

# **Summary of the Rural Emergency Hospital Conditions of Participation Proposed Rule**

On June 30, 2022, the Centers for Medicare & Medicaid Services (CMS) released proposed new conditions of participation (CoPs) for Rural Emergency Hospitals (REHs). The release of this proposed rule is the first step in implementation of this new provider type under Medicare. The calendar year (CY) 2023 Outpatient Prospective Payment System (OPPS) proposed rule, which will be released shortly, will include other REH proposals related to Medicare payment, quality reporting, and enrollment.

Comments on the REH CoPs are due in late August, and ACEP plans on submitting a robust response. The final rule for the REH CoPs is expected to be included in the CY 2023 OPPS final rule, which will be released on or around November 1, 2022.

#### **Background of Rural Emergency Hospitals**

Over the last decade, over 130 rural hospitals stopped providing inpatient services. According to CMS, between 2010 and 2012, 75 rural hospitals closed, and an additional 63 hospitals shut down their inpatient services but continued providing some type of outpatient services.

To help address the impact these hospital closures have on access to care in rural areas, Congress included a provision in the Consolidated Appropriations Act (enacted on December 27, 2020) that would allow critical access hospitals (CAHs) and small rural hospitals (those with less than 50 beds) to convert to Rural Emergency Hospitals (REHs) starting on January 1, 2023. REHs, once established, will not provide any inpatient services, but must be able to provide emergency services 24 hours a day, 7 days a week. Further, they must meet other requirements including, but not limited to: having a transfer agreement in place with a level I or level II trauma center; adhering to quality measurement reporting requirements that will be set by CMS; and following new CoPs that are developed by CMS.

To help inform the rulemaking process, CMS issued a request for information (RFI) last year as part of the CY 2022 OPPS Proposed Rule to get input on a broad range of issues. ACEP submitted a <u>response</u> to the RFI, where we specifically emphasized the need for all services delivered in REHs to be supervised by emergency physicians either in-person or virtually via telehealth. We also had the opportunity to meet with the White House to discuss the REHs CoPs before they were released.

#### **Overview of Proposed CoPs**

In the proposed rule, CMS proposes the following definitions for REHs and CoPs. It is important to note that many of the proposed CoPs align with those established for CAHs.

#### **Proposed Basic Definitions and Requirements:**

• CMS defines an REH "as an entity that operates for the purpose of providing emergency department services, observation care, and other outpatient medical and health services in which the annual per patient average length of stay does not exceed 24 hours. The REH



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-REH or posthospital extended care services."

- CMS proposes to certify a facility as an REH if the facility was, as of December 27, 2020, a CAH or a hospital with no more than 50 beds located in a rural county.
- REHs must be in compliance with applicable federal, state, and local laws and regulation. REHs also must be licensed in the state as an REH or be approved as meeting standards for licensing by the agency in the state or locality responsible for licensing hospitals.

#### Proposed CoP #1: Governing Body and Organizational Structure

- REHs must have an effective governing body, or responsible individual or individuals, that
  is legally responsible for the conduct of the REH. This aligns with the CAH CoP for
  organizational structure.
- The governing body will have the responsibility, in accordance with state law, to determine which categories of practitioners are eligible candidates for appointment to the medical staff.
- Telemedicine Credentialing and Privileging
  - CMS is proposing requirements similar to the telemedicine credentialing and privileging process requirements established for hospitals and CAHs that would allow for an optional and more streamlined credentialing and privileging process that REHs may use for practitioners providing telemedicine services for their patients.

#### **Proposed CoP #2: Provision of Services**

• CMS is proposing that REHs' health care services must be furnished in accordance with appropriate written policies that are consistent with applicable state law. The REH also must have policies that are 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. The policies must be reviewed at least biennially by this group of professional personnel.

#### **Proposed CoP #3: Emergency Services**

- REHs must comply with both the CAH and Hospital CoPs for emergency services. CAHs and hospitals are required to have emergency services that meet the needs of their respective patients presenting at the individual facility.
- REHs must have emergency services that are organized under the direction of a qualified member of the medical staff and are integrated with other departments of the REH.
- There must be adequate medical and nursing personnel qualified in emergency care to meet the needs of the facility.
- CMS is seeking comment on the proposed staffing requirements for the provision of emergency services in an REH to gain insight on the appropriateness of not requiring a practitioner to be on-site at the REH at all times.

#### **Proposed CoP #4: Laboratory Services**

• REHs must provide basic laboratory services that are essential to the immediate diagnosis



and treatment of the patient.

