

August 29, 2022

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

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

Submitted electronically via regulations.gov

Dear Administrator Brooks-LaSure,

The National Rural Health Association (NRHA) is pleased to offer comments on the Centers for Medicare and Medicaid Services (CMS) proposed rule for the Medicare Conditions of Participation for Rural Emergency Hospitals and Critical Access Hospitals. We appreciate CMS' continued commitment to the needs of the more than 60 million Americans that reside in rural areas, and we look forward to our continued collaboration to improve health care access throughout rural America.

NRHA is a non-profit membership organization with more than 21,000 members nationwide that provides leadership on rural health issues. Our membership includes nearly every component of rural America's health care, including rural community hospitals, critical access hospitals, long-term care providers, doctors, nurses, and patients. We work to improve rural America's health needs through government advocacy, communications, education, and research.

I. Background

B. Statutory Authority and Establishment of Rural Emergency Hospitals as a Medicare Provider Type

NRHA requests clarification on a number of issues not addressed in the proposed CoPs. NRHA understands that hospitals closed prior to passage of the Consolidated Appropriations Act, 2021, on December 27, 2020, are statutorily prohibited from converting to a Rural Emergency Hospital (REH). However, NRHA suggests that CMS clarify that hospitals closed after December 27, 2020, are eligible to convert to an REH. This action is not contrary to the statute and would provide needed clarification for our members.

Additionally, section 1861(kkk)(4)(a)(i) of the statute requires that a hospital applying to convert to an REH must submit, at a time and in a form as the Secretary may require, an action plan for initiating REH services including a detailed transition plan that lists the services the REH will retain, modify, add, and discontinue, and a list of intended outpatient services.¹ The proposed conditions of participation (CoPs) do not elaborate on the time and form required for these submissions. NRHA

¹ 42 U.S.C. § 1395x(4)(A)(i)-(ii) (2018).

requests clarification on how converting hospitals may submit this information, and whether it would be part of filing the Form 855A for conversion or through another process.

Further, 340B is a valuable program for rural hospitals. Several member hospitals have expressed to us their concern over converting without 340B funds. While NRHA recognizes that a change to the 340B statute would likely be required to allow REHs to participate, we stress the importance of this action and urge the Administration to work within its statutory authority and alongside Congress to ensure this change is made. Without REH participation in 340B far fewer hospitals will consider converting as 340B payments are vital to financial viability of rural hospitals.

NRHA also requests clarification on whether REHs that convert back to a prospective payment system (PPS) hospital will revert to the same classification held prior to REH status, such as Sole Community Hospital (SCH), Medicare-Dependent Hospital, or otherwise reclassified for wage index purposes. It is in the best interest of rural beneficiaries to allow converting hospitals to be able to retain their previous classification upon reverting from an REH in order to maintain access to needed services in rural communities.

Last, NRHA requests an explanation on how Graduate Medical Education (GME) training in an REH will be addressed. Medical residency training is currently occurring in Critical Access Hospitals (CAHs) and small rural hospitals that may consider converting to an REH. It is beneficial to maintain training arrangements given healthcare provider workforce shortages in rural areas. Therefore, NRHA requests that CMS issue guidance on how time spent in an REH will be counted for in Medicare GME.

II. Provisions of the Proposed Regulation

A.2. Definitions

NRHA understands the statutory constraints that CMS must work within when promulgating regulations, such as the 24-hour average patient stay. Nevertheless, NRHA asks that CMS investigate its ability to flexibly implement or enforce the 24-hour average patient stay requirement. Per the National Advisory Committee on Rural Health and Human Services' (NACRHHS) recommendation, the 24-hour average should be flexibly enforced for unexpected increases in volume due to COVID-19 and seasonal flu surges and other unforeseen circumstances.² CMS must also account for challenges with EMS transport and ambulance availability in certain rural communities and how that could impact a REH's 24-hour average patient stay. As discussed *infra*, section II.A.12, flexibility on the average stay would ease the burden on REHs faced with psychiatric patients that require transfer to an inpatient facility. Additionally, a flexible approach to the 24-hour average stay would be beneficial for potential labor and delivery patients. In many rural communities, available psychiatric beds are lacking, and transfers are difficult.

