Tribal Technical Advisory Group

To the Centers for Medicare & Medcaid

National Indian Health Board | 910 Pennsylvania Avenue SE, Washington, DC 20003 | (203) 507-4070 | (203) 507-4071 (fax)

August 26, 2022

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

Submitted via regulations.gov

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

Dear Dr. Brooks-LaSure:

On behalf of the CMS Tribal Technical Advisory Group (TTAG), I write to provide a response to the Centers for Medicare and Medicaid Services (CMS) proposed rule, "Medicare and Medicaid Programs; Conditions of Participation (CoPs) for Rural Emergency Hospitals (REH) and Critical Access Hospital CoP Updates" (CMS-3419-P).

Preamble to Comments:

Before commenting specifically on this proposal, we highlight the important context in which TTAG's comments are offered, and which should inform CMS's consideration of them: the deep inequities in this nation's health care delivery system, and the Biden administration's commitment and urgent effort to eliminate them. Over the last year the entire federal government, including CMS, has been working to respond to the President's Executive Order 13985 on Advancing Racial Equity and Support for Underserved Communities Through the Federal Government (EO 13985).

For the first time, the federal government is taking a systematic approach to address equity issues. CMS has responded by first issuing its CMS Strategic Plan, "Pillar: Health Equity" that laid out CMS' definition of health equity and a broad strategy to advance equity through its programs. More recently, CMS has published its Framework for Health Equity 2022-2032, which is a more detailed ten-year plan intended to address equity and health disparity issues across Medicare, Medicaid, CHIP, and the Health Insurance Marketplaces.

Important to understand about health disparities is that American Indian and Alaska Native (AI/AN) people were once one of the healthiest people on this continent, before colonialism and the United States policies of termination, assimilation, and boarding schools caused an "intergenerational pattern of cultural and familial disruption"[1] that drive health disparities to this day. These drivers have manifested in some of the worst health disparities for AI/AN people, including extraordinarily high and disproportionate rates of infant and maternal mortality, cancer, cardiovascular disease, depression and other behavioral health conditions, among other

ailments. The recent Department of Interior Boarding School Report explains that "Native Americans continue to rank near the bottom of all Americans in terms of health, education, and employment. Many AI/ANs face unique challenges and harsh living conditions resulting from the United States having removed their tribes to locations without access to adequate resources and basic infrastructure upon which their tribal governments can foster thriving communities."[2] It is important to acknowledge that efforts to address these disparities are often complicated by culturally inappropriate interventions and an inadequate understanding of the historical effects of United States policies and ongoing trauma of AI/AN people. [3] It is this history that is the root cause of the significant health disparities that affect AI/AN populations.

The TTAG is deeply appreciative that the President's EO 13985 and the CMS Framework for Health Equity provide an opportunity to focus on these concerns, and that the CMS Framework provides an opportunity to design, implement, and operationalize policies and programs to address health equity issues. The TTAG has always taken the position that CMS has ample legal authority to undertake distinct policies and programs specifically focused on AI/AN beneficiaries and the IHS programs that provide their care, because of their unique legal status under the U.S. Constitution and the duties owed by the federal government under its treaty and trust responsibilities to AI/ANs.[4]

Under established principles of Indian law, programs and policies that are specifically established for Indigenous people and organizations do not constitute prohibited race-based classifications; rather, they are based on the unique political relationship between the federal government and Indian Tribes. This unique legal relationship, taken together with EO 13985 and CMS' Framework for Health Equity, provides a sound basis for CMS to adopt the TTAG recommendations on the Proposed Rule. We trust you will agree that the TTAG recommendations are directly related to CMS' Framework discussed in "Priority 2: Assess Causes of Disparities Within CMS Programs, and Address Inequities in Policies and Operations to Close Gaps." These TTAG's recommendations fit clearly in the intended outcomes of this chapter of the Framework as well as other priority areas of the Framework.

