September 6, 2016

The Honorable Sylvia M. Burwell
Secretary
U.S. Department of Health and Human Services
200 Independence Ave SW
Washington, D.C. 20201

Andrew M. Slavitt,
Acting Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

BY ELECTRONIC DELIVERY

RE: Medicare Program; Revisions to 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 [CMS-1654-P]

Dear Secretary Burwell and Acting Administrator Slavitt:

The Diabetes Advocacy Alliance (DAA) appreciates the opportunity to provide comments related to the Centers for Medicare and Medicaid Services' (CMS) CY 2017 Physician Fee Schedule Proposed rule (the "Proposed Rule"), published July 15, 2016.

The DAA is a coalition of 21 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.

The DAA provides the following comments on the Proposed Rule.

Diabetes Self-Management Training (DSMT)

The DAA shares CMS' concern that only about 5 percent of Medicare patients with newly diagnosed diabetes utilize diabetes self-management training (DSMT) services. The American Diabetes Association, American Association of Diabetes Educators, and the Academy of Nutrition and Dietetics published a joint position statement on diabetes self-management

education and support for type 2 diabetes last year.[1] The position statement provides a valuable discussion of the four critical times to assess, provide and adjust DSMT including: at the time of diagnosis; annually for assessment of education, nutrition and emotional needs; when new complicating factors arise; and when transitions of care occur.

The position statement also describes some of the barriers that currently impact utilization of DSMT including confusion about how and when to make referrals, lack of access to and affordability of DSMT services, and lack of or poor reimbursement for DSMT. Furthermore, including hemoglobin A1c as an eligible criteria for diagnosing diabetes, allowing DSMT to be provided in additional clinical and non-clinical settings including the ability of hospital outpatient DSMT programs to be provided in local community settings, extending the availability of the initial 10 hours beyond the first year and covering additional hours of DSMT based on individual need, eliminating the restrictions on who is eligible for individual DSMT, and expanding the list of providers eligible to refer for DSMT should be considered to improve utilization of the benefit.

The DAA strongly believes clarifications and updates to the benefit are needed to help improve utilization rates. We urge CMS to increase efforts to make the benefit more accessible to Medicare beneficiaries with diabetes and improve utilization of DSMT. We look forward to the clarifications and opportunities to provide feedback to CMS.

Medicare Diabetes Prevention Program

In March 2016, the DAA was thrilled to hear you, Secretary Burwell, make the momentous announcement that the success of the Diabetes Prevention Program (DPP) prompted Medicare, with your leadership, to scale the program for all Medicare beneficiaries. The successful demonstration by the YMCA of the USA showed that DPP saved Medicare $2,650 over 15 months per participant.[2] We are pleased that coverage for and the opportunity to participate will be extended to many more Medicare beneficiaries who are at risk of developing diabetes. The DAA is a long-time supporter of the National Diabetes Prevention Program (National DPP) at the Centers for Disease Control and Prevention (CDC) and we strongly support Medicare expansion of the National DPP.

In general, the DAA urges CMS to align the MDPP benefit and supplier standards with the CDC's National DPP as closely as possible. The National DPP was established in 2010 under the Affordable Care Act (ACA) and requires that National DPP suppliers meet high standards set forth in the Diabetes Prevention Recognition Program (DPRP) in order to receive CDC

[1] Powers MA, Bardsley J, Cypress M, Duker P et al. Diabetes self-management education and support in type 2 diabetes: a joint position statement of the american diabetes association, the american association of diabetes educators and the academy of nutrition and dietetics. Diabetes Care 2015;38:1372-1382.

[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

recognition and be deemed an eligible National DPP supplier. Imposing different, potentially conflicting standards or criteria for qualifying as a MDPP supplier and delivery of MDPP services compared to those governing recognition under the DPRP may have a detrimental impact on suppliers seeking to provide diabetes prevention programs to both privately insured and Medicare enrollees.

