August 25, 2022

Chiquita Brooks-LaSure, MPP
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Baltimore, MD 21244

Submitted electronically via www.regulations.gov

RE: **Conditions of Participation (CoPs) for Rural Emergency Hospitals (REH) and Critical Access Hospital CoP Updates (CMS-3419-P)**

Dear Administrator Brooks-LaSure:

On behalf of the Emergency Department Practice Management Association (EDPMA), we appreciate the opportunity to provide comments on the Centers for Medicare and Medicaid Services' proposed rule regarding the Conditions of Participation (CoPs) for Rural Emergency Hospitals (REHs). Separately, we will also be submitting comments on the REH payment, enrollment, and quality reporting policies discussed in the calendar year (CY) 2023 Hospital Outpatient Prospective Payment System (OPPS) proposed rule.

EDPMA is the only professional physician trade association focused on the delivery of high-quality, cost-effective care in the emergency department. EDPMA's membership includes emergency medicine physician groups of all ownership models and sizes, many of whom serve rural communities, as well as billing, coding, and other professional support organizations that assist healthcare providers in our nation's emergency departments. Together, EDPMA's members deliver (or directly support) health care for about half of the 146 million patients that visit U.S. emergency departments each year.

1. General Eligibility

As directed by statute, the REH designation is only available to a pre-existing CAH or rural hospital without more than 50 beds as of the date of enactment or December 27, 2020. In reading the proposed rules, CMS provides no clarification if a CAH or rural hospital that otherwise meets these requirements but closed *after* December 27, 2020 is eligible to enroll as an REH. ***EDPMA urges CMS to provide an enrollment option for those CAHs or rural hospitals that otherwise meet the REH eligibility criteria but closed subsequent to December 27, 2020 to enroll as an REH.***[1] We strongly believe the goal of this legislation was to ensure access to emergency care in rural communities where access to care becomes ever more limited as demonstrated by the closure of over 120 Critical Access Hospitals (CAHs) in the last 10 years. Clarifying eligibility for facilities that closed after December 27, 2020 would align with the goals of the statute as well as comply with the statutory requirement that the facility exist "as of the date of the enactment."

2. Staffing & Staff Responsibilities

a. Minimum Staffing Requirements

EDPMA appreciates that CMS is anchoring the REH CoPs to existing CoPs for critical access hospitals (CAHs) and rural hospitals given that facilities would have already been subject to the CAH or hospital CoPs. However, we believe that CMS should pay special attention to the unique needs of REHs given the workforce needs of the communities in which they will exist and ensure that the minimum staffing requirements do not create a facility type that provides service at such a minimal level that the REH is not meeting the needs of the community. ***EDPMA believes it is imperative that the clinical services of an REH are physician-led and align with the need for these facilities to meet the requirements of Emergency Medical Treatment & Labor Act (EMTALA).*** While we believe that EMTALA and state licensing provisions will help ensure that REHs meet this level of service, we believe that the CoPs should support those mechanisms by ensuring an appropriate minimum level of service.

---

[1] According to data made available by The Cecil G. Sheps Center for Health Services Research as part of their tracking of rural hospital closures, 20 rural hospitals with at least 5 of those closing after the date of enactment of the REH statutory provisions: MercyOne Oakland Medical Center, Oakland, Nebraska; Community Health Care Systems- St. Mary's, St. Mary's, Kansas; Callaway Community Hospital, Fulton, Missouri; Audrain Community Hospital, Mexico, Missouri; Galesburg Cottage Hospital, Galesburg, Illinois); available at https://www.shepscenter.unc.edu/programs-projects/rural-health/rural-hospital-closures/ (accessed August 4, 2022).

b. Medical Director Requirements

CMS proposes to require that REHs meeting medical staffing requirements similar to critical access hospitals (CAHs). This includes that:

- *The emergency department of the REH must be staffed 24 hours a day, 7 days a week to receive patients and activate the appropriate medical resources*
- *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 and that any ancillary staff be supervised by the professional staff*
- *The doctor of medicine or osteopathy must:*
  - *Provide medical direction for the REH's health care activities and consultation for, and medical supervision of, the health care staff*
  - *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.*
  - *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.*
  - *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*
- *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.*[2]

Through its previous comment solicitation, CMS also acknowledged receipt of stakeholder input that a board-certified emergency physician should be required to serve as the REH medical director. In response, CMS encouraged REHs to have a board-certified emergency physician serve in that position if possible but does not propose to make it a requirement.

