Medicare and Medicaid Programs; Conditions of Participation (CoPs) for Rural Emergency Hospitals (REH) and Critical Access Hospital (CAH) CoP Updates Proposed Rule Summary

The Centers for Medicare & Medicaid Services (CMS) released a proposed rule on June 30, 2022 that would establish CoPs that Rural Emergency Hospitals (REH) must meet to participate in the Medicare and Medicaid programs. This proposed rule also includes changes to the CAH CoPs. Proposed payment and enrollment policies, quality measure specifications and quality reporting requirements for REHs will be in future rulemaking. CMS also modifies the provider agreement regulations to include REHs.

The proposed rule will be published in the July 6, 2022 issue of the *Federal Register*. **The public comment period will end on August 29, 2022.**

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I. Legislative History and Public Comments

A. Legislative History

Section 125 of the Consolidated Appropriations Act (CAA), 2021 establishes REHs as a new Medicare provider type that will furnish emergency department services and observation care. The REH must have a staffed emergency department 24 hours a day, 7 days a week. In addition, an REH may elect to furnish other medical and health services on an outpatient basis as the Secretary may specify through rulemaking. REHs may not provide acute inpatient services, with the exception of skilled nursing facility (SNF) services that are furnished in a distinct part unit.

An REH must have a transfer agreement in effect with a level I or level II trauma center and meet other conditions, including licensure, emergency department staffing, staff training and certification, and CoPs applicable to hospital emergency departments and CAHs for emergency services. REHs must have an annual per patient average length of stay of 24 hours or less.

Providers that are CAHs and small rural hospitals (50 or fewer beds) as of December 27, 2020, may convert to REHs. To be considered rural as of December 27, 2020, the hospital or CAH must have been either located in an area designated as rural by the Office of Management and Budget (OMB) or be treated as rural under the inpatient hospital prospective payment system (IPPS)—e.g., located in an urban area but reclassified to a rural area for all IPPS purposes.

B. Solicitation of Public Comments

In the 2022 outpatient prospective payment system proposed rule, CMS solicited public comments to inform its policy making for REHs on: (1) the type and scope of services they may offer; (2) health and safety standards, including licensure and CoPs; (3) health equity; (4) collaboration and care coordination; (5) quality measurement; (6) payment provisions; and (7) the enrollment process.

Specific comments summarized in the preamble of this proposed rule suggested CoPs, including requirements for staffing, transfers, and supervision, services that should be offered by REHs, and the health equity implications for REHs. Several commenters stated that the CoPs currently in place for CAHs would be sufficient for REHs. Commenters also recommended that REHs should provide maternal health, behavioral/mental health services and telehealth services to further support the communities that they will serve.

II. Conditions of Participation

A. REHs

CMS is proposing CoPs for REHs that are modeled closely after the CoPs for CAHs. In some instances, CMS has proposed requirements that are similar to the CoPs for hospitals and conditions for coverage (CfC) for Ambulatory Surgical Centers (ASCs). The below lists the CoPs that CMS proposes REHs must meet. To the extent relevant, this summary may either refer to an existing CoP (or CfC as applicable) without providing additional detail on the requirement or provide additional detail beyond just a reference to an existing CoP or CfC if there are new requirements being proposed.

1. Definition

CMS proposes to define an REH as 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 REH may not provide inpatient services, except those furnished in a unit that is a distinct part licensed as a SNF to furnish post-REH or post-hospital extended care services.[1]

[1] CMS' proposed rule sentence appears to be suggesting than an REH may provide Medicare covered post-REH SNF services. However, REH services by definition are not inpatient services and are limited to an average of 24 hours per patient that would make it impossible for an REH patient to meet the 3-day prior inpatient hospitalization required to receive Medicare covered post-hospital SNF services. The REH could, however, provide SNF services to a patient meeting the 3-day prior inpatient hospitalization requirement referred from a general acute care hospital. HPA is seeking clarification from CMS on this point.