MDPP Designation as "Additional Preventive Services"

DAA is pleased CMS is proposing to designate MDPP services as "additional preventive services" available under Medicare Part B. In the proposed rule, CMS explains it can use CMMI's waiver authority to designate MDPP as an "additional preventive service." However, CMS does not specifically indicate whether cost-sharing will be waived. By designating MDPP as an additional preventive service, we interpret the proposed rule to mean that eligible participants will not be responsible for any cost-sharing for participation. We urge CMS to confirm our interpretation by clearly defining MDPP as an additional preventive service that will require no cost-sharing from eligible participants. Ensuring benefit accessibility for eligible Medicare beneficiaries must be a foundational priority in this implementation; providing coverage with no cost-sharing will enhance program and participant success.

The DAA would also like to address CMS' underlying position in this section of the proposed rule which states: *"MDPP services do not meet the requirement in section 1861(ddd)(1)(B) of the Act that they have received a recommendation with a grade of A or B by the USPSTF."* The DAA would like to clarify that the final guideline issued by the U.S. Preventive Services Task Force (USPSTF) in October 2015, entitled *Abnormal Blood Glucose and Type 2 Diabetes Mellitus: Screening*, provided a B rating to "intensive behavioral counseling interventions" for patients with abnormal blood glucose to promote a healthful diet and physical activity.[3] The USPSTF recommendation is based on National DPP and Diabetes Prevention Program clinical trial evidence. We urge CMS to recognize this link, and revise this section in the final rule.

In multiple conversations with USPSTF officials, the DAA has received confirmation that the intent of the USPSTF was that insurance coverage and clinical practice decisions regarding patients with prediabetes should be guided by the full guideline including the "Clinical Considerations" section. USPSTF further clarified that both diabetes screening and participation in intensive behavioral counseling are considered preventive health services. Private health plans, including Anthem Blue Cross of California, are correctly interpreting the USPSTF guideline and providing coverage of National DPP to enrollees with no cost-sharing beginning as soon as July 2016.

The DAA understands there may be a concern that USPSTF guidelines only apply in clinical settings; however, the USPSTF has been clear their guidelines, when appropriate, also apply to

[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.

certain non-clinical, community based settings. In addition, section 915(a)(1) of the Public Health Service Act, 42 U.S.C. § 299b-4(a)(1), as amended by the Affordable Care Act, establishes the USPSTF and says: "Such Task Force shall review the scientific evidence related to the effectiveness, appropriateness, and cost-effectiveness of clinical preventive services for the purpose of developing recommendations for the health care community, and updating previous clinical preventive recommendations, to be published in the Guide to Clinical Preventive Services (referred to in this section as the ''Guide''), for *individuals and organizations delivering clinical services, including primary care professionals, health care systems, professional societies, employers, community organizations, non-profit organizations, Congress and other policy-makers, governmental public health agencies, health care quality organizations, and organizations developing national health objectives* [emphasis added]."[4] The statute does not specify where USPSTF "services" must be provided and in referencing "community organizations" and "non-profit organizations", it is clear that the intent was for USPSTF recommendations to be implemented in non-clinical settings when appropriate. The DAA urges CMS to clarify that National DPP has received a B grade from USPSTF and is thus eligible for Medicare coverage without beneficiary cost-sharing.

The DAA also supports CMS' proposed waiver of the requirement to use the national coverage determination (NCD) process to implement the program. We agree that use of the NCD process would not be appropriate given the associated implementation issues it would create and the extensive body of clinical evidence support the program.

MDPP Benefit Description

The DAA supports the concept that MDPP providers must offer a 12-month program and use a curriculum that has been approved by the CDC through its DPRP. The DAA believes that the wording in the proposed rule – which calls for suppliers "using **the** [emphasis added] CDC-approved DPP curriculum" – could imply that all MDPP suppliers must use the CDC PreventT2 curriculum, which could stifle innovation of curricula that achieve results similar to or better than that of the current CDC curriculum. Rather than codifying the standards in a rule, the DAA urges CMS to incorporate the CDC DPRP Curriculum standard in the final rule -- that MDPP suppliers must use 'a' CDC approved curriculum which, as stated in the DPRP standards, can include a curriculum developed by a supplier that has been submitted, reviewed, and approved by CDC to ensure it is based on evidence from efficacy and effectiveness trials.

