

National Indian Health Board



Submitted via: <http://www.regulations.gov>

September 6, 2016

The Honorable Andy Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1654-P
Mail Stop: C4-26-05
7500 Security Boulevard
Baltimore, MD 21244 – 1850

RE: Medicare Program: Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2017; Proposed Expansion of Medicare Diabetes Prevention Program Model (CMS-1654-P) Comment

Dear Acting Administrator Slavitt:

On behalf of the National Indian Health Board (NIHB), I write to submit comments on the proposed rule, published in the Federal Register on July 15, 2016, entitled “Medicare Program: Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2017; Medicare Advantage Pricing Data Release; Medicare Advantage and Part D Medical Low Ratio Data Release; Medicare Advantage Provider Network Requirements; Expansion of Medicare Diabetes Prevention Program Model.” NIHB fully supports the expansion of the Medicare Diabetes Prevention Program (MDPP) Model.

Established in 1972, the NIHB is an inter-Tribal organization that advocates on behalf of Tribal governments for the provision of quality health care to all American Indians and Alaska Natives (AI/ANs). The NIHB is governed by a Board of Directors consisting of a representative from each of the twelve Indian Health Service (IHS) Areas. Each Area Health Board elects a representative to sit on the NIHB Board of Directors. In areas where there is no Area Health Board, Tribal governments choose a representative who communicates policy information and concerns of the Tribes in that area with the NIHB. Whether Tribes operate their entire health care program through contracts or compacts with IHS under Public Law 93-638, the Indian Self-

Determination and Education Assistance Act (ISDEAA), or continue to also rely on IHS for delivery of some, or even most, of their health care, the NIHB is their advocate.

Background

The Medicare Diabetes Prevention Program (MDPP) is a structured lifestyle, evidence-based intervention with the goal of preventing the onset of diabetes through dietary coaching, behavioral change strategies, and increased physical activity in individuals who are pre-diabetic. The U.S. Department of Health and Human Services (HHS) has verified that the expansion of the MDPP model would lead to a reduced net Medicare spending. The MDPP expansion is projected to improve the quality of patient care without limiting benefits or coverage. Therefore, more Medicare beneficiaries will be able to access the benefits of the MDPP. CMS is proposing to expand the Medicare Diabetes Prevention Program beginning January 1, 2018.

The MDPP services will be categorized by CMS as “additional preventive services” under Medicare Part B. The primary goal of the lifestyle intervention is at least 5 percent average weight loss among participants. The clinical intervention consists of 16 intensive “core” sessions of a curriculum and then less intensive monthly follow-up meetings to assist the participants in maintaining health behaviors.

Special Diabetes Program for Indians (SDPI)

At a rate of 2.8 times the national average, American Indians and Alaska Natives (AI/ANs) have the highest prevalence of diabetes. In some AI/AN communities, over 50% of adults have been diagnosed with Type II diabetes, and AI/ANs are 177% more likely to die from diabetes. The Special Diabetes Program for Indians (SDPI) is changing these troubling AI/AN community statistics with improvements in average blood sugar levels, reductions in the incidence of cardiovascular disease, prevention and weight management programs, and a significant increase in the promotion of healthy lifestyle behaviors.

Congress established the Special Diabetes Program for Indians in 1997 as part of the Balanced Budget Act to address the growing epidemic of diabetes in American Indian and Alaska Native (AI/AN) communities. SDPI funding has enabled AI/AN communities to develop, sustain, and significantly increase access to successful quality diabetes programs where few resources exist. The Special Diabetes Program for Type I Diabetes (SDP) was established at the same time to address the opportunities in Type I diabetes research. These programs have become the nation’s most strategic, comprehensive, and effective effort to combat diabetes and its complications in Indian Country. The SDPI currently provides grants for 404 programs in 35 states.

On April 14, 2015, the U.S. Senate passed a two-year renewal of the Special Diabetes Program for Indians (SDPI). The extension of the Special Diabetes Program for Type I Diabetes and for Indians through FY2017 is included in Section 213 of the Medicare Access and CHIP Reauthorization Act (MACRA) of 2015, which became Public Law No: 114-10 on April 16, 2016.

