September 6, 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; CY 2023 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicare and Medicaid Provider Enrollment Policies, Including for Skilled Nursing Facilities; Conditions of Payment for Suppliers of Durable Medicaid Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS); and Implementing Requirements for Manufacturers of Certain Single-Dose Container or Single-Use Package Drugs To Provide Refunds With Respect to Discarded Amounts

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; CY 2023 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicare and Medicaid Provider Enrollment Policies, Including for Skilled Nursing Facilities; Conditions of Payment for Suppliers of Durable Medicaid Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS); and Implementing Requirements for Manufacturers of Certain Single-Dose Container or Single-Use Package Drugs To Provide Refunds With Respect to Discarded Amounts” (CMS-1770-P).

Preamble to Comments:

Before commenting specifically on this proposal, we highlight the important context in which TTAG’s leadership 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.

TTAG leadership 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

---

2 Ibid.
3 “Indigenous Health Equity,” Abigail Echo-Hawk, Director, Urban Indian Health Institute, August 7, 2019.
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:

The TTAG leadership has a few recommendations for CMS to consider in finalizing this proposed rule. The TTAG’s main goal in advocating for care in Indian Country is to make quality care as accessible as it can be to our people, increasing the overall health of our people, and ensuring that the federal government upholds its responsibility to account for the health and well-being of the first people of this nation. We support the proposals in this rule that expand access to value-based care from ACOs, drive behavioral health access, dental care, and cancer screenings, and the emphasis placed on rural and underserved areas. We offer the following recommendations for the agency to consider.

Recommendations:

I. Include LMFTs and LPCs as Eligible Provider Types Under Medicare

While we appreciate the proposal to allow for reimbursement of services rendered by Licensed Marriage and Family Therapists (LMFTs) and Licensed Professional Counselors (LPCs) as “incident to” a provider as a part of a patient’s primary care team, and the proposal to allow these behavioral health practitioners to provide services under general (rather than direct) supervision, this does not get us where we need to be. We again encourage CMS to continue to provide technical assistance to Congress to include LMFTs and LPCs as eligible provider types under Medicare. Being an eligible provider type would assist the Indian healthcare system in delivering much needed behavioral health care. Further, we encourage inclusion of other midlevel provider types in this category, including “auxiliary professionals” such as community health providers, and others that provide substance use disorder (SUD) services.

II. Allow for the Most Broad and Inclusive Definition of “Medically Necessary” Dental Care

Under the Social Security Act, Medicare Parts A and B generally exclude reimbursement for dental services. However, CMS is allowed to make payment for “dental services that are an integral part of the covered primary procedure or service furnished by another physician treating the primary medical illness.”5 Because this is not clearly defined in regulation or statute, Medicare beneficiaries are unreimbursed for their dental services requiring IHS and Tribal health facilities to cover these services through their purchased/referred care programs.

With more untreated tooth decay and periodontal disease than any other population group, the state of oral health among AI/AN people is alarming. AI/AN dental adult patients are more than twice as likely to have untreated decay compared to the general U.S. population, with 59 percent

of adults over age 65 having untreated decay.\textsuperscript{6} Of the AI/AN dental patients aged 40-64 years of age, 83 percent had teeth pulled because of tooth decay or gum disease compared to the national average of 66 percent.\textsuperscript{7} AI/AN people are more likely to report poor oral health, oral pain, and food avoidance than the general U.S. population.\textsuperscript{8}

For these reasons, we support the expansion of access to dental services and the proposal to codify and clarify where Medicare can pay for the services when deemed medically necessary to treat the primary health of the patient. We recommend that CMS interprets “medically necessary” dental services broadly so as to allow the widest range of care to be provided to our people. Some medical scenarios where dental services (examinations, extractions, root canals, and any other necessary dental procedure) should be covered, include for cardiac patients, diabetic patients, and patients seeking in-patient treatment for a substance use disorder as dental services may be inextricably linked to the success of their treatment program. Accessible dental care is important to preventing dental disease and keeping people healthy. It is an essential piece of health care. TTAG urges the agency to permit the provider to determine what is medically necessary for the care of the patient. Lastly, we recommend CMS to engage with TTAG and Tribal Nations on what dental services are medically necessary for purposes of Medicare Part A and B coverage.

III. Expand the List of Care Reimbursed by Medicare when Provided via Telehealth

Our TTAG leadership appreciates the proposal that CMS will keep current telehealth flexibilities for an additional 151 days beyond the ending of the public health emergency, allowing patients to continue receiving all those services in their homes or other community location. Continuing that coverage will be incredibly helpful in increasing access to care for people who are unable to travel to a facility to receive care, whether they are dealing with significant health concerns, distance to a facility, or other barriers to care.

