1) The medical staff must periodically conduct appraisals of its members.

Interpretive Guidelines §485.512(a)(1)

Guidance is pending and will be updated in future release

O-186

(Rev.)

§485.512(a) Standard: Eligibility and process for appointment to medical staff

(2) The medical staff must examine the credentials of all eligible candidates for medical staff membership and make recommendations to the governing body on the appointment of these candidates in accordance with state law, including scope-of-practice laws, and the medical staff bylaws, rules, and regulations. A candidate who has been recommended by the medical staff and who has been appointed by the governing body is subject to all

medical staff bylaws, rules, and regulations, in addition to the requirements contained in this section.

Interpretive Guidelines §485.512(a)(2)

Guidance is pending and will be updated in future release

O-188

(Rev.)

§485.512(a) Standard: Eligibility and process for appointment to medical staff

(3) When telemedicine services are furnished to the REH's patients through an agreement with a distant-site hospital, the governing body of the REH whose patients are receiving the telemedicine services may choose, in lieu of the requirements in paragraphs (a)(1) and (2) of this section, to have its medical staff rely upon the credentialing and privileging decisions made by the distant-site hospital when making recommendations on privileges for the individual distant-site physicians and practitioners providing such services, if the REH's governing body ensures, through its written agreement with the distant-site hospital, that all of the following provisions are met:

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

Interpretive Guidelines §485.512(a)(3)(i)-(iv)

Guidance is pending and will be updated in future release

O-190

(Rev.)

§485.512(a) Standard: Eligibility and process for appointment to medical staff

(4) When telemedicine services are furnished to the REH's patients through an agreement with a distant-site telemedicine entity, the governing body of the REH whose patients are receiving the telemedicine services may choose, in lieu of the requirements in paragraphs (a)(1) and (2) of this section, to have its medical staff rely upon the credentialing and privileging decisions made by the distant-site telemedicine entity when making recommendations on privileges for the individual distant-site physicians and practitioners providing such services, if the REH's governing body ensures, through its written agreement with the distant-site telemedicine entity, that the distant-site telemedicine entity furnishes services that, in accordance with paragraph (d) of this section, permit the REH to comply with all applicable conditions of participation for the contracted services. The REH's governing body must also ensure, through its written agreement with the distant-site telemedicine entity, that all of the following provisions are met:

(i) The distant-site telemedicine entity's medical staff credentialing and privileging process and standards at least meet the standards at § 485.510(a)(1) through (7) and paragraphs (a)(1) and (2) of this section.

(ii) The individual distant-site physician or practitioner is privileged at the distant-site telemedicine entity providing the telemedicine services, which provides the REH with a current list of the distant-site physician's or practitioner's privileges at the distant-site telemedicine entity.

(iii) The individual distant-site physician or practitioner holds a license issued or recognized by the state in which the REH whose patients are receiving such telemedicine services is located.

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

Interpretive Guidelines §485.512(a)(4)(i)-(iv)

Guidance is pending and will be updated in future release

O-192

(Rev.)

§485.512(b) Standard: Medical Staff Organization and Accountability

(b) The medical staff must be well organized and accountable to the governing body for the quality of the medical care provided to patients.

Interpretive Guidelines §485.512(b)

Guidance is pending and will be updated in future release

O-194

(Rev.)

§485.512(b) Standard: Medical Staff Organization and Accountability

(1) The medical staff must be organized in a manner approved by the governing body.

Interpretive Guidelines §485.512(b)(1)

Guidance is pending and will be updated in future release

O-196

(Rev.)

§485.512(b) Standard: Medical Staff Organization and Accountability

(2) If the medical staff has an executive committee, a majority of the members of the committee must be doctors of medicine or osteopathy.

Interpretive Guidelines §485.512(b)(2)

Guidance is pending and will be updated in future release

O-198

(Rev.)

§485.512(b) Standard: Medical Staff Organization and Accountability

(3) The responsibility for organization and conduct of the medical staff must be assigned only to one of the following:

(i) An individual doctor of medicine or osteopathy.

(ii) A doctor of dental surgery or dental medicine, when permitted by state law of the state in which the hospital is located.

(iii) A doctor of podiatric medicine, when permitted by state law of the state in which the hospital is located.

Interpretive Guidelines §485.512(b)(3)(i)-(iii)

Guidance is pending and will be updated in future release

O-200

(Rev.)

§485.512(b) Standard: Medical Staff Organization and Accountability

(4) If an REH is part of a system consisting of multiple separately certified hospitals, critical access hospitals, and/or REHs, and the system elects to have a unified and integrated medical staff for its member hospitals, critical access hospitals, and/or REHs after determining that such a decision is in accordance with all applicable state and local laws, each separately certified REH must demonstrate that:

(i) The medical staff members of each separately certified REH in the system (that is, all medical staff members who hold specific privileges to practice at that REH) have voted by majority, in accordance with medical staff bylaws, either to accept a unified and integrated medical staff structure or to opt out of such a structure and to maintain a separate and distinct medical staff for their respective REH;

(ii) The unified and integrated medical staff has bylaws, rules, and requirements that describe its processes for self-governance, appointment, credentialing, privileging, and oversight, as well as its peer review policies and due process rights guarantees, and which include a process for the members of the medical staff of each separately certified REH (that is, all medical staff members who hold specific privileges to practice at that REH) to be advised of their rights to opt out of the unified and integrated medical staff structure after a majority vote by the members to maintain a separate and distinct medical staff for their REH;

(iii) The unified and integrated medical staff is established in a manner that takes into account each member REH's unique circumstances and any significant differences in patient populations and services offered in each hospital, critical access hospital (CAH), and REH; and

(iv) The unified and integrated medical staff establishes and implements policies and procedures to ensure that the needs and concerns expressed by members of the medical staff, at each of its separately certified hospitals, CAHs, and REHs, regardless of practice or location, are given due consideration, and that the unified and integrated medical staff has mechanisms in place to ensure that issues localized to particular hospitals, CAHs, and REHs are duly considered and addressed.

Interpretive Guidelines §485.512(b)(4)(i)-(iv)

Guidance is pending and will be updated in future release

O-202

(Rev.)

§485.512(c) Standard: Medical Staff Bylaws

The medical staff must adopt and enforce bylaws to carry out its responsibilities. The bylaws must:

- (1) Be approved by the governing body.**
- (2) Include a statement of the duties and privileges of each category of medical staff (for example, active, courtesy, etc.).**
- (3) Describe the organization of the medical staff.**
- (4) Describe the qualifications to be met by a candidate in order for the medical staff to recommend that the candidate be appointed by the governing body.**
- (5) Include criteria for determining the privileges to be granted to individual practitioners and a procedure for applying the criteria to individuals requesting privileges. For distant-site physicians and practitioners requesting privileges to furnish telemedicine services under an agreement with the REH, the criteria for determining privileges and the procedure for applying the criteria are also subject to the requirements in § 485.510(a)(8) and (9) and paragraphs (a)(3) and (4) of this section.**

Interpretive Guidelines §485.512(c)(1)-(5)

Guidance is pending and will be updated in future release

O-250

(Rev.)

§485.514 Provision of Services

- (a) The REH's health care services must be furnished in accordance with appropriate written policies that are consistent with applicable state law.**

Interpretive Guidelines §485.514(a)

Guidance is pending and will be updated in future release

O-252

(Rev.)

§485.514 Provision of Services

- (b) The policies must be developed with the advice of members of the REH's professional health care staff, including one or more doctors of medicine or osteopathy and one or more physician assistants, nurse practitioners, or clinical nurse specialists, if they are on staff under the provisions of § 485.528(b)(1).**

Interpretive Guidelines §485.514(b)

Guidance is pending and will be updated in future release

O-254

(Rev.)

§485.514 Provision of Services

(c) The policies must include the following:

- (1) A description of the services the REH furnishes, including those furnished through agreement or arrangement.**
- (2) Policies and procedures for emergency medical services.**
- (3) Guidelines for the medical management of health problems that include the conditions requiring medical consultation and/or patient referral, the maintenance of health care records, and procedures for the periodic review and evaluation of the services furnished by the REH.**
- (4) Policies and procedures that address the post-acute care needs of patients receiving services in the REH.**

Interpretive Guidelines §485.514(c)(1)-(4)

Guidance is pending and will be updated in future release

O-256

(Rev.)

§485.514 Provision of Services

(d) The policies must be reviewed at least biennially by the group of professional personnel required under paragraph (b) of this section and updated as necessary by the REH.

Interpretive Guidelines §485.514(d)

Guidance is pending and will be updated in future release

O-300

(Rev.)

§485.516 Emergency Services

The REH must provide the emergency care necessary to meet the needs of its patients in accordance with acceptable standards of practice.

Interpretive Guidelines §485.516

Guidance is pending and will be updated in future release

O-302

(Rev.)

§485.516(a) Standard: Organization and Direction

a) The emergency services of the REH must be—

- (1) Organized under the direction of a qualified member of the medical staff; and**
- (2) Integrated with other departments of the REH.**

Interpretive Guidelines §485.516(a)(1)(2)

Guidance is pending and will be updated in future release

O-304

(Rev.)

§485.516(b) Standard: Personnel

(b) There must be adequate medical and nursing personnel qualified in emergency care to meet the written emergency procedures and needs anticipated by the facility.

Interpretive Guidelines §485.516(b)

Guidance is pending and will be updated in future release

O-306

(Rev.)

§485.516(c) Standard: Compliance with CAH Requirements

(c) The REH must meet the requirements specified in § 485.618, with respect to:

- (1) 24-hour availability of emergency services (§ 485.618(a)).**
- (2) Equipment, supplies, and medication (§ 485.618(b)).**
- (3) Blood and blood products (§ 485.618(c)).**
- (4) Personnel (§ 485.618(d)).**
- (5) Coordination with emergency response systems (§ 485.618(e)).**

Interpretive Guidelines §485.516(c)(1)-(5)

Guidance is pending and will be updated in future release

O-320

(Rev.)

§485.518 Laboratory Services

The REH must provide basic laboratory services essential to the immediate diagnosis and treatment of the patient consistent with nationally recognized standards of care for emergency services, patient population, and services offered. The REH must ensure that—

(a) Laboratory services are available, either directly or through a contractual agreement with a certified laboratory that meets requirements of part 493 of this chapter.

(b) Emergency laboratory services are available 24 hours a day.