NIHB applauds the CMS effort to expand services delivered by community-based organizations to Medicare beneficiaries diagnosed with pre-diabetes through the Medicare Diabetes Prevention Program. We are pleased that CMS proposes to designate the Medicare Diabetes Prevention Program as an “additional preventive service” available under Medicare Part B for Medicare beneficiaries to utilize this service without being subjected to beneficiary co-pays. NIHB supports CMS for the promotion and expansion of the evidence-based intervention program targeted to individuals with pre-diabetes.

Tribal and Urban Indian health providers appreciate and share these goals, but the structure of the proposed rule is problematic with respect to IHS, Tribal, and Urban Indian health programs (I/T/Us), for several reasons. The Indian health care system as a whole is chronically underfunded, at about 59% of need,¹ and overburdened. Our programs often lack the resources and/or staffing to make needed reforms and upgrades, or to meet reporting and technology requirements. Further, our health programs are frequently forced to prioritize limited funding, resulting in a lack of resources for preventive care and other measures that would be expected to improve outcomes and maximize efficiency, but that require an up-front investment.

Medicare Diabetes Prevention Program Supplier Enrollment

CMS is contemplating whether the MDPP should be expanded nationally in the first year of the program or if it should be phased in at first with populations in specific regions or by a subpopulation of MDPP suppliers. NIHB encourages CMS to implement a national program. However, if CMS decides to phase in the program, NIHB urges CMS to include current SDPI participants in the first phase.

The requirement that a program be recognized by the Centers for Disease Control and Prevention (CDC) to provide diabetes prevention program (DPP) services in order to be eligible to apply for enrollment as a Medicare supplier puts an unnecessary requirement on the SDPI Diabetes Prevention (SDPI DP) programs that have already been successfully implemented. The majority of SDPI programs are already designated as Medicare providers and will only have to obtain a National Provider Identification (NPI) number for their lifestyle coaches. On the other hand, the CDC recognition process can take up to two years to accomplish full CDC-recognition status. A majority of Tribal health care programs are unaware of the process, the criteria, and the period of time it takes programs to become CDC-recognized.

The landmark study led by the National Institutes of Health of the Health-led Diabetes Prevention Program (NIH DPP) included a subset of American Indians, and due to its remarkable results in reducing the incidence of Type II diabetes in the intervention group, was the basis for the CDC Diabetes Prevention (DP) recognition program as well as the SDPI DP program. For over ten years, AI/AN communities have been implementing the SDPI DP program and continue to achieve similar results as the NIH DPP lifestyle intervention group.² As stated in the IHS SDPI Report to Congress in 2014, “achieving results that come close to those of

¹ NATIONAL TRIBAL BUDGET FORMULATION WORKGROUP’S RECOMMENDATION ON THE INDIAN HEALTH SERVICE FISCAL YEAR 2017 BUDGET, 8 (2015).

² IHS SDPI Report to Congress 2011; IHS SDPI Report to Congress 2014.

the NIH DPP lifestyle intervention group indicates that the SDPI DP successfully implemented the program in diverse AI/AN communities and reduced progression to diabetes.”³ Given the fact that the SDPI DP program was modelled after the NIH DPP intervention, and that the SDPI DP program has proven and documented success, applying for CDC recognition status would be superfluous and impose an unnecessary burden on the established SDPI DP programs. NIHB recommends that currently operating SDPI DP programs be given automatic CDC DP recognition.

For future diabetes prevention program implementation by I/T/U sites, NIHB recommends that CMS minimize the number of federal agencies that an I/T/U program would have to coordinate with and recommends that CMS authorize a SDPI DP recognition status program developed by the IHS.

Eligible Beneficiaries

CMS is proposing to define an eligible pre-diabetic patient as a beneficiary having a body mass index (BMI) of 25 or greater (a BMI of 23 or greater for Asian beneficiaries) in addition to a hemoglobin A1c test with a value of 5.7 – 6.4 percent, or a fasting plasma glucose of 110-125mg/dL within the last 12 months, or 2-hour plasma glucose of 140-199 mg/dL after the 75 gram oral glucose tolerance test, and no previous diagnosis of diabetes or life-threatening conditions, mobility issues, etc., that would prohibit them from participating in the program. Beneficiaries can be physician-referred, community-referred, or self-referred. NIHB recommends that CMS collaborate with SDPI and recipients to ensure there is alignment, collaboration, and consistency with program eligibility.