We urge CMS to include as many services as possible in the Category 1 and 2 levels of telehealth, in order to allow reimbursement for a wider range of services on a permanent basis. This is necessary to increasing health equity for AI/AN populations that face unique barriers to care.

Tribes are very pleased to see that CMS has proposed adding more services to the Category 3 list, allowing these services to be covered at least through CY 2023, while CMS continues to evaluate their eligibility for inclusion in Category 2. However, many of these services have already demonstrated their value, and should immediately be designated as Category 2 services, instead. This is particularly true for behavioral health services.

Among the factors CMS says it considers in deciding whether a service qualifies for Category 2 are “whether the use of a telecommunications system to furnish the service produces


\textsuperscript{7} Id.

\textsuperscript{8} Id.
demonstrated clinical benefit to the patient,” as well as whether that modality increases the “[a]bility to diagnose a medical condition in a patient population without access to clinically appropriate in-person diagnostic services,” or creates a “treatment option for a patient population without access to clinically appropriate in-person treatment options.”

Ample evidence demonstrates that virtually all tele-mental health services meet those criteria, not only by removing or lowering long-standing barriers to care, but by improving clinical interactions and patient outcomes.

The Kaiser Family Foundation found that telehealth access to mental health services during the PHE has dramatically increased their utilization, especially by recipients living in rural areas, a clear indication that traditional service delivery modalities are insufficient to meet patient’s needs. And CMS’s own sister agency, SAMHSA, recently published a report that summarizes – and cites extensive research that demonstrates – the many advantages of using telehealth modalities to deliver behavioral health services, including: (1) improved access to experienced providers and high quality services in rural and remote areas that lack local providers; (2) enhanced ability of clinicians to assess the client’s home environment; (3) removal of psychological barriers to care for patients who have anxiety about leaving their home to receive care (e.g., patients with panic disorder or agoraphobia); (4) removal of social barriers to care that arise from the stigma that is still associated with mental health issues; and (5) reduced social and economic barriers to care for patients who cannot travel for care due to care-giving responsibilities or employment obligations.

We strongly recommend that CMS immediately move to Category 2 all the behavioral health services it has proposed for Category 3, allowing these vital services to be permanently covered by Medicare. Doing so is not only important for Medicare beneficiaries. It will help send a strong signal to the many State Medicaid programs that are now actively deciding whether to continue or expand Medicaid coverage of tele-mental health services after the PHE expires. Those programs should not be left with the impression that CMS doubts the appropriateness, medical need for, or efficacy of tele-behavioral health services.

Our Tribal leadership supports the agency’s decision in the CY 2022 PFS final rule to finalize a change to the definition of “telecommunications system” to allow telehealth services for the diagnosis, evaluation, and treatment of mental health conditions to be furnished through audio-only technology in certain circumstances after the end of the PHE. However, the agency noted that “[f]or telehealth services other than mental health care, […] two-way, audio-video communications technology is the appropriate standard that will apply for telehealth services after the PHE ends.” We believe this to be an over-simplification of the use of audio-only

---

telehealth. There are circumstances outside of mental health that we believe would warrant the use of audio-only communications.

Given the rural nature of much of Indian Country, telehealth plays a crucial role in bridging geographic gaps between provider and patient. During the COVID-19 pandemic, CMS allowed telehealth to be used in places requiring direct supervision of diagnostic tests, physicians’ services and some hospital outpatient services. We recommend that CMS make these temporary changes permanent.

IV. Reimburse Audio-Only Mental Health Services at the Same Rate as In-Person Services.

Tribes urge the agency to revisit how it will reimburse mental health services that are furnished via “audio-only” telecommunications systems. The preamble to the proposed rule correctly notes that the Social Security Act requires Medicare distant-site providers of telehealth services at the same rate as if they furnished the service in person. Yet CMS proposes paying for audio-only telehealth services at a much lower rate than any in-person mental health service, on the questionable grounds that audio-only services are “inherently non-face-to-face services, since they are furnished exclusively through remote, audio-only communications,” and consequently are not “analogous” to covered in-person services.

While we do not question CMS’s good intentions and we greatly appreciate the proposal to cover the services, the supposed “inherent” difference is something of a sleight-of-hand, stemming entirely from the decision to assign unique codes to audio-only services, no matter how much they may otherwise resemble in-person mental health services. In our view, this likely violates the statute’s same-reimbursement-rate mandate for telehealth services. Congress could not have intended to allow CMS to deny reimbursement parity for some telehealth services simply by assigning them unique codes or definitions.