A.4. Designation and Certification of REHs

² NATIONAL ADVISORY COMMITTEE ON RURAL HEALTH AND HUMAN SERVICES, *Rural Emergency Hospital Policy Brief and Recommendations to the Secretary*, 6 (Oct. 2021) <https://www.hrsa.gov/sites/default/files/hrsa/advisory-committees/rural/publications/2021-rural-emergency-hospital-policy-brief.pdf>.

NRHA requests clarification on the definition of “beds” as used in the proposed 42 C.F.R. § 485.506(b) to describe one type of hospital eligible to convert to an REH. CMS must clarify whether this means licensed beds or staffed beds given that either definition would change eligibility status for some hospitals. NRHA believes that the definition used should be available staffed beds.

To further support equity in rural areas, NRHA recommends that CMS allow REH conversion for Indian Health Service (IHS) and Tribal PPS hospitals and CAHs. We have engaged with multiple IHS hospitals that would like to convert to an REH. NRHA believes that as long as the hospitals meet other statutory requirements, i.e., being a CAH or small rural hospital with less than 50 beds, IHS and Tribal hospitals should be eligible to convert.

A.6. Governing Body and Organizational Structure of the REH

NRHA applauds CMS’ efforts to allow maximum flexibility for REH structure and staffing. In particular, NRHA supports the option for the governing body to grant medical staff privileges to nurse practitioners (NP) and physician assistants (PA), as allowable under state scope of practice laws. Authorizing NPs and PAs to practice at the top of their education and license is an important step to mitigating some workforce challenges that rural communities face.

NRHA supports the ability of REHs to provide needed telemedicine services to rural beneficiaries. However, we are concerned with the potential for opening the door for third-party, for-profit companies to serve as distant site telemedicine entities without clear ties to primary care and needed care coordination services. The streamlined credentialing and privileging process, meant to afford flexibility and relieve REHs of associated burdens, may allow for-profit actors to benefit and potentially lessen the quality of care provided through telemedicine. We agree that REHs likely lack the resources to carry out traditional credentialing and privileging processes, and that such processes would be a burden. But NRHA believes that it is important for care to be well-coordinated, including telemedicine, and emphasizes the critical role that a community-based provider plays in quality patient care. NRHA advises CMS to establish parameters that provide needed flexibility to REHs, while protecting against abuses from for-profit distant site telemedicine entities.

A.8. Emergency Services

NRHA supports CMS’ proposal to adopt CAH emergency services CoPs for personnel. Allowing a physician, PA, NP, or clinical nurse specialist (CNS) to be on call within thirty minutes of the REH provides needed flexibility for providing care in rural areas. Staffing flexibilities are crucial as workforce is a pressing and enduring challenge for rural providers. Provider-to-population ratios are significantly lower in rural versus urban areas and the impacts of COVID-19 have exacerbated this situation.³ It is appropriate, given the expected low volume of patients and services, that a practitioner is not required to be on-site at all times. This also aligns with the CoP that a registered nurse (RN), CNS, or licensed practical nurse (LPN) must be on duty whenever there is one or more patients receiving emergency services and the CoP that the emergency department be staffed 24/7.

³ Coates, et al., *Toward a Sustainable and Diversified Rural Health Workforce*, NATIONAL RURAL HEALTH ASSOCIATION (Feb. 2022), https://www.ruralhealth.us/NRHA/media/Emerge_NRHA/Advocacy/Policy%20documents/NRHA-Toward-aSustainable-Rural-Health-Workforce-Policy-Brief-2022.pdf.

NRHA believes that these policies will allow for sufficient personnel to be on-site to care for patients in the interim when a physician or other non-physician practitioner (NPP) is absent.

Additionally, the partnership of REHs and emergency air medical service providers will continue to be essential in many rural settings to ensure patients receive timely and appropriate emergency care. Emergency air medical services are critical to fill gaps in health care by providing lifesaving flights when REHs may have limited resources and patients need access to higher tertiary care. It is important that CMS recognizes this critical partnership between rural hospitals and air ambulance providers and takes steps to ensure that these emergency services receive appropriate Medicare reimbursement so rural air bases can continue to operate.