Interpretive Guidelines §485.518(a)(b)

Guidance is pending and will be updated in future release

O-330

(Rev.)

§485.520 Radiologic Services

The REH must maintain, or have available, diagnostic radiologic services. If therapeutic services are also provided, the therapeutic services, as well as the diagnostic services, must be furnished by the REH and provided by personnel qualified under state law. The REH must ensure that REH patients or personnel are not exposed to radiation hazards.

Interpretive Guidelines §485.520

Guidance is pending and will be updated in future release

O-332

(Rev.)

§485.520(a) Standard: Radiologic Services

(a) The REH must maintain, or have available, radiologic services according to needs of the patients.

Interpretive Guidelines §485.520(a)

Guidance is pending and will be updated in future release

O-334

(Rev.)

§485.520(b) Standard: Safety for Patients and Personnel

(b) The radiologic services, particularly ionizing radiology procedures, must be free from hazards for patients and personnel.

Interpretive Guidelines §485.520(b)

Guidance is pending and will be updated in future release

O-336

(Rev.)

§485.520(b) Standard: Safety for Patients and Personnel

(1) Proper safety precautions must be maintained against radiation hazards. This includes adequate shielding for patients, personnel, and facilities, as well as appropriate storage, use, and disposal of radioactive materials.

Interpretive Guidelines §485.520(b)(1)

Guidance is pending and will be updated in future release

O-338

(Rev.)

§485.520(b) Standard: Safety for Patients and Personnel

(2) Periodic inspection of equipment must be made and hazards identified must be promptly corrected.

Interpretive Guidelines §485.520(b)(2)

Guidance is pending and will be updated in future release

O-340

(Rev.)

§485.520(b) Standard: Safety for Patients and Personnel

(3) Radiation workers must be checked periodically, by the use of exposure meters or badge tests, for amount of radiation exposure.

Interpretive Guidelines §485.520(b)(3)

Guidance is pending and will be updated in future release

O-342

(Rev.)

§485.520(b) Standard: Safety for Patients and Personnel

(4) Radiologic services must be provided only on the order of practitioners with clinical privileges or, consistent with state law, of other practitioners authorized by the medical staff and the governing body to order the services.

Interpretive Guidelines §485.520(b)(4)

Guidance is pending and will be updated in future release

O-344

(Rev.)

§485.520(c) Standard: Personnel

(1) The REH must have a full-time, part-time, or consulting qualified radiologist, or other personnel qualified under State law, to interpret only those radiologic tests that are determined by the medical staff to require specialized knowledge. For purposes of this section, a radiologist is a doctor of medicine or osteopathy who is qualified by education and experience in radiology.

(2) Only personnel designated as qualified by the medical staff may use the radiologic equipment and administer procedures.

Interpretive Guidelines §485.520(c)(1)(2)

Guidance is pending and will be updated in future release

O-346

(Rev.)

§485.520(d) Standard: Records

(d) Records of radiologic services must be maintained.

(1) The radiologist or other practitioner who performs radiology services must sign reports of their interpretations.

(2) The REH must maintain the following for at least 5 years:

(i) Copies of reports and printouts.

(ii) Films, scans, and other image records, as appropriate.

Interpretive Guidelines §485.520(d)(1)(2)(i)(ii)

Guidance is pending and will be updated in future release

O-360

(Rev.)

§485.522 Pharmaceutical Services

The REH must have pharmaceutical services that meet the needs of its patients. The REH must have a pharmacy or a drug storage area that is directed by a registered pharmacist or other qualified individual in accordance with state scope of practice laws. The medical staff is responsible for developing policies and procedures that minimize drug errors. This function may be delegated to the REH's registered pharmacist or other qualified individual.

Interpretive Guidelines §485.522

Guidance is pending and will be updated in future release

O-362

(Rev.)

§485.522(a) Standard: Pharmacy Management and Administration

(a) The pharmacy or drug storage area must be administered in accordance with accepted professional principles and in accordance with state and Federal laws.

Interpretive Guidelines §485.522(a)

Guidance is pending and will be updated in future release

O-364

(Rev.)

§485.522(a) Standard: Pharmacy Management and Administration

(1) A pharmacist or competent individual in accordance with state scope of practice laws must be responsible for developing, supervising, and coordinating all the activities of the pharmacy services. The pharmacist or competent individual in accordance with state law and scope of practice must be available for a sufficient time to provide oversight of the REH's pharmacy services based on the scope and complexity of the services offered at the REH.

Interpretive Guidelines §485.522(a)(1)

Guidance is pending and will be updated in future release

O-366

(Rev.)

§485.522(a) Standard: Pharmacy Management and Administration

(2) The pharmaceutical service must have an adequate number of personnel to ensure quality pharmaceutical services for the provision of all services provided by the REH.

Interpretive Guidelines §485.522(a)(2)

Guidance is pending and will be updated in future release

O-368

(Rev.)

§485.522(a) Standard: Pharmacy Management and Administration

(3) Current and accurate records must be kept of the receipt and disposition of all scheduled drugs.

Interpretive Guidelines §485.522(a)(3)

Guidance is pending and will be updated in future release

O-370

(Rev.)

§485.522(b) Standard: Delivery of Services

(b) Drugs and biologicals must be controlled and distributed in accordance with applicable standards of practice, consistent with Federal and state law, to ensure patient safety.

Interpretive Guidelines §485.522(b)

Guidance is pending and will be updated in future release

O-372

(Rev.)

§485.522(b) Standard: Delivery of Services

(1) All compounding, packaging, and dispensing of drugs must be done by a licensed pharmacist or a licensed physician, or under the supervision of a pharmacist or competent

individual in accordance with state law and scope of practice and performed consistent with state and Federal laws.

Interpretive Guidelines §485.522(b)(1)

Guidance is pending and will be updated in future release

O-374

(Rev.)

§485.522(b) Standard: Delivery of Services

(2) All drugs and biologicals must be kept in a secure area, and locked when appropriate.

(i) All drugs listed in Schedules II, III, IV, and V of the Comprehensive Drug Abuse Prevention and Control Act of 1970 ([21 U.S.C. 801 et seq.](#)) must be kept locked within a secure area.

(ii) Only authorized personnel may have access to locked areas.

Interpretive Guidelines §485.522(b)(2)(i)(ii)

Guidance is pending and will be updated in future release

O-376

(Rev.)

§485.522(b) Standard: Delivery of Services

(3) Outdated, mislabeled, or otherwise unusable drugs and biologicals must not be available for patient use.

Interpretive Guidelines §485.522(b)(3)

Guidance is pending and will be updated in future release

O-378

(Rev.)

§485.522(b) Standard: Delivery of Services

(4) Drugs and biologicals must be removed from the pharmacy or storage area only by personnel designated in the policies of the medical staff and pharmaceutical service, in accordance with Federal and state law.

Interpretive Guidelines §485.522(b)(4)

Guidance is pending and will be updated in future release

O-380

(Rev.)

§485.522(c) Standard: Administration of Drugs

(c) Drugs must be prepared and administered according to established policies and acceptable standards of practice.

Interpretive Guidelines §485.522(c)

Guidance is pending and will be updated in future release

O-382

(Rev.)

§485.522(c) Standard: Administration of Drugs

(1) Adverse reactions must be reported to the physician responsible for the patient and must be documented in the record.

Interpretive Guidelines §485.522(c)(1)

Guidance is pending and will be updated in future release

O-384

(Rev.)

§485.522(c) Standard: Administration of Drugs

(2) Blood transfusions, blood products, and intravenous medications must be administered in accordance with state law and approved medical staff policies and procedures.

Interpretive Guidelines §485.522(c)(2)

Guidance is pending and will be updated in future release

O-386

(Rev.)

§485.522(c) Standard: Administration of Drugs

(3) Orders given orally for drugs and biologicals must be followed by a written order, signed by the prescribing physician or other authorized prescriber.

Interpretive Guidelines §485.522(c)(3)

Guidance is pending and will be updated in future release

O-388

(Rev.)

§485.522(c) Standard: Administration of Drugs

(4) There must be an REH procedure for reporting transfusion reactions, adverse drug reactions, and errors in administration of drugs.

Interpretive Guidelines §485.522(c)(4)

Guidance is pending and will be updated in future release

O-400

(Rev.)

§485.524 Additional Outpatient Medical and Health Services

If the REH provides outpatient medical and health services in addition to providing emergency services and observation care, the medical and health services must be appropriately organized and meet the needs of the patients in accordance with acceptable standards of practice.

Interpretive Guidelines §485.524

Guidance is pending and will be updated in future release

O-402

(Rev.)

§485.524(a) Standard: Patient Services

(a) The REH may provide outpatient and medical health diagnostic and therapeutic items and services that are commonly furnished in a physician's office or at another entry point into the health care delivery system that include, but are not limited to, radiology, laboratory, outpatient rehabilitation, surgical, maternal health, and behavioral health services. If the REH provides outpatient and medical health diagnostic and therapeutic items and services, those items and services must align with the health needs of the community served by the REH. If the REH provides outpatient medical and health services in addition to providing emergency services, the REH must—

Interpretive Guidelines §485.524(a)

Guidance is pending and will be updated in future release

O-404

(Rev.)

§485.524(a) Standard: Patient Services

(1) Provide items and services based on nationally recognized guidelines and standards of practice;

Interpretive Guidelines §485.524(a)(1)

Guidance is pending and will be updated in future release

O-406

(Rev.)

§485.524(a) Standard: Patient Services

(2) Have a system in place for referral from the REH to different levels of care, including follow-up care, as appropriate;

Interpretive Guidelines §485.524(a)(2)

Guidance is pending and will be updated in future release

O-408

(Rev.)

§485.524(a) Standard: Patient Services

(3) Have effective communication systems in place between the REH and the patient (or responsible individual) and their family, ensuring that the REH is responsive to their needs and preferences;

Interpretive Guidelines §485.524(a)(3)

Guidance is pending and will be updated in future release

O-410

(Rev.)

§485.524(a) Standard: Patient Services

(4) Have established relationships with hospitals that have the resources and capacity available to deliver care that is beyond the scope of care delivered at the REH; and

Interpretive Guidelines §485.524(a)(4)

Guidance is pending and will be updated in future release

O-412

(Rev.)

§485.524(a) Standard: Patient Services

(5) Have personnel providing these services who meet the requirements at paragraph (b) of this section.