- REHs should provide laboratory services that are consistent with nationally recognized standards of care for emergency services. In addition to the laboratory services identified in the CAH CoPs, CMS encourages the REH to provide laboratory services that include a complete blood count, basic metabolic panel (also known as a "chem 7"), magnesium, phosphorus, liver function tests, amylase, lipase, cardiopulmonary tests (troponin, brain natriuretic peptide, and d-dimer), lactate, coagulation studies (prothrombin time, partial thromboplastin time, and international normalized ratio), arterial blood gas, venous blood gas, quantitative human chorionic gonadotropin, and urine toxicology.
- REHs must have emergency laboratory services available that would be essential to the immediate diagnosis of the patient, 24 hours a day.

## **Proposed CoP #5: Radiologic Services**

- The proposed REH radiologic requirements mirror the radiologic requirements for CAHs.
- The services must be furnished by personnel qualified under state law and do not expose patients or staff to radiation hazards.
- REHs must provide diagnostic radiologic services. All radiologic services furnished by the REH must be provided by qualified personnel in accordance with state law and do not expose REH patients or personnel to radiation hazards. Like hospitals, CMS is also proposing to require that the REH must have radiologic services that meet the needs of their patients.
- CMS is proposing basic factors relating to safety hazard standards for patients and personnel.
- CMS is proposing to require that a qualified radiologist or other personnel qualified under state law either full-time, part-time, or on a consulting basis interpret radiologic tests that require specialized knowledge. This requirement can be fulfilled through arrangements with off-site providers via telehealth.

#### **Proposed CoP #6: Pharmaceutical Services**

- REHs' pharmaceutical services must meet the needs of the patients.
- REH must have a pharmacy or drug storage area that is administered in accordance with accepted professional principles and in accordance with state and Federal laws.
- A registered pharmacist or other qualified individual in accordance with state scope of practice laws must direct the pharmaceutical services or, when appropriate, have a drug storage area that is supervised by an individual who is competent to do so. This individual would not be required to be a full-time pharmacist.
- 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 other qualified individual in accordance with state scope of practice laws and be performed consistent with state and Federal laws.
- All drugs and biologicals must be kept in secure areas and locked when appropriate.

#### Proposed CoP #7: Additional Outpatient Medical and Health Services

• REHs are allowed to provide additional medical and health outpatient services that include, but are not limited, to radiology, laboratory, outpatient rehabilitation, surgical, maternal



- health, and behavioral health services. REHs should provide maternal health services that include prenatal care, low-risk labor and delivery, and postnatal care.
- With respect to behavioral health services, REHs can be opioid treatment providers as long as the treatment remains an outpatient service.
- CMS proposes to require that the provision of the additional service be based on nationally recognized guidelines and standards of practice. CMS further proposes to require that the REH have a system in place for referral from the REH to different levels of care, including follow-up care, as appropriate.
- CMS proposes personnel requirements for REHs who choose to provide additional outpatient medical and health services.
- Finally, CMS sets forth standards for an REH performing outpatient surgical services that are consistent with the CAH requirements for surgical services.

## **Proposed CoP #8: Infection Prevention and Control and Antibiotic Stewardship Programs**

- CMS is proposing a CoP for infection prevention and control and antibiotic stewardship
  programs for REHs that mirrors similar infection prevention and control requirements for
  hospitals and CAHs.
- REHs also must have facility-wide infection prevention and control and antibiotic stewardship programs that are coordinated with the REH quality assessment and performance improvement (QAPI) program, for the surveillance, prevention, and control of hospital-acquired infections and other infectious diseases and for the optimization of antibiotic use through stewardship. CMS proposes requirements for these programs in the rule.

#### Proposed CoP #9: Staffing and Staff Responsibilities

- CMS believes that REHs should have the flexibility to determine how to staff the emergency department at the REH 24 hours, 7 days a week.
- CMS does not believe that it is necessary that a doctor of medicine or osteopathy, nurse
  practitioner, clinical nurse specialist, or physician assistant is available to furnish
  patient care services at all times in the REH. Instead, CMS is proposing that a physician
  or practitioner with training or experience in emergency care be on call and immediately
  available by telephone or radio contact and available on site within specified timeframes.
- In response ACEP's comment on the RFI about having care supervised by board-certified emergency physicians, CMS states that:
  - "While we agree that having a board-certified emergency physician serving as the medical director of the REH would benefit patients by ensuring that the REH is overseen by a highly qualified physician with a high level of expertise in emergency medicine, we believe that requiring this of REHs would be unduly burdensome due to the challenges faced by rural communities in obtaining and retaining medical professionals to provide health care services. While we are not proposing to require that REHs have a board-certified emergency physician serve as the medical director, we would encourage REHs to have such a physician serve in the capacity of medical director if possible."