A.9. Laboratory Services

NRHA agrees that REHs must provide laboratory services that are essential to the immediate diagnosis and treatment of patients. CMS must consider the ongoing workforce issue with diagnostics and laboratory personnel. Laboratories are seeing increasing vacancies due to high attrition and burnout, plus a high retirement rate and rapidly increasing demand for diagnostics. This was true prior to the COVID-19 pandemic, which has strained laboratories further.

Consequently, while many of the basic laboratory services listed should be encouraged and supported at REHs, not all need to be required. For example, requiring primary culturing for transmittal⁴ may be unnecessary, and should instead be encouraged. For some laboratory services it would be more efficient for REHs to provide prompt access to rapid microbiological diagnostics and ensure samples can be processed at labs better equipped with diagnostic capabilities. In considering what laboratory services REHs must provide, CMS should weigh if the requirement puts an undue burden on rural laboratories by requiring services that cannot feasibly be fulfilled because of limited staffing or infrastructure.

A.11. Pharmaceutical Services

NRHA commends CMS on the flexibilities afforded for pharmaceutical services in REHs. We thank CMS for recognizing that rural areas often face challenges recruiting pharmacists. We support proposals to allow qualified individuals, other than pharmacists, to operate and oversee drug storage areas and to allow physicians to compound, package, and dispense drugs in place of a pharmacist. Additionally, NRHA agrees that it is appropriate that if an REH employs a pharmacist, the individual does not have to be employed full-time as other qualified individuals may cover pharmacist duties.

A.12. Additional Outpatient Medical and Health Services

NRHA thanks CMS for recognizing that REHs should furnish outpatient services according to the needs of the community served by an REH. We applaud CMS for not placing limits on the types of outpatient services that REHs may choose to furnish. Allowing an REH to provide outpatient services that are typically delivered at a physician's office or another point of entry increases access to critical health care for rural communities.

⁴ 42 C.F.R. § 485.635(b)(2)(vi) (2021). (This is a CAH CoP that CMS references for basic laboratory services that REHs should offer.)

NRHA requests clarification from CMS regarding provider-based rural health clinics (RHCs). Consistent with legislative intent⁵, NRHA believes that CMS must provide guidelines for REH operation of provider-based RHCs. However, as the CoPs currently stand, it is unclear whether REHs are authorized to operate provider-based RHCs. NRHA requests that this be explicitly stated in the CoPs. Further, many hospitals considering converting to an REH currently operate provider-based RHCs and want reassurance that their current provider-based RHCs payment methodology will be maintained in conversion. NRHA acknowledges that REH payment policies are part of the proposed Outpatient Prospective Payment System rule. However, NRHA would like to reiterate here that CMS must allow REHs to maintain operation of existing provider-based RHCs at payment rates grandfathered as of 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 RHC's per visit payment amount (or AIR) instead of the national statutory payment limit.⁶

NRHA supports allowing the option for REHs to provide low-risk labor and delivery services, as well as any outpatient surgical procedures associated with labor and delivery, as appropriate. This would create another point of entry to care for pregnant people in rural communities. This is crucial as rural areas are seeing obstetric (OB) units close at startling rates. As of 2018, only 40% of rural counties had a hospital providing OB care.⁷ The most remote rural counties felt the largest loss of OB units and overall had the fewest number of hospitals offering OB care.⁸ NRHA recognizes that providing labor services may not be feasible for many hospitals that convert to an REH; however, we believe it is important to have the option available for hospitals with labor and delivery services that are considering converting.

Should an REH provide low-risk labor and delivery services, clarification is needed on how it will impact the 24-hour annual average patient stay. Generally, the average length of stay following labor and delivery is longer than 24 hours.⁹ CMS notes that patients requiring surgery related to labor and delivery must be stabilized at the REH and then transferred. However, CMS does not address patients that do not undergo surgery and deliver vaginally. In many instances, these patients will need to recover at the REH for more than 24 hours even if delivery is uncomplicated. If labor and delivery at

⁵ § 1395x(kkk)(6)(B) (“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)”).

⁶ CENTERS FOR MEDICARE AND MEDICAID SERVICES, Update to Rural Health Clinic (RHC) All Inclusive Rate (AIR) Payment Limit for Calendar Year (CY) 2022 (Nov. 19, 2021)

<https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/R11130CP.pdf>.

