August 26, 2022

Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, D.C. 20201

SUBJECT: CMS–3419–P,* Medicare and Medicaid Programs; Conditions of Participation (CoPs) for rural emergency hospitals and critical access hospital CoPs Updates *(Vol 87, No 128), July 6, 2022

Dear Administrator Brooks-LaSure:

On behalf of our more than 400 member hospitals and health systems, as well as their related post-acute care providers, the California Hospital Association (CHA) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) proposed rule updating the critical access hospital (CAH) conditions of participation (CoPs) and establishing the CoPs for the new rural emergency hospital (REH) provider type.

CHA is deeply concerned about the ongoing crisis in rural health care. Between January 2013 and February 2020 over 100 rural hospitals closed[1]; three of those facilities were in California. The closing of a rural hospital has a disproportionately negative impact on those who are in poor health and are experiencing poverty. Residents who live in areas affected by a rural hospital closure are more likely to live in poverty (13.3% vs. 9.3%). Further, Medicare beneficiaries who live in areas that have experienced a rural hospital closure are more likely to suffer from one or more of the 10 most common chronic conditions. And the closing of these facilities significantly reduces access to care for all patients, especially Medicare beneficiaries. The distance patients are required to travel to access inpatient services increases by 20 miles; for services like substance abuse treatment, it increases by almost 40 miles. Therefore, we believe that if the administration is to achieve its goals related to reducing inequitable health outcomes, it must take steps to shore up the health care delivery system in rural areas.

In general, CHA believes that the proposed rule will contribute to this goal. While we believe that CMS' clarified definition of "primary road" used to calculate the CAH distance requirements is an improvement over the definition in the state operations manual, we ask the agency to develop a process to grandfather in existing CAHs that lose their status as a result of this definitional change. Further, we appreciate CMS'

[1] https://www.gao.gov/products/gao-21-93

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efforts in the revised CAH CoPs to allow hospitals that are part of a larger organization to meet the requirements of the CoPs if they participate in the system's unified or integrated structure. CHA believes taking advantage of system structures will allow the CAH to meet the CoP requirements and protect patients in a less resource-intensive manner.

Related to the REH, CHA believes there is much potential in the model to maintain services in a community that can no longer support an acute care hospital. However, at this time, our members will not be able to participate in it, as California does not license the type of facility contemplated in the REH model. While we generally believe that CMS strikes the right balance in the proposed CoPs, we also believe there are several places where CMS is making the requirements more stringent — and, therefore, more resource intensive — than is necessary for the suite of services that will be provided by an REH.

Below, please find our detailed comments on the proposals related to the CAH and REH CoPs.

CAH CoPs

Location Requirements — Definition of '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. This sub-regulatory change would have resulted in several California hospitals losing their CAH status. This, despite the fact that the CAH in question didn't move (or wasn't within 35 miles of another hospital). **CHA strongly opposes the definition of "primary road" that CMS put forth in the 2015 revision of the SOM. It would result in hospitals losing CAH status and could reduce access to services. The resulting loss of services, as discussed above, would have a disproportionately negative impact on those in the community who are most vulnerable and would exacerbate existing inequities in health outcomes.**

In an effort to address the flaws in the definition of "primary road" put forth in the 2015 revision of the SOM, CMS proposes to revise 42 CFR § 485.610(c) to clarify that a "primary road" is a numbered federal highway. This includes interstates, intrastates, expressways, or any other numbered federal highway; or a numbered state highway with two or more lanes each way.

CHA appreciates CMS' efforts to clarify the definition of "primary road" and preserve access to necessary hospital services in rural communities. We cautiously support this change but believe the definition of primary road requires further clarification. CHA respectfully asks CMS to clarify that for a numbered federal highway (including interstates, intrastates, expressways, or other numbered federal highway) to be considered a "primary road" for purposes of determining a hospital's eligibility for critical access status, it must continuously have two lanes in each direction between the critical access hospital (or potential critical access hospital) in question and the next closest hospital. It is not uncommon for federal highways with two lanes in each direction to narrow to one lane in each direction for a section. When a road narrows to one lane in each direction it significantly increases the risk of temporary road closure due to accidents, inclement weather, flooding, wildfire, or other natural disasters. We are concerned that without this clarification a hospital may lose CAH status even though the community it

serves could be cut off from access to another hospital several times a year for extended periods of time due to closure of a section of a federal highway that narrows to one lane in each direction.

Finally, CHA respectfully asks CMS to provide a mechanism to grandfather in hospitals that lose their CAH status as a result of this proposal. Additional details of such a grandfathering process are provided below.

