



Tribal Technical Advisory Group



To the Centers for Medicare & Medicaid Services

c/o National Indian Health Board | 910 Pennsylvania Avenue, SE | Washington, DC 20003 | (202) 507-4070 | (202) 507-4071 fax

September 13, 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 Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Organ Acquisition; Rural Emergency Hospitals: Payment Policies, Conditions of Participation, Provider Enrollment, Physician Self-Referral; New Service Category for Hospital Outpatient Department Prior Authorization Process; Overall Hospital Quality Star Rating

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 Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Organ Acquisition; Rural Emergency Hospitals: Payment Policies, Conditions of Participation, Provider Enrollment, Physician Self-Referral; New Service Category for Hospital Outpatient Department Prior Authorization Process; Overall Hospital Quality Star Rating” (CMS-1772-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

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equity and health disparity issues across Medicare, Medicaid, CHIP, and the Health Insurance Marketplaces.

It is important to understand regarding 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 factors 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

Acknowledging 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

¹ [“Federal Indian Boarding School Initiative Investigative Report”](#), Department of Interior, Assistant Secretary Bryan Newland, May 2022.

² *Ibid.*

³ [“Indigenous Health Equity”](#), Abigail Echo-Hawk, Director, Urban Indian Health Institute, August 7, 2019.

⁴ See “Legal Basis for Special CMS Provisions for American Indian and Alaska Native,” Appendix A, CMS-TTAG Strategic Plan 2020-2025.

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 that CMS is addressing issues such as transparency, competition, 340B drug pricing, rural health, and behavioral health in this rule. These issues are prominent in Indian Country, and the expansion of access to behavioral health is a focal point of TTAG priorities, especially as we continue to deal with the repercussions of the COVID-19 pandemic and the isolation it has caused.

Recommendations:

I. We Support Allowing Hospital Staff to Remotely Provide Behavioral Health Services to Patients in Their Homes; Tribal and IHS hospitals Should be Paid for Such Services at the IHS OMB Rate

We appreciate the agency's recognition that hospital clinical staff should be able to provide behavioral health services to a patient in their home using telehealth communications technology. Flexibility for hospital providers to provide care beyond the reach of the hospital facility itself is incredibly important to ensuring that quality care is provided where it is most needed, in our rural and underserved areas. The COVID-19 pandemic has exacerbated many of the behavioral health issues our communities have faced for years and has caused these concerns to spread to communities with more resources, bringing these issues to the forefront of the nation and the agency's concern.

As you well know, this flexibility is currently available through the PHE-specific policy referred to as "hospitals without walls," but the emergency waivers that enable this flexibility will expire with the PHE. Discontinuing this mode of treatment would hinder mental health treatment and would certainly result in negative patient outcomes, especially for those living in remote communities who have no access to in-person treatment. We appreciate the agency's recognition of this concern, and we look forward to continuing to engage with CMS on these behavioral health specific issues as we near the end of the PHE.

Tribes support the proposal to consider these mental health services to be covered outpatient department services payable under the OPSS, under proposed 42 C.F.R. § 410.27. However, the rule should make clear, or CMS should otherwise expressly recognize, that when these services are furnished by hospitals that are owned or operated by the Indian Health Service, Indian Tribes, or Tribal Organizations, they are also covered, but will be paid at the applicable OMB Rate that is established and published annually by the Indian Health Service rather than under the OPSS, in accordance with 42 C.F.R. § 419.20(b) and CMS's longstanding practice.

II. We Strongly Support Allowing Mental Health Services to be furnished via Audio-Only in Order to Improve Health Equity; But Patient-Specific Determinations Should Not be Required for Patients Located in Communities with Limited or No Broadband Infrastructure

Tribes appreciate CMS's recognition that individuals face very different circumstances and barriers when seeking out care. We strongly support the proposal to allow

exceptions to the in-person visit requirement based on beneficiary circumstances. And we are particularly supportive of the proposal to allow the use of audio-only interactive telecommunications systems when the beneficiary is not capable of, or does not consent to, the use of two-way, audio/video technology. As you know, many AI/ANs face barriers in their community or personal circumstances that do not allow for regular visits to a hospital setting, and that prevent them from being able to communicate via audio/video communications.

The flexibility to receive care via audio-only communications is a huge step forward for Indian Country.

