



August 29, 2022

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

[Re: Docket: CMS-3419-P; RIN: 0938-AU92. Submitted electronically via
<http://www.regulations.gov>]

Dear Administrator Brooks-LaSure:

The Joint Commission appreciates the opportunity to comment on the CMS proposed rule *Medicare and Medicaid Programs; Conditions of Participation (CoPs) for Rural Emergency Hospitals (REH) and Critical Access Hospital (CAH) CoP Updates*.

Founded in 1951, The Joint Commission seeks to continuously improve health care for the public in collaboration with other stakeholders, by evaluating health care organizations (HCOs) and inspiring them to excel in providing safe and effective care of the highest quality and value. An independent, not-for-profit organization with a global presence, The Joint Commission has programs that accredit or certify more than 22,000 HCOs and programs in the United States. The Joint Commission evaluates across the continuum of care, including most of the nation's hospitals. Although accreditation is voluntary, a variety of federal and state government regulatory bodies, including CMS, recognize The Joint Commission's decisions and findings for Medicare or licensure purposes.

The Joint Commission provides the following comments regarding several sections of the proposed rule.

II. Provisions of the Proposed Regulation

A. Rural Emergency Hospital Conditions for Participation (Proposed Part 485, Subpart E) 8. Condition of participation: Emergency Services (Proposed § 485.516)

In accordance with Section 1861(kkk)(2)(D)(iv) of the Social Security Act (the Act), as added by Section 125(a)(1)(B) of the Consolidated Appropriations Act of 2021, the REH must comply with the CAH emergency services requirements at § 485.618 as well as the hospital emergency services requirements, which are located at § 482.55, as determined to be applicable... CMS proposes at § 485.516 to require the REH provide the emergency care necessary to meet the needs of its patients in accordance with acceptable standards of practice. The REH must also

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 at § 485.516(a)...At § 485.516(b), CMS proposes that there be adequate medical and nursing personnel qualified in emergency care to meet the needs of the facility. To comply with this requirement, CMS expects the REH to conduct an analysis based on the anticipated staffing needs and once the REH begins to provide services, the analysis would include actual staffing needs. Lastly, at § 485.516(c), CMS proposes to require the REH provide emergency services that meet the CAH requirements specified at § 485.618(a) through (e), as required by section 1861(kkk)(2)(D)(iv)(I) of the Act. CMS is also seeking comment on the proposed staffing requirements for the provision of emergency services in the REH to gain insight on the appropriateness of not requiring a practitioner to be always on-site at the REH.

The Joint Commission Comments:

The Joint Commission agrees that the REH must meet emergency services requirements consistent with CAH requirements at § 485.618 as well as the hospital emergency services requirements at § 482.55. We recognize that CMS is providing flexibility regarding REH emergency services staffing requirements because rural facilities often face resource challenges that make it difficult to comply with prescriptive requirements. However, we strongly believe guardrails should be in place to ensure REH clinicians have appropriate training and expertise to deliver high-quality emergency services. We also strongly believe that a clinician with training and experience in emergency services must be immediately available at all times because the intent of the law is to ensure patients have access to emergency services. If the patient must wait for the clinician to arrive to be evaluated and treated, then emergency services are not readily available. We understand and appreciate the workforce staffing challenges. However, we must ensure patients in rural areas at a minimum truly have access to emergency services, which require a clinician to be always on-site and ready to receive patients.

9. Condition of participation: Laboratory services (Proposed § 485.518)

In accordance with the Clinical Laboratory Improvement Amendments of 1988 (CLIA), at § 485.518(a), CMS proposes to require that the REH must ensure that all laboratory services provided to its patients are performed in a facility certified in accordance with the CLIA requirements at 42 CFR part 493. Furthermore, at § 485.518(b) CMS is also proposing that the REH have emergency laboratory services available that would be essential to the immediate diagnosis of the patient, 24 hours a day. This proposal is appropriate given the provision that the REH must provide emergency services 24 hours a day. In addition, this proposal is consistent with comments received through the REH request for information noting that laboratory services should be required for the REH.

The Joint Commission Comments:

The Joint Commission agrees that the REH must provide emergency laboratory services essential to the immediate diagnosis and care of the patient. Laboratory diagnostics play a critical role in triaging and evaluating patients presenting to the emergency department.