Interpretive Guidelines §485.524(a)(5)

Guidance is pending and will be updated in future release

O-414

(Rev.)

§485.524(b) Standard: Personnel for Additional Outpatient and Medical Health Services

The REH must—

(1) Assign one or more individuals to be responsible for outpatient services.

Interpretive Guidelines §485.524(b)(1)

Guidance is pending and will be updated in future release

O-416

(Rev.)

§485.524(b) Standard: Personnel for Additional Outpatient and Medical Health Services

The REH must—

(2) Have appropriate professional and nonprofessional personnel available at each location where outpatient services are offered, based on the scope and complexity of outpatient services.

Interpretive Guidelines §485.524(b)(2)

Guidance is pending and will be updated in future release

O-418

(Rev.)

§485.524(b) Standard: Personnel for Additional Outpatient and Medical Health Services

The REH must—

(3) For any specialty services offered at the REH, have a doctor of medicine or osteopathy, nurse practitioner, clinical nurse specialist, or physician assistant providing services with experience and training in the specialty service area and in accordance with their scope of practice.

Interpretive Guidelines §485.524(b)(3)

Guidance is pending and will be updated in future release

O-420

(Rev.)

§485.524(c) Standard: Orders for Outpatient Medical and Health Services

(c) Outpatient medical and health services must be ordered by a practitioner who meets the following conditions:

(1) Is responsible for the care of the patient.

(2) Is licensed in the state where they provide care to the patient.

(3) Is acting within their scope of practice under state law.

(4) Is authorized in accordance with state law and policies adopted by the medical staff, and approved by the governing body, to order the applicable outpatient services. This applies to the following:

(i) All practitioners who are appointed to the REH's medical staff and who have been granted privileges to order the applicable outpatient services.

(ii) All practitioners not appointed to the medical staff, but who satisfy the requirements of paragraphs (c)(1) through (4) of this section for authorization by the medical staff and the REH for ordering the applicable outpatient services for their patients.

Interpretive Guidelines §485.524(c)(1)-(4)(i)(ii)

Guidance is pending and will be updated in future release

O-422

(Rev.)

§485.524(d) Standard: Surgical Services

(d) If the REH provides outpatient surgical services, surgical procedures must be performed in a safe manner by qualified practitioners who have been granted clinical privileges by the governing body, or responsible individual, of the REH in accordance with the designation requirements under paragraph (a) of this section.

(1) *Designation of qualified practitioners.* The REH designates the practitioners who are allowed to perform surgery for REH patients, in accordance with its approved policies and procedures, and with state scope of practice laws. Surgery is performed only by—

(i) A doctor of medicine or osteopathy, including an osteopathic practitioner recognized under section 1101(a)(7) of the Act;

(ii) A doctor of dental surgery or dental medicine; or

(iii) A doctor of podiatric medicine.

Interpretive Guidelines §485.524(d)(1)(i)-(iii)

Guidance is pending and will be updated in future release

O-424

(Rev.)

§485.524(d) Standard: Surgical Services

(2) Anesthetic risk and evaluation. (i) A qualified practitioner, as specified in paragraph (a) of this section, must examine the patient immediately before surgery to evaluate the risk of the procedure to be performed.

(ii) A qualified practitioner, as specified in paragraph (d)(3) of this section, must examine each patient before surgery to evaluate the risk of anesthesia.

(iii) Before discharge from the REH, each patient must be evaluated for proper anesthesia recovery by a qualified practitioner, as specified in paragraph (d)(3) of this section.

Interpretive Guidelines §485.524(d)(2)(i)-(iii)

Guidance is pending and will be updated in future release

O-426

(Rev.)

§485.524(d) Standard: Surgical Services

(3) *Administration of anesthesia.* The REH designates the person who is allowed to administer anesthesia to REH patients in accordance with its approved policies and procedures and with state scope-of-practice laws.

(i) Anesthesia must be administered by only—

- (A) A qualified anesthesiologist;**
- (B) A doctor of medicine or osteopathy other than an anesthesiologist; including an osteopathic practitioner recognized under section 1101(a)(7) of the Act;**
- (C) A doctor of dental surgery or dental medicine;**
- (D) A doctor of podiatric medicine;**
- (E) A certified registered nurse anesthetist (CRNA), as defined in § 410.69(b) of this chapter;**
- (F) An anesthesiologist's assistant, as defined in § 410.69(b) of this chapter; or**
- (G) A supervised trainee in an approved educational program, as described in § 413.85 or §§ 413.76 through 413.83 of this chapter.**

Interpretive Guidelines §485.524(d)(3)(i)

Guidance is pending and will be updated in future release

O-428

(Rev.)

§485.524(d) Standard: Surgical Services

(ii) In those cases in which a CRNA administers the anesthesia, the anesthetist must be under the supervision of the operating practitioner except as provided in paragraph (e) of this section. An anesthesiologist's assistant who administers anesthesia must be under the supervision of an anesthesiologist.

Interpretive Guidelines §485.524(d)(3)(ii)

Guidance is pending and will be updated in future release

O-430

(Rev.)

§485.524(d) Standard: Surgical Services

(4) *Discharge.* All patients are discharged in the company of a responsible adult, except those exempted by the practitioner who performed the surgical procedure.

Interpretive Guidelines §485.524(d)(4)

Guidance is pending and will be updated in future release

O-432

(Rev.)

§485.524(d) Standard: Surgical Services

(5) Standard: State exemption. (i) An REH may be exempted from the requirement for physician supervision of CRNAs as described in paragraph (d)(3) of this section, if the state in which the REH is located submits a letter to CMS signed by the Governor, following consultation with the state's Boards of Medicine and Nursing, requesting exemption from physician supervision for CRNAs. The letter from the Governor must attest that they have consulted with the state Boards of Medicine and Nursing about issues related to access to and the quality of anesthesia services in the state and has concluded that it is in the best interests of the state's citizens to opt-out of the current physician supervision requirement, and that the opt-out is consistent with state law.

(ii) The request for exemption and recognition of state laws and the withdrawal of the request may be submitted at any time, and are effective upon submission.

Interpretive Guidelines §485.524(d)(5)(i)(ii)

Guidance is pending and will be updated in future release

O-460

(Rev.)

§485.526 Infection Prevention and Control and Antibiotic Stewardship Program

The REH must have active facility-wide programs for the surveillance, prevention, and control of healthcare-associated infections (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 facility-wide quality assessment and performance improvement (QAPI) program.

Interpretive Guidelines §485.526

Guidance is pending and will be updated in future release

O-462

(Rev.)

§485.526 (a) Standard: Infection Prevention and Control Program Organization and Policies

(a) The REH 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, or responsible individual, 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 §485.526(a)(1)

Guidance is pending and will be updated in future release

O-464

(Rev.)

§485.526 (a) Standard: Infection Prevention and Control Program Organization and Policies

The REH must demonstrate that:

(2) The infection prevention and control program, as documented in its policies and procedures, employs methods for preventing and controlling the transmission of infections within the REH and between the REH and other health care settings;

Interpretive Guidelines §485.526(a)(2)

Guidance is pending and will be updated in future release

O-466

(Rev.)

§485.526 (a) Standard: Infection Prevention and Control Program Organization and Policies

The REH must demonstrate that:

(3) The infection prevention and control program include surveillance, prevention, and control of HAIs, including maintaining a clean and sanitary environment to avoid sources and transmission of infection, and that the program also addresses any infection control issues identified by public health authorities; and

Interpretive Guidelines §485.526(a)(3)

Guidance is pending and will be updated in future release

O-468

(Rev.)

§485.526 (a) Standard: Infection Prevention and Control Program Organization and Policies

The REH must demonstrate that:

(4) The infection prevention and control program reflects the scope and complexity of the services furnished by the REH.

Interpretive Guidelines §485.526(a)(4)

Guidance is pending and will be updated in future release

O-470

(Rev.)

§485.526(b) Standard: Antibiotic Stewardship Program Organization and Policies

The REH 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, or responsible individual, 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 §485.526(b)(1)

Guidance is pending and will be updated in future release

O-472

(Rev.)

§485.526(b) Standard: Antibiotic Stewardship Program Organization and Policies

The REH must demonstrate that —

(2) The facility-wide antibiotic stewardship program:

(i) Demonstrates coordination among all components of the REH 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;

(ii) Documents the evidence-based use of antibiotics in all departments and services of the REH; and

(iii) Documents any improvements, including sustained improvements, in proper antibiotic use;

Interpretive Guidelines §485.526(b)(2)(i)-(iii)

Guidance is pending and will be updated in future release

O-474

(Rev.)

§485.526(b) Standard: Antibiotic Stewardship Program Organization and Policies

The REH must demonstrate that —

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

Interpretive Guidelines §485.526(b)(3)

Guidance is pending and will be updated in future release

O-476

(Rev.)

§485.526(b) Standard: Antibiotic Stewardship Program Organization and Policies

The REH must demonstrate that —

(4) The antibiotic stewardship program reflects the scope and complexity of the services furnished by an REH.

Interpretive Guidelines §485.526(b)(4)

Guidance is pending and will be updated in future release

O-478

(Rev.)

§485.526(c) Standard: Leadership Responsibilities

(c) (1) The governing body, or responsible individual, 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.

(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 the REH's QAPI leadership.

Interpretive Guidelines §485.526(c)(1)(i)(ii)

Guidance is pending and will be updated in future release

O-480

(Rev.)

§485.526(c) Standard: Leadership Responsibilities

(2) The infection prevention and control professional(s) are responsible for:

(i) The development and implementation of facility-wide infection surveillance, prevention, and control policies and procedures that adhere to nationally recognized guidelines.

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

(iii) Communication and collaboration with the REH's QAPI program on infection prevention and control issues.

(iv) Competency-based training and education of REH personnel and staff, including medical staff, and, as applicable, personnel providing contracted services in the REH, on the practical applications of infection prevention and control guidelines, policies and procedures.

(v) The prevention and control of HAIs, including auditing of adherence to infection prevention and control policies and procedures by REH personnel.

(vi) Communication and collaboration with the antibiotic stewardship program.

Interpretive Guidelines §485.526(c)(2)(i)-(vi)

Guidance is pending and will be updated in future release

O-482

(Rev.)

