September 29, 2022

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-3419-P
Submitted electronically to: http://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 Premier healthcare alliance serving approximately 4,400 hospitals and health systems and 250,000 other provider organizations, we appreciate the opportunity to submit comments on the Conditions of Participation (CoPs) for Rural Emergency Hospitals (REH) and Critical Access Hospital (CAH) CoP Updates proposed rule. With integrated data and analytics, collaboratives, supply chain solutions, and consulting and other services, Premier enables better care and outcomes at a lower cost. Premier plays a critical role in the rapidly evolving healthcare industry, collaborating with providers to co-develop long-term innovations that reinvent and improve the way care is delivered to patients nationwide. Additionally, Premier maintains the nation's most comprehensive repository of hospital clinical, financial and operational information and operates one of the leading healthcare purchasing networks. Our comments primarily reflect the concerns of our member hospitals and health systems which, as service providers, have a vested interest in rural payment policy. Below, the Premier healthcare alliance provides detailed comments with suggested modifications to the policies proposed by the Centers for Medicare & Medicaid Services (CMS).

Under the Consolidated Appropriations Act (CAA) of 2021, Congress established a new Medicare provider type – Rural Emergency Hospitals (REHs) – effective for calendar year (CY) 2023. Under this policy, Critical Access Hospitals (CAHs) and other small rural hospitals will have the opportunity to apply to become an REH, whereby they will only furnish emergency department services, observation care and certain outpatient services. Additionally, REHs will be required to meet other requirements, including maintaining a staffed emergency department 24 hours a day, 7 days a week and having an annual per patient average length of stay (ALOS) of 24 hours or less.

CMS is proposing to implement these policies through two separate rules: a standalone rule that covers the CoPs that REHs will need to meet, as well as through the CY 2023 Outpatient Prospective Payment System (OPPS) Proposed Rule, where CMS proposes policies related to payment, quality reporting, and enrollment. Our comments below are generally in reference to the proposals put forth in the CoP proposed rule.

STATUTORY AUTHORITY

REHs are intended to protect access to essential healthcare services in rural communities by providing hospitals with an opportunity to discontinue inpatient care but still meet the needs of their communities for emergency and outpatient services. CAHs and rural hospitals that have 50 or fewer beds (as of enactment of the CAA of 2021) are eligible to convert to this new provider. While REHs will be eligible for

increased OPPS payment and a monthly facility fee, statutory restrictions may still make this new provider type financially untenable for many hospitals that could benefit or may result in the loss of other services to rural communities. As we note in more detail below, **we encourage CMS to work with Congress to modify relevant statute to address these challenges and ensure this new provider type is a viable option for rural hospitals and their communities**.

First, REHs would not qualify under the statutory definition of eligible entities for the 340B Drug Discount Program. For nearly three decades, the 340B program has been critical in helping covered entities expand access to lifesaving prescription drugs and comprehensive healthcare services to low-income, underinsured and uninsured individuals in communities across the country, including rural areas. Many CAHs and small rural hospitals have greatly benefited from the 340B program and would lose much needed funding with the conversion to a REH. **We strongly urge CMS to work with Congress to modify statute to ensure that REHs are eligible for 340B Drug Discount Programs.**

Second, statute restricts REHs from furnishing any inpatient services, except skilling nursing services that are furnished in a separate and distinct unit of the REH. This would exclude REHs from maintaining inpatient psychiatric or rehabilitative services, even if furnished in a separate and distinct unit. Rural patients often face limited access to both psychiatric care and rehabilitation services and rely on rural hospitals to furnish these services. **We encourage CMS to work with Congress to expand statute to allow REHs to furnish inpatient psychiatric and inpatient rehabilitative services if furnished in a separate and distinct unit.** This would allow communities to expand care, potentially utilizing space that might be available as the CAH or small rural hospital converts out of inpatient care into emergency services.

Third, statute restricts CAHs and rural hospitals with 50 or fewer beds that may have closed on or before December 27, 2020 (date of enactment of the CAA of 2021) from converting to REH status. Since 2010, nearly 140 hospitals have closed,[1] leaving many rural communities without access to critical medical services and resulting in widening disparities in health care. For some of these communities, the opening of an REH could help to narrow these gaps in care and improve access. **We urge CMS to work with Congress to broaden eligibility to include communities where hospitals may have closed prior to the passage of the CAA of 2021.** Additionally, statue does *not* preclude hospitals that may have closed after December 27, 2020 from REH conversion. We recommend that CMS clarify in regulation that these hospitals are eligible for conversion and the process for reenrolling in Medicare as an REH.

WORKFORCE REQUIREMENTS

As part of this proposed rule, CMS is establishing the staffing and workforce requirements for REHs, which generally align with the requirements for CAHs but do include additional flexibilities that will allow REHs to maximize their workforce. We support and applaud efforts by CMS to ensure REHs have sufficient flexibility arounds staffing and other requirements related to workforce.