Quality Measure Reporting and Payment Structure

CMS is proposing a payment structure which links payment for MDPP services to the number of MDPP sessions attended and the achievement and maintenance of minimum weight loss. NIHB believes that Tribal consultation on eligibility, measures, and payment structure specifically with respect to I/T/U providers is necessary prior to adoption of a final rule. NIHB recommends Medicare reimbursement through the encounter rate for all outpatient services in the MDPP as the established reimbursement rate for Indian Health Care Providers (IHCPs).

CMS is considering which quality metrics should be reported by MDPP entities, specifically which quality metrics should be considered for public reporting (not for payment) to guide beneficiary choice of entities. NIHB recommends using the current quality metrics within the Government Performance Results Act (GPRRA) that IHCPs are already utilizing and providing for diabetes measures.

Additionally, relying on change in one risk factor alone—change in weight loss—provides an extremely narrow definition of success for MDPP programs. The goal of diabetes

³ IHS SDPI Report to Congress 2014, p. 4.

prevention programs is to reduce the incidence of Type II diabetes, and reaching that goal is more complicated than merely implementing a weight loss program. Lifestyle change is not a linear process and should not be reduced to one measurement. The social and environmental conditions in which behavior change occurs can greatly affect one's lifestyle change progress and often communities with the highest risk of chronic disease also have the most challenging social and environmental conditions. Further, individuals that temporarily backslide with regard to their weight loss goals should not be forever barred from further participation in the MDPP program.

It is well documented that American Indians and Alaska Natives (AI/ANs) have the highest risk of Type II diabetes and many are also challenged by lack of quality medical care, lack of access to healthy food and lack of access to safe or adequate places for physical activity. Reliance on weight loss alone may not adequately reflect the overall progress a participant is making toward lasting lifestyle changes and the prevention of diabetes. Tribal health programs, especially SDPI, should be granted the flexibility to determine their own diabetes prevention measures of success. Examples of other measures to consider include reductions in blood sugar levels, reduced hypertension risk, lower BMI levels, increased intake of healthy foods, or increased rates of physical activity.

The Centers for Medicare and Medicaid Services (CMS) must take into account the unique position of Tribal and Urban Indian health care programs in the national health care system. To that end, it is critical that CMS engage in face-to-face consultation with Indian Tribes and Urban Indian health organizations, so that we can determine how the proposed payment system will function with respect to I/T/Us.

IT Considerations and Capabilities

CMS is proposing to require CDC-recognized MDPP entities to submit claims to Medicare using standard claims forms and procedures, submitted electronically in batches. MDPP entities would also be required to maintain and handle any beneficiary Protected Health Information or Personally Identifiable Information, in compliance with the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and CMS standards. NIHB represents 567 federally recognized Tribes who reside in some of the most rural locations. Many Tribes that are located in rural areas are plagued by high unemployment, extreme poverty, and disparate health outcomes. These geographic factors could reduce the ability of I/T/Us to participate in electronic submission of claims to Medicare. The rural nature of what is referred to as "Indian Country" not only causes difficulty with IT infrastructure, but even the most basic technological needs like access to running water or electricity can be hard to come by. NIHB concurs with these standards for an efficient process for reimbursement. However, NIHB requests that CMS take into consideration the lack of availability of internet access and barriers for rural Tribal health care organizations to obtain a vast up-to-date IT infrastructure and make efforts to accommodate non-electronic claims submission.

Program Integrity Initiatives

CMS is contemplating the best approaches to mitigate program integrity risks, with the intent to develop policies to monitor and audit MDPP entities. NIHB recommends that CMS collaborate with the SDPI, which has been a fundamental prevention program in Indian Country, to determine best practices and learning opportunities from which the MDPP could benefit.

Site of Service Requirements

CMS is contemplating allowing diabetes prevention service delivery in-person or virtually, clarifying that virtual services would not be considered part of current tele-health benefits. CMS seeks whether there are quality or program integrity concerns regarding the use of virtual sessions. NIHB applauds CMS efforts to potentially include MDPP services through virtual service capabilities for reimbursement for Tribal health care programs with broadband capabilities. Tribal health programs that serve patients in rural geographic regions could increase patient access to the Medicare preventive diabetes services.