However, we ask CMS to consider modifying slightly the proposed requirement that the circumstances supporting the use of audio-only communications technology must be documented on an individual basis in each patient's record. In Indian Country, many communities have extremely limited or no broadband infrastructure, making audio communication the only viable and reliable option. We respectfully ask that providers serving such communities, including IHS and Tribal programs, be permitted to document the need for audio-only services on a community-by-community basis, and that they be spared what would be the pointless burden of documenting that lack in each patient's record each time an audio-only service is furnished.

That said, we deeply appreciate CMS's recognition of the importance of telehealth and audio-only services, and we look forward to seeing how the agency continues to expand access to care for rural and underserved communities.

III. Permit Mental Health Services Performed Remotely to be Provided by Professionals Licensed in Either the State the Professional or the Patient is Located

The agency noted in this proposal that consistent with the conditions of participation for hospitals at 42 C.F.R. § 482.11(c), all hospital staff performing these services must be licensed to furnish them consistent with all applicable state laws regarding scope of practice. During the PHE, however, providers may provide telehealth services to those in a state the provider is not licensed in. This will soon become an issue of concern, once the PHE ends, so it would be beneficial to receive set guidance on how this will be handled moving forward. This is especially important in remote areas like Alaska, or in border communities like Oklahoma, near the Texas border. Currently, during the PHE, our Oklahoma partners are able to provide care to their many patients in Texas just across the state line. This has immensely helped provide services to those in need, and we hope this practice may be permitted by the agency. As an example, this is especially important in the instance of emergent and life-threatening care in Alaska and other rural and/or remote areas across the country.

IV. Permit Clinical Staff to Furnish Services Remotely from Outside the Hospital

Tribes know the agency proposed that the hospital clinical staff be physically located in the hospital when furnishing services remotely using communications technology for purposes of satisfying the requirements at 42 C.F.R. §§ 410.27(a)(1)(iii) and 410.27(a)(1)(iv)(A), which refer to covered therapeutic outpatient hospital services

incident to a physician's or nonphysician practitioner's service as being "in" a hospital outpatient department. Requiring the hospital clinical staff to be located in the hospital when furnishing the mental health service remotely to the beneficiary in their home would be overly burdensome and disruptive to existing models of care delivery developed during the PHE. We recommend that CMS revise the regulatory text in the provisions cited above to remove references to the practitioner being "in" the hospital outpatient department.

We reiterate this request to other services permitted via telehealth, in addition to mental health services. Requiring that the clinical staff to furnish telehealth services from a specific clinical setting in this instance is overly burdensome and it disrupts delivery of care to the patient.

V. Take Caution in any Additional Restrictions of Services Permitted via Telehealth

In addressing telehealth and permitting some services to be provided via telehealth over others, we caution the agency to be careful in limiting services, as this could impact the decisions that State Medicaid agencies make in coverage determinations. Further, in any determinations for what is "medically necessary" or "clinically appropriate," we encourage the agency to permit this decision to be made by providers – those who know best the care needed by their patients and the care that is appropriate to administer via telehealth.

VI. Provide Separate Payment for Non-Opioid Pain Management Approaches to Acute Pain Patients

We urge the CMS to provide separate payment for non-opioid pain management approaches to acute pain patients, particularly those among populations at increased risk for developing an opioid use disorder, such as individuals in long-term recovery and those with a mental health condition. Doing so will greatly expand access to and use of non-opioid pain management therapies and prevent opioid addiction among millions of Americans. The COVID-19 brought record-breaking overdose deaths – according to the Centers for Disease Control and Prevention (CDC), over 107,600 Americans died from a drug overdose last year.⁵ Approximately 75 percent of these deaths involved opioids. Furthermore, the data revealed the crisis' pronounced toll on communities of color. Overdose death rates among AI/ANs increased by a staggering 39 percent.⁶ Despite these numbers, the healthcare system continues to expose patients to potentially addictive pain management approaches.

Reimbursement policy incentivizes the use of prescription opioids as first-line treatment for postsurgical pain. Approximately 90 percent of surgical patients receive opioid-

⁵ Centers for Disease Control and Prevention, National Vital Statistics System. *Provisional Drug Overdose Death Counts*, updated Feb. 9, 2022: <https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm>.