In the proposed rule, CMS states it will review all hospitals and CAHs within a 50-mile radius of the CAH during each review of eligibility, and then subsequently on a three-year cycle. Following the initial review, further investigations would focus primarily on expanded health care 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. 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.

CHA appreciates CMS' effort to streamline the review process to redetermine hospitals' CAH status. However, CMS does not define what it considers a "new" hospital for purposes of the CAH distance review. **CHA respectfully asks the agency to, in the final rule, clarify that a "new hospital" is one that is a new acute care facility built in the community *and* a facility that began billing services under its CMS Certification Number (CCN) since the last CAH eligibility review cycle. Further, CHA asks CMS to clarify in the final rule that a "rebuilt hospital" that previously served the community and billed under a CCN that existed prior to the last CMS eligibility review cycle *is not* a "new hospital."**

CHA is concerned that a CAH that rebuilds its facility in the same community it currently serves (either due to the need to modernize the facility or rebuild it in the wake of a natural disaster) will be flagged for additional scrutiny even though the facility is not "new" to the community and has previously served it. We ask that CMS clarify these items to ensure the proposed streamlined CAH redetermination requirements achieve their goal of reducing the resources required by both CMS and the impacted facilities to manage the tri-annual CAH redetermination process as efficiently as possible.

Finally, CHA remains deeply concerned that some hospitals may lose CAH status as a result of an arbitrary administrative change instigated by CMS. Given the well-documented financial challenges facing small, rural, prospective payment system (PPS) hospitals, we are concerned that any hospital stripped of CAH status will end up closing, which will deprive a community of ready access to necessary health care. These concerns are not unfounded. A recent study found that 65% of rural hospitals that closed between 2010 and 2019 were PPS hospitals[2]. And prior to the COVID-19 public health emergency (PHE), up to 9% of rural hospitals in California were deemed at risk of closure based on analysis by the Chartis Center for Rural Health.

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[2] https://www.chartis.com/sites/default/files/documents/The%20Rural%20Health%20Safety%20Net%20Under%20Pressure-The%20Chartis%20Group.pdf

Congress created the REH model to allow for the provision of emergency and outpatient services in communities that can no longer support an acute care facility. However, this is not a viable model in many states — like California — that do not recognize and license this innovative provider type. **CHA respectfully asks that CMS allow any CAH that no longer meets the distance requirements as a result of the new "primary road" definition to retain its CAH status (e.g., be grandfathered in) if it is located in a state that does not allow for licensure of REHs.** If CMS does not provide a grandfathering mechanism — particularly in states like California where converting to an REH is not possible — the agency will exacerbate existing access issues and increase outcome disparities that are contrary to its stated goals.

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 with the current standards for hospitals. **CHA supports the proposal. We appreciate CMS' efforts to allow health systems to take advantage of economies of scale to reduce the resources required to meet the CAH CoPs.**

Unified and Integrated Infection Prevention and Control and Antibiotic Stewardship: Multi-Facility System
CMS proposes establishing the same CoPs for infection prevention and control in CAHs 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 its member facilities, including any CAHs. The system's single governing body would be responsible for ensuring that each of its separately certified CAHs meet all the requirements. **CHA supports the proposal. We appreciate CMS' efforts to allow health systems to take advantage of economies of scale to reduce the resources required to meet the CAH CoPs. Further, providing this flexibility to CAHs that are part of health systems furthers CMS' goal of reducing hospital-acquired infections and antibiotic resistance.** A unified and integrated infection control and antibiotic stewardship program will facilitate data collection and analysis to develop and identify best practices in both areas. Further, once a best practice is confirmed, an integrated and unified model will speed dissemination and adoption.

Unified and Integrated Quality Assessment and Performance Improvement (QAPI) Program: Multi-Facility System
CMS is proposing to allow CAHs that are part of a multi-facility system consisting of multiple separately certified facilities 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. 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. **CHA supports the proposal. We appreciate CMS' efforts to allow health systems to take advantage of economies of scale to reduce the resources required to meet the CAH CoPs. Further, offering CAHs that are part of health systems furthers CMS' goal of improving outcomes for all patients.** A unified and integrated QAPI program will facilitate data collection and analysis to develop and identify best practices in both areas. Further, once a best practice is confirmed, an integrated and unified model will speed dissemination and adoption.

REH CoPs

Definition of an REH

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.