The DAA supports the concept of additional monthly maintenance sessions beyond the 12 month program for beneficiaries who complete the year-long program, and requests that CMS clarify how these sessions would be implemented taking into consideration the operation capabilities of community-based providers as well as considering the objective and reasonable costs of providing these maintenance sessions.

[4] Public Health Service Act, 42 U.S.C. § 299b-4(2010).Available online: http://uscode.house.gov/view.xhtml?req=(title:42%20section:299b-4%20edition:prelim)

In the MDPP guidance, CMS proposes that MDPP be a one-time benefit for Medicare beneficiaries at risk for type 2 diabetes. The DAA encourages CMS to include in future rule-making an exception for participants who experience a major life event that may impact his/her ability to attend MDPP sessions. Examples of major life events may include: newly developed health condition by the participant or a loved one; or death of a loved one. Furthermore, successful completion of MDPP and attainment of desired weight loss should be given the flexibility to access the benefit again if they experience a major life event.

Finally, in describing the curriculum requirements, the proposed rule suggests that "each MDPP session be at least an hour in duration." CMS should focus on completion of modules in the required curriculum, not session-based time standards, since module completion requires active participation, while a time-based standard does not. There is evidence that time spent completing a module does not correlate with impact on outcomes. Instead, it is the participant's comprehension and ability to turn learning into action that is a greater predictor of their success in achieving clinically-meaningful weight loss. This recommendation is consistent with the CDC standards, which require that "each session must be of sufficient duration to convey the session content OR approximately one hour in length."

Enrollment of New MDPP Suppliers

The DAA supports CMS' proposal that any organization recognized by the CDC, with either preliminary or full recognition, is eligible to apply for enrollment in Medicare as a supplier beginning on or after January 1, 2017. However, as currently written, the definition of "preliminary recognition" is only vaguely defined. It is unclear what CMS intended to propose.

The CDC DPRP standards set forth requirements for organizations seeking "pending" or "full" recognition to deliver National DPP. The standards state that an organization will receive pending recognition from CDC if it agrees to the curriculum, duration and intensity requirements established under DPRP. The DAA notes that CMS uses the term "preliminary" in the proposed rule and in seeking to align the MDPP with the National DPP, we urge CMS to clarify that "preliminary" has the same meaning as the CDC's definition of "pending" in the DPRP. If the agency instead intends to create a new category of "preliminary" providers, DAA urges CMS to designate CDC as the entity responsible for recognizing organizations with "preliminary" recognition, just as they are responsible for "pending" and "full" recognition.

DAA also urges CMS to clarify its proposed requirements for organizations seeking to achieve "preliminary" status. In the proposed rule, CMS proposes that organizations must meet CDC DPRP performance standards and reporting requirements for 12 consecutive months immediately following the organization's application to participate in the DPRP. DAA encourages CMS to clarify that the "performance standards and reporting requirements" it is referring to in its proposed definition of "preliminary recognition" are the requirements to begin offering CDC-approved curriculum within 6 months of the effective date of the application and to submit at

least six months of participant data at 12 months post-effective date of the application. CMS should be clear that organizations are not expected to achieve any particular outcomes standard to obtain "preliminary" recognition.

Furthermore, DAA urges CMS to add to its existing definition of "preliminary" recognition by ensuring that both DPP suppliers that have 12 months of demonstrated experience offering DPP are deemed "preliminary" for purposes of reimbursement on January 1, 2018. Without grandfathering DPP providers with significant existing experience, there is a very real risk that there will be no providers able to achieve "preliminary" recognition, and serve patients, on January 1, 2018. We urge CMS and CDC to release guidance as soon as possible to clarify which current "pending" organizations have "preliminary" recognition, and to set forth additional detail on the standards organizations seeking "preliminary" status will need to achieve.