⁶ Kariisa M, Davis NL, Kumar S, et al. *Vital Signs: Drug Overdose Deaths, by Selected Sociodemographic and Social Determinants of Health Characteristics — 25 States and the District of Columbia, 2019–2020*. *MMWR Morb Mortal Wkly Rep* 2022; 71:940–947.

based treatments to manage their acute pain.⁷ The surgical setting is often the first-time patients are exposed to opioids, but many of these patients will initiate a long-term opioid use following such exposure. CMS is uniquely positioned to impact the trajectory of the opioid crisis by addressing the barriers that limit patient and provider access to non-opioid approaches.

Previously, CMS has successfully expanded access to non-opioid approaches to patients treated in an ambulatory surgery center, which resulted in an increase in the utilization of non-opioid pain management approaches. Clearly, providing separate payment for non-opioid approaches is a proven way to increase access to these tools. To prevent opioid misuse among patients, we urge CMS to increase access to the full suite of available non-opioid modalities by providing separate payment for such approaches in both the hospital outpatient and ambulatory surgery center settings.

VII. Permit Hospitals to Convert Back from an REH if the Provider Type Doesn't Suit the Needs of the Facility and its Patient Population and Shield Them at Least Temporarily from Lost Revenue

Tribes support CMS's proposal to permit CAHs and rural hospitals to enroll as REHs without having to terminate their existing enrollments and to allow an REH to convert back to a CAH or rural hospital, as applicable. This will be especially important for IHS and Tribal REHs that convert from acute hospital status, because of the risk that they would receive less reimbursement under the REH reimbursement methodology than they have historically received under the OMB All-Inclusive Rate established annually by the Indian Health Service. While the detailed reimbursement methodology set forth in the statute suggests Congress carefully devised a reimbursement methodology that was likely to substantially increase reimbursement for CAHs and non-Tribal acute care hospitals, it unfortunately seems not to have considered whether that methodology would also benefit IHS and Tribal hospitals.

We generally support CMS's proposals on how it will calculate the monthly facility fee payable to REHs, particularly the proposal to include beneficiary co-payments. As CMS noted, excluding such co-payments in the calculation would result in a dramatically lower monthly facility fee payment (nearly 50 percent, by CMS's calculations), and would be contrary to the statute's clear intent "to provide incentives for CAHs and small rural hospitals that might otherwise close to convert to REHs and continue to provide outpatient hospital services in rural communities."⁸

Tribes strongly encourage the agency to shield REHs at least temporarily from unexpected loss following their conversion to an REH. This could be done, for example, by allowing REHs to be paid under their former methodology if they elect to convert back to their prior acute-care or CAH status. Another option would be to make supplemental payments to REHs that experience a revenue loss due to their status change, to bring their total reimbursement up to their highest recent pre-conversion levels. We are deeply concerned that, without such a guarantee, many IHS and Tribal

⁷ Hill MV, McMahan ML, Stucke RS, Barth RJ Jr. *Wide Variation and Excessive Dosage of Opioid Prescriptions for Common General Surgical Procedures*. *Ann Surg*. 2017 Apr; 265(4):709-714.

⁸ 87 Fed. Reg. at 44780.

hospitals that might well benefit from becoming REHs, would retain their current status rather than face that financial risk. Yet another option may be to give IHS and Tribal REHs the option – in lieu of being paid at OPPS rates plus 5 percent – to be paid at the applicable IHS encounter or per-diem rate plus 5 percent, plus the monthly facility fee.

As you know, IHS and acute care hospitals are exempt from the OPPS and are currently paid at per-patient per-day encounter rates established annually for all such hospitals based on average costs – currently \$541 for facilities in the lower-48 states and \$792 for those in Alaska. While we recognize that the statute established the OPPS plus 5 percent REH reimbursement rate, we believe the Secretary retains the discretion to equitably adjust the rate for IHS and Tribal facilities, to help fulfill the clear intent of the REH statutory provisions and the nation's trust responsibility for Indian health.

VIII. Develop REH CoPs that Expand Access to Care and Increase Participation in this New Provider Type

Tribes support the development of conditions of participation that expand access to care and increase the ability for hospitals to participate as this new provider type. CMS expects REHs to help address the barriers in access to health care, particularly emergency services and other outpatient services that result from rural hospital closures to help address observed inequities in health care in rural areas. Therefore, we urge CMS to be flexible with facilities that hope to adopt this new provider type, and that it assist interested facilities in the transition process. We look forward to continuing to engage with the agency on the REH provider type and how it may help expand access to care for AI/ANs in rural communities.

Conclusion

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