[2] Medicare and Medicaid Programs; Conditions of Participation (CoPs) for Rural Emergency Hospitals (REH) and Critical Access Hospital CoP Updates, 87 Fed. Reg. 40395 (July 6, 2022)(to be codified as § 485.528(c)(2)).

First, regarding the qualifications of an REH medical director, ***EDPMA strongly believes that the clinical services delivered at an REH must be led by a physician with, at the minimum, experience in the practice of emergency medicine; the expertise of a board-certified emergency physician should be relied upon whenever medically necessary and available***. We also believe that the staffing needs of REHs, which often contend with serious workforce challenges, can often safely and appropriately be met through remote physician supervision of non-physician clinical staff. This should extend to the services provided by an REH medical director and the utilization of remote supervision policies can allow for a greater number of REHs to meet their medical director requirements by relying on the services of a board-certified emergency physicians. We appreciate the guidance provided in this proposed rule regarding privileging of distant site physicians and practitioners. While we understand general remote supervision rules will apply to REHs, ***EDPMA encourages express guidance from CMS on the ability of emergency physicians who are performing the medical director and other supervisory responsibilities to meet these requirements remotely, provided all remote supervision requirements are met***.

Second, regarding the availability of a physician at an REH, as listed above, CMS proposes to require that the MD or DO:

1. Be **present** for sufficient periods of time to provide medical direction, consultation, and supervision for the services provided in the REH; **and**
2. Is **available** through direct radio or telephone communication or electronic communication for consultation, assistance with medical emergencies, or patient referral.

Because we believe that access to care, quality of care, and patient safety are paramount, ***EDPMA recommends that CMS add "24/7" to the second clause to ensure that care is always provided with the available expertise of a physician***. We agree that the "presence" requirement is appropriately limited to "sufficient periods of time." However, because REHs are functioning emergency facilities and communities should be able to rely on them as such, we believe that the "availability" CoP should offer greater patient protection by ensuring that availability is always the case even when presence is not. Therefore, we believe the second clause should read to the effect of, "*is available 24 hours a day 7 days a week through direct radio or telephone communication or electronic communication for consultation, assistance with medical emergencies, or patient referral.*"

3. Telemedicine & Privileging

In this proposed rule, CMS addresses the privileging of distant site physicians and practitioners. If several requirements are met, the REH is allowed to rely on information provided by a distant-site hospital "as a more efficient means of privileging the individual distant-site physicians and practitioners." In these scenarios, REHs would not

prohibit the REH's medical staff from "continuing to perform its own periodic appraisals of telemedicine members of its staff, nor would it bar them from continuing to use the proposed traditional credentialing and privileging process." As part of these requirements, CMS states that the REH must "*ensure that the distant-site physician/practitioner holds a license in the state in which the REH, whose patients are receiving the telemedicine services, is located*."

EDPMA appreciates the REH CoPs proposed rule provisions cannot address all reciprocity and state licensing issues. However, ***EDPMA urges CMS to work with Congress and state governments to address the complexities and variations in the abilities of physicians to provide telemedicine services across state lines.*** As we have learned throughout the COVID-19 public health emergency (PHE), the variations in the requirements among states regarding whether and how a physician can furnish services remotely have often created impediments in the ability to meet the medical needs of patients. EDPMA believes that patient safety and quality of care is paramount. However, to the extent CMS can reduce the administrative complexity of getting patients the care they need, we would encourage CMS to do so. As part of CMS' requirement that an REH maintain an agreement with a Level 1 or 2 trauma center, CMS explicitly allows that trauma center to be in a different state than the REH. While we understand that without this flexibility, some communities would find it difficult to meet this requirement, it is still an important example of how the needs of certain facilities, whether because of geography, system affiliation, or otherwise, are met by providers in states other than the one in which the REH is located.