Technical Assistance for Participation

CMS envisions providing education, training, and technical assistance on Medicare enrollment, data security, claims submissions, and medical record keeping for MDPP entities. NIHB recommends that currently operating SDPI Diabetes Prevention programs be granted automatic CDC DP recognition. The Indian Health Service (IHS) has been the administrator of the SDPI grant as well as providing technical assistance to Indian Health Service, Tribal, and Urban Indian health care programs (I/T/Us) and coordinating program evaluation since the inception of the SDPI, requiring I/T/U programs to coordinate with an additional federal agency, the CDC, regarding recognition will prove to be a cumbersome and inefficient process. Alternatively, if CMS is unable to provide SDPI programs automatic CDC DP recognition, NIHB urges CMS to at the least conduct an outreach and education initiative for SDPI and Tribal health care programs to become CDC-recognized Diabetes Prevention Program organizations in order to enroll in the MDPP beginning on January 1, 2018.

Tribal Consultation

NIHB appreciates the opportunity to submit comments on the Medicare Reimbursement Expansion of the Diabetes Prevention Program. We note, however, that the public notice and comment period is not a substitute for Tribal consultation pursuant to the CMS Tribal Consultation Policy and Executive Order 13175. The Federal government's trust responsibility provides the legal justification and moral foundation for Indian specific health policymaking—with the objectives of enhancing their access to health care and overcoming the chronic health status disparities of this segment of the American population. It is important to underscore that when Congress passed the Patient Protection and Affordable Care Act (ACA), Indian-specific provisions were included to honor the federal trust responsibility to provide health care to AI/ANs.

Under the CMS Tribal Consultation Policy, CMS is to consult with Tribes throughout all stages of the process when developing a proposed regulation that would impose substantial compliance costs on Indian Tribes.⁴ Moreover, CMS shall:

- Encourage Indian Tribes to develop their own policies to achieve program objectives;
- Where possible, defer to Indian Tribes to establish standards; and,
- In determining whether to establish federal standards, consult with Tribal officials as to the need for federal standards and any alternatives that would limit the scope of federal standards or otherwise preserve the prerogatives and authority of Indian Tribes.⁵

Indian health care programs are unique. Tribal health programs implement the United States' trust responsibility to provide health care services to AI/ANs.⁶ The IHS is the primary federal agency tasked with carrying out this responsibility; however, the federal trust responsibility extends to every branch of the federal government and to every Executive Department and agency, including CMS. CMS must not abdicate its trust responsibility by failing to account for the unique needs of the Indian Health system as it finalizes this rule. The trust responsibility requires that the federal government assist I/T/Us in meeting the highest standards for efficiency and quality of patient care.

The federal government's trust responsibility requires it to take affirmative steps to improve the health status of AI/ANs. AI/AN communities are significantly different and AI/AN Medicare beneficiaries experience additional hardships that CMS must take into consideration in order to ensure that AI/AN communities can participate in the MDPP. NIHB urges CMS to engage in Tribal consultation with the Indian Health Care system, including I/T/Us, prior to publication of a final rule in addition to consideration of these comments.

Conclusion

NIHB hopes that CMS, in the spirit of its partnership and shared interest in improving AI/AN access to its resources and services, will work with I/T/Us to advance access to quality health care prevention services through community-based the Indian health care programs, especially the SDPI grantees. We would like to reiterate our request for Tribal consultation on the final proposed rule, as it is of the utmost importance that the Indian Health Service and Medicare units within CMS conduct consultation for coordination so that the federal agencies are coordinated in their efforts. We thank you for this opportunity to provide our comments and recommendations and look forward to further engagement with CMS on this important proposed

⁴ Centers for Medicare & Medicaid Services, Tribal Consultation Policy § 5.7 (Dec. 10, 2015).

⁵ *Id.* at § 5.6.

⁶ *See, e.g.*, 25 U.S.C. § 1601 ("Federal health services to maintain and improve the health of the Indians are consonant with and required by the Federal Government's historical and unique legal relationship with, and resulting responsibility to, the American Indian people."); The White House, *Memorandum for Heads of Executive Departments and Agencies re: Tribal Consultation* (Nov. 5, 2009), <https://www.whitehouse.gov/the-press-office/memorandum-Tribal-consultation-signed-president>.

rule. Please contact NIHB's Director of Federal Relations, Devin Delrow, at ddelrow@nihb.org or (202) 507-4072 if there are any additional questions or comments on the issues addressed in these comments.

Sincerely,

A handwritten signature in blue ink, appearing to read "Lester Secatero".

Lester Secatero
Chairman, National Indian Health Board

Cc: Kitty Marx, Director, CMS Division of Tribal Affairs
Mary Smith, Principal Deputy Director, Indian Health Service