Public comments indicated CMS should allow the average length of stay to be increased from 24 hours in certain instances. In the proposed rule, CMS indicates its expectation that an REH transfer patients that require a higher level of care as soon as possible. There may be occasional circumstances in which a facility is not immediately available to provide a higher level of care, resulting in patients receiving services at the REH for more than 24 hours. However, CMS does not believe that this will occur at a frequency that will seriously affect the REH's average length of stay.

2. Provider Agreement and Emergency Treatment and Active Labor Act (EMTALA)

Consistent with the CAA, 2021, CMS is proposing to amend the provider agreement regulations to include REHs. This means that REHs must adhere to the requirements for submission and acceptance of provider agreements.

Further, CAA, 2021 subjects REHs to the provision of section 1867 of the Act with respect to responsibilities of hospitals that have emergency departments. CMS is modifying the applicable regulations to subject REHs to EMTALA just as it does for CAHs and hospitals with emergency departments.

3. Designation and Certification

CMS proposes that an REH must have been a CAH or an IPPS hospital with not more than 50 beds either located in a county (or equivalent unit of local government) considered rural (as defined by OMB) or treated as rural for IPPS purposes as of December 27, 2020.

4. Compliance with Federal, State, and Local Laws and Regulations

CMS proposes to require the REH to be in compliance with applicable Federal laws, state, and local laws and regulations. Consistent with the law, the REH must be located in a state that provides for the licensing of such hospitals under state or applicable local law and 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.

5. Governing Body and Organizational Structure

CMS proposes to require the REH to have an effective governing body, or responsible individual or individuals, that is legally responsible for the conduct of the REH. This requirement is consistent with the hospital and CAH CoPs. With respect to services delivered via telemedicine, CMS is proposing to require the governing body of the REH (or responsible individual) ensure that the distant-site telemedicine entity furnishes its services in a manner that enables the REH to comply with all applicable CoPs and standards.

6. Provision of Services

CMS' proposal will require that the REH's health care services must be furnished in accordance with appropriate written policies that are the same as in the CAH CoPs.

7. Emergency Services.

Consistent with the hospital and CAH CoPs, CMS is proposing the REH must provide the emergency care necessary to meet the needs of its patients in accordance with acceptable standards of practice. The REH 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. CMS proposes that there must be adequate medical and nursing personnel qualified in emergency care to meet the needs of the facility but is not requiring a physician or non-physician practitioner to be on site at the facility at all times. CMS requests comments on appropriateness of not requiring a physician or non-physician practitioner to be on-site at the REH at all times.

8. Laboratory Services

CMS proposes the same CoP that applies to hospitals at 42 CFR § 482.27 and to provide the same laboratory services identified in the CAH CoPs. REH laboratory services must be performed in a facility certified in accordance with the Clinical Laboratory Improvement Act (CLIA).

9. Radiologic Services

CMS proposes REH radiologic requirements consistent with the hospital and CAH radiologic requirements found at 42 CFR § 482.26 and at 42 CFR § 485.635(b)(3) respectively and the interpretative guidelines for CAHs in Appendix W of the State Operations Manual (SOM).

10. Pharmaceutical Services

CMS is proposing REH CoPs for pharmaceutical services consistent with those for CAHs.

11. Additional Outpatient Medical and Health Services

Public commenters recommended that CMS allow REHs to furnish radiology, laboratory, outpatient rehabilitation, surgical, maternal health, and behavioral health services. CMS is proposing that REHs be allowed to provide additional medical and health outpatient services that include, but are not limited, to those identified by commenters. CMS proposes to apply the same standards to additional services provided by REHs that apply to hospitals at 42 CFR § 482.54(c).

Consistent with the 482.26 and Administration's priorities in improving access to maternal health services, CMS believes it would be beneficial for REHs to provide maternal health services that include prenatal care, low-risk labor and delivery and postnatal care. CMS is seeking input on whether REHs should be permitted to provide low-risk labor and delivery, and whether or not it should require that the REH also provide outpatient surgical services in the event surgical labor and delivery intervention is necessary.

