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Submitted electronically via: www.regulations.gov

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

Re: Medicare and Medicaid Programs; Conditions of Participation (CoPs) for Rural Emergency Hospitals (REH) and Critical Access Hospital CoP Updates (CMS-3419-P)

Dear Administrator Brooks-LaSure,

Vizient, Inc. appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) proposed rule detailing the Medicare and Medicaid conditions of Participation (CoPs) for the new Rural Emergency Hospital (REH) designation and updating regulations for Critical Access Hospitals (CAHs) (hereinafter, "Proposed Rule"). Healthcare access in rural America is reaching a crisis point in many areas of the country. Providing flexible and timely updates to regulations is vital in ensuring that existing resources like CAHs will be able to serve patients in need, and new lifelines may be deployed through the REH designation to preserve access to critical trauma care and other outpatient services. Vizient appreciates the agency's efforts to increase stakeholder engagement on these issues and looks forward to working more closely with CMS as the agency continues moving forward with critical reforms.

Background

Vizient, Inc. provides solutions and services that improve the delivery of high-value care by aligning cost, quality and market performance for more than 60% of the nation's acute care providers, which includes 97% of the nation's academic medical centers, and more than 20% of ambulatory providers. Vizient provides expertise, analytics, and advisory services, as well as a contract portfolio that represents more than $130 billion in annual purchasing volume, to improve patient outcomes and lower costs. Headquartered in Irving, Texas, Vizient has offices throughout the United States.

Conditions of Participation for Rural Emergency Hospitals

Vizient appreciates the approach that CMS took in the Proposed Rule to recognize the unique challenges faced by facilities that may be considering conversion to the new REH designation. While such facilities are critical to support the health care needs of their communities – both for urgent trauma services and routine outpatient care – many are facing incredibly challenging financial situations due to low and inconsistent

volumes, staffing shortages, increased costs and other challenges facing care delivery in rural America.

In our comments on the Calendar Year 2022 Outpatient Prospective Payment System proposed rule, which included the agency's Request for Information related to the new REH designation, Vizient recommended the agency adopt CoPs, quality measures and licensure requirements that largely mirror those currently utilized by the converting facility. Vizient's recommendation was based, in part, on the premise that converting facilities would better adapt to familiar requirements. In addition, Vizient urged the agency to fully assess to what degree existing requirements can be safely scaled back to avoid unnecessary administrative burden for REHs. Under the Proposed Rule, CMS proposes that many of the REH CoPs significantly mirror existing CoPs for CAHs or, at times, the Conditions for Coverage (CFCs) for Ambulatory Surgery Centers (ASCs). Generally, Vizient supports that approach to help support a more seamless transition to the new REH designation while maintaining patient safety.

Given the uncertainty related to the uptake of the new designation, Vizient encourages the agency to continually communicate with stakeholders and assess to what degree the proposed regulations, including CoPs, can be safely modified to further ease administrative and regulatory burden. While Vizient does not provide comments on the full array of CoPs being considered for REHs, we continue to urge flexibility and ongoing evaluation of the necessary requirements to support a sustainable REH, while ensuring patient safety. However, below we are pleased to offer feedback on specific examples where the agency has sought stakeholder input.

Condition of Participation: Emergency Services

While flexibility is critical to REH's ability to provide ongoing care, for such facilities to be successful, the use of telehealth services will be necessary for REHs to provide access to appropriate providers and specialists. In the Proposed Rule, CMS seeks comment on the proposed staffing requirements for the provision of emergency services, including insight into the appropriateness of not requiring an advanced practitioner to be on-site at all times.

CMS details multiple requirements to ensure that emergency care services meet the needs of patients, including having trained medical and nursing personnel on site at all times, integrated care considerations with other REH services and written policies and procedures for appraisal of emergencies, initial treatment, and referrals when appropriate. Given these requirements, Vizient agrees with CMS that it is not essential that a physician, physician assistant, nurse practitioner or clinical nurse specialist with training or experience in emergency care to be physically on-site at all times, provided they are on call and readily available to provide in-person care with short notice. Additionally, Vizient encourages CMS to consider incentives for REHs such that emergency response services also be supplemented by eEmergency and virtual triage telehealth services that may support critical emergency interventions.

Condition of Participation: Additional Outpatient Medical and Health Services

In the Proposed Rule, CMS provides flexibility, with limitations, regarding the potential outpatient medical and health services an REH may provide. CMS also seeks feedback on whether an REH should be permitted to provide low-risk labor and delivery services, and whether an REH should be required to provide outpatient surgical services in the event a surgical intervention is necessary. Vizient appreciates the agency raising this important question. Improving maternal mortality and morbidity is a necessity across many rural areas of the country. Vizient believes that maintaining critical safety precautions for labor and delivery is essential to ensure necessary maternal and post-natal safety. Should an REH provide labor and delivery services, it would be important for CMS to ensure that educational supports are provided to clinical providers serving in REH settings so that they may be sufficiently familiar with Neonatal Resuscitation Guidelines, the use of equipment required for resuscitation efforts and the use of the Apgar scoring system to facilitate the evaluation of newborns and be prepared to deliver timely interventions to maximize newborn well-being. Similarly, for REHs assessing whether to offer such services to meet the needs of their communities, it is worth consideration whether they would have the necessary resources available to support the wide range of assessments that are needed prior to the newborn infant's discharge, including a newborn screen, hearing screen, car seat test, discharge planning for follow-up visits, vaccinations and more. All of these items can be resource intensive and are important for the health and wellbeing of the newborn.