10. Condition of participation: Radiologic services (Proposed § 485.520)

CMS proposes that the REH radiologic requirements mirror the hospital radiologic requirements found at § 482.26, which is consistent with the current CAH standard at § 485.635(b)(3) and interpretative guidelines for CAHs in Appendix W of the State Operations Manual (SOM).

The Joint Commission Comments:

Similarly to laboratory services, radiological services is another essential component of emergency care. Therefore, we agree the REH should have radiological requirements consistent with hospital and CAH radiological requirements.

13. Condition of participation: Infection prevention and control and antibiotic stewardship programs (Proposed § 485.526)

CMS proposes a CoP for infection prevention and control and antibiotic stewardship programs for the REH at § 482.526 to mirror similar infection prevention and control requirements for hospitals and CAHs (at §§ 482.42 and 485.640, respectively) that reflect state-of-the-art practices and terminology...CMS also proposes allowing for the governing body of the REH to elect to have unified and integrated infection prevention and control and antibiotic stewardship programs with the health care system of which it may be a part.

The Joint Commission Comments:

The Joint Commission believes it is appropriate to require the REH meet infection prevention and control and antibiotic stewardship programs requirements consistent with CAH requirements at § 485.640 as well as the hospital requirements at § 482.42. Because the COVID-19 pandemic renewed vigilance towards preventing the spread of infectious diseases, the REH should be required to comply with infection prevention and control requirements consistent with other HCOs. In addition, The Joint Commission strongly supports requiring the REH develop an antibiotic stewardship program and has been a leader requiring its accredited organizations meet similar requirements. We also support allowing a REH that is part of a health care system to have unified and integrated programs. This will reduce administrative burden on the REH while still holding it accountable for meeting appropriate standards.

14. Condition of participation: Staffing and staff responsibilities (Proposed § 485.528)

CMS does not believe that it is necessary to apply the CAH requirement that a doctor of medicine or osteopathy, nurse practitioner, clinical nurse specialist, or physician assistant is available to always furnish patient care services (§ 485.631(a)(4)) to the REH. Instead, CMS is proposing to require that the REH standards align with the CAH emergency services requirements at § 485.618. The CAH provision at § 485.618(d) requires 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. This allows for the alignment of the REH proposed provisions with the CAH emergency services standards, as required by the statute.

The Joint Commission Comments:

As previously noted above, The Joint Commission strongly believes CMS should require the REH to have a clinician with training and experience in emergency services immediately available to render appropriate care. Ensuring clinicians with appropriate training can promptly provide care to patients reflects the intent of the law and will ensure rural communities have access to emergency services.

16. Condition of participation: Discharge planning (Proposed § 485.532)

CMS proposes to closely align the proposed discharge planning requirements for the REH with the requirements for hospitals and CAHs. Specifically, CMS proposes at § 485.532 to require that the patient's discharge plan address the patient's goals of care and treatment preferences...CMS also recommends that the REH follow the National Standards for Culturally and Linguistically Appropriate Services (CLAS) in Health and Health Care.

The Joint Commission Comments:

The Joint Commission believes it is appropriate to require the REH meet discharge planning requirements that are closely aligned with the requirements for hospitals and CAHs. In addition, a REH that delivers patients discharge planning consistent with CLAS is taking proactive steps to deliver more equitable care. Improving health equity should be an organizational priority for the REH and all HCOs because it will improve the quality of care delivered to all patients. We encourage the REH to assess community needs so that it can develop culturally appropriate discharge planning materials and training for the patients it serves.

18. Condition of participation: Quality assessment and performance improvement program (QAPI program) (Proposed § 485.536)

CMS proposes to require the REH develop, implement, and maintain an effective, ongoing, REH-wide, data-driven QAPI program. CMS also proposes allowing the REH to elect to have a unified and integrated QAPI program with the health care system of which it may be a part.

The Joint Commission Comments:

The Joint Commission believes it is appropriate to require the REH meet QAPI program requirements consistent with CAH QAPI requirements at § 485.641 and hospital QAPI requirements at § 482.21. As the health care delivery system transitions from the demands imposed by the COVID-19 pandemic, renewing focus on quality improvement is critical towards improving patient outcomes. Therefore, the REH should be required to comply with these requirements consistent with other HCOs. We also support allowing a REH that is part of a health care system to have a unified and integrated program. This will reduce administrative burden on the REH while still holding it accountable for meeting appropriate standards.