Several commenters indicated that REHs should provide behavioral health services that include substance use disorder treatment. CMS indicates that these services could be provided at the

option of the REH. If the REH chooses to provide additional outpatient medical and health services, CMS proposes to require that the provision of the additional service be based on nationally recognized guidelines and standards of practice, aligning the proposed requirement with the hospital CoPs for outpatient services. CMS further proposes to require that the REH have a referral system in place to different levels of care, including follow-up care, as appropriate.

12. Infection Prevention and Control; Antibiotic Stewardship

CMS is proposing a CoP for infection prevention and control and antibiotic stewardship programs consistent with hospitals and CAHs (at 42 CFR §§ 482.42 and 485.640, respectively).

13. Staffing and Staff Responsibilities

CAA, 2021 requires that the emergency department of the REH be staffed 24 hours a day, 7 days a week. CMS believes that REHs should have the flexibility to determine how to staff the emergency department with the expectation that the individual(s) staffing the emergency department is competent to receive patients and activate appropriate medical resources for the treatment of the patient. CMS proposes that REHs meet the applicable CAH requirements at 42 CFR § 485.631 for staffing and staff responsibilities.

CMS is proposing the REH standards align with the CAH emergency services CoP at 42 CFR § 485.618 requiring that there be a doctor of medicine or osteopathy, a physician assistant, a nurse practitioner, or a clinical nurse specialist, with training or experience in emergency care, on call and immediately available by telephone or radio contact, and available on site within specified timeframes.

While CMS is not proposing to require that REHs have a board-certified emergency physician serve as the medical director, it encourages REHs to have such a physician serve in the capacity of medical director if possible.

14. Nursing Services

As REHs only provide outpatient services, CMS does not believe that all of the nursing services requirements for hospitals and CAHs would be appropriate for REHs. Consistent with the hospital requirements, CMS proposes to require that REHs have an organized nursing service that is available to provide 24-hour nursing services for the provision of patient care.

15. Discharge Planning

CMS proposes to closely align the discharge planning requirements for REHs with the requirements for hospitals and CAHs. In addition, in order to encourage patient engagement and understanding of their discharge plan or instructions, CMS recommends that providers follow the

National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care.[2]

16. Patient's Rights

CMS proposes to establish the patient's rights CoP for REHs based on the patient's rights CoP for hospitals at 42 CFR § 482.13. CMS proposes to add these same patient's rights to the CAH CoPs as well (as explained in the next section). Some of these requirements are currently in the SOM for CAHs while some are not explicitly required. The patient's rights CoPs for REHs and CAHs is less prescriptive than those for hospitals based on the scope of services they provide and patient populations that they serve. CMS' proposal includes:

- Notice of Rights. CMS proposes that 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. This includes a proposal to require the REH to establish a process for the oversight and prompt resolution of patient grievances and for informing each patient whom to contact to file a grievance.
- Exercise of Rights. CMS proposes to specify those rights a patient has regarding their medical care, which includes the right to make informed decisions including the right to request or refuse treatment (but not demand inappropriate or unnecessary treatment).
- Privacy, Safety, and Confidentiality of Patient Records. CMS proposes that the patient has the right to personal privacy, confidentiality of records, receive care in a safe setting, be provided access to medical records and be free from all forms of abuse or harassment.
- Use of Restraints and Seclusion. CMS is proposing requirements that are less burdensome than those for hospitals because the need for REHs to utilize restraints and seclusion should be low and patients in need of restraint and seclusion should be transferred to a higher level of care. CMS explicitly requests comments on the potential need to require standards that are more stringent to address patient protections, and the feasibility of implementing such requirements in rural communities.
- Staff Training Requirements for the Use of Restraints or Seclusion. The same proposed training requirements would apply to REHs and CAHs.
- Death Reporting Requirements. These requirements are similar to those for hospitals at 42 CFR § 482.13 when reporting deaths associated with the use of seclusion or restraint.
- Patient Visitation Rights. CMS proposes to establish requirements related to a patient's visitation rights consistent with the current hospital and CAH regulations.

