Congress of the United States
Washington, DC 20515

August 22, 2016

Acting Administrator Andy Slavitt
Centers for Medicare and Medicaid Services
United States Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

RE: Comments on Proposed Rule Proposing to Expand the Medicare Diabetes Prevention Program Model. 81 Fed. Reg. 46161, July 15, 2016.

File Code: CMS-1654-P

Dear Acting Administrator Slavitt:

On July 15, 2016, the Centers for Medicare and Medicaid Services (CMS) issued a proposed rule expanding the Medicare Diabetes Prevention Program (MDPP) Model and requested comments from the public regarding the proposed rule. The notice requests comments on a proposal to expand the MDPP Model, in particular the modification to eligible beneficiaries to encompass disparities in minority patients. We commend CMS for taking an active role in addressing an issue of great importance to many Americans, specifically minorities who are more likely to be diagnosed with type 2 diabetes.

In 2012, 29.1 million Americans – 9.3 percent of the population – had diabetes, with 8.1 million of them undiagnosed.[1] According to the Centers for Disease Control and Prevention (CDC), 86 million people have prediabetes and 90 percent of them are unaware of it.[2] Three-quarters of those with prediabetes are over the age of 60.[3] Total medical costs and lost wages for those afflicted with diabetes is $245 billion, twice as high than healthier Americans.[4] Not only do they suffer from complications associated with the disease, they also have higher rates of death.[5] In fact, the CDC listed diabetes as the seventh leading cause of death in the United States.[6] Unfortunately, these numbers are far higher for minorities who have a higher prevalence of diabetes than non-minorities.[7] Without action, it is estimated that one in three Americans will

[1] 2014 National Diabetes Statistics Report, Centers for Disease Control and Prevention, May 15, 2015.
[2] *Id.*
[3] *Id.*
[4] *Id.*
[5] *Id.*
[6] Jiaquan Xu et al., Deaths: Final Data for 2013, tables 9, 10, 11, National Vital Statistics Report, Feb. 16, 2016.
[7] Elias K. Spanakis and Sherita Hill Golden, Rac/Ethnic Difference in Diabetes and Diabetic Complications, Curr Diab Rep, Dec. 2013.

suffer from diabetes by 2050.[8] These statistics prove the importance of supporting early intervention and preventive measures at the federal level, such as the Diabetes Prevention Program.

In 2002, the Diabetes Prevention Program (DPP) demonstrated that intensive lifestyle intervention was effective and successfully reduced risk for developing diabetes by 58 percent and 71 percent for those over 60 years of age.[9] These findings were later replicated at a lower cost to a community classroom setting, which led to the creation of the National DPP overseen by the CDC.

The National DPP is a public-private partnership consisting of an intensive, evidence-based intervention program that includes weekly core sessions followed by monthly maintenance sessions. Delivered by trained coaches, the National DPP provides a supportive, small group environment to promote healthier eating habits and increase physical activity, with goals of reducing body weight by 5 to 7 percent. In 2010, the National DPP was authorized by Congress as part of the Affordable Care Act to build an infrastructure of programs across the country using community-based organizations.

Both randomized trials and real-world implementation studies haven proven that the DPP is effective in preventing or delaying type 2 diabetes by 60 percent.[10] Not only has the DPP been successful in helping seniors lose an average of 5 percent of their body weight,[11] it has resulted in fewer adults developing diabetes each year[12] and led to reductions in inpatient hospital admissions and Emergency Department visits.[13] CMS also concluded that Medicare beneficiaries enrolled in the program were successful in preventing and delaying diabetes at lower costs when compared to those not enrolled in the program. In fact, a savings of $2,650 for each enrollee over a 15-month period resulted from this program.[14]

Due to these promising findings, CMS announced in its proposed rule its intention to expand the DPP into Medicare beginning January 1, 2018. Through its expansion, more Medicare beneficiaries would be able to access the benefits of the Diabetes Prevention Program, which could lead to the prevention of diabetes, improved health, and reduced costs. We are encouraged that CMS recognizes the importance of such a preventive program in assisting people who are at risk of developing type 2 diabetes and appreciate the opportunity to comment on ways to successfully expand the program to assist Medicare beneficiaries.