⁷ Katy B. Kozhimannil, et al., *Rural Hospital Administrators' Beliefs About Safety, Financial Viability, and Community Need for Offering Obstetric Care*, 3 JAMA HEALTH FORUM 2 (2022),

<https://jamanetwork.com/journals/jama-health-forum/fullarticle/2790544>.

⁸ Peiyin Hung, et al., *Closure of Hospital Obstetric Services Disproportionately Affects Less-Populated Rural Counties*, UNIVERSITY OF MINNESOTA RURAL HEALTH RESEARCH CENTER (Apr. 2017), 2

https://rhrc.umn.edu/wpcontent/files_mf/1491501904UMRHRCOBclosuresPolicyBrief.pdf.

⁹ Wendy Wisner, *What to Expect at the Hospital After Giving Birth*, VERY WELL FAMILY (June 14, 2021)

<https://www.verywellfamily.com/what-to-expect-at-hospital-after-giving-birth-5088542#:~:text=For%20an%20uncomplicated%20vaginal%20birth,should%20expect%20to%20stay%20longer>.

REHs is authorized in the final rule, CMS must clarify how labor and delivery patients will count towards the 24-hour average patient stay.

NRHA believes that CMS should further consider authorizing distinct part inpatient psychiatric and inpatient rehabilitation facilities, without limitations on the number of beds, like the distinct part skilled nursing facility (SNF). NRHA members have expressed their desire for REHs to be authorized to operate these distinct units, particularly psychiatric units. The units would be physically distinct and fiscally separate for cost-reporting purposes and thus would not threaten the outpatient nature of the REH or the 24-hour average patient stay. An inpatient psychiatric facility would also alleviate concerns over transferring patients requiring mental or behavioral health intervention outside of the scope of the REH, discussed *infra*, section II.A.19. The units could make use of vacated inpatient acute space from the CAH or small rural hospital's conversion out of inpatient care into an REH.

Finally, NRHA asks CMS to reconsider its supervision requirements for certified registered nurse anesthetists (CRNA). CRNAs often serve as the sole anesthesia provider in rural hospitals and are more likely to work in areas with lower median incomes and higher uninsured or Medicaid beneficiary populations, both of which often overlap with rural areas.¹⁰ To continue CMS' commitment to flexibility for REHs, it must remove the requirement for an operating practitioner to supervise a CRNA administering anesthesia at the proposed 42 C.F.R. § 485.524(d)(3)(ii). There is no evidence that physician supervision of CRNAs improves patient safety or quality of care, yet research indicates that physician supervision may restrict access and increase costs.¹¹

A.13. Infection Prevention and Antibiotic Stewardship Programs

NRHA supports the inclusion of a CoP for infection prevention and antibiotic stewardship programs. Rural hospitals face unique challenges implementing stewardship programs due to limited resources and staff bandwidth. The proposed unified and integrated approach is essential to combatting antibiotic resistance and infections.

However, to achieve this goal, CMS should ensure that CAHs and REHs have adequate resources to take on more antibiotic stewardship and infectious disease reporting responsibilities as they work to integrate their reporting systems. This includes providing adequate reimbursement and technical assistance, as appropriate, for consistent training in antibiotic resistance reporting and best practices for staff.

A.14. Staffing and Staff Responsibilities

NRHA thanks CMS for the flexibilities regarding staffing at REHs given their smaller size and scope of services. Less stringent staffing regulations allow REHs to operate without pressures related to workforce shortages while best serving the needs of the community. NRHA suggests that CMS expand such flexibility by adopting a NACRHHS recommendation on physician physical presence

¹⁰ C. Jason Liao, Jihan A. Quarashi, & Lorraine M. Jordan, *Geographical Imbalance of Anesthesia Providers and its Impact On the Uninsured and Vulnerable Populations*, 33 NURSE ECON. 263 (2015).