4. Additional Outpatient Services

a. Maternal Health Services

EDPMA strongly supports the Administration's commitment to ensuring access to maternal health services as well as addressing the impact access to maternal health services can have on reducing disparities in health. We appreciate the focus brought to these issues in the proposed rule. As CMS reviews the services that REHs are <u>allowed</u> to provide versus those that REHs are <u>required</u> to provide, EDPMA agrees that maternal health services should be allowed but not required. CMS specifically requests input on low risk labor and delivery services, and we believe that a policy that allows but does not require these services is appropriate here as well. In the interest of ensuring that the services and functions required to be provided by REHs to maintain their status as an REH, we believe it is imperative that the services required beyond emergency and observation services be minimal in order to support the goals of the statute: to ensure basic access to emergency services in rural communities. We are concerned that while there are a set of services that would ideally be readily available in all communities, workforce shortages can seriously impede a facility's ability to provide those services. The REH policies should ensure that the core emergency department needs of communities are met and that facilities can add whichever additional outpatient services are deemed

appropriate based on the needs of that community and the availability of the appropriate providers to deliver those services.

b. Outpatient Surgery

In the categories of services that REHs are allowed to provide versus those that REHs are required to provide, EDPMA also agrees that outpatient surgery services should be allowed but not required. As previously mentioned, we believe it is imperative that the services required beyond emergency and observation services be minimal in order to support the goals of the statute: to ensure basic access to emergency services in rural communities. We are concerned that while there are a set of services that would ideally be readily available in all communities, workforce shortages can seriously impede a facility's ability to provide those services. We believe that patient safety will be protected when REHs ensure that the appropriate transfer agreements are in place. However, the REH policies should ensure that the core emergency department needs of communities are met and that facilities can add whichever additional outpatient services are deemed appropriate based on the needs of that community, the availability of the appropriate providers to deliver those services, and the ability of REHs to provide those services on a consistent basis without undermining the financial viability of the facility.

5. Physician Accessibility & Transfers

We appreciate that CMS proposes to require that all REHs maintain written agreements with Level 1 or Level 2 trauma centers. In the preamble, CMS states that nothing precludes an REH from entering written agreements with other trauma level facilities.

Separately, CMS also 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*" and "*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*."[3] However, these provisions *only* apply to an REH that offers "additional medical and outpatient services" (beyond emergency and observation services).

As we previously mentioned, ***EDPMA strongly believes that the clinical services delivered at an REH must be led by a physician with, at the minimum, experience in the practice of emergency medicine; the expertise of a board-certified emergency physician should be relied upon whenever medically necessary and available***. Given that REHs will often be the most proximate emergency facility to serious accidents and other events, regardless of complexity of the case, patients will often present to the REH. In many instances, these cases will be in need of a transfer, and we believe that the

[3] Medicare and Medicaid Programs; Conditions of Participation (CoPs) for Rural Emergency Hospitals (REH) and Critical Access Hospital CoP Updates, 87 Fed. Reg. 40391 (July 6, 2022)(to be codified as § 485.524(a)).

CoPs should require a mechanism or process to consult with a physician from a facility at one of those transfer sites when needed. For this reason, ***EDPMA recommends that CMS add provisions to the REH CoP that require the "written agreements" with Level 1 and Level 2 trauma centers and the "system . . . for referral from an REH to different levels of care" to include the capacity for telemedicine capabilities with a physician with, at the minimum, experience in the practice of emergency medicine; the expertise of a board-certified emergency physician should be relied upon whenever medically necessary and available. EDPMA also believes that this requirements should be in effect regardless of whether the REH offers "additional medical and outpatient services."*** While we understand the flexibilities that the Agency is seeking to provide REHs, the facilities with which the REH will have transfer agreements should have physicians with this emergency medicine expertise, and the ability to communicate with experienced physicians at these facilities should be captured in the REH CoPs. We would remind CMS that its telemedicine privileging CoPs require that the health care practitioner furnishing the telemedicine service be licensed in the state where the REH is located, yet separately CMS states that the Level 1 or 2 trauma center with which the REH must have a "written agreement" can be located in a different state. We believe that a CoP that guarantees telemedicine capacity with the trauma centers and hospitals with which an REH has transfer agreements will help ensure that patients have access to the expertise of emergency medicine, at the very least, when a transfer is expected, pending, or imminent.

****

We thank you for the opportunity to comment on these issues and look forward to providing you additional input on the REH policies in the CY 2023 OPPS proposed rule. If you have any questions or comments, please do not hesitate to contact EDPMA Executive Director Cathey Wise at cathey.wise@edpma.org.

Sincerely,

Don Powell, DO FACEP
Chair
Emergency Department Practice Management Association