Comments:

We appreciate the agency's dedication to considering the input of Indian Country in developing the new Rural Emergency Hospital provider type, by holding its public listening sessions and presenting at the TTAG meeting earlier this summer. We encourage CMS to continue this engagement with us as the Rural Emergency Hospital (REH) provider type rolls out, to address any unforeseen concerns that may arise as some IHS and Tribal (I/T) facilities transition to this new provider type.

We have the following comments and recommendations for CMS to consider in developing the REH conditions of participation, and to make sure this promising category of facility works for our health care delivery system and adds value to our rural communities. We greatly appreciate the consideration that CMS has already put into this proposed rule, including provisions that make it more efficient for REHs to credential and privilege clinicians who provide telemedicine services for REH patients. We support the CMS proposal at § 485.516(c) that there be no requirement that a partitioner be on-site at the REH at all times. We further appreciate that there

is flexibility in the requirement that REH have radiological services – the allowance for interpretations to be furnished off-site via telemedicine is appreciated and supported by the TTAG.

Recommendations:

I. Allow ancillary provider-based clinics to remain provider-based if their hospital counterpart transitions to the REH provider type

REH status is reserved for hospitals that were operating as small rural hospitals or Critical Access Hospitals as of the authorizing legislation's effective date. Some eligible hospitals that might consider transitioning to REH status have ancillary provider-based clinics whose services are billed and reimbursed on the same basis as the main provider's. But neither the authorizing statute nor the proposed rule indicates what would happen to those provider-based clinics if the main provider becomes an REH. We encourage the agency to allow (but not require) ancillary provider-based clinics to continue to be provider-based when the main provider becomes an REH. We request clarity on this point either in this rule or in official guidance, where applicable, to inform the decision whether to convert a facility to REH status and to avoid any disruption to the operation of the provider-based clinics.

II. Regarding the proposed change to the "primary road" definition for CAH status, determine whether any IHS and Tribal (I/T) Hospitals would be affected, exempt them if it would, and confirm that when measuring distance between hospitals for CAH status, I/T hospitals are measured in distance from other I/T hospitals only

The proposed rule would make several changes to the CAH CoPs, including how "primary road" is defined for purposes of determining whether the hospital meets the requirement that it be at least 15-miles from any other hospital by primary road, or 30-miles from any other hospital by secondary road or in mountainous terrain. The proposed new definition would for the first time include numbered state roads, rather than just federally numbered roads; it seems likely this would push some current CAH's out of the CAH designation, especially in rural areas. The proposed rule does not identify which or how many CAHs might be affected by the change, and we have not had the opportunity to independently determine whether any I/T hospitals are potentially affected. We think that data is essential to a reasoned agency decision. We urge CMS to defer adopting the rule until the data is collected, and to exempt I/T hospitals if the data reveal that some would lose CAH status under the revised definition.

We urge the agency to take this opportunity to formalize in regulations its long-standing policy and practice, currently stated in sub-regulatory materials, that when the distance between facilities is measured, IHS and Tribal hospitals are measured in distance from other I/T hospitals, and not from non-I/T hospitals (and vice-versa). This policy is clearly articulated in the State Operations Manual's (SOM) interpretive guidelines on 42 C.F.R. 485.610(c). As CMS explains there, "Given that IHS and Tribal CAHs and hospitals serve distinctly different populations, IHS CAHs and hospitals are excluded from consideration when determining the proximity of non-IHS hospitals seeking CAH certification to other CAHs or hospitals. For the same reason, when an IHS or Tribal hospital applies for certification to participate in Medicare as a CAH, CMS will

consider only its proximity to other IHS and Tribal CAHs and hospitals in determining whether it meets the location requirement under section 485.610(c)."[1]

III. Collaborate on necessary adjustments to the statutory annual per patient average length of stay if proven to be an issue

We know that CMS would expect an REH to transfer patients whom the REH determines require a higher level of care as soon as possible, and that the agency understands that there may be occasions when a patient cannot be transferred within 24 hours of admission to the REH. Although CMS believes this will occur at a frequency that will not seriously affect the REH's average length of stay, we trust that the agency will allow for adjustments down the road if this does indeed prove to be an issue for these facilities that may potentially be at risk for exceeding the statutory annual per patient average length of stay of 24 hours or less. Tribes are very concerned that this requirement will be difficult for some hospitals to meet as it can be difficult to locate a transfer destination for patients due to overcrowding, or when extreme weather conditions prevent travel. While we understand that this is a statutory requirement, we encourage a collaborative approach to see how this could be handled if it proves a challenge for REHs down the road.