¹¹ Brighita Negrusa, et al., *Scope of Practice Laws and Anesthesia Complications*, 54 MEDICAL CARE 913-920 (2016); Brian Dulisse & Jerry Cromwell, *No Harm Found When Nurse Anesthetists Work Without Supervision By Physicians*, 29 HEALTH AFFAIRS (2010).

requirements.¹² During the COVID-19 Public Health Emergency (PHE) CMS waived the physical presence requirement in 42 C.F.R. § 485.631(b)(2) which has allowed physicians in CAHs to provide medical direction, consultation, and supervision of services remotely.¹³ NRHA suggests that CMS make this waiver permanent for CAHs and incorporate it into the REH CoPs permanently as well. This would allow REHs to use NPPs¹⁴ to the fullest extent possible and provide flexibility where rural areas see provider and workforce shortages.

A.19. Agreements

NRHA thanks CMS for clarifying in the preamble to the proposed rule that REHs may retain existing, or negotiate new, transfer agreements with level III or IV trauma centers in addition to the required agreements with level I or II trauma centers. Members have expressed gratitude that once their hospital converts, they are able to maintain relationships with lower-level trauma centers.

NRHA proposes that CMS acknowledge the difficulty of transfers for mental and behavioral health patients, and work within its authority to address this issue. In many parts of the country an emergency department may be the only access point for rural individuals experiencing an acute mental health crisis. Members have expressed concern that when an REH is faced with a patient requiring mental health care outside of its scope, there likely will not be available inpatient psychiatric beds for transfer or the transfer process will exceed 24 hours.

In the preamble to this proposed rule, CMS notes that comments in response to the Request for Information in the CY 2022 Outpatient Prospective Payment proposed rule expressed concern over delays in transferring mental health patients due to limited psychiatric bed availability. CMS claims that this would happen infrequently and thus not impact the 24-hour annual average patient stay. However, assuming that is true, REHs should not allow a patient requiring mental health intervention to languish in an emergency department for an extended period of time. These patients, known as emergency department “boarders” are often those most in need of care and boarding increases the stress on an already vulnerable patient.¹⁵

CMS must investigate its authority to assist REHs with patients requiring acute psychiatric care. CMS should allow REHs to enter into transfer agreements with inpatient psychiatric facilities where it is feasible for both the REH and inpatient facility. Another potential solution, discussed *supra*, section II.A.12, is to authorize REHs to maintain distinct unit inpatient psychiatric facilities, should associated CoPs be met.

NRHA also requests that CMS explore the option of allowing an exception to the 24-hour average patient stay for psychiatric patients as feasible within the statute. NRHA recognizes that emergency

¹² NACRHHS, *supra* note 2, at 6-7.

¹³ CENTERS FOR MEDICARE AND MEDICAID SERVICES, *COVID-19 Emergency Declaration Blanket Waivers for Health Care Providers*, 10 (May 24, 2021) <https://www.cms.gov/files/document/summary-covid-19-emergency-declaration-waivers.pdf>.

¹⁴ Nonphysician practitioners include nurse practitioners, physician assistants, and clinical nurse specialists.

¹⁵ THE JOINT COMMISSION, *ED Boarding of Psychiatric Patients – A Continuing Problem* (July 2021) <https://www.jointcommission.org/resources/news-and-multimedia/newsletters/newsletters/quick-safety/quick-safety--issue-19-alleviating-ed-boarding-of-psychiatric-patients/alleviating-ed-boarding-of-psychiatric-patients/#.Yv-bOnbMI2w>.

departments, especially REHs, are not equipped to handle mental health crises because, by nature, they are geared towards medical care rather than mental health care. We urge CMS to explore pathways to alleviate this issue and ensure that psychiatric patients receive the care that they require in a timely manner.

A.23. Skilled Nursing Facility Distinct Part Unit

NRHA applauds CMS for its proposed rulemaking on distinct part SNFs. NRHA believes the ability for an REH to house a distinct part SNF is an important step amid a nursing home closure crisis primarily affecting rural areas. Over 10% of rural counties are nursing home deserts, compared to 3.7% of metropolitan counties, and SNFs in rural areas across the country closing at unprecedented rates.¹⁶ REHs with a distinct part SNF will now offer another access point for post-acute care in rural communities. NRHA recognizes that swing bed services are not allowable under the current statute; however, we urge CMS to employ flexibilities around SNF services where possible in order to maintain these critical services in rural communities.