#### **Proposed CoP #10: Nursing Services**

• CMS is proposing to require that REHs have an organized nursing service that is available to provide 24-hour nursing services for the provision of patient care. REHs must employ a director of nursing who is a licensed registered nurse and who is responsible for the operation of the nursing services.

#### **Proposed CoP #11: Discharge Planning**

- CMS proposes a series of discharge planning requirements that align with those required for CAHs.
- CMS refers to previously issued guidance on providing discharge instructions in a culturally and linguistically appropriate manner. Discharge planning should focus on returning the patient to a home or community-based setting to the fullest extent possible with necessary supports and service.

#### **Proposed CoP #12: Patients' Rights**

- CMS proposes a CoP for patients' rights that would set forth the rights of all patients to receive care in a safe setting and provide protection for a patient's emotional health and safety as well as their physical safety. Patients also have the right to personal privacy, to receive care in a safe setting, and to be free from all forms of abuse or harassment. Overall, the patients' rights CoP for REHs closely to the patients' rights CoP for hospitals.
- CMS proposes patients' rights relating to the use of restraints and seclusion, including staffing training requirements and death reporting requirements.
- CMS proposes to establish requirements related to a patient's visitation rights.

# Proposed CoP #13: Quality Assessment and Performance Improvement Program (QAPI Program)

- CMS is proposing to require that every REH develop, implement, and maintain an effective, ongoing, REH-wide, data-driven QAPI program. The proposed QAPI program contains the following five parts: (a) Program and scope; (b) Program data collection and analysis; (c) Program activities; (d) Executive responsibilities; and (e) Unified and integrated QAPI program for an REH in a multi-hospital system.
- CMS is interested in input from the public regarding possible unintended consequences that could occur as a result of allowing REHs to participate in a unified and integrated QAPI program.

#### **Proposed CoP #14: Agreements**

• In line with the requirement in the Consolidated Appropriations Act for REHs to have transfer agreements in place, CMS is proposing to require that REHs have in effect an agreement with at least one Medicare-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.

# **Proposed CoP #15: Medical Records**

• CMS proposes to require that the REH maintain a medical records system in accordance with written policies and procedures; that the records must be legible, complete, accurately



- documented, readily accessible, and systematically organized; and that a designated member of the professional staff is responsible for maintaining the records.
- CMS also proposes to require that the REH maintains a detailed record for each patient that includes specifically prescribed information. The record must include dated signatures of the doctor of medicine or osteopathy or other health care professional.
- Finally, CMS proposes a standard for electronic notifications if the REH utilizes an electronic medical records system or other electronic administrative system.

#### **Proposed CoP #16: Emergency Preparedness**

- CMS is proposing emergency preparedness requirements that align with the existing emergency preparedness standards for Medicare and Medicaid providers.
- As part of that approach, REHs must develop and maintain an emergency preparedness plan that must be reviewed and updated at least every 2 years. REHs must also develop and maintain an emergency preparedness training and testing program that is reviewed and updated at least every 2 years.
- REHs must conduct exercises to test the emergency plan at least annually. Specifically, REHs must conduct two testing exercises, a full-scale or functional exercise, and an additional exercise of its choice, every 2 years.

#### **Proposed CoP #17: Physical Environment**

• CMS is proposing that REHs be constructed, arranged, and maintained to ensure the safety of the patient and to provide facilities for diagnosis and treatment and for special hospital services appropriate to the needs of the community. CMS proposes certain requirements around the condition of the physical plant and the overall REH environment to achieve this goal.

#### **Proposed CoP #18: Skilled Nursing Facility (SNF) Distinct Part Unit**

• REHs are allowed to establish a unit that is a distinct part licensed as a SNF to furnish post-REH or post-hospital services. A distinct part SNF is an area that is separately licensed and certified to provide SNF services at all times. A distinct part SNF must be physically distinguishable from the REH, must be fiscally separate for cost reporting purposes, and the beds in the certified distinct part SNF unit of an REH must meet certain Medicare requirements prescribed for long-term care facilities.

#### **Proposed Changes to CAH CoPs**

In the rule, CMS also proposes changes to the CAH CoPs in the following areas:

- Adding the definition of "primary roads" to the CoP on status and location;
- Modifying the CoP related to patients' rights, including requirements around the use of restraints and seclusion; and
- Aligning the CoP for staffing and staff responsibilities with current standards for hospitals in order to allow for either a unique medical staff for each CAH or for a unified and integrated medical staff shared by multiple hospitals, CAHs, and REHs within a health care system.