17. Quality Assessment and Performance Improvement (QAPI) Program

CMS proposes to require that every REH develop, implement and maintain an effective, ongoing, REH-wide, data-driven QAPI program. The REH would be required to measure, analyze and track quality indicators. Similar to the program activities standard for hospitals at 42 CFR § 482.21(c), CMS proposes to require the REH to set priorities for its performance improvement activities and that these activities are focused on high-risk, high-volume, or

[2] Culturally and Linguistically Appropriate Services - Think Cultural Health (hhs.gov)

problem-prone areas. Consistent with a new CoP being proposed for CAHs and one already in existence for hospitals, CMS proposes to allow REHs that are part of a multi-facility system consisting of multiple separately certified hospitals, CAHs, and/or REHs to elect to have a unified and integrated QAPI program.

18. Transfer Agreements

By law, REHs must have a transfer agreement with a level I or level II trauma center. CMS is proposing to require that REHs must 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. While CMS expects REHs to have a transfer agreement in place with a level I or II trauma center, REHs may also have a transfer agreement with a hospital that is not designated as a level I or II trauma center.

As the law subjects REHs to EMTALA requirements under section 1867 of the Act, CMS is modifying the EMTALA regulations to include their application to REHs.

19. Medical Records

CMS proposes the same requirements for REHs that apply to CAHs at 42 CFR § 485.638.

20. Emergency Preparedness

CMS is proposing emergency preparedness requirements consistent with those for CAHs. The emergency preparedness requirements for all Medicare-participating providers and suppliers are consistent, with some differences based on the provider type (such as inpatient versus outpatient).

21. Physical Environment

All Medicare and Medicaid participating providers and suppliers are currently subject to the 2012 edition Health Care Facilities portion of the Life Safety Code (LSC), a compilation of fire safety requirements for new and existing buildings that is updated and published every 3 years by the National Fire Protection Association. Chapters 7, 8, 12, and 13 would not apply to REHs. The provisions of the LSC would not apply in a state if CMS finds that a fire and safety code imposed by state law adequately protects patients. CMS proposes to allow for waivers of these provisions under the same conditions and procedures that it currently uses for waivers of applicable provisions of the LSC to other health care providers.

22. SNF Distinct Part Unit

CMS proposes that 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 and must be fiscally separate for cost reporting purposes. The beds in the certified distinct part SNF unit of an REH must meet the requirements applicable to distinct part SNFs at

42 CFR part 483, subpart B. A distinct part SNF of an REH is not subject to the REH's length of stay limits of less than an annual per patient average of 24 hours.

B. CAHs

1. Location Requirements

To meet the CAH location requirements, a CAH must be (1) located more than a 35-mile drive from a hospital or another CAH (or 15 miles in the case of mountainous terrain or areas with only secondary roads available); or (2) certified before January 1, 2006, by the state as being a necessary provider of health care services to residents in the area. A secondary road is a road that is not a primary road.

In 2015, CMS refined the definition of "primary road" described in the State Operations Manual (SOM), Chapter 2, Section 2256A. The purpose of this refinement was to make the definition of "primary road" more consistent across regions of the U.S. and make measuring distances between facilities more consistent. CMS did not hospitals anticipate this refinement would have any significant impact on the eligibility of existing CAHs to maintain their certification. However, a number of CAHs raised concerns that CMS' sub-regulatory clarification would preclude their recertification even though the CAH's circumstances were unchanged—they neither moved nor did any hospitals or CAHs move closer to them.

In this proposed rule, CMS is further refining and codifying the definition to offer maximum flexibility to providers to meet the distance criteria. Presently, primary roads are defined as any U.S. highway, including any road (1) in the National Highway System, as codified at 23 U.S.C. section 103(b); (2) in the Interstate System, as defined at 23 U.S.C. section 103(c); or (3) which is a U.S.-Numbered Highway (also called "US Routes" or "US Highways") as designated by the American Association of the State Highway and Transportation Officials regardless of whether it is also part of the National Highway System. This definition exists in sub-regulatory guidance only.