NRHA recommends two actions that would allow for flexible staffing across the REH and a distinct part SNF. First, NRHA recommends that the REH administrator be permitted to serve as the nursing home administrator or for a nearby nursing home administrator to do so in order to meet SNF CoPs.¹⁷ Second, NRHA supports the ability of NPPs to perform the initial SNF visit to a patient required in 42 C.F.R. § 483.30(c)(3). Under § 483.30(c)(3), the initial visit must be performed by a physician. Throughout the PHE, and until May 7, 2022, CMS waived this requirement and allowed NPPs to perform the initial visit.¹⁸ We recommend that CMS reinstate this waiver on a permanent basis at SNFs that are distinct part units of REHs to allow NPPs to perform the initial visit. For SNFs associated with REHs, it is incredibly important to allow NPPs to practice at the top of their training and license to improve access to care and meet the needs of patients in a facility that likely has less staff.

B.1.a. Adding the Definition of “Primary Roads”

We thank CMS for clarifying the CAH distance requirements by codifying the definition of “primary roads” used in sub-regulatory guidance. In general, NRHA supports CMS’ proposed definition of primary roads and believes that it provides necessary clarification for many rural communities.

However, we ask that CMS consider excluding Federal highways with one lane in each direction from the primary road definition. NRHA members have expressed that one lane Federal highways in their respective states do not align with the characteristics of the other examples of “primary roads.” Many one lane Federal highways are not well maintained by the Federal government or the state and are in poor condition. These roads are very common across rural areas. In Pennsylvania, a member noted that there are no differences in road conditions, maintenance, or upkeep between Federal and state highways in rural areas. For this member, their hospital is 26 miles from the next nearest hospital on

¹⁶ Sharma, et al., *Trends in Nursing Home Closures in Nonmetropolitan and Metropolitan Counties in the United States, 2008-2018*, RUPRI CENTER FOR RURAL HEALTH POLICY ANALYSIS (Feb. 2021), 1 <https://rupri.public-health.uiowa.edu/publications/policybriefs/2021/Rural%20NH%20Closure.pdf>.

¹⁷ 42 C.F.R. § 483.70(d) (2021).

¹⁸ CENTER FOR CLINICAL STANDARDS AND QUALITY/QUALITY, SAFETY & OVERSIGHT GROUP, CENTERS FOR MEDICARE AND MEDICAID SERVICES, *Update for COVID-19 Emergency Declaration Blanket Waivers for Specific Providers*, 3 (Apr. 7, 2022) <https://www.cms.gov/files/document/qso-22-15-nh-nltc-lsc.pdf>.

a one-lane Federal highway that is through treacherous terrain, and it is in worse shape than a secondary road maintained by the state that is twenty miles to another hospital. Yet, because the Federal highway is within the 35-mile radius, the member's hospital cannot convert to a CAH.

One lane Federal highways, in many instances, are not comparable to two or three lane highways because of sporadic maintenance varying by state, and therefore should be excluded from the definition of "primary roads." Including one lane Federal highways excludes otherwise eligible rural PPS hospitals from achieving CAH status. Further, if state one lane highways are exempt from the definition, it follows that Federal one lane highways should be as well. In many instances, Federal one lane highways do not differ from state one lane highways, especially in terms of upkeep. For consistency, both Federal one lane highways and state one lane highways should be excluded from the proposed definition.

Additionally, we request clarification from CMS on primary roads and road improvements. One implication of codifying the "primary roads" definition is that road improvements may jeopardize CAH status. For example, a road outside of the definition of "primary roads" may be improved upon, and therefore become a primary road. This could result in a CAH losing its status because it is now within 35 miles of another hospital on a newly minted primary road. NRHA has heard of at least one example of road improvements beginning that would jeopardize CAH status. Every other condition, like health care access in the surrounding community, remains unchanged, except for the hospital losing its needed designation. Arguably, without CAH status, a hospital would be vulnerable to closure and access to care would be threatened further only due to road improvements wholly outside of a CAH's control. We ask that CMS clarify what would happen in this situation and how a CAH could retain its designation.