§485.526(c) Standard: Leadership Responsibilities

(3) The leader(s) of the antibiotic stewardship program is responsible for:

(i) The development and implementation of a facility-wide antibiotic stewardship program, based on nationally recognized guidelines, to monitor and improve the use of antibiotics.

(ii) All documentation, written or electronic, of antibiotic stewardship program activities.

(iii) Communication and collaboration with medical staff, nursing, and pharmacy leadership, as well as the REH's infection prevention and control and QAPI programs, on antibiotic use issues.

(iv) Competency-based training and education of REH personnel and staff, including medical staff, and, as applicable, personnel providing contracted services in the REH, on the practical applications of antibiotic stewardship guidelines, policies, and procedures.

Interpretive Guidelines §485.526(c)(3)(i)-(iv)

Guidance is pending and will be updated in future release

O-484

(Rev.)

§485.526(d) Standard: Unified and Integrated Infection Prevention and Control and Antibiotic Stewardship Programs for Multi-Facility Systems.

(d) If a REH is part of a system consisting of multiple separately certified hospitals, CAHs, and/or REHs using a system governing body that is legally responsible for the conduct of two or more hospitals, CAHs, and/or REHs, the system governing body can elect to have unified and integrated infection prevention and control and antibiotic stewardship programs for all of its member facilities 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 REHs meets all of the requirements of this section. Each separately certified REH subject to the system governing body must demonstrate that:

Interpretive Guidelines §485.526(d)

Guidance is pending and will be updated in future release

O-486

(Rev.)

§485.526(d) Standard: Unified and Integrated Infection Prevention and Control and Antibiotic Stewardship Programs for Multi-Facility Systems.

(1) The unified and integrated infection prevention and control and antibiotic stewardship programs are established in a manner that takes into account each member REH's unique circumstances and any significant differences in patient populations and services offered in each REH;

Interpretive Guidelines §485.526(d)(1)

Guidance is pending and will be updated in future release

O-488

(Rev.)

§485.526(d) Standard: Unified and Integrated Infection Prevention and Control and Antibiotic Stewardship Programs for Multi-Facility Systems.

(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 REHs, regardless of practice or location, are given due consideration;

Interpretive Guidelines §485.526(d)(2)

Guidance is pending and will be updated in future release

O-490

(Rev.)

§485.526(d) Standard: Unified and Integrated Infection Prevention and Control and Antibiotic Stewardship Programs for Multi-Facility Systems.

(3) The unified and integrated infection prevention and control and antibiotic stewardship programs have mechanisms in place to ensure that issues localized to particular REHs are duly considered and addressed; and

Interpretive Guidelines §485.526(d)(3)

Guidance is pending and will be updated in future release

O-492

(Rev.)

§485.526(d) Standard: Unified and Integrated Infection Prevention and Control and Antibiotic Stewardship Programs for Multi-Facility Systems.

(4) A qualified individual (or individuals) with expertise in infection prevention and control and in antibiotic stewardship has been designated at the REH 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 REH staff.

Interpretive Guidelines §485.526(d)(4)

Guidance is pending and will be updated in future release

O-494

(Rev.)

§485.526 (e) Standard: COVID-19 and Seasonal Influenza Reporting

(e) Beginning at the conclusion of the COVID-19 Public Health Emergency, as defined in § 400.200 of this chapter, and continuing until April 30, 2024, except when the Secretary specifies an earlier end date for the requirements of this paragraph (e), the REH must electronically report information about COVID-19 and seasonal influenza in a standardized format specified by the Secretary.

Interpretive Guidelines §485.526(e)

Guidance is pending and will be updated in future release

O-496

(Rev.)

§485.526 (e) Standard: COVID-19 and Seasonal Influenza Reporting

(1) Related to COVID-19, to the extent as required by the Secretary, this report must include the following data elements:

- (i) Suspected and confirmed COVID-19 infections among patients and staff.**
- (ii) Total COVID-19 deaths among patients and staff.**
- (iii) Personal protective equipment and testing supplies.**
- (iv) Ventilator use, capacity, and supplies.**
- (v) Total patient census and capacity.**
- (vi) Staffing shortages.**
- (vii) COVID-19 vaccine administration data of patients and staff.**
- (viii) Relevant therapeutic inventories or usage, or both.**

Interpretive Guidelines §485.526(e)(1)(i)-(viii)

Guidance is pending and will be updated in future release

O-498

(Rev.)

§485.526 (e) Standard: COVID-19 and Seasonal Influenza Reporting

(2) Related to seasonal influenza, to the extent as required by the Secretary, this report must include the following data elements:

(i) Confirmed influenza infections among patients and staff.

(ii) Total influenza deaths among patients and staff.

(iii) Confirmed co-morbid influenza and COVID-19 infections among patients and staff.

Interpretive Guidelines §485.526(e)(2)(i)-(iii)

Guidance is pending and will be updated in future release

O-500

(Rev.)

§485.526 (f) Standard: Reporting of Data Related to Viral and Bacterial Pathogens and Infectious Diseases of Pandemic and Epidemic Potential

(f) The REH must electronically report information on acute respiratory illness (including, but not limited to, seasonal influenza virus, influenza-like illness, and severe acute respiratory infection), SARS-CoV-2/COVID-19, and other viral and bacterial pathogens and infectious diseases of pandemic or epidemic potential only when the Secretary has declared a Public Health Emergency (PHE), as defined in § 400.200 of this chapter, directly related to such specific pathogens and infectious diseases. The requirements of this paragraph (f) will be applicable to local, state, regional, or national PHEs as declared by the Secretary.

Interpretive Guidelines §485.526(f)

Guidance is pending and will be updated in future release

O-502

(Rev.)

§485.526 (f) Standard: Reporting of Data Related to Viral and Bacterial Pathogens and Infectious Diseases of Pandemic and Epidemic Potential

(1) The REH must electronically report information about the infectious disease pathogen, relevant to the declared PHE, in a standardized format specified by the Secretary. To the extent as required by the Secretary, this report must include, the following:

(i) Suspected and confirmed infections of the relevant infectious disease pathogen among patients and staff.

(ii) Total deaths attributed to the relevant infectious disease pathogen among patients and staff.

(iii) Personal protective equipment and other relevant supplies in the REH.

(iv) Capacity and supplies in the REH relevant to the immediate and long term treatment of the relevant infectious disease pathogen, such as ventilator and dialysis/continuous renal replacement therapy capacity and supplies.

(v) Total patient census, capacity, and capability.

(vi) Staffing shortages.

(vii) Vaccine administration data of patients and staff for conditions monitored under this section and where a specific vaccine is applicable.

(viii) Relevant therapeutic inventories or usage, or both.

(ix) Isolation capacity, including airborne isolation capacity.

(x) Key co-morbidities or exposure risk factors, or both, of patients being treated for the pathogen or disease of interest in this section that are captured with interoperable data standards and elements.

Interpretive Guidelines §485.526(f)(1)(i)-(x)

Guidance is pending and will be updated in future release

O-504

(Rev.)

§485.526 (f) Standard: Reporting of Data Related to Viral and Bacterial Pathogens and Infectious Diseases of Pandemic and Epidemic Potential

(2) Unless the Secretary specifies an alternative format by which the REH must report these data elements, the REH must report the applicable infection (confirmed and suspected) and vaccination data in a format that provides person-level information, which must include medical record identifier, race, ethnicity, age, sex, residential county and zip code, and relevant comorbidities for affected patients. Facilities must not report any directly or potentially individually-identifiable information for affected patients (for example, name, social security number) that is not set out in this section or otherwise specified by the Secretary.

Interpretive Guidelines §485.526(f)(2)

Guidance is pending and will be updated in future release

O-506

(Rev.)

§485.526 (f) Standard: Reporting of Data Related to Viral and Bacterial Pathogens and Infectious Diseases of Pandemic and Epidemic Potential

(3) The REH must provide the information specified in this paragraph (f) on a daily basis, unless the Secretary specifies a lesser frequency, to the Centers for Disease Control and Prevention's (CDC) National Healthcare Safety Network or other CDC-supported surveillance systems as determined by the Secretary.

Interpretive Guidelines §485.526(f)(3)

Guidance is pending and will be updated in future release

O-508

(Rev.)

§485.526(g) Standard: COVID-19 Vaccination of REH Staff

(g) Until November 4, 2024, unless the Secretary specifies an earlier end date for the requirements of this paragraph (g), the REH must develop and implement policies and procedures to ensure that all staff are fully vaccinated for COVID-19. For purposes of this section, staff are considered fully vaccinated if it has been 2 weeks or more since they completed a primary vaccination series for COVID-19. The completion of a primary vaccination series for COVID-19 is defined here as the administration of a single-dose vaccine, or the administration of all required doses of a multi-dose vaccine.

Interpretive Guidelines §485.526(g)

Guidance is pending and will be updated in future release

O-510

(Rev.)

§485.526 (g) Standard: COVID-19 Vaccination of REH Staff

(1) Regardless of clinical responsibility or patient contact, the policies and procedures must apply to the following REH staff, who provide any care, treatment, or other services for the REH and/or its patients:

(i) REH employees;

(ii) Licensed practitioners;

(iii) Students, trainees, and volunteers; and

(iv) Individuals who provide care, treatment, or other services for the REH and/or its patients, under contract or by other arrangement.

Interpretive Guidelines §485.526(g)(1)(1)-(iv)

Guidance is pending and will be updated in future release

O-512

(Rev.)

§485.526 (g) Standard: COVID-19 Vaccination of REH Staff

(2) The policies and procedures of this section do not apply to the following REH staff:

(i) Staff who exclusively provide telehealth or telemedicine services outside of the REH setting and who do not have any direct contact with patients and other staff specified in paragraph (f)(1) of this section; and

(ii) Staff who provide support services for the REH that are performed exclusively outside of the REH setting and who do not have any direct contact with patients and other staff specified in paragraph (f)(1) of this section.

Interpretive Guidelines §485.526(g)(2)(i)(ii)

Guidance is pending and will be updated in future release

O-514

(Rev.)