For example, CMS proposes to allow the governing body to grant medical staff privileges to nurse practitioners (NPs) and physician assistants (PAs) to the extent allowable under state law. Allowing NPs and PAs to practice at the top of their education and license will help mitigate some workforce challenges that rural communities face. Additionally, CMS proposes to allow a physician, PA, NP, or clinical nurse

[1] University of North Carolina, Sheps Center, Rural Hospital Closures, https://www.shepscenter.unc.edu/programs-projects/rural-health/rural-hospital-closures/

specialist (CNS) to be on call within thirty minutes. This would allow REHs, which may have low-patient volume, the flexibility to align their workforce with the needs of their communities.

As part of the COVID-19 Public Health Emergency (PHE), CMS waived several requirements related to scope of practice to ensure providers can fully maximize their workforce. These waivers had the effect of deferring policy to state laws and requirements related to supervision and licensure. Oftentimes, Medicare scope of practice requirements are duplicative of existing requirements at the state level and, in some cases, may be more stringent. This can be overly burdensome to providers as they track various requirements to ensure compliance.

For example, during the PHE, CMS waived requirements that a certified registered nurse anesthetist (CRNAs) be under the supervision of a physician. CRNAs often serve as the sole anesthesia provider in rural hospitals. We urge CMS to adopt this flexibility permanently for REHs, which will help improve access to these services in rural communities. As CMS looks to establish the scope of practice requirements for REHs, we would encourage CMS to take lessons learned from the PHE to ensure the requirements it establishes are not duplicative of state or licensing board efforts.

Additionally, CMS revised the definition of direct supervision for the duration of the PHE to allow for direct supervision to be provided using real-time interactive technology that has audio and video capability, or a virtual presence. Direct supervision requires that a physician or other practitioner be immediately available when services are being furnished to Medicare beneficiaries. Advances in technology allow physicians and other practitioners to stay connected virtually, which in some cases may be more expeditious and efficient than if the practitioner was physically present. **We encourage CMS to provide REHs with the discretion to determine the best means of providing appropriate direct supervision**. At a minimum, CMS should explore allowing direct supervision to be met through virtual presence for certain services.

Finally, many rural communities continue to face notable challenges with recruiting and maintaining healthcare workers. We encourage CMS to work with Congress and other agencies, such as the Health Resources and Services Administration (HRSA), to develop programs and incentives aimed at growing the rural healthcare workforce.

ADDITIONAL OUTPATIENT MEDICAL AND HEALTH SERVICES

While REHs are required to furnish emergency department services and observation care, they have the option of furnishing other outpatient medical and health services. CMS is proposing to broadly define outpatient services as all outpatient department services that are payable under the Outpatient Prospective Payment System (OPPS). **We support CMS' decision to not limit the types of outpatient services that REHs can choose to furnish.** This will ensure REHs have the flexibility to define and furnish outpatient services that best meet the needs of their communities and will increase access for healthcare in rural communities.

RURAL HEALTH CLINICS AND SHARED SPACE WITH OTHER PRVODIERS

As the proposed rule is written, it is unclear if REHs are authorized to operate rural health clinics (RHCs). However, the CAA of 2021 specifies that REHs operating provider-based RHCs will be considered

"grandfathered" for purposes of new RHC payment limits.[2] This seems to indicate that Congress intended for REHs to be allowed to operate RHCs. We urge CMS to clarify the requirements for REHs operating provider-based RHCs, including how their payment limits will be set given the CAA of 2021 language regarding grandfathering.

We also continue to urge CMS to allow REHs flexibility when sharing space with other providers at distinct times, or sequential shared spaced. Rural communities often lack healthcare specialists, leaving patients with few options but to travel long distances to receive needed care -- often at significant personal cost to the patient through lost wages and incurred travel expenses. Hospitals and other providers have tried to partner with rural providers to bring specialists closer to patients. However, providers have been hindered by a lack of clarity and sometimes inconsistent guidance on when shared space between providers is allowed.

Currently, rural providers have primarily two options when it comes to partnering with other providers to bring in specialists to a community: the rural provider, usually a hospital, can 1) contract a specialist from another provider or 2) lease space to the other provider. Both options have their own unique challenges:

- The contracted specialist must be reimbursed at fair market value. This approach can be cost prohibitive for many rural providers, which must weigh several factors such as payor mix and whether there is enough patient volume to offset the cost of contracting the physician.
- Visiting providers also have the option of leasing space from the rural hospital at fair market value. However, based on guidance from CMS Regional Offices, once this space has been leased it cannot be used by the rural hospital. This policy has resulted in an inefficient allocation of space, as most specialists only visit a facility a few times per month. As a result, the space often remains empty the remainder of the month. Additionally, many rural hospitals have limited physical space or resources to invest in extra space. For those who have additional space, survey and certification guidance may make it challenging for rural providers to carve out separate space. For example, guidance has indicated that the space must be clearly demarcated from the hospital and have its own entrance, hallways, bathrooms, and waiting room.

