November 20, 2017

Ms. Seema Verma
Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Dear Administrator Verma:

The Diabetes Advocacy Alliance (DAA) appreciates the opportunity to provide comments on the Centers for Medicare & Medicaid Services (CMS) Innovation Center New Direction Request for Information (New Direction/RFI) released on September 20, 2017. The DAA is a coalition of 22 diverse member organizations, representing patient, professional and trade associations, other non-profit organizations, and corporations, all united in the desire to change the way diabetes is viewed and treated in America. Since 2010, the DAA has worked to increase awareness of, and action on, the diabetes epidemic among legislators and policymakers. The organizations that comprise the DAA share a common goal of elevating diabetes on the national agenda so we may ultimately defeat diabetes.

As you know, both the human and economic toll of diabetes is devastating. Over 30 million Americans have diabetes and an additional 84 million adults are at risk of developing the disease. By 2050, it is estimated that one out of every three Americans will have diabetes. In addition, the annual cost of this public health emergency has skyrocketed to $322 billion and will continue to rise unless something is done. Further, the Medicare program and older adults are disproportionately affected by diabetes. Approximately 12 million Americans over the age of 65 (nearly 30 percent) have diabetes and half of all those over the age of 65 have prediabetes. In addition, Medicare currently spends one out of every three dollars on care for people with diabetes.[1] Given the burden diabetes places on seniors and the Medicare program, the DAA strongly recommends the Innovation Center focus attention on this serious and costly disease as it develops and tests innovative approaches and models to improve quality and value of care for Medicare beneficiaries.

Medicare Diabetes Prevention Program Expanded Model

First and foremost, the DAA would like to recognize the work of the Innovation Center in moving forward with an expanded model test that will allow seniors at risk for diabetes to participate in an evidence-based diabetes prevention program. Through a pilot that enrolled more than 8,000 Medicare beneficiaries, the Innovation Center found seniors can prevent or delay onset of type 2 diabetes by participating in a community-based diabetes prevention program and save the Medicare programs approximately $2,650 over 15 months.[2] The

[1] Centers for Medicare and Medicaid Services. Medicare Health Support Overview. Baltimore, MD: CMS. Available at: http://www.cms.gov/ccip.downloads/overview_ketchum_70116.pdf

[2] Spitalnic P. Certification of medicare diabetes prevention program. Office of the Actuary at the Centers for Medicare & Medicaid Services, March 2016. Available online: https://www.cms.gov/Research-Statistics-Data-and-Systems/Research/ActuarialStudies/Downloads/Diabetes-Prevention-Certification-2016-03-14.pdf

Medicare diabetes prevention program (MDPP) expanded model clearly illustrates the Innovation Center's potential to bring effective, cost-saving new models of care and prevention to our nation's seniors.

As expressed in our comments related to the 2018 Medicare Physician Fee Schedule proposed rule, the DAA is disappointed that virtual delivery of MDPP was not included in the proposed rule. The DAA would like to reiterate that virtual and other innovative forms of DPP delivery is essential for beneficiary choice as well as access (particularly for vulnerable populations, individuals with transportation needs or those in rural areas with no access to an in-person program.) We stand ready to work with the Innovation Center on a separate model test of virtual and other innovative delivery of DPP services conducted in parallel with the MDPP expanded model as was described in the proposed rule. Coverage of virtual and other innovative programs will ensure Medicare beneficiaries have access to MDPP regardless of where they live and in the format of their choosing. Although we emphasize the need for the virtual model test to happen quickly to assure full access, we also urge the Innovation Center to be as transparent as possible in the development of the virtual model test (ideally, opening it for public comment) and work closely with stakeholders to ensure a successful test and future implementation. The DAA looks forward to working with CMS to implement the new MDPP benefit beginning April 2018.

Guiding Principles
The new direction outlined in the RFI for the Innovation Center is of particular interest to the DAA given its emphasis on patient-centered care and focus on reforms that increases choices that drive quality, improved outcomes, and reduced costs. The DAA strongly supports the guiding principles related to patient-centered care and transparent model design and evaluation. It is critical that patients be at the center of these important health care decisions and models which will help empower beneficiaries and their families. In addition, the DAA strongly believes patients should not be harmed by model tests and urges the Innovation Center to safeguard patient access and quality of care.