§485.526 (g) Standard: COVID-19 Vaccination of REH Staff

(3) The policies and procedures must include, at a minimum, the following components:

(i) A process for ensuring all staff specified in paragraph (f)(1) of this section (except for those staff who have pending requests for, or who have been granted, exemptions to the vaccination requirements of this section, or those staff for whom COVID-19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations) have received, at a minimum, a single-dose COVID-19 vaccine, or the first dose of the primary vaccination series for a multi-dose COVID-19 vaccine prior to staff providing any care, treatment, or other services for the REH and/or its patients;

(ii) A process for ensuring that all staff specified in paragraph (f)(1) of this section are fully vaccinated for COVID-19, except for those staff who have been granted exemptions to the vaccination requirements of this section, or those staff for whom COVID-19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations;

(iii) A process for ensuring the implementation of additional precautions, intended to mitigate the transmission and spread of COVID-19, for all staff who are not fully vaccinated for COVID-19;

(iv) A process for tracking and securely documenting the COVID-19 vaccination status of all staff specified in paragraph (f)(1) of this section;

(v) A process for tracking and securely documenting the COVID-19 vaccination status of any staff who have obtained any booster doses as recommended by the CDC;

- (vi) A process by which staff may request an exemption from the staff COVID-19 vaccination requirements based on an applicable Federal law;**
- (vii) A process for tracking and securely documenting information provided by those staff who have requested, and for whom the REH has granted, an exemption from the staff COVID-19 vaccination requirements based on recognized clinical contraindications or applicable Federal laws;**
- (viii) A process for ensuring that all documentation, which confirms recognized clinical contraindications to COVID-19 vaccines and which supports staff requests for medical exemptions from vaccination, has been signed and dated by a licensed practitioner, who is not the individual requesting the exemption, and who is acting within their respective scope of practice as defined by, and in accordance with, all applicable state and local laws, and for further ensuring that such documentation contains:
 - (A) All information specifying which of the authorized COVID-19 vaccines are clinically contraindicated for the staff member to receive and the recognized clinical reasons for the contraindications; and**
 - (B) A statement by the authenticating practitioner recommending that the staff member be exempted from the REH's COVID-19 vaccination requirements for staff based on the recognized clinical contraindications;****
- (ix) A process for ensuring the tracking and secure documentation of the vaccination status of staff for whom COVID-19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations, including, but not limited to, individuals with acute illness secondary to COVID-19, and individuals who received monoclonal antibodies or convalescent plasma for COVID-19 treatment; and**
- (x) Contingency plans for staff who are not fully vaccinated for COVID-19.**

Interpretive Guidelines §485.526(g)(3)(i)-(x)

Guidance is pending and will be updated in future release

O-550

(Rev.)

§485.528 Staffing and Staff Responsibilities

Interpretive Guidelines §485.528

Guidance is pending and will be updated in future release

O-552

(Rev.)

§485.528 (a) Standard: Emergency Department Staffing

(a) The emergency department of the REH must be staffed 24 hours a day, 7 days a week by an individual or individuals competent in the skills needed to address emergency medical care. This individual(s) must be able to receive patients and activate the appropriate medical resources to meet the care needed by the patient.

Interpretive Guidelines §485.528(a)

Guidance is pending and will be updated in future release

O-554

(Rev.)

§485.528 (b) Standard: Staffing

(b) (1) The REH must have a professional health care staff that includes one or more doctors of medicine or osteopathy, and may include one or more physician assistants, nurse practitioners, or clinical nurse specialists.

(2) Any ancillary personnel are supervised by the professional staff.

(3) The staff is sufficient to provide the services essential to the operation of the REH.

(4) A registered nurse, clinical nurse specialist, or licensed practical nurse is on duty whenever the REH has one or more patients receiving emergency care or observation care.

Interpretive Guidelines §485.528(b)(1)-(4)

Guidance is pending and will be updated in future release

O-556

(Rev.)

§485.528 (c) Standard: Responsibilities of the Doctor of Medicine or Osteopathy

(c) (1) The doctor of medicine or osteopathy must —

(i) Provide medical direction for the REH's health care activities and consultation for, and medical supervision of, the health care staff.

(ii) In conjunction with the physician assistant and/or nurse practitioner member(s), participate in developing, executing, and periodically reviewing the REH's written policies governing the services it furnishes.

(iii) In conjunction with the physician assistant and/or nurse practitioner members, periodically review the REH's patient records, provide medical orders, and provide medical care services to the patients of the REH.

(iv) Periodically review and sign a sample of outpatient records of patients cared for by nurse practitioners, clinical nurse specialists, certified nurse midwives, or physician

assistants only to the extent where state law requires record reviews or co-signatures, or both, by a collaborating physician.

Interpretive Guidelines §485.528(c)(1)(i)-(iv)

Guidance is pending and will be updated in future release

O-558

(Rev.)

§485.528 (c) Standard: Responsibilities of the Doctor of Medicine or Osteopathy

(2) A doctor of medicine or osteopathy must be present for sufficient periods of time to provide medical direction, consultation, and supervision for the services provided in the REH, and is available through direct radio or telephone communication or electronic communication for consultation, assistance with medical emergencies, or patient referral.

Interpretive Guidelines §485.528(c)(2)

Guidance is pending and will be updated in future release

O-560

(Rev.)

§485.528 (d) Standard: Physician Assistant, Nurse Practitioner and Clinical Nurse Specialist

(d) (1) The physician assistant, the nurse practitioner, or clinical nurse specialist members of the REH's staff must —

(i) Participate in the development, execution and periodic review of the written policies governing the services the REH furnishes; and

(ii) Participate with a doctor of medicine or osteopathy in a periodic review of the patients' health records.

Interpretive Guidelines §485.528(d)(1)(i)(ii)

Guidance is pending and will be updated in future release

O-562

(Rev.)

§485.528 (d) Standard: Physician Assistant, Nurse Practitioner and Clinical Nurse Specialist

(2) The physician assistant, nurse practitioner, or clinical nurse specialist performs the following functions to the extent they are not being performed by a doctor of medicine or osteopathy:

(i) Provides services in accordance with the REH's policies.

(ii) Arranges for, or refers patients to, needed services that cannot be furnished at the REH, and assures that adequate patient health records are maintained and transferred as required when patients are referred.

Interpretive Guidelines §485.528(d)(2)(i)(ii)

Guidance is pending and will be updated in future release

O-564

(Rev.)

§485.528 (d) Standard: Physician Assistant, Nurse Practitioner and Clinical Nurse Specialist

(3) Whenever a patient is placed in observation care at the REH by a nurse practitioner, physician assistant, or clinical nurse specialist, a doctor of medicine or osteopathy on the staff of the REH is notified of the patient's status.

Interpretive Guidelines §485.528(d)(3)

Guidance is pending and will be updated in future release

O-566

(Rev.)

§485.528 (e) Standard: Periodic Review of Clinical Privileges and Performance

(e) The REH requires that —

(1) The quality and appropriateness of the diagnosis and treatment furnished by nurse practitioners, clinical nurse specialists, and physician assistants at the REH must be evaluated by a member of the REH staff who is a doctor of medicine or osteopathy or by another doctor of medicine or osteopathy under contract with the REH.

Interpretive Guidelines §485.528(e)(1)

Guidance is pending and will be updated in future release

O-568

(Rev.)

§485.528 (e) Standard: Periodic Review of Clinical Privileges and Performance

(2) The quality and appropriateness of the diagnosis and treatment furnished by doctors of medicine or osteopathy at the REH must be evaluated by one of the following —

(i) One Quality Improvement Organization (QIO) or equivalent entity.

(ii) In the case of distant-site physicians and practitioners providing telemedicine services to the REH's patient under an agreement between the REH and a distant-site hospital, the distant-site hospital; or

(iii) In the case of distant-site physicians and practitioners providing telemedicine services to the REH's patients under a written agreement between the REH and a distant-site telemedicine entity, one Quality Improvement Organization (QIO) or equivalent entity.

Interpretive Guidelines §485.528(e)(2)(i)-(iii)

Guidance is pending and will be updated in future release

O-570

(Rev.)

§485.528 (e) Standard: Periodic Review of Clinical Privileges and Performance

(3) The REH staff consider the findings of the evaluation and make the necessary changes as specified in paragraphs (b) through (d) of this section.

Interpretive Guidelines §485.528(e)(3)

Guidance is pending and will be updated in future release

O-600

(Rev.)

§485.530 Nursing Services

The REH must have an organized nursing service that is available to provide 24-hour nursing services for the provision of patient care. The nursing services must be furnished and supervised by a registered nurse. Nursing services must meet the needs of patients.

Interpretive Guidelines §485.530

Guidance is pending and will be updated in future release

O-602

(Rev.)

§485.530 (a) Standard: Organization and Staffing

(a) Patient care responsibilities must be delineated for all nursing service personnel. Nursing services must be provided in accordance with recognized standards of practice.

Interpretive Guidelines §485.530(a)

Guidance is pending and will be updated in future release

O-604

(Rev.)

§485.530 (b) Standard: Nursing Leadership

(b) The director of the nursing service must be a licensed registered nurse. The individual is responsible for the operation of the service, including determining the types and numbers of nursing personnel and staff necessary to provide nursing care for all areas of the REH.

Interpretive Guidelines §485.530(b)

Guidance is pending and will be updated in future release

O-630

(Rev.)

§485.532 Discharge Planning

An REH must have an effective discharge planning process that focuses on the patient's goals and treatment preferences and includes the patient and their caregivers/support person(s) as active partners in the discharge planning for post-discharge care. The discharge planning process and the discharge plan must be consistent with the patient's goals for care and their treatment preferences, ensure an effective transition of the patient from the REH to post-discharge care, and reduce the factors leading to preventable hospital admissions or readmissions.

Interpretive Guidelines §485.532

Guidance is pending and will be updated in future release

O-632

(Rev.)

§485.532 (a) Standard: Discharge Planning Process

(a) The REH's discharge planning process must identify, at an early stage of the provision of services, 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 §485.532(a)

Guidance is pending and will be updated in future release

O-634

(Rev.)

§485.532 (a) Standard: Discharge Planning Process

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

Interpretive Guidelines §485.532(a)(1)

Guidance is pending and will be updated in future release

O-636

(Rev.)

§485.532 (a) Standard: Discharge Planning Process

(2) A discharge planning evaluation must include an evaluation of a patient's likely need for appropriate services following those furnished by the REH, including, but not limited to, hospice care services, post-REH 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 §485.532(a)(2)

Guidance is pending and will be updated in future release

O-638

(Rev.)

§485.532 (a) Standard: Discharge Planning Process

(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 §485.532(a)(3)

Guidance is pending and will be updated in future release

O-640

(Rev.)

