American Hospital Association™
Advancing Health in America

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The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
7500 Security Blvd
Baltimore, MD 21244

RE: Comments on Conditions of Participation for Rural Emergency Hospitals and Critical Access Hospital Conditions of Participation Updates (CMS-3419-P)

Dear Administrator Brooks-LaSure:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, including our rural and critical access hospitals (CAHs), our clinician partners — including more than 270,000 affiliated physicians, 2 million nurses and other caregivers — and the 43,000 health care leaders who belong to our professional membership groups, the American Hospital Association (AHA) appreciates the opportunity to provide comments on the Centers for Medicare & Medicaid Services' (CMS) proposed conditions of participation (CoPs) for rural emergency hospitals (REHs) and CAHs.

Ensuring all communities have access to high quality health care is a top priority for the AHA and its members. While this commitment is true for all communities, it is clear that particular focus must be paid to rural communities. Rural hospitals and CAHs struggle to attract and retain sufficient numbers of physicians, nurses and other health care providers; they frequently are the only available source of urgent and emergent care for many miles; they have to stretch available resources due to financial constraints, especially for the past several years; and they face new challenges as a result unprecedented workforce burnout. These difficulties, compounded by the COVID-19 pandemic, played key roles in a record number of rural hospital closures in 2020 with 19 rural hospitals closing in that year alone.

We remain dedicated to making sure every community has access to critical health care services. As we continue to look for ways to meet the health care needs of rural communities, we appreciate CMS' efforts to assist rural providers as they navigate these exceptionally difficult times. We support the agency's proposal to allow rural providers to continue to serve their communities by becoming an REH. This new model will help preserve necessary health care services in already underserved areas. We

also are supportive of CMS' proposal to update certain CoPs for CAHs including embracing a system-level compliance approach for certain requirements, establishing a patient's bill of rights and streamlining the CAH distance determination process.

Through this proposed rule, CMS is taking important steps to assist America's rural hospitals and health systems. We look forward to continuing to work with the agency to ensure a seamless and thoughtful implementation of these changes.

Our specific comments follow.

RURAL EMERGENCY HOSPITAL DESIGNATION

Established by the Consolidated Appropriations Act of 2021, the new REH designation seeks to address concerns that certain rural hospitals likely will not be able to sustain current operations given financial, workforce and other challenges. If those hospitals were forced to close completely, critical health care services in the area would evaporate, and individuals would be forced to travel much farther to receive needed care. The new REH designation will provide CAHs and certain other rural hospitals with the opportunity to convert to an REH and thereby continue offering certain health care services. **The AHA supports the REH designation and appreciates CMS' thoughtfulness in its proposed implementation approach to ensure that health care delivery can be preserved in rural communities.**

Specifically, we appreciate the agency's stated intent of aligning many of the proposed REH CoPs with already existing CAH or ambulatory surgical center CoPs. This alignment will make the REH conversion and compliance processes less burdensome for those providers seeking the new designation. For example, the alignment of REH governing body requirements with current CAH regulations will allow our members seeking an REH designation to maintain the same set of standards and expectations that currently exist for their governing bodies. The agency's approach of aligning new REH CoPs with existing programs will give newly established REHs a clear understanding of the regulatory and compliance expectations and provide a roadmap for ensuring continued compliance after converting to an REH.

While many of the proposed CoPs are in alignment with existing CoPs for other provider types, the agency makes clear that several new, REH-specific CoPs will need to be established given the unique circumstances of the new REH designation. Given the initial stages of implementing the REH program, the agency seeks comments on the following proposals.

Provision of Low-Risk Labor and Delivery Services and Related Outpatient Surgical Services

In its proposal, CMS seeks comments on the ability of an REH to provide low-risk childbirth-related labor and delivery services. It is undeniable that access to maternal

and child care services is lacking in certain areas of the country, including many rural communities. **Therefore, we support the agency's proposal to allow REHs to provide labor and delivery services.** Allowing REHs to offer these services means more communities will have the pre-natal and birthing services needed by pregnant women and their babies.

In instances where REHs are able to provide low-risk childbirth labor and delivery services, the agency asks whether there should be a requirement that the REH also provide outpatient surgical services in the event that surgical labor and delivery intervention is necessary. Experience has taught every hospital that there can be occasions when a seemingly easy delivery becomes problematic rapidly and surgical intervention may be immediately needed to protect the life of the mother and/or the baby. Not being able to provide rapid intervention to stabilize or treat the patient could pose significant and avoidable health risks. While we do not expect all REHs to have the staff or capabilities to manage serious complications onsite, several training resources and tools exists, like those in the American Academy of Family Physicians Advanced Life Support for Obstetrics (ALSO) program, which can help prepare REH staff in treating and stabilizing patients prior to transferring them to facility with such capabilities.