The DAA has been fortunate to engage with the Innovation Center over the last several years and believes a strong partnership and collaboration between the Innovation Center and external stakeholders will yield the best ideas and ultimately improved care for patients. While the statute establishing the Innovation Center required broad stakeholder engagement, the DAA encourages the Innovation Center to develop a formal strategy for stakeholder engagement so that external parties, particularly patients and/or consumers, have the opportunity to contribute to model development and testing.

Gaps in Diabetes Care
As previously mentioned, diabetes is an epidemic affecting an increasing number of Americans and consuming more and more healthcare dollars. The Medicare diabetes prevention program expanded model filled a gap that previously existed in the Medicare program; that diabetes prevention was not a covered service for seniors. The DAA is pleased the Innovation Center's model test will result in Medicare coverage for diabetes prevention beginning April 2018 but there is more the Innovation Center can do in terms of filling gaps that exist in diabetes care. A few examples are highlighted below.

Diabetes Screening
As previously mentioned, over 30 million Americans have diabetes. Unfortunately, 7.2 million are undiagnosed which includes over 2 million Medicare beneficiaries who are not getting the care they need to manage their disease. In addition, only 11.6% of the 84 million Americans with prediabetes know they have it. Despite the fact that the U.S. Preventive Services Task Force (USPSTF) recommends screening adults aged 40 to 70 years who are overweight or obese for diabetes[3] and Medicare covers two diabetes screening tests a year for eligible beneficiaries, millions of Americans remain undiagnosed and are not receiving the care and treatment they need. Given the sheer number of people living with diabetes or at risk of the disease and the hundreds of billions of dollars spent on diabetes, the DAA recommends the Innovation Center test new approaches to outreach and screening to improve diabetes screening rates. Improving Medicare diabetes screening rates may also help drive uptake of the new Medicare diabetes prevention program benefit by seniors with prediabetes which goes into effect in 2018.

Related to diabetes screening, the Medicare program currently covers and reimburses fasting plasma glucose (FPG) tests to screen for diabetes. However, the hemoglobin A1c test is only covered and reimbursed under Medicare if a patient has already been diagnosed with diabetes and it's ordered by a doctor. The hemoglobin A1c test is often preferred by physicians for its convenience[4] and research suggests the FPG may underestimate the burden of undiagnosed diabetes compared to the A1c test.[5] The DAA urges the Innovation Center to test using the hemoglobin A1c test for diabetes screening which may help reduce the number of Medicare beneficiaries with undiagnosed prediabetes and diabetes and get them the care they need.

Patient Centered Diabetes -Management
Diabetes is a complex disease that requires ongoing self-management by patients, including integrating lifestyle modifications and making numerous decisions throughout the day, as part of their management and treatment regimen. Two out of three Medicare beneficiaries have diabetes or prediabetes. Because of the impact the disease has on the program, people with diabetes should not be treated in a "one-size-fits all" manner. There are many great examples of evidence-based services and programs, including some that are community-based, that lead to improved health outcomes for people with type 2 diabetes. The DAA recommends that the Innovation Center develop a robust set of pilots to test innovative models and programs that delivery patient centered diabetes management – including new approaches to delivery of Medicare diabetes self-management training (DSMT) and community based programs that lead to improved outcomes.

Diabetes Self-Management Training – new delivery models
Medicare covers DSMT which is an evidence-based service that teaches people with diabetes how to effectively self-manage their diabetes and cope with the disease. Studies have found that DSMT is associated with improved diabetes knowledge and self-care behaviors, lower hemoglobin A1c, lower weight, improved quality of life, healthy coping and reduced health care costs[6], and it is a