§485.532 (a) Standard: Discharge Planning Process

(4) Upon the request of a patient's physician, the REH must arrange for the development and initial implementation of a discharge plan for the patient.

Interpretive Guidelines §485.532(a)(4)

Guidance is pending and will be updated in future release

O-642

(Rev.)

§485.532 (a) Standard: Discharge Planning Process

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

Interpretive Guidelines §485.532(a)(5)

Guidance is pending and will be updated in future release

O-644

(Rev.)

§485.532 (a) Standard: Discharge Planning Process

(6) The REH'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 §485.532(a)(6)

Guidance is pending and will be updated in future release

O-646

(Rev.)

§485.532 (a) Standard: Discharge Planning Process

(7) The REH must assess its discharge planning process on a regular basis. The assessment must include ongoing periodic review of a representative sample of discharge plans.

Interpretive Guidelines §485.532(a)(7)

Guidance is pending and will be updated in future release

O-648

(Rev.)

§485.532 (a) Standard: Discharge Planning Process

(8) The REH 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, home health agency (HHA), skilled nursing facility (SNF), inpatient rehabilitation facility (IRF), or long term care hospital (LTCH) data on quality measures and data on resource use measures. The REH must ensure that the post-acute care data on quality measures and data on resource use measures is relevant and applicable to the patient's goals of care and treatment preferences.

Interpretive Guidelines §485.532(a)(8)

Guidance is pending and will be updated in future release

O-650

(Rev.)

§485.532 (b) Standard: Discharge of the Patient and Provision and Transmission of the Patient's Necessary Medical Information.

The REH 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 §485.532(b)

Guidance is pending and will be updated in future release

O-680

(Rev.)

§485.534 Patient Rights

An REH must protect and promote each patient's rights.

Interpretive Guidelines §485.534

Guidance is pending and will be updated in future release

O-682

(Rev.)

§485.534 (a) Notice of Rights

(a) (1) An REH must inform each patient, or when appropriate, the patient's representative (as allowed under state law), of the patient's rights, in advance of furnishing or discontinuing patient care whenever possible.

Interpretive Guidelines §485.534 (a)(1)

Guidance is pending and will be updated in future release

O-684

(Rev.)

§485.534 (a) Notice of Rights

(2) The REH must establish a process for prompt resolution of patient grievances and must inform each patient whom to contact to file a grievance. The REH's governing body or responsible individual must approve and be responsible for the effective operation of the grievance process and must review and resolve grievances, unless it delegates the responsibility in writing to a grievance committee. The grievance process must include a mechanism for timely referral of patient concerns regarding quality of care or premature discharge to the appropriate Utilization and Quality Control Quality Improvement Organization. At a minimum:

(i) The REH must establish a clearly explained procedure for the submission of a patient's written or verbal grievance to the REH.

(ii) The grievance process must specify time frames for review of the grievance and the provision of a response.

(iii) In its resolution of the grievance, the REH must provide the patient with written notice of its decision that contains the name of the REH contact person, the steps taken on behalf

of the patient to investigate the grievance, the results of the grievance process, and the date of completion.

Interpretive Guidelines §485.534 (a)(2)(i)-(iii)

Guidance is pending and will be updated in future release

O-686

(Rev.)

§485.534 (b) Standard: Exercise of Rights

(b) The patient has the right to—

(1) Participate in the development and implementation of their plan of care.

Interpretive Guidelines §485.534 (b)(1)

Guidance is pending and will be updated in future release

O-688

(Rev.)

§485.534 (b) Standard: Exercise of Rights

(2) Make informed decisions regarding their care, including being informed of their health status, and being able to request or refuse treatment. This right must not be construed as a mechanism to demand the provision of treatment or services deemed medically unnecessary or inappropriate.

Interpretive Guidelines §485.534 (b)(2)

Guidance is pending and will be updated in future release

O-690

(Rev.)

§485.534 (b) Standard: Exercise of Rights

(3) Formulate advance directives and to have REH staff and practitioners who provide care in the REH comply with these directives, in accordance with §§ 489.100, 489.102, and 489.104 of this chapter.

Interpretive Guidelines §485.534 (b)(3)

Guidance is pending and will be updated in future release

O-692

(Rev.)

§485.534 (c) Standard: Privacy and Safety

The patient has the right to—

(1) Personal privacy.

Interpretive Guidelines §485.534 (c)(1)

Guidance is pending and will be updated in future release

O-694

(Rev.)

§485.534 (c) Standard: Privacy and Safety

The patient has the right to—

(2) Receive care in a safe setting.

Interpretive Guidelines §485.534 (c)(2)

Guidance is pending and will be updated in future release

O-696

(Rev.)

§485.534 (c) Standard: Privacy and Safety

The patient has the right to—

(3) Be free from all forms of abuse or harassment.

Interpretive Guidelines §485.534 (c)(3)

Guidance is pending and will be updated in future release

O-698

(Rev.)

§485.534 (d) Standard: Confidentiality of Patient Records.

(d) (1) The patient has the right to the confidentiality of their medical records.

Interpretive Guidelines §485.534 (d)(1)

Guidance is pending and will be updated in future release

O-700

(Rev.)

§485.534 (d) Standard: Confidentiality of Patient Records.

(2) The patient has the right to access their medical records, including current medical records, upon an oral or written request.

(i) The records must be provided in the form and format requested by the individual, if it is readily producible in such form and format. This includes in an electronic form or format when such medical records are maintained electronically or if not, in a readable hard copy form or such other form and format as agreed to by the facility and the individual.

(ii) The records must be provided within a reasonable time frame. The REH must not frustrate the legitimate efforts of individuals to gain access to their own medical records and must actively seek to meet these requests as quickly as its record keeping system permits.

Interpretive Guidelines §485.534 (d)(2)(i)(ii)

Guidance is pending and will be updated in future release

O-702

(Rev.)

§485.534 (e) Standard: Restraints or Seclusion

(e) *Standard: Restraint or seclusion.* All patients have the right to be free from physical or mental abuse, and corporal punishment. All patients have the right to be free from restraint or seclusion, of any form, imposed as a means of coercion, discipline, convenience, or retaliation by staff. Restraint or seclusion may only be imposed to ensure the immediate physical safety of the patient, a staff member, or others and must be discontinued at the earliest possible time.

Interpretive Guidelines §485.534 (e)

Guidance is pending and will be updated in future release

O-704

(Rev.)

§485.534 (e) Standard: Restraints or Seclusion

(1)(i) A *restraint* is —

(A) Any manual method, physical or mechanical device, material, or equipment that immobilizes or reduces the ability of a patient to move their arms, legs, body, or head freely; or

(B) A drug or medication when it is used as a restriction to manage the patient's behavior or restrict the patient's freedom of movement and is not a standard treatment or dosage for the patient's condition.

(C) A restraint does not include devices, such as orthopedically prescribed devices, surgical dressings or bandages, protective helmets, or other methods that involve the physical holding of a patient for the purpose of conducting routine physical examinations or tests, or to protect the patient from falling out of bed, off of a stretcher, or out of a chair, or to permit the patient to participate in activities without the risk of physical harm (this does not include a physical escort).

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

Interpretive Guidelines §485.534 (e)(1)(i)(ii)

Guidance is pending and will be updated in future release

O-706

(Rev.)

§485.534 (e) Standard: Restraints or Seclusion

(2) Restraint or seclusion may only be used when less restrictive interventions have been determined to be ineffective to protect the patient, a staff member or others from harm.

Interpretive Guidelines §485.534 (e)(2)

Guidance is pending and will be updated in future release

O-708

(Rev.)

§485.534 (e) Standard: Restraints or Seclusion

(3) The type or technique of restraint or seclusion used must be the least restrictive intervention that will be effective to protect the patient, a staff member, or others from harm.

Interpretive Guidelines §485.534 (e)(3)

Guidance is pending and will be updated in future release

O-710

(Rev.)

§485.534 (e) Standard: Restraints or Seclusion

(4) The REH must have written policies and procedures regarding the use of restraint and seclusion that are consistent with current standards of practice.

Interpretive Guidelines §485.534 (e)(4)

Guidance is pending and will be updated in future release

O-712

(Rev.)

§485.534 (f) Standard: Restraint or Seclusion: Staff Training Requirements.

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

Interpretive Guidelines §485.534 (f)

Guidance is pending and will be updated in future release

O-714

(Rev.)

§485.534 (f) Standard: Restraint or Seclusion: Staff Training Requirements.

(1) The REH must provide patient-centered competency-based training and education of REH personnel and staff, including medical staff, and, as applicable, personnel providing contracted services in the REH, on the use of restraint and seclusion.

Interpretive Guidelines §485.534 (f)(1)

Guidance is pending and will be updated in future release

O-716

(Rev.)

§485.534 (f) Standard: Restraint or Seclusion: Staff Training Requirements.

(2) The training must include alternatives to the use of restraint/seclusion.

Interpretive Guidelines §485.534 (f)(2)

Guidance is pending and will be updated in future release

O-718

(Rev.)

§485.534 (g) Standard: Death Reporting Requirements

(g) REHs must report deaths associated with the use of seclusion or restraint.

Interpretive Guidelines §485.534 (g)

Guidance is pending and will be updated in future release

O-720

(Rev.)

§485.534 (g) Standard: Death Reporting Requirements

(1) With the exception of deaths described under paragraph (g)(2) of this section, the REH 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 REH 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.

Interpretive Guidelines §485.534 (g)(1)(i)-(iii)

Guidance is pending and will be updated in future release

O-722

(Rev.)

§485.534 (g) Standard: Death Reporting Requirements

(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 REH 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.

Interpretive Guidelines §485.534 (g)(2)(i)(ii)

Guidance is pending and will be updated in future release

O-724

(Rev.)

§485.534 (g) Standard: Death Reporting Requirements

(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

(ii) Recorded in the internal log or other system for deaths described in paragraph (g)(2) of this section.

Interpretive Guidelines §485.534 (g)(3)(i)(ii)

Guidance is pending and will be updated in future release

O-726

(Rev.)

§485.534 (g) Standard: Death Reporting Requirements

(4) For deaths described in paragraph (g)(2) of this section, entries into the internal 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 practitioner who is responsible for the care of the patient, 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 §485.534 (g)(4)(i)-(iii)

Guidance is pending and will be updated in future release

O-728

(Rev.)