With those considerations in mind, expanding access to low-risk labor and delivery services may be possible, but only with sufficient resources and patient-safety considerations in mind. Also, Vizient suggests CMS provide additional information regarding how these services may interact with other aspects of the Proposed Rule, especially as labor and delivery services may extend beyond a 24-hour length of stay – particularly in cases where surgical intervention may be necessary, as CMS notes in the Proposed Rule.

Also, regarding outpatient surgical services, while having a full outpatient surgical suite capable of emergency surgical and labor interventions would be ideal in crisis situations, maintaining staffing and having resources available for such instances may not be feasible for all REHs. At the same time, in some instances, an REH may be the closest option for labor and delivery services in rural areas, and further surgical support may be necessary, even in expected low-risk deliveries. Given those considerations, Vizient encourages CMS to work carefully and closely with stakeholders to identify whether a risk-based approach would be appropriate. For example, factors in such an approach could include potential distance and time for transfers to trauma centers that may be more well positioned to perform emergency surgical interventions.

Proposed Changes for Critical Access Hospital Conditions of Participation

The Proposed Rule also seeks to update the CoPs for CAHs by seeking to codify the definition of a "primary road" for the purposes of the determining eligibility to be a CAH

under distance standards. For a hospital to qualify as a CAH using the distance standards, it must be “located more than a 35-mile drive (or, in the case of mountainous terrain or in areas with only secondary roads available, a 15-mile drive) from a hospital on primary roads". The proposed rule seeks to modify the definition of primary road with respect to the CAH distance requirement regulations, for both the 35-mile drive requirement, and 15-mile requirement in the case of mountainous terrain or in areas with only secondary roads available from a hospital or another CAH.

Specifically, the proposed rule specifies that the primary road of travel for determining the driving distance of a CAH and its proximity to other providers is “a numbered Federal highway, including interstates, intrastates, expressways or any other numbered Federal highway; or a numbered state highway with two or more lanes each way”.

Vizient supports the modified definition of primary road to include roads with two or more lanes in each direction. The added clarity offers recognition of the transportation challenges in much of rural America, and the limitations of rural roads with only one or two lanes. The proposed update to the definition may provide greater certainty for existing CAHs regarding eligibility status to continue operations under their current designation and could potentially open the door for more hospitals to have the ability to convert to a CAH designation. Many such facilities are truly rural in nature, though may not technically conform under the current interpretation of what constitutes a “primary road”. At the same time, while the updated definition is positive, it should be noted that transportation investments to make road improvements, such as adding lanes in certain areas, may jeopardize eligibility for existing CAHs and may serve as a possible disincentive for communities to make necessary transportation improvements.

CMS also seeks comment on whether the “primary roads” definition of including two or more lanes each way should also apply to numbered Federal highways with only one lane in each direction. Vizient appreciates the agency’s consideration and believes that numbered Federal highways with only one lane in each direction should not be considered as a primary road. In many cases, there is no meaningful difference in road conditions, maintenance or upkeep between numbered Federal highways with one lane in each direction and similar state highways that would necessitate a distinction for the purposes of determining what would be considered a primary road. Excluding numbered Federal highways with only one-lane in each direction from the definition of primary roads would more accurately recognize the different transportation characteristics and challenges between two and four-lane roads, regardless of whether the highway is designated and maintained by state or federal authorities.

The rule also proposes to establish a consistent, data-driven process for CMS’s review and recertification for CAH eligibility. The rule clarifies that CMS intends to conduct recertification for existing CAHs by assessing all hospitals and CAHs within a 50-mile radius of the CAH during each eligibility review, and then on a 3-year cycle. Then, in that process, the agency indicated it would focus on the availability of new or expanded health care services within the 35-mile radius of the CAH, and less so on

the technical distance by road. Recognizing that CMS must take steps to ensure providers are eligible under statute, Vizient appreciates the agency's proposed approach in reviewing CAH eligibility with a focus on care access. Vizient urges the agency to fully examine the entirety of the health care environment in the region as it conducts CAH eligibility reconsiderations with the primary focus on the potential impact on patient access to care in cases where a CAH may be non-compliant due to strict technical enforcement of distance eligibility standards. It is important that strict applications of the distance standards do not threaten unnecessary hospital closures or reduce patient access to care. As such, Vizient appreciates the approach outlined in the Proposed Rule, and urges the agency to continue to extend appropriate flexibility and work with impacted facilities to ensure access is not reduced and care disruptions do not take place.

Conclusion

Vizient thanks CMS for issuing the Proposed Rule and its thoughtful approach in supporting care options for rural America. We are pleased to offer our feedback and support for many of the approaches laid out in the Proposed Rule. As CMS continues to move forward with establishing the new REH designation and further refines the oversight of CAHs in their work to serve their communities, we continue to urge the agency to maintain engagement with stakeholders, including rural organizations and hospitals, to ensure access to care is preserved.

Vizient membership includes a wide variety of hospitals ranging from independent and rural, community-based hospitals to large, integrated health care systems that serve acute and non-acute care needs. Additionally, many are specialized, including academic medical centers and pediatric facilities. Our members are integral partners in their local communities, and many are ranked among the nation's top health care providers. In closing, on behalf of Vizient, I would like to thank CMS for providing us the opportunity to respond to the Proposed Rule. Please feel free to contact me, or Jenna Stern at jenna.stern@vizientinc.com, if you have any questions or if Vizient may provide any assistance as you consider these issues.

Respectfully submitted,

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