CMS proposes to revise 42 CFR § 485.610(c) to clarify that a "primary road" is a numbered Federal highway, including interstates, intrastates, expressways or any other numbered Federal highway; or a numbered state highway with two or more lanes each way. In the proposed rule, CMS specifically solicits comments on whether numbered Federal highway should exclude those with only one lane in each direction and include only those with two or more lanes in each direction, similar to the description of numbered state highways.

In the proposed rule, CMS indicates plans to enforce the revised location requirements using a centralized, data-driven review procedure that focuses on hospitals being certified in proximity to a CAH, rather road classifications. CMS would review all hospitals and CAHs within a 50-mile radius of the CAH during each review of eligibility, and then subsequently on a 3-year cycle.

Following the initial review of distance and location, further investigations would focus primarily on expanded healthcare capacity and access to care within the 35-mile radius of the

CAH. Those CAHs with no new hospitals within 50 miles would be immediately recertified. Those CAHs with new hospitals within 50 miles will receive additional review based on the distance from the new hospital and the definitions for primary roads and mountainous terrain.

To facilitate this review, CMS will utilize the geocoding of hospitals to identify those CAHs that are located within 50 miles of another certified hospital. Those CAHs that do not meet the regulatory distance and location requirements at the time of review would be identified as non-compliant and may face enforcement actions.

2. Patient's Rights

CAHs do not currently have any patient's rights CoPs in the CFR—only in subregulatory guidance (the SOM). CMS proposes to establish patient's rights CoPs that are similar to those for hospitals although less prescriptive. The proposed rule would allow CAHs to develop policies and procedures based on the scope of services they provide and patient populations they serve. The proposed patients' rights provisions of CAHs are the same as those being proposed for REHs described earlier (i.e., less stringent than hospital requirements as a CAH would not be expected to encounter patient situations where restraint and seclusion are required and if those are encountered, those patients would be referred to a better equipped facility).

CMS is specifically soliciting comments on the appropriateness of the patient's rights requirements proposed for restraint and seclusion, the potential need to require standards that are more stringent to address patient protections, and the feasibility of implementing such requirements in rural communities.

3. Unified and Integrated Medical Staff: Multi-Facility System

CMS proposes requirements for a unified and integrated medical staff in multi-facility CAH systems that are in alignment the current standards for hospitals. These same standards would apply to REHs and would:

- Allow for either a unique medical staff for each facility or for a unified and integrated medical staff shared by multiple hospitals, CAHs, and REHs within a health care system.
- Hold a CAH or REH responsible for showing that it actively addresses its use of a system unified and integrated medical staff model.
- Require that the medical staff members holding privileges at each separately certified CAH or REH in the system have voted either to participate in a unified and integrated medical staff structure or to opt out of such a structure, and to maintain a CAH or REH-specific separate and distinct medical staff for their respective CAH/REH.
- Require that 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, which include a process for the members of the medical staff of each separately certified CAH/REH (that is, all medical staff members who hold specific privileges to practice at that CAH/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 CAH/REH.

- The unified and integrated medical staff must be established in a manner that takes into account each CAH/REH's unique circumstances, and any significant differences in patient populations and services offered in each CAH/REH.
- The unified and integrated medical staff give due consideration to the needs and concerns of members of the medical staff, regardless of practice or location, and the CAH/REH has mechanisms in place to ensure that issues localized to particular CAHs/REHs are duly considered and addressed.

4. Unified and Integrated Infection Prevention and Control and Antibiotic Stewardship: Multi-Facility System

CMS proposes to establish the same CoP for infection prevention and control in CAHs and REHs as hospitals in multi-facility systems. The governing body for a multi-facility system could elect to have unified and integrated infection prevention and control and antibiotic stewardship programs for all of its member facilities, including any CAHs/REHs, after determining that such a decision is in accordance with all applicable state and local laws. The system's single governing body would be responsible for ensuring that each of its separately certified CAHs/REHs meet all of the requirements.

