

August 29, 2022

The Honorable Chiquita Brooks-LaSure Administrator Centers for Medicare & Medicaid Services Hubert H. Humphrey Building 200 Independence Avenue, S.W. Room 4445-G Washington, DC 20201

RE: CMS 3419-P, Medicare Program: Conditions of Participation for Rural Emergency Hospitals and Critical Access Hospital Conditions of Participation Updates

Dear Administrator Brooks-LaSure:

On behalf of 118 Iowa community hospitals, the Iowa Hospital Association (IHA) appreciates the opportunity to submit the following comments on the Centers for Medicare & Medicaid Services' (CMS) proposed rule for the Conditions of Participation for Rural Emergency Hospitals (REHs) and updates on the Conditions of Participation for Critical Access Hospitals (CAHs). IHA was pleased to see this proposed rule, as well as the payment proposal for REHs in the Outpatient Prospective Payment System proposed rule, as the topic has been a top priority for IHA. IHA would also like to express support for the comments on this proposed rule submitted by the American Hospital Association.

As an overall general comment, it is critical for CMS to understand how valuable of a program 340B is for rural hospitals, especially in Iowa. While it sounds possible that a change to the 340B statue could be needed in order to allow REHs to participate, we stress the importance of this action and urge the Administration to work alongside Congress to ensure the program is available for facilities transitioning to REH. Without REH participation in 340B, far fewer hospitals will able to consider converting as 340B payments are vital to the financial viability of rural hospitals.

Finally, IHA asks for clarification from CMS on provider-based rural health clinics (RHCs). Consistent with legislative intent, CMS should provide guidelines for REH operation of provider-based RHCs. As the CoPs stand, it is unclear whether REHs are authorized to operate provider-based RHCs. Many hospitals that might be considering converting to an REH currently operate provider-based RHCs. CMS must allow REHs to maintain operation of existing provider-based RHCs as grandfathered by April 1, 2021, that meet the qualifications in section 1833(f)(3)(B) of the Social Security Act, at the special payment rules that establish a payment limit based on the

specified provider-based RHS's per visit payment amount instead of the national statutory payment limit and this should be explicitly stated in the CoPs. IHA believes that REHs that are considering conversion and have a provider-based RHCs that is crucial to their community will make this a factor in determining if conversion to a REH is practical.

Comments on the REH CoPs

Within the proposed rule, CMS details a number of Conditions of Participation (CoP) for REHs. Many of these provisions would align REH CoPs with those for Critical Access Hospitals (CAHs). IHA is supportive of this strategy and urged the Agency to pursue this route in our response to the request for information on REHs contained in the CY2022 OPPS Proposed Rule. IHA appreciates, for example, the alignment of REH governing body requirements with current CAH regulations, which will allow lowa hospitals seeking an REH designation to maintain the same set of standards and expectations that currently exist for their governing bodies.

IHA also thanks the Agency for clarifying that an REH could have a transfer agreement with a neighboring hospital that is a level III or level IV trauma center in addition to having a transfer agreement with a level I or a level II trauma center. This will allow REHs the ability to ensure patient care is provided as close to home as possible and as medically appropriate.

IHA would urge CMS to exercise caution in a couple of areas. IHA has some concerns with the proposals related to the quality requirements REHs would be subject to. As of right now, participation in a quality reporting program is optional for CAHs, and though several CAHs participate in the Outpatient Quality Reporting program, not all of them do. All Iowa hospitals, including those who may transition to becoming an REH, take quality and safety very seriously. Hospitals want to ensure that people living in their communities are well taken care of and that people see their local hospital as an integral part of their health care needs. IHA believes additional time should be devoted to working with rural stakeholders to develop low-cost and efficient methods of appropriately measuring patient experience and quality of care in REHs. The scope of services offered will dramatically impact the quality measures appropriate to ensure patient outcomes. This would make comparing one REH to another impossible. We encourage CMS to avoid replicating a quality reporting program with similar complexity to that of acute hospitals providing inpatient services. If the administration decides to move forward with the proposed quality reporting program for REHs, IHA encourages CMS to take an approach that would phase in any reporting requirements and for any quality metrics to be appropriate for the REH setting. It is not fair to evaluate rural areas in the same way as larger areas and REHs should be compared only to other REHs and no other hospital designation.

Other proposed CoPs of concern for hospitals include requirements for laboratory services as well as discharge planning. Hospitals do not believe REHs should be required to include more laboratory services than that of a CAH. Hospitals could provide additional services based on the scope and complexity of services offered. The laboratory requirements for emergency services for a CAH should be the established baseline. In addition, the requirement to complete a discharge evaluation and plan will result in patients being in the emergency department longer. Currently, emergency department and less than 24-hour observation patients would have a discharge evaluation and plan established only upon request of the physician, the patient or their representative. It is reasonable to adopt such a requirement for an REH without applying

the requirement to every patient.