Our TTAC leadership urges you to reconsider this issue, and to follow Congress’s instruction by paying distant-site providers of Medicare telehealth services at the same rate as for essentially comparable in-person services, including when they are furnished via audio-only telecommunications systems.

V. CMS Should Make Permanent the Authority to Provide Required Supervision via Real-Time Audio/Video Technology.

Thank you for specifically inviting comment on whether CMS should make permanent the flexibility to furnish required direct supervision through the use of real-time, audio/video technology.

The TTAG leadership strongly supports making this option permanently available. It would be difficult to overstate its importance to the Indian Health System. A high percentage of our recipients reside in rural and remote locations, where it is difficult to attract and retain physicians.

---

12 Social Security Act §1834(m)(2)(A).
14 87 Fed. Reg. at 45901.
and other practitioners who are authorized to practice without direct supervision. Allowing services to be directly supervised via audio or video technology has the potential to dramatically expand access to care for our largely AI/AN patients and would be an important step towards achieving the health care equity to which the Biden administration is committed.

VI. We Support Establishing Codes and Separate Payment for Coordinated and Collaborative Care Services, Chronic Pain Management Services, and General Behavioral Health Integration Services Furnished by FQHCs

TTAG leadership appreciates the agency’s engagement in its multi-year examination of coordinated and collaborative care services in professional settings, resulting in established codes and separate payments in the PFS to separately recognize and pay for these vital services. We are hopeful that this will adequately describe the non-face-to-face care management activities that is involved in coordinating primary care. These services are vital to the care provided to our people and raising the level of health in our communities to the highest level possible. We support this effort in regard to chronic pain management services and behavioral health integration services furnished by FQHCs as well. We support these changes intended to account for and reflect the additional resources necessary to provide this care.

VII. We Support the Proposed Expanded Coverage for Colorectal Cancer Screening Services.

AI/AN people suffer from significantly higher rates and earlier onset of colorectal cancer than other groups. We therefore thank you for proposing to expand coverage for colorectal cancer screening services, and we strongly support the proposal. Our leadership agrees completely with your assessment that the proposals “will expand access to quality care and improve health outcomes … [and] directly advance health equity by promoting access and removing barriers for much needed cancer prevention and early detection within rural communities and communities of color that are especially impacted by the incidence of [colorectal cancer].”

VIII. Engage the TTAG in Developing Sub-Regulatory Guidance

TTAG knows that CMS will not be utilizing their usual regulatory process to inform the public of next steps, but instead will be issuing guidance and using the sub-regulatory process. We understand the time restraints that are present due to the short transition period following the end of the PHE, in addition to the uncertainty of when the end of the PHE will be declared, and the limitation this would put on opportunities for public comment. Despite this tight timeframe and the noted need for sub-regulatory guidance, we encourage the agency to engage with the TTAG in developing this guidance and in ensuring that the I/T hospitals and the Indian health care system as a whole are engaged and educated on the long list of changes that will be implemented following the end of the PHE and the end of the 151-day grace period that follows.

15 87 Fed. Reg. at 46081.
IX. Ensure ACO Shared Savings Program Incentives Address the Lack of ACO Access for the Indian Health System

While this proposal acknowledges that access to ACOs appears inequitable for certain populations including AI/AN beneficiaries and proposes changes to the program to incentivize ACOs to better serve these minority populations, it does not go far enough in specifically addressing the lack of access to ACOs for the Indian health system. The National Institute of Health (NIH) came out with a study in 2017 showing that ACOs served few minorities; when they did, they did so poorly.\(^\text{16}\)

The National Indian Health Board (NIHB) submitted comment on the ACO proposed rules in 2011 – comment we will attach in order to provide the agency more context on this issue. In short, NIHB noted real concern that the ACO program would likely have little impact or benefit for Indian Country, focusing on the ability of Indian health system providers to form an ACO or to participate in one, and on factors that may limit or impeded the ability of Indian health system providers to continue to build a revenue base that is sufficient to adequately serve AI/ANs. Both sets of issues raise concern over whether the ACO program will be successful in furthering efforts of the Indian health system to improve the coordination and quality of care provided to our people. We have since seen these concerns manifest in the last decade and encourage the agency to work on reshaping the ACO program to account for these inequities.

**Conclusion**

Our TTAG leadership appreciates 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

\(^{16}\) Lewis et al., *Accountable Care Organizations Serving High Proportions of Racial and Ethnic Minorities Lag in Quality Performance.*