It is our expectation that REHs choosing to **offer labor and delivery services also should be required to have the capacity to perform certain services, including having the necessary staff, equipment and medications to ensure that the patient can be treated or stabilized and transferred depending on the severity of the complication.** CMS should consider other approaches to ensuring the skills and resources needed will be on hand to provide life sustaining care in the event of an unexpected complication during delivery**.**

Appropriateness of Provider On-Call and Proximity

The agency seeks comments on if it is appropriate for an REH to allow a doctor of medicine or osteopathy, physician assistant, nurse practitioner or clinical nurse specialist, with training or experience in emergency medicine, to be on-call and immediately available by telephone or radio contact and available on-site within a specified timeframe. We are supportive of including this provision, which is similar to what is required of CAHs. Given the unique circumstances of REHs, we ask the agency to carefully consider the appropriateness of the CAH timeframe in making its determination. Moreover, while we support this approach, **we want to be clear that in lieu of one of the listed medical professionals being present at the REH, a nurse or other health care worker must be on site at all times to ensure admission and initial care and treatment of individuals when they arrive at the REH.**

Annual per Patient Average Length of Stay Not to Exceed 24 Hours

In the proposed rule, CMS states its intention to limit the average annual length of stay per patient to 24 hours. We understand and appreciate the agency's rationale for this decision, and agree that limiting the annual average length of stay to 24 hours is reasonable. **However, we urge CMS to give serious consideration to two specific exceptions to the 24-hour length of stay requirement.** First, for those REHs able to offer low-risk childbirth labor and delivery services, it is impractical to expect those patients to be discharged within 24 hours, especially in instances where surgical intervention is required. We understand the 24-hour length of stay is an average of all patients in the REH over the course of a year; however, it is possible that labor and delivery patients could move the REH average beyond the 24-hour limit. **Given the nature of these services, we urge CMS to consider expressly excluding labor and delivery patients from the 24-hour annual length of stay requirements**.

Second, there are certain patients, like those individuals requiring behavioral health and psychiatric care that could prove to be more difficult to discharge successfully within 24 hours. Oftentimes, even when providers are prepared to discharge these patients, there is no bed available for them in an appropriate facility. These factors fall well outside of the control of the REH, but will play a significant role in determining whether the REH is meeting the average 24-hour length of stay requirement. Given the implications of these potential hurdles, **we urge CMS to afford REHs the opportunity to demonstrate compliance with the 24-hour length of stay requirement by providing documentation that shows their efforts to discharge and transfer a patient. When the REH has taken reasonable steps but is unable to comply through no fault of their own, the agency should deem the REH to be in compliance with the 24-hour average length of stay CoP.**

Established Transfer Agreements with Level I or Level II Trauma Centers

CMS proposes that a provider designated as an REH must have in effect a transfer agreement with at least one Medicare-certified hospital that is a level I or level II trauma center. We agree with the agency that transfer agreements with level I or level II trauma centers are vital to ensure those patients requiring serious medical care are able to receive it. While we understand the frequency at which REH patients will require level I or level II trauma care likely will be limited, having a transfer agreement in place will establish efficiencies and processes that will be critical in instances where transfer of a patient is medically necessary. In many instances, especially when geographic limitations may make transfer to a level I or level II trauma center impractical, we encourage REHs to have in place a transfer agreement with a closer hospital that has specialists or subspecialists able to address many common reasons for hospitalization, even if that hospital is not a level I or level II trauma center.

UPDATES TO CRITICAL ACCESS HOSPITAL CONDITIONS OF PARTICIPATION

In its rule, CMS proposes three changes to current CAH CoPs. First, the agency proposes updating the current location and distance requirements for CAHs. Specifically, CMS proposes adding a definition for "primary roads" to its location and distance requirements as well as clarifying that the location distance for a CAH is more than a 35-mile drive *on primary roads* from a hospital or another CAH. "Primary road" in this instance would be specified as "a numbered Federal highway or a numbered state highway with two or more lanes each way." Further, the agency intends to utilize a centralized, data-driven review process of all CAHs and hospitals within a 50-mile radius of the CAH. In instances where other providers exist in the 50-mile radius, CMS will conduct a follow-up investigation to determine if the CAH meets the 35-mile rule requirements. Not only does this proposal clarify and simplify CMS' expectations, but it alleviates the significant challenges associated with surveyors needing to physically measure each CAH's distance from the nearest hospital. **The AHA supports CMS' plan to utilize a data-driven, more efficient and streamlined approach to CAH location and distance requirement compliance.**

Second, the agency seeks to establish a CoP for patient's 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 and physical safety. The newly established CoP would include requirements for the CAH to inform patients of their rights; address privacy and safety; adhere to confidentiality of patient records; ensure appropriate use of restraint and seclusion; and adhere to patient visitation rights. These provisions already exist for other provider types and will help to ensure that CAH patients and their families are treated properly and safely while also formally requiring the safeguarding of patient medical information. **We support the agency's proposal to include these important protections as CAH CoPs.**

Lastly, CMS proposes to allow CAHs that are part of a system to use a unified and integrated systems approach for certain CoP requirements. Specifically, this system-level approach would apply to requirements for infection control and prevention and antibiotic stewardship programs, medical staff and quality assessment and performance programs. **The AHA strongly supports the agency's intention of allowing CAHs to utilize system-level approaches to comply with these provisions.** Currently, hospitals are permitted to utilize this approach and we appreciate the opportunity for CAHs to now do the same. For those providers that are part of a larger system, allowing for compliance at a system-level where possible allows for increased efficiency and coordination that previously was not permissible under the CoPs.

We thank you for the opportunity to comment on these important topics. As our rural members continue to navigate the challenging landscape ahead of them, we appreciate CMS' commitment to taking steps to preserve access to health care in rural communities. We look forward to continuing to work with the agency throughout the implementation of the new REH designation and are encouraged by the proposed

changes to current CAH CoPs. Please contact me if you have questions, or feel free to have a member of your team Mark Howell, director of policy, at 202-626-2317 or mhowell@aha.org.

Sincerely,

/s/

Ashley B. Thompson
Senior Vice President
Public Policy Analysis and Development