§485.534 (h) Standard: Patient Visitation Rights

(h) An REH must have written policies and procedures regarding the visitation rights of patients, including those setting forth any clinically necessary or reasonable restriction or limitation that the REH may need to place on such rights and the reasons for the clinical restriction or limitation. An REH must meet the following requirements:

Interpretive Guidelines §485.534 (h)

Guidance is pending and will be updated in future release

O-730

(Rev.)

§485.534 (h) Standard: Patient Visitation Rights

(1) Inform each patient (or support person, where appropriate) of their visitation rights, including any clinical restriction or limitation on such rights, when they are informed of their other rights under this section.

Interpretive Guidelines §485.534 (h)(1)

Guidance is pending and will be updated in future release

O-732

(Rev.)

§485.534 (h) Standard: Patient Visitation Rights

(2) Inform each patient (or support person, where appropriate) of the right, subject to their consent, to receive the visitors whom they designate, including, but not limited to, a spouse, a domestic partner (including a same-sex domestic partner), another family member, or a friend, and their right to withdraw or deny such consent at any time.

Interpretive Guidelines §485.534 (h)(2)

Guidance is pending and will be updated in future release

O-734

(Rev.)

§485.534 (h) Standard: Patient Visitation Rights

(3) Not restrict, limit, or otherwise deny visitation privileges on the basis of race, color, national origin, religion, sex, gender identity, sexual orientation, or disability.

Interpretive Guidelines §485.534 (h)(3)

Guidance is pending and will be updated in future release

O-736

(Rev.)

§485.534 (h) Standard: Patient Visitation Rights

(4) Ensure that all visitors enjoy full and equal visitation privileges consistent with patient preferences.

Interpretive Guidelines §485.534 (h)(4)

Guidance is pending and will be updated in future release

O-760

(Rev.)

§485.536 Quality Assessment and Performance Improvement Program

The REH must develop, implement, and maintain an effective, ongoing, REH-wide, data-driven quality assessment and performance improvement (QAPI) program. The REH's governing body must ensure that the program reflects the complexity of the REH's organization and services; involves all REH 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 REH must maintain and demonstrate evidence of its QAPI program for review by CMS.

Interpretive Guidelines §485.536

Guidance is pending and will be updated in future release

O-762

(Rev.)

§485.536 (a) Standard: Program Scope

(a) (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 and identify and reduce medical errors.

Interpretive Guidelines §485.536(a)(1)

Guidance is pending and will be updated in future release

O-764

(Rev.)

§485.536 (a) Standard: Program Scope

(2) The REH must measure, analyze, and track quality indicators, including adverse patient events, staffing, and other aspects of performance that assess processes of care including REH service and operations.

Interpretive Guidelines §485.536(a)(2)

Guidance is pending and will be updated in future release

O-766

(Rev.)

§485.536 (b) Standard: Program Data Collection and Analysis

(b) The program must incorporate quality indicator data including patient care data, and other relevant data, in order to achieve the goals of the QAPI program.

Interpretive Guidelines §485.536(b)

Guidance is pending and will be updated in future release

O-768

(Rev.)

§485.536 (c) Standard: Program Activities

(c) (1) The REH 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.

Interpretive Guidelines §485.536(c)(1)(i)-(iii)

Guidance is pending and will be updated in future release

O-770

(Rev.)

§485.536 (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 REH. An adverse patient event means an untoward, undesirable, and usually unanticipated event that causes death or serious injury or the risk thereof. Medical error means an error that occurs in the delivery of health care services.

Interpretive Guidelines §485.536(c)(2)

Guidance is pending and will be updated in future release

O-772

(Rev.)

§485.536 (c) Standard: Program Activities

(3) The REH must take actions aimed at performance improvement and, after implementing those actions, the REH must measure its success, and track performance to ensure that improvements are sustained.

Interpretive Guidelines §485.536(c)(3)

Guidance is pending and will be updated in future release

O-774

(Rev.)

§485.536 (d) Standard: Executive Responsibilities

(d) The REH's governing body (or organized group or individual who assumes full legal authority and responsibility for operations of the REH), 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 REH-wide quality assessment and performance improvement efforts address priorities for improved quality of care and patient safety; and that all improvement actions are evaluated.

(3) That clear expectations for safety are established.

(4) That adequate resources are allocated for measuring, assessing, improving, and sustaining the REH's performance and reducing risk to patients.

Interpretive Guidelines §485.536(d)(1)-(4)

Guidance is pending and will be updated in future release

O-776

(Rev.)

§485.536 (e) Standard: Unified and Integrated QAPI Program for an REH in a Multi-Facility System

(e) If an REH is part of a system consisting of multiple separately certified hospitals, CAHs, and/or REHs using a system governing body that is legally responsible for the conduct of two or more hospitals, CAHs, and/or REHs, the system governing body can elect to have a unified and integrated QAPI program for all of its member facilities 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 REHs meets all of the requirements of this section. Each separately certified REH subject to the system governing body must demonstrate that—

Interpretive Guidelines §485.536(e)

Guidance is pending and will be updated in future release

O-778

(Rev.)

§485.536 (e) Standard: Unified and Integrated QAPI Program for an REH in a Multi-Facility System

(1) The unified and integrated QAPI program is established in a manner that takes into account each member REH's unique circumstances and any significant differences in patient populations and services offered in each REH; and

Interpretive Guidelines §485.536(e)(1)

Guidance is pending and will be updated in future release

O-780

(Rev.)

§485.536 (e) Standard: Unified and Integrated QAPI Program for an REH in a Multi-Facility System

(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 REHs, 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 REHs are duly considered and addressed.

Interpretive Guidelines §485.536(e)(2)

Guidance is pending and will be updated in future release

O-800

(Rev.)

§485.538 Agreements

The REH must have in effect an agreement with at least one certified hospital that is a level I or level II trauma center for the referral and transfer of patients requiring emergency medical care beyond the capabilities of the REH that is—

(a) Licensed as a hospital in a state that provides for the licensing of hospitals under state or applicable local law or approved by the agency of such state or locality responsible for licensing hospitals, as meeting standards established for licensing established by the agency of the state; and

(b) Licensed or designated by the state or local government authority as level I or level II trauma center or is verified by the American College of Surgeons as a level I or level II trauma center.

Interpretive Guidelines §485.538

Guidance is pending and will be updated in future release

O-820

(Rev.)

§485.540 Medical Records

Interpretive Guidelines §485.540

Guidance is pending and will be updated in future release

O-822

(Rev.)

§485.540 (a) Standard: Records System

(a) (1) The REH must maintain a medical records system in accordance with written policies and procedures.

Interpretive Guidelines §485.540(a)(1)

Guidance is pending and will be updated in future release

O-824

(Rev.)

§485.540 (a) Standard: Records System

(2) The records must be legible, complete, accurately documented, readily accessible, and systematically organized.

Interpretive Guidelines §485.540(a)(2)

Guidance is pending and will be updated in future release

O-826

(Rev.)

§485.540 (a) Standard: Records System

(3) A designated member of the professional staff is responsible for maintaining the records and for ensuring that they are completely and accurately documented, readily accessible, and systematically organized.

Interpretive Guidelines §485.540(a)(3)

Guidance is pending and will be updated in future release

O-828

(Rev.)

§485.540 (a) Standard: Records System

(4) For each patient receiving health care services, the REH must maintain a record that includes, as applicable—

(i) Identification and social data, evidence of properly executed informed consent forms, pertinent medical history, assessment of the health status and health care needs of the patient, and a brief summary of the episode, disposition, and instructions to the patient;

(ii) Reports of physical examinations, diagnostic and laboratory test results, including clinical laboratory services, and consultative findings;

(iii) All orders of doctors of medicine or osteopathy or other practitioners, reports of treatments and medications, nursing notes and documentation of complications, and other pertinent information necessary to monitor the patient's progress, such as temperature graphics, progress notes describing the patient's response to treatment; and

(iv) Dated signatures of the doctor of medicine or osteopathy or other health care professional.

Interpretive Guidelines §485.540(a)(4)(i)-(iv)

Guidance is pending and will be updated in future release

O-830

(Rev.)

§485.540 (b) Standard: Protection of Record Information

(b) (1) The REH must maintain the confidentiality of record information and provides safeguards against loss, destruction, or unauthorized use.

Interpretive Guidelines §485.540(b)(1)

Guidance is pending and will be updated in future release

O-832

(Rev.)

§485.540 (b) Standard: Protection of Record Information

(2) The REH must have written policies and procedures that govern the use and removal of records from the REH and the conditions for the release of information.

Interpretive Guidelines §485.540(b)(2)

Guidance is pending and will be updated in future release

O-834

(Rev.)

§485.540 (b) Standard: Protection of Record Information

(3) The patient's written consent is required for release of information not required by law.

Interpretive Guidelines §485.540(b)(3)

Guidance is pending and will be updated in future release

O-836

(Rev.)

§485.540 (c) Standard: Retention of Records

(c) The records must be retained for at least 5 years from date of last entry, and longer if required by state statute, or if the records may be needed in any pending proceeding.

Interpretive Guidelines §485.540(c)

Guidance is pending and will be updated in future release

O-838

(Rev.)

§485.540 (d) Standard: Electronic Notifications

(d) If the REH 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 REH must demonstrate that—

Interpretive Guidelines §485.540(d)

Guidance is pending and will be updated in future release

O-840

(Rev.)

§485.540 (d) Standard: Electronic Notifications

(1) The system's notification capacity is fully operational and the REH uses it in accordance with all state and Federal statutes and regulations applicable to the REH's exchange of patient health information.

Interpretive Guidelines §485.540(d)(1)

Guidance is pending and will be updated in future release

O-842

(Rev.)

§485.540 (d) Standard: Electronic Notifications

(2) The system sends notifications that must include at least patient name, treating practitioner name, and sending institution name.

Interpretive Guidelines §485.540(d)(2)

Guidance is pending and will be updated in future release

O-844

(Rev.)

§485.540 (d) Standard: Electronic Notifications

(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 the patient's registration in the REH's emergency department.

Interpretive Guidelines §485.540(d)(3)

Guidance is pending and will be updated in future release

O-846

(Rev.)

§485.540 (d) Standard: Electronic Notifications

(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 the patient's discharge or transfer from the REH's emergency department.

Interpretive Guidelines §485.540(d)(4)

Guidance is pending and will be updated in future release

O-848

(Rev.)