IV. Clarify the process to determine the timeframe to allow adequate staff to come on-site given patient volume and allow this to be flexible based on rurality of REH

We appreciate the proposal that, while REHs must ensure there are adequate medical and nursing personnel qualified in emergency care to meet the needs of the facility, each REH should have substantial flexibility to determine how to comply with that requirement, by conducting an analysis of its anticipated and actual staffing needs. This flexibility is appropriate for this provider type, as it would truly set it apart in being able to address the emergency needs of these rural communities.

We appreciate and support the agency's proposal to allow REHs to meet the statute's 24/7 staffing requirement simply by ensuring that the individual(s) staffing the facility's Emergency Department are competent to receive patients and to activate the appropriate medical resources for the treatment of the patient. The proposal that such staff may include a nurse, nurse assistant, clinical technician, or an emergency medical technician (EMT) is a sign of true understanding by the agency of the severe shortage of health care professionals in rural areas, and of the fact that each REH will have different staffing needs and challenges that will depend in part on how remote it is and the characteristics of the patients it treats.

For these same reasons, we support CMS's proposal that REHs will not be held to the same staffing levels as CAHs, except for the emergency services requirements specified at § 485.618(d), which require that there be a doctor of medicine or osteopathy, a physician assistant, a nurse practitioner, or a clinical nurse specialist, with training or experience in emergency care, on call and immediately available by telephone or radio contact, and available

[1] CMS State Operations Manual, Appendix W, "Survey Protocol, Regulations and Interpretive Guidelines for Critical Access Hospitals (CAHs) and Swing Beds in CAHs," https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/som107ap_w_cah.pdf.

on site within specified timeframes. This level of staffing and the on-call provisions should be sufficient to meet the emergency health care needs of patients, while recognizing the staffing challenges faced by rural hospitals and the fact that, without a local REH, patients in many underserved communities would have no timely access to emergency and life-saving care. We firmly feel the proposed rule strikes the right balance between ensuring high-quality care to REH patients and the realistic staffing availability in rural areas.

We support the proposal to require that a registered nurse, clinical nurse specialist, or licensed practical nurse be on duty whenever the REH has one or more patients receiving emergency services or observation care. However, we recommend that CMS allow a grace period here, to allow time for this level of provider to get to the hospital once patients needing these services arrive at the hospital. Some grace period is implied by the provision that would require the hospital to be staffed 24/7 by lower-level staff, but we request this be made more explicit either in the rule itself or in sub-regulatory advice. We recommend the rule allow the REH to determine the appropriate grace-period based on its own analysis of its anticipated staffing needs, perhaps up to some maximum established by the rule. We know the CAH CoPs have the expectation that required professionals must arrive in 30 to 60 minutes. We recommend the allowance for REH staff be longer, given the fact that REHs are likely to be in even more rural areas, and reasonable travel times may be longer due to distance, road quality, proximity to residential housing, and other geographical barriers to quick commuting times for staff.

Finally, we would like to thank the agency for proposing that on-call staff may be available by telephone or by *radio*. In many rural communities we serve, radio is the most available and reliable means of communication. The agency's recognition of that fact will be especially appreciated by residents and providers of our most remote communities.

Conclusion

Again, we appreciate the agency's dedication to setting realistic standards for this new provider type, its clear effort to strike a sound balance between the demands of patient safety and the realities of furnishing health care services in Indian Country and other remote communities. We appreciate your consideration of the above comments and recommendations and look forward to engaging with the agency further.

Sincerely,

W. Ron Allen, CMS/TTAG Chair
Jamestown S'Klallam Tribe, Chairman/CEO