Finally, the DPRP standards are updated every three years by CDC and are slated to be updated next in 2018. The DAA urges CMS to address how Medicare standards will be updated in the future and consider how to align these updates with the DPRP update.

Expected MDPP Reimbursement

In the proposed rule, CMS proposes "value-based payments" tied to session attendance and weight loss. The CDC's National DPP, as well as the Diabetes Prevention Program clinical trial which it is modeled after, is a year-long lifestyle intervention for the prevention of type 2 diabetes. The DAA requests additional clarification from CMS on how MDPP suppliers will be reimbursed for the second 6 months of the year-long intervention if a beneficiary fails to achieve the minimum 5 percent weight loss. The DAA wants to ensure that beneficiaries have access for the entire year-long intervention and we are concerned the proposed rule suggests an unsustainable program and reimbursement structure.

Furthermore, the DAA notes that the proposed "required minimum weight loss" for Medicare beneficiaries is a higher bar than that set by the CDC DPRP. While the proposed rule would require a minimum 5% weight loss per participant, the CDC DPRP requires DPP organizations to demonstrate an average 5% weight loss across program participants.

We encourage CMS to align its proposed weight loss requirements with CDC DPRP standards – rather than creating its own new standard – to ensure consistency across programs; to reflect scientific evidence indicating that weight loss of less than 5% can still be effective in reducing the risk of chronic disease; and to ensure that all eligible patients have access to MDPP regardless of any demographic or social factors that may make it harder for them to lose weight.

MDPP Eligible Beneficiaries

The DAA acknowledges the proposed rule defines an eligible individual as someone having a fasting plasma glucose (FPG) level of 110-125 mg/dL which aligns with the World Health

Organization's definition of prediabetes but is not consistent with the American Diabetes Association's (ADA) evidence-based Standards of Medical Care which defines prediabetes as a FPG of 100-125 mg/dL. The discrepancy between the DPRP eligibility standards, which follows the ADA's definition of prediabetes, and the proposed MDPP standards could cause immense confusion for physicians and other individuals who may refer participants to the program. The DAA encourages CMS to prioritize education of providers and beneficiaries in order to reduce the potential confusion that may arise from these varying definitions of diabetes risk.

In the proposed rule, CMS sets forth the following criteria for MDPP eligible beneficiaries: (1) are enrolled in Medicare Part B; (2) have as of the date of attendance at the first Core Session a body mass index (BMI) of at least 25 if not self-identified as Asian and a BMI of at least 23 if self-identified as Asian. The DAA would like to note that these BMI thresholds are inconsistent with the thresholds set in the CDC's DPRP. The CDC requirements state that "all of a program's participants must be 18 years of age or older and have a BMI of greater than or equal to 24 (greater than or equal to 22 if Asian)."[5] The DAA urges CMS to align the MDPP eligibility standards with the CDC program standards whenever possible. We ask that CMS clarify why the BMI measures differ between the DPRP and MDPP and to clearly communicate the varying requirements in order to allay confusion about the benefit.

The DAA is pleased that the eligibility criteria CMS is proposing allow for screening and diagnosis of prediabetes using the following tests: hemoglobin A1c, fasting plasma glucose, or oral glucose tolerance. It is important that health care professionals and patients have a range of blood glucose test options to screen for prediabetes and determine eligibility. However, we urge CMS to clarify in the final rule that Medicare will begin reimbursing for hemoglobin A1c as a screening test for prediabetes and diabetes. Currently, Medicare covers and reimburses fasting blood sugar tests to screen for diabetes. 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 DAA supports CMS' proposal allowing for self-referral, community-referral, or health care practitioner referral to obtain MDPP services. In addition, the DAA is pleased CMS allows for a beneficiary with previous diagnosis of gestational diabetes (GDM) to be eligible for MDPP. A recent study shows an increase in GDM prevalence from 0.3% in 1979 to 1980 to 5.8% in 2008 to 2010.[6] We urge CMS to clarify that individuals with previous GDM will be able to self-report their history of GDM to become eligible for MDPP.