21. Condition of participation: Emergency preparedness (Proposed § 485.542)

CMS proposes to require the REH meet emergency preparedness requirements that align with the existing standards for Medicare and Medicaid participating providers and suppliers.

The Joint Commission Comments:

The Joint Commission believes it is appropriate to require the REH meet emergency preparedness requirements consistent with CAH requirements. Like other HCOs, the REH will face situations which will require staff to rely on emergency preparedness training. We also agree that a REH should have a comprehensive emergency management program that utilizes an all-hazards approach to respond to the wide range of emergencies that are becoming more frequent and widespread.

B. Proposed Changes for Critical Access Hospital Conditions of Participation

2. Condition of participation: Patient's Rights (§ 485.614)

CMS proposes to require the CAH comply with patient's rights requirements, including those relating to the use of restraints and seclusion. The CAH must provide patient-centered, trauma-informed, competency-based training and education to staff for the use of restraints and seclusion.

The Joint Commission Comments:

The Joint Commission believes it is appropriate to require the CAH meet patient's rights requirements consistent with hospital requirements at § 482.13. We recommend, though, that CMS define the terms "patient-centered" and "competency-based" because the terms are not included in the hospital requirements and there may be confusion what constitutes a compliant training program. In addition, we recommend that CMS remove the word "trauma-informed" from the staff training requirements to remain consistent with related hospital and proposed REH requirements that do not include this term.

While we appreciate that requirements related to the use of restraints and seclusion generally are less burdensome than those for hospitals, we urge the adoption of certain hospital requirements at § 482.13 that are not included in the proposed CAH requirements. These requirements would provide additional guardrails for the use of restraint or seclusion on patients. These include:

- Ensuring that the use of restraint or seclusion is only provided under a physician or licensed practitioner's specific orders (§ 482.13 (e)(4) through (e)(6))
- Requiring monitoring by a physician, licensed practitioner, or trained staff when the use of restraint or seclusion is exercised and discontinued when appropriate (§ 482.13 (e)(9) and (e)(10))
- Requiring face-to-face interaction with a physician, licensed practitioner, or trained registered nurse when the use of restraint or seclusion is exercised for the management of violent or self-destructive behavior (§ 482.13 (e)(12) through (e)(14)).

3. Condition of participation: Staffing and staff responsibilities (§ 485.631)

CMS proposes to allow the CAH to either have a unique medical staff or to participate in a health care system's unified and integrated medical staff.

The Joint Commission Comments:

The Joint Commission believes it is appropriate to require the CAH meet staffing and staff responsibility requirements consistent with hospital requirements. We support allowing a CAH that is part of a health care system to have unified and integrated staff because it will allow the CAH access to a range of staff throughout the system, most notably specialists. The proposed changes will also allow the CAH flexibility in meeting staff needs while still being accountable for meeting appropriate staffing standards.

4. Condition of participation: Infection prevention and control and antibiotic stewardship programs (§ 485.640).

CMS proposes to allow the CAH governing body to elect to have unified and integrated infection prevention and control and antibiotic stewardship programs with the health care system of which it may be a part.

The Joint Commission Comments:

Like the proposed REH requirements, we support allowing a CAH to have unified and integrated infection prevention and control and antibiotic stewardship programs with the health care system of which it may be a part. This will reduce administrative burden on the CAH while still holding it accountable for meeting appropriate standards.

5. Condition of participation: Quality assessment and performance improvement program (§ 485.641).

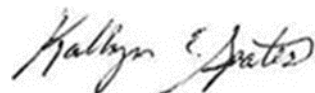
CMS proposes to allow the CAH to elect to have a unified and integrated QAPI program with the health care system of which it may be a part.

The Joint Commission Comments:

Like the proposed REH requirement, we support allowing a CAH to have a unified and integrated QAPI program with the health care system of which it may be a part. This will reduce administrative burden on the CAH while still holding it accountable for meeting appropriate standards.

The Joint Commission is pleased to answer any questions you may have regarding our comments. If you have any questions, please do not hesitate to contact me or staff: Tim Jones, Senior Associate Director, Federal Relations, at tjones2@jointcommission.org or 202-783-6655.

Sincerely,



Kathryn E. Spates, JD
Executive Director, Federal Relations