Last, NRHA is concerned with the language surrounding the distance requirement for secondary roads. 42 C.F.R. § 485.610(c) states that a CAH meets the distance requirement if it is a 15-mile drive on *only* secondary roads. By retaining the word "only" as it pertains to secondary roads CMS may be unintentionally preventing hospitals from converting to a CAH.

Members have raised examples of hospitals that meet the 15-mile drive requirement, primarily on secondary roads, to the next nearest hospital, except for a short one- to two-mile drive on a Federal highway that is a primary road. A hospital in this situation would not meet the current proposed requirement because only 13 or 14 miles are on secondary roads and a short one-to-two-mile section is on a Federal highway. NRHA recommends that CMS consider reworking the regulatory language around secondary roads to avoid this situation. CMS should remove the word "only" as a qualifier for the secondary road requirement. NRHA proposes that CMS amend § 485.610(c) to read:

"(c) Standard: Location relative to other facilities or necessary provider certification. (1) The CAH is located more than a 35-mile drive on primary roads (or, in the case of mountainous terrain, a 15-mile drive; or in the case of areas where the shortest route includes secondary roads, a 15-mile drive with at least 90% on secondary roads) from a hospital or another CAH [...]."

We also ask CMS to clarify its proposals for CAH distance verification. In the preamble of this proposed rule, CMS notes that it will review CAH certification status by looking at the 50-mile radius around a CAH. If there is no new hospital within 50 miles, the CAH at issue will be automatically

recertified. If there is a new hospital, CMS will review the CAH's status using the distance requirement of 35 miles along with the "primary road" definition. NRHA has heard from members who would like CMS to clarify whether the 50-mile radius is 50 road miles or "as the crow flies." It is imperative that hospitals understand the methodology behind CMS' review process. In the State Operations Manual, the 35-mile distance requirement is reviewed via web-based map services, like Google Maps.¹⁹ NRHA recommends that the 50-mile radius is reviewed using this method as well. Additionally, we request clarification that CAHs granted necessary provider status are not subject to this periodic mileage review given that they are grandfathered in and not subject to other distance requirements.

Relatedly, we request that CMS make three changes to the CAH distance requirements. NRHA recommends that CMS add new language for computing the CAH distance verification. First, NRHA suggests that CMS measure the distance from the CAH to the next nearest "like" hospital or CAH. The term "like hospital" is used in the SCH regulations at 42 C.F.R. § 412.19(a)(1) and is not a new term for CMS to incorporate. This addition would preempt situations where a prospective payment system hospital opens a hospital-based clinic within 35 miles of the CAH, causing confusion around the CAH's status. Mileage should be measured to the nearest hospital that functions "like" a CAH. NRHA proposes that CMS amend § 485.610(c) to read:

"The CAH is located more than a 35-mile drive [...] from a *like* hospital or another CAH [...]."

NRHA further recommends that CMS amend § 485.610(c) to explicitly exclude REHs from the distance determination for CAHs. Considering that REHs only provide emergency department services, and can optionally furnish outpatient services, REHs serve a different purpose than CAHs. Following our suggestion above, an REH is not a "like" hospital when compared to a CAH. While some services, like an emergency department, may overlap, a CAH provides inpatient services and should not lose its status because an emergency and outpatient only hospital is nearby.

Last, we urge CMS to codify sub-regulatory guidance on IHS and Tribal hospital proximity to CAHs from the State Operations Manual, Chapter 2, at 2256A.²⁰ This guidance explains that the proximity of IHS and Tribal hospitals or CAHs and non-IHS or Tribal hospitals or CAHs to each other is not considered when determining CAH distance requirements.² CMS currently follows this at a sub-regulatory level, so codifying this guidance would not change the verification process except to give hospitals clear expectations.

Thank you for the chance to offer comments on this proposed rule and for your consideration of our comments. We very much look forward to continuing our work together to ensure our mutual goal of improving quality and access to care. If you would like additional information, please contact Alexa McKinley at amckinley@ruralhealth.us or 202-639-0550.

¹⁹ CENTERS FOR MEDICARE AND MEDICAID SERVICES, *State Operations Manual, Chapter 2 – The Certification Process, 2256A*, 241 (March 11, 2022) <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/som107c02.pdf>.

²⁰ *Id.*

Sincerely,



Alan Morgan
Chief Executive Officer
National Rural Health Association