Site of Service

[5] Centers for Disease Control and Prevention. Centers for Disease Control and Prevention Diabetes Prevention Recognition Program – Standards and Operating Procedures. January 2015. Available online: http://www.cdc.gov/diabetes/prevention/pdf/dprp-standards.pdf

[6] Lavery JA, Friedman AM et al. Gestational diabetes in the united states; temporal changes in prevalence rates between 1979 and 2010. BJOG 2016: 123(10).

The DAA commends CMS for proposing to allow in-person and remote/virtual delivery of MDPP services. One reason the CDC's National DPP has been so successful is because it is modality neutral. As CMS prepares to roll-out a benefit for which approximately half of all Medicare beneficiaries may be eligible, patient access to eligible programs – and the flexibility to choose the modality which best fits their lives – will be critical in the implementation, participation levels, and ultimate success of the program. We urge CMS to be mindful of the practical implications of its proposed requirements in both in-person and virtual settings, taking care to craft the program so that a variety of providers are able to offer compliant services to Medicare beneficiaries.

The certification by the CMS Actuary is clear that it applies to a variety of DPP programs, without regard to modality. There is significant evidence that virtual programs offer comparable quality MDPP services to in-person services as is assessed in the recent evidence report of diabetes prevention programs conducted by the Institute for Clinical and Economic Review (ICER).[7] A recent study on virtual DPP was presented at the International Society for Pharmacoeconomics and Outreach Research. This study showed that a digital, remotely-delivered intensive behavioral counseling (IBC) program helped seniors with risk factors for diabetes and cardiovascular disease achieve significant weight loss (6.8 – 7.2% over 26 weeks) with a cumulative per capita medical expenditure savings over 3, 5, and 10 years ranged from $1,720 to $1,770 (3 years), $3,840 to $4,240 (5 years) and $11,550 to $14,200 (10 years).[8]

Quality Monitoring and Reporting

Once again, DAA urges CMS to align quality monitoring and reporting standards for MDPP suppliers with that of the CDC National DPP. In addition, in order to increase awareness of this benefit and increase participation by patients with prediabetes to evidence-based lifestyle change programs, the DAA recommends that CMS develop and adopt a quality measure (or measures) for prediabetes/diabetes screening and referral to MDPP.

Timing of MDPP Expansion

The DAA strongly urges CMS to expand MDPP nationally for a January 1, 2018 start date. The CDC's National DPP, which is the foundation of the MDPP, has been in place for nearly five years and has been immensely successful at building and developing program infrastructure, standards, and certification. We are not aware of any way that the program could be feasibly implemented through a phased-in approach, and with half of all Medicare beneficiaries at risk for type 2 diabetes, we do not think it is advisable to wait. Implementing this benefit nationally in its first year will provide critically important access and coverage of the National DPP our nation's

[7] Institute for Clinical and Economic Review. Diabetes prevention programs: effectiveness and value. July 2016. Available online: https://icer-review.org/wp-content/uploads/2016/07/CTAF_DPP_Final_Evidence_Report_072516.pdf
[8] http://www.ispor.org/research_pdfs/52/pdffiles/BI1.pdf

at-risk seniors, helping them prevent or delay the onset of this costly and debilitating disease and its complications.

Thank you the opportunity to provide comments on the Proposed Rule and for considering our comments. We look forward to continuing to engage with the agency as the regulatory process proceeds. If you have any questions or need additional information, please free to contact one of the DAA Co-chairs: Karin Gillespie at kgil@novonordisk.com or Dr. Henry Rodriguez at hrodrig1@health.usf.edu.

Sincerely,

Academy of Nutrition and Dietetics

American Association of Diabetes Educators

American Clinical Laboratory Association

American Podiatric Medical Association

Diabetes Hands Foundation

Endocrine Society

Healthcare Leadership Council

National Community Pharmacists Association

Novo Nordisk Inc.

Omada Health

Pediatric Endocrine Society

Weight Watchers International, Inc.

YMCA of the USA