Additionally, IHA understands and appreciates the agency's rationale for limiting the average annual length of stay per patient to 24-hours, though we believe there needs to be greater flexibility in the enforcement of the policy. IHA urges CMS to give serious consideration to two specific exceptions to the policy and allow 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. CMS should also account for challenges with EMS transport and ambulance availability in certain rural communities and how that could impact an REH's 24-hour average patient stay.

First, we encourage an exception for patients requiring behavioral health and psychiatric care. Across the nation, hospitals are seeing increases in the length of time behavioral health and substance abuse patients remain in emergency departments. This is partially due to shortages in inpatient behavioral health beds and inadequate community resources for these patients, particularly in rural areas. 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.

Second, if REHs are 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. IHA understands 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.

Further, the public health emergency (PHE) has resulted in hospitals turning inward to take a close look at their practices and their role during a public health crisis. As such, IHA asks CMS to provide information, or consider including information in future rulemaking, on what the role of REHs would be in the event of a future PHE. This is particularly important since REHs will not be providing inpatient care. In lowa, like in many other states, there was a time when hospitals were full and there were very few inpatient beds available. If something were to happen where hospitals find themselves in a similar situation, IHA would encourage CMS to allow for REHs to provide inpatient care for a time period appropriate to the situation.

Comments on Proposed REH-specific Provisions

Within the proposed rule, CMS asks for feedback on proposed REH-specific provisions around labor and delivery. Specifically, The Agency asks for feedback on REHs providing low-risk childbirth-related labor and delivery services. IHA urges CMS to proceed with any policy related to this with careful consideration. Within IHA's comments in 2021 to the request for information on REHs, IHA suggested that REHs could serve maternal health patients during prenatal care as well as postnatal care and have the patient deliver at a facility providing inpatient care. REHs would need to ensure effective care coordination with any facility providing the delivery services to ensure proper communication and execution of any treatment plans. This would allow maternal health patients to receive pregnancy-related care close to home while delivering at a location that routinely provides delivery services.

Additionally, if CMS allows for REHs to provide labor and delivery services, there would need to be specific exceptions made for these patients on the 24-hour average requirement for discharge as detailed above.

Comments on the Updates to the CAH CoPs

Within the proposed rule, CMS suggests changes to some of the CoPs for CAHs. In general, IHA urges the Administration to take extreme caution with changes to the CAH CoPs so as to not put any additional excessive burdens on these hospitals that would take efforts away from patient care. If CMS decides to finalize the changes to the CAH CoPs outlined in the rule, IHA encourages them to ensure restrictions on additional changes in the future. Despite this caution, IHA does view the suggested changes to be helpful.

CMS is suggesting an addition to the definition for "primary roads" to its location and distance requirements as well as a clarification that the location distance for a CAH is more than a 35-mile drive on primary roads from a hospital or another CAH. This change has the potential to ease the process for a small prospective payment system hospital to move to a CAH if a neighboring CAH transitions to being an REH. IHA would advocate for the definition of primary road to be clarified to exclude Federal numbered highways with one lane in each direction. One lane Federal highways are common in rural areas and, in many instances, are not comparable to two or three lane highways because of sporadic maintenance varying by state. In many instances, Federal one lane highways do not differ from state one lane highways, which are excluded from the proposed definition. Maintenance of one lane highways whether federal or state is the same in terms of weather-related conditions.

IHA is concerned with the provision that a new hospital built within 50 miles of a CAH would trigger a review. Each of the 82 CAHs in Iowa are designated as necessary providers, and IHA would appreciate CMS clarifying that, if finalized, the necessary provider status of a CAH would be protected. Further, IHA asks that CMS make a change to the CAH distance requirements. We ask that CMS specifically exclude REHs from the distance determination for CAHs. Considering that REHs only provide emergency department services, furnish no inpatient services, and can optionally furnish outpatient services, REHs serve a different purpose than CAHs and PPS hospitals. Existing CAHs are also one type of hospital eligible to convert to an REH. CAHs are excluded from the distance requirement relative to other CAHs, thus a CAH that converts to an REH should remain excluded from distance requirements.

Finally, CMS proposes to allow CAHs that are part of a system containing more than one hospital or CAH to utilize a system-level approach to comply with several CoPs. IHA is very supportive of this, particularly when it comes to peer reviews. Being able to use a network hospital to satisfy a CAH's peer review requirements would ensure that CAHs have an easier time completing the requirement. Hospitals also see that this could help with staffing issues as some small hospitals struggle with having staff to complete all of the reviews. Currently, PPS hospitals are permitted to utilize this approach and IHA appreciates 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.

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We appreciate your consideration of these comments. Please do not hesitate in reaching out to me if you have any questions.

Sincerely,

Erin Cubit

Senior Director of Government Relations

Iowa Hospital Association

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