5. Unified and Integrated QAPI Program: Multi-Facility System

CMS is proposing to allow CAHs/REHs that are part of a multi-facility system consisting of multiple separately certified hospitals, CAHs, and/or REHs to elect to have a unified and integrated QAPI program after determining that such a decision is in accordance with all applicable state and local laws. Once again, the system's governing body is responsible and accountable for ensuring that each of its separately certified CAHs/REHs meets the proposed QAPI program requirements.

III. Collection of Information Requirements (ICR)

A. REHs CoPs

To determine the cost of information collection for the new REH provider type, CMS relied heavily on the North Carolina Rural Health Research Program's study titled, "How Many Hospitals Might Convert to a Rural Emergency Hospital (REH)?"[3] and a study by the consulting firm CLA titled "A Path Forward: CLA's Simulations on Rural Emergency Hospital Designation."[4]

A key takeaway from both studies is that available data support a possible wide range of conversion decisions—for instance, the CLA study indicates between 11 and 600 CAHs would

[3] How Many Hospitals Might Convert to a Rural Emergency Hospital (REH)? - Sheps Center (unc.edu)
[4] A Path Forward: CLA's Simulations on Rural Emergency Hospital Designation : 2022 : Articles : Resources : CLA (CliftonLarsonAllen) (claconnect.com)

benefit from conversion to REH status. For the ICR estimates, CMS assumed 68 CAHs or small rural hospitals would convert to REHs.

When considering the ICR burden for REHs, given that the proposed CoPs align closely with existing standards, CMS considered both the existing burden estimates for CAHs and hospitals, as well as its ongoing experience with these provider types. CMS also considered that REHs would only be furnishing outpatient services, which would lessen their burden compared to providing inpatient and outpatient services as a hospital or CAH.

To determine cost, CMS used average hourly wages from the Bureau of Labor Statistics for eight labor categories.[5] Using these average hourly wages, CMS estimated a burden level in hours associated with paperwork compliance with each CoP. Table 2 in the preamble of the proposed regulation shows the aggregate compliance burden for 68 REHs converting from hospital or CAH status at 18,939 hours and a total cost of $1,538,800.

B. CAHs CoPs

Additional ICR burden on CAHs will result from requiring CAHs to notify patients of their rights and whom to contact to file a grievance. CMS believes that in large measure, CAHs would be able to use existing systems for providing patients with information and handling complaints, and the elements listed in the regulation only serve to give basic assurance that these systems are responsive to patient grievances and act effectively.

Costs associated with formalizing a process and modifying any existing notices or processes will most likely be offset by a reduction in patient-initiated lawsuits regarding care compared to a less specific approach, and should provide a valuable tool for targeting internal quality assurance mechanisms. CMS estimates that the notice of rights will result in 98,600 aggregate burden hours at a total cost to CAHs of $3.7 million.

CMS indicates that any burden estimates associated with new restraint and seclusion requirements being newly imposed on CAHs are exempt from ICR burden estimation because the time, effort, and financial resources necessary to comply with the requirement are incurred in the normal course of their activities.

IV. Impacts

CMS indicates the proposed CoPs for the new REH provider type are similar to those already met by the facilities that will potentially convert to REH status. Assuming the estimated number of hospitals converting to the new program is approximately correct, the provisions of this proposed rule do not reach the threshold (economic impact of $100 million or more in any single year) to be considered a major rule. This would remain the case if the number converting were to be significantly higher. For this reason, a regulatory impact analysis is not required.

[5] Physician, Registered Nurse, Administrator, Physician Assistants, Nurse Practitioner, Clerical Staff, Facilities Director and Mid-Level Practitioner.

Payment policies for REHs will be developed in separate rulemaking. CMS expects that the total economic impact—including the CoPs and the payment provisions—will exceed $150 million and be considered a major rule. A regulatory impact analysis will be provided with the rulemaking implementing the REH payment provisions.