CMS should establish clear guidance that would allow REHs to share space with other types of providers. Precedents for this type of policy exists. For example, RHCs and federally qualified health clinics (FQHC) can sequentially share space. These entities are required to clearly state hours of operations for each distinct provider. Practitioners are required to bill under the rate corresponding with the hours of operation (e.g., bill for RHC services when the space is being used as an RHC).

Under the sequential shared space policy, providers would be required to notify patients whether they are affiliated with the hospital or another provider and any cost-sharing implications. CMS should also allow for shared public spaces. For example, the REH and provider leasing a space could utilize the same entrance, public hallways, and restrooms.

PREVENTION AND CONTROL AND ANTIBIOTIC STEWARDSHIP

CMS proposes that REHs will follow the same infection prevention and control and antibiotic stewardship CoPs as CAHs. We support establishment of these requirements, but also remind CMS to consider the workforce challenges that rural healthcare providers face. Many providers have limited clinical and

[2] "A rural emergency hospital may be considered a hospital with less than 50 beds for purposes of the exception to the payment limit for rural health clinics under section 1833(f)", 42 U.S.C. § 1395x(kkk)(6)(B)

administrative staff available for reporting. **As a result, CMS should continue to explore how to automate and simplify these requirements as much as possible.**

Clinical analytics technologies are currently widely leveraged in hospitals and acute settings to detect patient care issues through surveillance, interventions and reporting capabilities that are needed to support antimicrobial stewardship programs. These systems utilize data from EHRs and have significantly helped clinicians and pharmacists in acute settings identify overuse of antibiotics and drug-bug mismatches, reduce time-to-appropriate therapy and enhance therapy for difficult-to-treat pathogens. Those health systems already utilizing clinical surveillance technology were well positioned to respond to COVID-19 before the pandemic hit. **CMS should continue to explore ways to support REHs and other rural providers in implementing EHRs and electronic clinical surveillance technology to provide meaningful assistance with infection control.** Given many rural providers may lack the financial resources to support the infrastructure necessary for electronic clinical surveillance, CMS should avoid requiring REHs or rural providers from implementing these types of systems at this time. Instead, CMS should work with Congress to secure funding to support rural providers in implementing electronic clinical surveillance.

DEFINITION OF "PRIMARY ROADS"

As part of this rule, CMS clarifies the CAH distance requirement by adding a definition of "primary roads." We appreciate CMS clarifying these requirements and generally support the definition. However, we would urge that CMS consider excluding federal numbered highways with one lane in each direction, which are common in rural areas. These types of highways do not differ from state one-lane highways, which are excluded from the proposed definition. We also ask that CMS clarify how it will verify a CAH's distance. In the preamble, CMS notes that it will review certification status by looking at the 50-mile radius but does not clarify if that is 50 road miles or 50 miles "as the crow flies."

Finally, we recommend that CMS exclude REHs from the distance determination for CAHs. Since REHs will only be furnishing emergency departments services and some outpatient services, REHs will have a distinct and unique role from other CAHs or IPPS hospitals. It would make sense to have a policy to exclude REHs from the CAH distance requirements, since many REHs will be converted from CAHs.

OTHER REQUIREMENTS APPLICABLE TO CAHS

CAHs are currently subject to two requirements related to average length of stay (ALOS). As a CoP, CAHs must maintain an annual ALOS of 96 hours or less across all patients. Additionally, as a condition of payment, a CAH must certify that a patient is not expected to require a stay of more than 96 hours. This requirement was established under the Balanced Budget Act of 1997, but CMS has practiced enforcement discretion since 2018 due to the financial burden it places on CAHs. Additionally, CMS waived this requirement as part of the COVID-19 PHE.

As noted, the 96-hour certification requirement creates unnecessary burden on CAHs and is generally duplicative of the existing CoP requiring an annual ALOS of 96 hours or less. **We urge CMS to continue to practice enforcement discretion after the conclusion of the PHE and classify it as a low-priority item for auditors.** Additionally, we urge CMS to work with Congress to permanently repeal this policy.

INCENTIVIZING MOVEMENT TO VALUE-BASED CARE

CMS should continue to explore ways to include REHs in value-based care initiatives. As we've noted in the past, there are several barriers that discourage or prevent rural providers from participating in alternative payment models (APMs), including inability to absorb high discount rates commonly applied under APMs. **CMS should continue to work with stakeholders to adapt existing APMs to be more inclusive of rural providers, including REHs, and to ensure rural providers have the necessary flexibilities and tools to succeed in value-based care.**

CONCLUSION

In closing, the Premier healthcare alliance appreciates the opportunity to submit these comments on the CoPs for REHs and CAH CoP Updates. If you have any questions regarding our comments or need more information, please contact Melissa Medeiros, Director, Payment Policy & Analysis, at melissa_medeiros@premierinc.com or (202) 879-4107.

Sincerely,

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Senior Vice President, Government Affairs
Premier healthcare alliance