

# National Indian Health Board



*Submitted via:*

<http://www.regulations.gov>

September 11, 2016

The Honorable Seema Verma,  
Administrator  
Centers for Medicare & Medicaid Services  
U.S. Department of Health and Human Services Attention: CMS-1676-P  
P.O. Box 8016  
Baltimore, MD 21244-8013

**RE: “Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2018; Medicare Shared Savings Program Requirements; and Medicare Diabetes Prevention Program” (CMS-1676-P)**

Dear Administrator Verma:

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 20, 2017, entitled: “Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2018; Medicare Shared Savings Program Requirements; and Medicare Diabetes Prevention Program; Proposed Rule.

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 reduced 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 April 1, 2018.

The MDPP services will be categorized by CMS as “additional preventative services” under Medicare Part B and will be administered by a non-physician community-based organization. The primary goal of the lifestyle intervention is at least 5 percent average weight loss among participants. The clinical intervention consists of 16 core maintenance sessions of a curriculum and then less intensive monthly ongoing sessions to assist the participants in maintaining healthy behaviors. CMS is proposing to include a 2-year limit on the ongoing maintenance sessions, assuming attendance and weight loss goals are met. Therefore, the MDPP service period will include a 3-year period consisting of 1-year of core maintenance sessions and 2-years of ongoing maintenance sessions. There are 16 core sessions offered at least a week apart during the first 6 months and core maintenance sessions are offered at least once per month in the remaining 6 months of the first year. NIHB has heard from Tribal representatives that a 1-year core maintenance session is not a realistic time period to see lifestyle behavior changes.

### ***Special Diabetes Program for Indians (SDPI)***

An estimated 25% of Americans 65 or older have developed Type II diabetes and nearly 48.3% of adults aged 65 years or older have prediabetes.<sup>1</sup> 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.

Tribes as sovereign nations have the inherent authority to address and meet the health and welfare needs of their citizens; and many tribes assume responsibility for education, health and social service programs for their citizens under the Indian Self-Determination and Education Assistance Act (ISDEAA). Diabetes is a chronic disease that tribes have made a priority. During the 17 years of the Special Diabetes Program for Indians (SDPI), the Indian Health Service (IHS), tribal, and urban (I/T/U) health programs have implemented evidence-based and community-driven strategies to prevent and treat diabetes. SDPI is changing these disproportionate 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 SDPI in 1997 as part of the Balanced Budget Act to address the growing epidemic of diabetes in AI/AN communities. The SDPI provides grants for diabetes treatment and prevention services to 301 I/T/U Indian health programs in 35 states.<sup>2</sup> The SDPI funding has enabled AI/AN communities to develop, sustain, and significantly increase access to successful quality diabetes programs where few resources are available. Approximately 780,000 people are served each year through the SDPI.<sup>3</sup> 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.

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 FY 2017 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 and Tribes applaud the effort of CMS to expand services delivered by community-based

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<sup>1</sup> CDC 2017 National Diabetes Statistics Report.

<sup>2</sup> Indian Health Service Special Diabetes Program for Indians – Changing the Course of Diabetes Fact Sheet.

<sup>3</sup> *Id.*

organizations to Medicare beneficiaries diagnosed with pre-diabetes through the MDPP. However, the structure of the MDPP is problematic with respect to I/T/Us participation. The Indian health care system as a whole is chronically underfunded, at about 59% of need,<sup>4</sup> and overburdened. Our health 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.

### ***MDPP Beneficiary Eligibility***

CMS proposes that if a beneficiary develops diabetes while participating in the MDPP program, the diabetes diagnosis would not prevent the beneficiary from continuing to receive MDPP services. NIHB and Tribes are pleased that CMS will not prevent beneficiaries who develop diabetes from receiving the MDPP services. However, the program should not be limited to individuals with pre-diabetes. Medicare beneficiaries who have already been diagnosed with diabetes need assistance and support as well. We recommend that Medicare beneficiaries with type II diabetes be included as eligible beneficiaries and that there is collaboration with the SDPI and recipients to ensure alignment, collaboration, and consistency with program eligibility.

CMS is proposing that MDPP beneficiaries must attend 3 sessions and maintain a 5% weight loss at least once in the previous ongoing maintenance session to be eligible for additional intervals. NIHB has heard from Tribes that the 5% weight loss goal is unacceptable. Not only is the 5% weight loss program participation requirement culturally insensitive, weight loss alone does not adequately reflect the overall progress a participant is making toward lasting lifestyle changes and the prevention of diabetes. We recommend separate categories for weight loss goals for men and women. Along with the sedentary lifestyle and metabolism barriers, Native women struggle with weight loss more than Native men because of hormonal body changes and gradual lean muscle loss that come with age. We recommend that CMS also take into consideration medical conditions (ex. Thyroid cancer) of Medicare beneficiaries that could further limit the possibility to meet the 5% weight loss goal. These are factors that can put further restrictions on the types of Medicare beneficiary participants. However, NIHB has consistently heard from Tribes that Tribal Health Programs be granted the flexibility to determine their own diabetes prevention measures of success.

### ***MDPP Supplier Enrollment***

The proposed rule discusses the inability of a supplier/provider to refuse service to beneficiaries. However, the Indian health care system is limited to the Indian Health Service eligibility requirements found at 42 CFR 136.12 - Persons to whom services will be provided, which reads as follows:

§ 136.12 Persons to whom services will be provided.