CHA's members remain concerned about the requirement that REHs have an annual per-patient average stay of 24 hours or less. CHA's members (like other rural hospitals) report significant challenges transferring patients in a mental health crisis to an inpatient psychiatric hospital due to the lack of beds. Further, during the PHE, many rural hospitals have struggled to transfer acutely ill patients to facilities that can provide the appropriate level of care due to a lack of inpatient capacity at hospitals in nearby urban and exurban areas. **Therefore, CHA asks that CMS remove any patient who is transferred (or expires awaiting transfer) from the calculation of an REH's length of stay.** Otherwise, we are concerned that some hospitals that initially qualify as an REH may not be able to maintain the designation because they fail to meet the average patient stay requirement.

Further, the Consolidated Appropriations Act of 2021 allows for providers that are CAHs and small rural hospitals (50 or fewer beds) as of December 27, 2020, to convert to REHs. **CHA respectfully asks CMS to grandfather in any hospital that was in existence prior to December 27, 2020, but ceased operations as an acute care hospital due to a natural disaster.** An example of the need for some form of grandfathering or other regulatory flexibility is one California hospital that — assuming state licensure issues are resolved — is an ideal candidate for the REH model but would not qualify if the December 27, 2020, date is strictly applied. The facility was closed in 2018 due to wildfire damage and is currently not operating as an acute care facility.

Emergency Medical Treatment and Labor Act (EMTALA)

The CAA of 2021 subjects REHs to the provision of section 1867 of the Act with respect to the 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.

CHA respectfully asks CMS to provide a waiver that allows REHs to divert patients to a higher-level facility on the continuum if the clinical staff at the REH doesn't believe the facility can provide the appropriate level of care and the patient is stable enough to transport. CMS has the ability to modify the EMTALA regulations to provide this flexibility to REHs. Given the distances between an REH and a facility that can provide the appropriate level of care, CHA believes this is a crucial patient safety issue. We are concerned that valuable time would be wasted attempting to provide care at the REH when the patient is stable enough to transport and it is clear from the outset that the REH cannot provide the appropriate level of care.

Radiologic Services

CMS proposes REH radiologic requirements consistent with the hospital and CAH radiologic requirements found at 42 CFR § 482.26 and the interpretative guidelines for CAHs in Appendix W of the SOM.

CHA is deeply concerned that, while the requirements at § 482.26 for hospitals may be consistent with the CAH requirements at § 485.635(b)(3), the hospital requirements are far more complex and onerous. While CMS states this is also consistent with the SOM, CHA notes that it is not as detailed as the requirements at § 482.26. Given the increased complexity of the hospital radiology CoPs, CHA believes that a CAH that converts to an REH will have to actually invest additional resources to meet the proposed CoPs. Given that the level of care provided at an REH will be far less complex than that provided at a CAH, we question the logic of requiring REHs to unnecessarily invest additional resources to meet a more stringent standard. **Therefore, CHA respectfully encourages CMS to reconsider this and limit the requirements to the CAH CoPs related to radiology at § 485.635(b)(3).**

Pharmaceutical Services

The proposed rule states CMS is aligning the REH CoPs with the requirements of CAHs. However, it proposes to require REHs to adhere to the more detailed and onerous hospital CoPs for pharmaceutical services (42 CFR 482.25). This is despite the fact that REHs will provide a far more limited number of pharmaceuticals. Similar to the radiology CoPs, a CAH converting to an REH will actually have to invest additional resources to enhance policies and procedures related to pharmaceutical services to meet the proposed requirements, despite providing less complex care. CHA respectfully asks CMS in the final rule to limit the REH CoPs related to pharmaceutical services to 42 CFR 485.635(a)(3).

Additional Outpatient Services

CMS proposes a CoP for additional outpatient services at CFR § 485.524(a)(3) that requires REHs to "Have effective communication systems in place between the REH and the patient (or responsible individual) and their family, ensuring that the REH is responsive to their needs and preferences." CHA understands the importance of communications with patients, their families, and/or their caregivers to ensure that the patients' preferences are respected, and the best possible clinical outcome is facilitated for the patient. However, we are concerned that an "effective communications system" is not defined in the CoPs, and examples are not provided in the proposed rule's preamble. Given that what constitutes an "effective communications system" is open to interpretation, CHA is deeply concerned that a surveyor's interpretation of this requirement will differ from the REH's and create compliance issues that are completely avoidable. **Therefore, CHA respectfully asks CMS to propose a definition and/or provide examples of what constitutes an "effective communications system" in a final rule with comment period.** We believe it is important that stakeholders have the opportunity to provide feedback on this definition and/or examples.

CHA appreciates the opportunity to comment on the proposed CoPs for CAHs and REHs. If you have any questions, please contact me at cmulvany@calhospital.org or (202) 270-2143.

Sincerely,

/s/
Chad Mulvany
Vice President, Federal Policy