§485.540 (d) Standard: Electronic Notifications

(5) The REH 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 their care.

Interpretive Guidelines §485.540(d)(5)(i)-(iii)

Guidance is pending and will be updated in future release

No Tag

(Rev.)

Refer to all applicable E-Tags

§485.542 Emergency Preparedness

Interpretive Guidelines §485.542

For all applicable requirements under Emergency Preparedness, please refer to Appendix Z of the State Operations Manual. REH Facilities must also comply with the requirements outlined in Appendix Z.

O-940

(Rev.)

§485.544 Physical Environment

The REH must be constructed, arranged, and maintained to ensure the safety of the patient, and to provide facilities for diagnosis and treatment and for special services appropriate to the needs of the community.

Interpretive Guidelines §485.544

Guidance is pending and will be updated in future release

O-942

(Rev.)

§485.544 (a) Standard: Building

(a) The condition of the physical plant and the overall REH environment must be developed and maintained in such a manner that the safety and well-being of patients are ensured.

Interpretive Guidelines §485.544 (a)

Guidance is pending and will be updated in future release

O-944

(Rev.)

§485.544 (a) Standard: Building

(1) There must be emergency power and lighting in at least the operating, recovery, 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 §485.544 (a)(1)

Guidance is pending and will be updated in future release

O-946

(Rev.)

§485.544 (a) Standard: Building

(2) There must be facilities for emergency gas and water supply.

Interpretive Guidelines §485.544 (a)(2)

Guidance is pending and will be updated in future release

O-948

(Rev.)

§485.544 (a) Standard: Building

(3) The REH must have a safe and sanitary environment, properly constructed, equipped, and maintained to protect the health and safety of patients.

Interpretive Guidelines §485.544 (a)(3)

Guidance is pending and will be updated in future release

O-950

(Rev.)

§485.544 (b) Standard: Facilities

(b) The REH must maintain adequate facilities for its services.

Interpretive Guidelines §485.544 (b)

Guidance is pending and will be updated in future release

O-952

(Rev.)

§485.544 (b) Standard: Facilities

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

Interpretive Guidelines §485.544 (b)(1)

Guidance is pending and will be updated in future release

O-954

(Rev.)

§485.544 (b) Standard: Facilities

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

Interpretive Guidelines §485.544 (b)(2)

Guidance is pending and will be updated in future release

O-956

(Rev.)

§485.544 (b) Standard: Facilities

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

Interpretive Guidelines §485.544 (b)(3)

Guidance is pending and will be updated in future release

O-958

(Rev.)

§485.544 (b) Standard: Facilities

(4) There must be proper ventilation, light, and temperature controls in patient care, pharmaceutical, food preparation, and other appropriate areas.

Interpretive Guidelines §485.544 (b)(4)

Guidance is pending and will be updated in future release

O-960

(Rev.)

§485.544 (c) Standard: Safety from Fire

(c) (1) Except as otherwise provided in this section, the REH must meet the provisions applicable to Ambulatory Health Care Occupancies, regardless of the number of patients served, 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).

Interpretive Guidelines §485.544 (c)(1)

Guidance is pending and will be updated in future release

O-962

(Rev.)

§485.544 (c) Standard: Safety from Fire

(2) In consideration of a recommendation by the state survey agency or accrediting organization or at the discretion of the Secretary, CMS may waive, for periods deemed appropriate, specific provisions of the Life Safety Code, which would result in unreasonable hardship upon an REH, but only if the waiver will not adversely affect the health and safety of the patients.

Interpretive Guidelines §485.544 (c)(2)

Guidance is pending and will be updated in future release

O-964

(Rev.)

§485.544 (c) Standard: Safety from Fire

(3) The provisions of the Life Safety Code do not apply in a state if CMS finds that a fire and safety code imposed by state law adequately protects patients in an REH.

Interpretive Guidelines §485.544 (c)(3)

Guidance is pending and will be updated in future release

O-966

(Rev.)

§485.544 (c) Standard: Safety from Fire

(4) An REH may place alcohol-based hand rub dispensers in its facility if the dispensers are installed in a manner that adequately protects against inappropriate access.

Interpretive Guidelines §485.544 (c)(4)

Guidance is pending and will be updated in future release

O-968

(Rev.)

§485.544 (c) Standard: Safety from Fire

(5) When a sprinkler system is shut down for more than 10 hours, the REH 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 §485.544 (c)(5)(i)(ii)

Guidance is pending and will be updated in future release

O-970

(Rev.)

§485.544 (d) Standard: Building Safety

(d) *Standard: Building safety.* Except as otherwise provided in this section, the REH must meet the applicable provisions and must proceed in accordance with the 2012 edition of 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 an REH.

(2) If application of the Health Care Facilities Code required under paragraph (d) of this section would result in unreasonable hardship for the REH, 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 §485.544 (d)(1)(2)

Guidance is pending and will be updated in future release

O-972

(Rev.)

§485.544 (e) Standard: Incorporation by Reference

(e) *Incorporation by reference.* The material listed in this paragraph (e) is incorporated by reference into this section with the approval the Director of the Federal Register in accordance with [5 U.S.C. 552\(a\)](#) and [1 CFR part 51](#). To enforce any edition other than that specified in this section, CMS must publish a document in the Federal Register and the material must be available to the public. All approved material is available for inspection at CMS and the National Archives and Records Administration (NARA). Contact CMS at: CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD, email scott.cooper@cms.hhs.gov or call (410) 786-9465. For information on the availability of this material at NARA, email fr.inspection@nara.gov or go to: www.archives.gov/federal-register/cfr/ibr-locations.html. The material may be obtained from the following source(s) in this paragraph (e).

(1) National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02169, www.nfpa.org, 1.617.770.3000.

(i) NFPA 99, Health Care Facilities Code, 2012 edition, issued August 11, 2011.

(ii) Technical interim amendment (TIA) 12-2 to NFPA 99, issued August 11, 2011.

(iii) TIA 12-3 to NFPA 99, issued August 9, 2012.

(iv) TIA 12-4 to NFPA 99, issued March 7, 2013.

(v) TIA 12-5 to NFPA 99, issued August 1, 2013.

(vi) TIA 12-6 to NFPA 99, issued March 3, 2014.

(vii) NFPA 101, Life Safety Code, 2012 edition, issued August 11, 2011;

(viii) TIA 12-1 to NFPA 101, issued August 11, 2011.

(ix) TIA 12-2 to NFPA 101, issued October 30, 2012.

(x) TIA 12-3 to NFPA 101, issued October 22, 2013.

(xi) TIA 12-4 to NFPA 101, issued October 22, 2013.

(2) [Reserved]

Interpretive Guidelines §485.544 (e)(1)(i)-(xi)

Guidance is pending and will be updated in future release

O-990

(Rev.)

§485.546 Skilled Nursing Facility Distinct Part Unit.

If the REH provides skilled nursing facility services in a distinct part unit, the services furnished by the distinct part unit must be separately licensed and certified and comply with the requirements of participation for long-term care facilities specified in part 483, subpart B, of this chapter.

Interpretive Guidelines §485.546

Guidance is pending and will be updated in future release

EXHIBIT

(Rev.)

Model Attestation of Compliance for Rural Emergency Hospital Enrollment and Conversion

(Date of Request)

Name of Facility

Street Address

City, State, ZIP code

Dear (State Agency),

[**Name of facility**] is requesting enrollment and conversion to a Rural Emergency Hospital (REH). [**Name of facility**] is an eligible facility because as of December 27, 2020, the facility was operating as (choose one of the following options):

1. A critical access hospital
2. A hospital, as defined in section 1861(d)(1)(B) of the Social Security Act (the Act), with not more than 50 beds located in a county (or equivalent unit of local government) that is considered rural (as defined in section 1881(d)(2)(D) of the Act)
3. A hospital, as defined in section 1881(d)(1)(B) of the Act, with not more than 50 beds that was treated as being located in a rural area that has had an active reclassification from urban to rural status as specified in 42 C.F.R. § 412.103 as of December 27, 2020

I understand that as an REH, [**Name of facility**] must meet all the Conditions of Participation (CoPs) in 42 CFR Part 485, Subpart E, including but not limited to the following:

___ §485.514 CoP: Provision of Services

___ §485.516 CoP: Emergency Services

___ §485.526 CoP: Infection prevention and control and antibiotic stewardship programs

___ §485.528 CoP: Staffing and staff responsibilities

___ §485.534 CoP: Patient Rights

___ §485.538 CoP: Agreements (**attach copy of transfer agreement with a certified level I or II trauma center**)

___ §485.544 CoP: Physical Environment

Based upon my personal knowledge and belief, I attest that [**Name of facility**] currently meets and will continue to meet all of the requirements for Rural Emergency Hospitals set forth in the statute and implementing regulations in Subpart E of 42 C.F.R. Part 485.

[Name of Facility]

I understand that the Centers for Medicare & Medicaid Services or the state survey agency of the state where [Name of facility] is located may conduct an on-site survey at any time to validate and determine compliance with all applicable requirements for REHs.

Signature: _____
(*The Action Plan should be signed by the Administrator or Legal Representative of the REH.*)

Title: _____

Date: _____

EXHIBIT

Model Action Plan Template for Rural Emergency Hospitals

Facility Name:

Current CCN:

Summary of Conversion Plan:

{Include details regarding the facility's efforts to initiate REH services for the provision of emergency care, observation care and other medical and health services. Include details regarding the discontinuation of inpatient services and transfer of care outside of the REH's capabilities. Include staffing details for the provision of REH services (number and type of qualified staff)}

List the specific services the facility will retain (including a distinct part skilled nursing facility if applicable):

List the specific services the facility will modify:

List the specific services the facility will add (including a distinct part skilled nursing facility if applicable):

List the specific services the facility will discontinue: {This should include the provision of inpatient services}

Provide a description of services the facility elects to provide on an outpatient basis (such as behavioral health services, laboratory, radiology, maternal health, surgical services outpatient rehabilitation):

Provide information regarding how the facility intends to use the additional facility payment. This includes a description of the services that the additional facility payment would be supporting such as the operation and maintenance of the facility and furnishing of services (i.e. telehealth services, ambulance services etc.).

Signature: _____
(The Action Plan should be signed by the Administrator or Legal Representative of the REH.)

Title: _____

Date: _____