(1) In general. Services will be made available, as medically indicated, to persons of Indian descent belonging to the Indian community served by the local facilities and program. Services will also be made available, as medically indicated, to a non-Indian woman pregnant with an eligible Indian's child but only during the period of her pregnancy through postpartum (generally about 6 weeks after delivery). In cases where the woman is not married to the eligible Indian

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<sup>4</sup> NATIONAL TRIBAL BUDGET FORMULATION WORKGROUP'S RECOMMENDATION ON THE INDIAN HEALTH SERVICE FISCAL YEAR 2017 BUDGET, 8 (2015).

under applicable state or tribal law, paternity must be acknowledged in writing by the Indian or determined by order of a court of competent jurisdiction. The Service will also provide medically indicated services to non-Indian members of an eligible Indian's household if the medical officer in charge determines that this is necessary to control acute infectious disease or a public health hazard.

(2) Generally, an individual may be regarded as within the scope of the Indian health and medical service program if he/she is regarded as an Indian by the community in which he/she lives as evidenced by such factors as tribal membership, enrollment, residence on tax-exempt land, ownership of restricted property, active participation in tribal affairs, or other relevant factors in keeping with general Bureau of Indian Affairs practices in the jurisdiction.

Therefore, since the Indian health care system is limited by law to provide services only to eligible beneficiaries and are eligible Medicare providers, we recommend language be inserted in the final rule which reflects the Indian health care system as an eligible supplier/provider for the MDPP.

NIHB request that SDPI programs are granted grandfathered recognition, using the SDPI measurement and reporting criteria through a CDC pilot project or CMS pilot project. NIHB recommend that CMS work with IHS and Tribes through meaningful Tribal consultation to incorporate SDPI and Tribal participation in the MDPP. Additionally, NIHB recommends CMS and CDC 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 April 1, 2018.

CMS is proposing that MDPP lifestyle coaches obtain a national provider identifier (NPI) number to ensure that CMS integrity requirements are met and are seeking comment on possible enrollment in the Medicare program. NIHB and Tribes support the proposal for MDPP lifestyle coaches to obtain an NPI number. The majority of SDPI programs are already designated as Medicare providers and will only have to obtain an NPI number for their lifestyle coaches. NIHB request that more trainings be available to become lifestyle coaches, especially in remote areas.

CMS is proposing that an entity may be eligible to enroll in Medicare as an MDPP supplier if they have achieved CMS interim preliminary recognition or CDC preliminary recognition (when established), or full recognition status. The purpose of the CMS interim preliminary recognition is to allow organizations to enroll in Medicare and bridge the gap until CDC creates standards for a CDC preliminary recognition certification. The MDPP supplier must meet the interim preliminary recognition standards with a 12-month data submission to CDC. NIHB has heard from Tribes that they are concerned about the 12-month data submission to CDC because it is not applicable in our communities to collect the data when there is no support or funding within an already under-served health care community. 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. For over ten years, AI/AN communities have been implementing the SDPI DP program and continue to achieve similar results as the National Institutes of Health DPP lifestyle intervention group.<sup>5</sup> The SDPI DP Toolkit was developed over five years ago to ensure that Tribes are able to implement a cost effective, highly successful, diabetes risk reduction and prevention program that works. NIHB again recommends that CMS conduct a pilot program for currently operating SDPI Diabetes Prevention programs to be certified as grandfathered in to provide services and receive

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<sup>5</sup> IHS SDPI Report to Congress 2011; IHS SDPI Report to Congress 2014.

reimbursement through the MDPP.

Furthermore, while this proposed rule affects only the Medicare program, NIHB recommend implementation of a similar program for Medicaid. In the implementation of a Medicaid Diabetes Prevention Program model, we urge that a mechanism be developed to allow Federally Qualified Health Centers (FQHC) and IHS/Memorandum of Agreement (MOA) clinic providers to receive additional reimbursement outside of their all-inclusive rate when providing these preventive services.

### ***Tribal Consultation***

We appreciate 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. 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.<sup>6</sup> 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.<sup>7</sup>

Indian health care programs are unique. Tribal health programs implement the United States' trust responsibility to provide health care services to AI/ANs.<sup>8</sup> 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 and implements 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

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<sup>6</sup> Centers for Medicare & Medicaid Services, Tribal Consultation Policy § 5.7 (Dec. 10, 2015).

<sup>7</sup> *Id.* at § 5.6.

<sup>8</sup> *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>.

beneficiaries experience additional hardships that CMS must take into consideration in order to ensure that AI/AN communities can participate in the MDPP. NIHB requests that CMS engage in Tribal consultation prior to publication of a final rule in addition to consideration of these comments.

***Conclusion***

NIHB and Tribes stand ready to work with CMS to advance access to quality health care prevention services through community-based Indian health care programs, especially the SDPI grantees. We thank you for this opportunity to provide our comments and recommendations and look forward to further engagement with CMS on this important proposed rule.

Sincerely,

A handwritten signature in cursive script that reads "Vinton Hawley". The signature is written in dark ink and is positioned above the typed name and title.

Vinton Hawley  
Chairman, National Indian Health Board

Cc: Kitty Marx, Director, CMS Division of Tribal Affair