[3] Sui AL, on behalf of the U.S. Preventive Services Task Force. Screening for abnormal blood glucose and type 2 diabetes mellitus: U.S. preventive services task force recommendation statement. Ann Intern Med 2015; 163(11):861-868.
[4] Mehta S, Mocarski M, Wisniewski T, Gillespie K, Narayan KMV, and Lang K. Primary care physicians' utilization of type 2 diabetes screening guidelines and referrals to behavioral interventions: a survey-linked retrospective study. BMJ Open Diab Res Care 2017;**5**:e000406. doi:10.1136/bmjdrc-2017-000406.
[5] Ho-Pham LT, Nguyen UDT, Tran TX, Nguyen TV. Discordance in the diagnosis of diabetes: comparison between HbA1c and fasting plasma glucose. PLoS ONE 2017; 12(8): e0182192. https://doi.org/10.1371/journal.pone.0182192
[6] American Diabetes Association. Standards of Medical Care in Diabetes – 2017. Diabetes Care 2017; 40 (Suppl.1): S34.

recommended component of care in a joint position statement of the American Diabetes Association, American Association of Diabetes Educators, and Academy of Nutrition and Dietetics[7] Unfortunately, despite its critical importance for people with diabetes and the fact that DSMT has been a covered benefit under Medicare for over 15 years, a recent study found only five percent of Medicare beneficiaries with newly diagnosed diabetes used DSMT services.[8]

CMS highlighted the "significant underutilization" of DSMT in the CY 2011 and CY 2017 Medicare Physician Fee Schedule, and solicited public comment on barriers contributing to access and the under-utilization of the benefit. The DAA provided comments to the agency on existing barriers and recommends the Innovation Center test new approaches to delivering DSMT, including virtual delivery, in an effort to increase utilization of this important benefit.

New, community based, models of patient centered diabetes management

Community-based programs have many benefits compared to those delivered in a clinical setting including greater scalability, accessibility, and affordability. One example of an innovative model of care for people with type 2 diabetes found that combining community based and online diabetes education with popular commercial weight loss, resulted in greater A1c reduction and weight loss compared to standard nutrition and diabetes education.[9] In addition, the interventions led to improvements in psychosocial outcomes often seen in individuals with type 2 diabetes.[10] The MDPP expanded model is helping to establish community health workers role in the Medicare program as it relates to diabetes prevention; however, the Innovation Center should look further and consider a model test based on the aforementioned intervention to help explore the role of these workers in the care and treatment of people with diabetes.

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Thank you for the opportunity to comment on this Request for Information for the new direction of the Innovation Center. We support the Agency's efforts to promote patient-centered care and drive quality and improve outcomes. We look forward to working with CMS to address critical gaps in diabetes care and ensuring our healthcare system is affordable, accessible, and puts patients first. If you have any questions or need additional information, please free to contact one of us: Meghan Riley at mriley@diabetes.org; Karin Gillespie at kgil@novonordisk.com; or Dr. Henry Rodriguez at hrodrig1@health.usf.edu.

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[7] Powers MA, Bardsley J, Cypress M, et al. Diabetes self-management education and support in type 2 diabetes; a joint position statement of the American Diabetes Association, American Association of Diabetes Educators, and the Academy of Nutrition and Dietetics. Diabetes Care 2015;38:1372-1382.

[8] Strawbridge LM, Lloyd JT, Meadow A, et al. Use of medicare's diabetes self-management training benefit. Health Education Behavior 2015;42:530-8.

[9] O'Neil PM, Miller-Kovach K, Tuerk PW, Becker LE, et al. Randomized controlled trial of a nationally available weight control program tailored for adults with type 2 diabetes. Obesity 2016;24:2269-2277.

[10] Holland-Carter L, Tuerk PW, Wadden TA, Fujioka KN, et al. Impact on psychosocial outcomes of a nationally available weight management program tailored for individuals with type 2 diabetes: results of a randomized controlled trial. Journal of Diabetes and Its Complications 2017, http://dx.doi.org/10.1016/j.jdiacomp.2017.01.022

Sincerely,

Academy of Nutrition and Dietetics
American Association of Diabetes Educators
American Diabetes Association
American Podiatric Medical Association
Endocrine Society
Healthcare Leadership Council
National Kidney Foundation
Novo Nordisk, Inc.
Omada Health
Pediatric Endocrine Society
VSP Vision Care
Weight Watchers International, Inc.
YMCA of the USA