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[8] Number of Americans with Diabetes Projected to Double or Triple by 2050, Centers for Disease Control and Prevention, Press Release, Oct. 22, 2010.
[9] American Diabetes Association, National Diabetes Prevention Program Named the First Preventive Health Initiative Eligible for Medicare Coverage via CMMI Expansion, Mar. 23, 2016.
[10] Ann Albright, How Effective Are Diabetes Prevention Programs?, Medscape, Sep. 29, 2014.
[11] Independent Experts Confirm that Diabetes Prevention Model Supported by the Affordable Care Act Saves Money and Improves Health, Department of Health and Human Services Press Release, Mar. 23, 2016.
[12] Diabetes Prevention Program, National Institute of Diabetes and Digestive and Kidney Diseases, Oct. 2008).
[13] Diabetes Prevention Program Independent Evaluation Report Summary, Centers for Medicare and Medicaid Services, Mar. 23, 2016.
[14] *Id.*

The Notice outlines several proposals related to the expansion of the program to Medicare beneficiaries, including but not limited to the payment structure, IT considerations, eligible beneficiaries, site of service requirements, and the timeframe. We would like to comment specifically on the eligibility of beneficiaries.

Under the eligible beneficiary proposal, CMS would define an eligible pre-diabetic patient as a beneficiary having a body mass index (BMI) of 25 kg/m^2 or greater, except for Asian beneficiaries. This proposal allows for the inclusion of only Asian beneficiaries meeting a BMI of 23 kg/m^2 or greater. Generally, obesity is defined as a BMI of at least 30 kg/m^2 with the risk of prediabetes at a BMI of 25 kg/m^2 or greater. Yet, for Asian Americans this number is much lower. As studies have shown, diabetes can develop sooner at lower BMI levels because of differences in body composition. Because of these generalized standards, over half of diabetes diagnoses among Asian Americans are missed.[15]

We applaud CMS for including a lower BMI for Asian beneficiaries as it is critical to diagnose diabetes as early as possible. As you are aware, the American Diabetes Association modified their recommended BMI cut points for Asian Americans in 2015 and has been included as a risk factor for the National Institutes of Health and Centers for Disease Control's National Diabetes Education Program. While studies and research have shown slight differences in BMI cut points for Asian American subgroups, a rounded BMI cut point of 23 kg/m^2 is practical. The approach taken in the proposed rules balances the sensitivity and specificity required to provide a valuable screening tool without risking many false positives. To treat, intervene, and even prevent diabetes, a racially sensitive guideline is important. Doing so means detecting an additional 215,000 undiagnosed cases of diabetes and over 430,000 prediabetes cases within the Asian American community.

Furthermore, as CMS moves forward on finalizing the rule, we urge the agency to continue to study racial disparities within diabetes. Although this is an important step in the right direction, we ask CMS to take further steps within the MDPP to research and promote BMI thresholds for other racial and ethnic minorities. As studies suggest, more must be done to create tailored guidance for different minority populations because people from South Asia will have different needs than those from India or of African descent. Finally, we respectfully suggest CMS take advantage of the expansion of the DPP to Medicare to work with community-based organizations to raise awareness of the disparities leading to higher risk of diabetes within minority populations.

Again, we would like to thank you for taking an active role in this issue. Diabetes is no longer the same life-threatening, life-limiting condition it was a century ago. However, without increased prevention and early diagnosis the benefits of these strategies will not be fully realized. Because Asian Americans' risk for diabetes is under-recognized based on the existing BMI criteria, this population may not be afforded the same opportunity as others for increased prevention and early diagnosis. It is imperative to better screen and diagnose America's fastest-growing ethnic group based on the BMI cut point that more appropriately applies to them.

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[15] Andy Menke, et al., Prevalence of and Trends in Diabetes Among Adults in the United States, 1988-2012, Journal of the American Medical Association, Sep. 8, 2015.

We realize there are multiple considerations under this proposal along with other issues to be resolved in this area and we look forward to working with CMS to address this very important issue. If you have any questions or comments, feel free to contact Melissa Jung, at 202-225-4038 or via email at melissa.jung@mail.house.gov.

We appreciate your consideration in this matter.

Sincerely,

Nydia M. Velázquez
Member of Congress

Grace Meng
Member of Congress

Judy Chu
Member of Congrress