BY ELECTRONIC DELIVERY

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS 1676-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

September 11, 2017

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

Dear Secretary Price and Administrator Verma:

The Diabetes Advocacy Alliance (DAA) is excited that the Centers for Medicare & Medicaid Services (CMS) is moving forward with an expanded model test that will allow seniors at risk for diabetes to participate in an evidence-based diabetes prevention program. The DAA appreciates the opportunity to provide comments related to the CMS CY 2018 Physician Fee Schedule Proposed rule (the "Proposed Rule"), published July 21, 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 such, DAA members are united in their belief that the expansion of the National Diabetes Prevention Program (National DPP) to Medicare beneficiaries has the potential to completely transform the trajectory of this chronic disease. By empowering those at risk to prevent or delay diabetes, we can help people to reach their full health potential through this program. Successful implementation of this benefit is a top priority for the DAA and many of our member organizations. To that end, the DAA provides the following comments on the Medicare Diabetes Prevention Program (MDPP) portion of the Proposed Rule.

Key Points
Each of the below points, as well as others, are addressed in detail in the body of our letter. Our key points are as follows:

- **Consistency with CDC DPRP Standards:** The DAA is pleased that in the Proposed Rule CMS repeatedly underlines its intent to align with the Centers for Disease Control and

Prevention's (CDC) Diabetes Prevention Recognition Program (DPRP) guidelines. We urge CMS to maintain close alignment with the evidence-based DPRP so MDPP suppliers are not hampered by conforming to two different and complex standards. For example, we appreciate that CMS aligned the body mass index (BMI) requirement with the DPRP but are concerned with a misalignment in the payment policies. The proposed DPRP standards indicate that the DPRP will monitor outcomes in individuals attending 3 or more core sessions, but MDPP is basing payment on the goal of attendance at 4 core sessions. Inconsistencies such as this will generate confusion and unnecessary complexity for MDPP suppliers.

- **Align with Evidence:** Proposals around maintenance sessions and the once-per-lifetime limit should align with the evidence-base for DPP and existing Medicare coverage policy for comparable preventive services such as obesity counseling or smoking cessation programs.
- **Ensuring Access:** Access to this health-improving, cost-saving benefit remains a concern of the DAA. The Proposed Rule excludes qualified virtual DPP providers from delivering this benefit for Medicare beneficiaries and we are concerned this may lead to large rural areas or underserved communities without reasonable access to MDPP suppliers. The fundamental value of community-based programs is delivery of needed services where consumers live and work, i.e. through a multitude of access points and modalities. Lack of widespread access for eligible beneficiaries has the potential not only to result in less access for beneficiaries, but also decreased cost savings for the Medicare program.

Expanded Model Start Date

The DAA commends CMS for moving forward with MDPP implementation in a timely fashion and are delighted that services will begin on April 1, 2018. We agree that a 90 day delay from January 1, 2018, is both reasonable and necessary to ensure MDPP suppliers will be ready to deliver services by April 1. We encourage CMS to move quickly to create a process and provide guidance about the enrollment of MDPP providers so that MDPP suppliers can be enrolled as smoothly as possible. Since CMS plans to create a MDPP-specific enrollment application prior to January 1, 2018, we ask that the application be made available as soon as possible.

In this section we would also like to applaud CMS for designating MDPP as an additional preventive service and specifically stating that beneficiary cost-sharing will be waived. As we stated in our 2017 Proposed Fee Schedule comment letter, ensuring benefit accessibility must be a foundational priority and providing coverage with no beneficiary cost-sharing will enhance program and participant success.

Mid-Program Diabetes Diagnosis

The DAA supports CMS's intention of allowing beneficiaries who develop type 2 diabetes to continue to receive the MDPP benefit after they have begun the program. We support the justifications given—that "the DPP model test, which demonstrated cost savings did not exclude from the model individuals who developed diabetes" and it would be "impractical and unduly burdensome" for suppliers to verify diabetes status and blood test results continually. Additionally, we note that the education gained in MDPP programs is generally appropriate for

individuals with type 2 diabetes, as well as those with cardiovascular disease, and will help them better manage their disease. We urge CMS to encourage MDPP suppliers to suggest newly diagnosed type 2 participants talk to their physician about their diabetes diagnosis and the potential benefits of additional Medicare services such as Diabetes Self-Management Training (DSMT). We also seek a clarification from CMS in this section. The Proposed Rule states "For example, a beneficiary receiving DSMT furnished by certified diabetes educators acquires knowledge for self-care and life style changes including blood sugar monitoring, insulin usage, medication management, and crisis management." The DAA asks CMS to clarify they intended to refer to a Medicare certified DSMT program given by health professionals with experience in diabetes education, not certified diabetes educators. The National Standards for Diabetes Self-Management Education and Support do not require health professionals to hold a certification in diabetes education.[1]

Finally, we want to call out an area of misalignment between MDPP and DPRP related to mid-program diabetes diagnosis. DPRP suggests that CDC will no longer want the DPRP program to submit data on any participant who received a type 2 diagnosis. This will cause a gap in the MDPP supplier's cross-walk between their DPRP data sheet and their documentation for the participant for invoicing CMS. DAA highly recommends that CMS and DPRP align on this topic of how to address, track and best support participants that receive a type 2 diagnosis during the MDPP benefit period.

Maintenance Sessions

We appreciate CMS is creating access to this important evidence-based program for Medicare beneficiaries at risk for diabetes. While the DAA is pleased that CMS reduced the burden on suppliers from offering maintenance sessions for an indefinite period, we remain concerned about this MDPP service as defined in the Proposed Rule. Translational research testing DPP in group classes by community-based organizations varied in length from one to two years and all participants, not just those who achieved a 5% weight loss goal, were eligible for the maintenance portion of the intervention.[2,3] The DAA strongly urges CMS to follow the translational research trial and structure the MDPP benefit as a two year benefit, with 6 months of core service and monthly maintenance for the next 18 months for all participants. The DAA encourages CMS to ensure maintenance sessions are adequately resourced if our recommendation on benefit structure is adopted.

We urge CMS to consider that seniors who enter maintenance sessions may desire to receive their maintenance sessions in a different location than where they received their core sessions. Many seniors travel to warmer climates for the winter or to be near family and might need to change their supplier accordingly. Furthermore, as the baby boom generation ages into

[1] Beck J, Greenwood DA, Blanton L, et al. 2017 national standards for diabetes self-management education and support [published online July 28, 2017]. Diabetes Care. 2017; **https://doi.org/10.2337/dci17-0025**.

[2] Ackermann RT, Finch EA, Brizendine E, Zhou H and Marrero DG. Translating the diabetes prevention program into the community The DEPLOY pilot study. Am J Prev Med 2008; 35: 357–363.

[3] Katula JA, Blackwell CS, Rosenberger EL, and Goff DC. Translating diabetes prevention programs implications for dissemination and policy. N C Med J 2011; 72: 405-408.

Medicare, we expect those seniors will be more accustomed to changing providers and "shopping around" for different experiences than previous cohorts of seniors. This has important implications not only for the maintenance sessions but also the ability of seniors to switch MDPP suppliers mid-program, as proposed by CMS elsewhere in this rule. (See below for our comments on how payment can ensure suppliers are able to provide for seniors who make the choice to switch during the core sessions or during the maintenance phase.) Additionally, approval of virtual suppliers to provide MDPP services would have a positive impact on this potential issue, as geographical changes wouldn't require a beneficiary to switch MDPP suppliers.

Once-Per-Lifetime Set of Services

The DAA is seriously concerned about the once-per-lifetime limit for MDPP included in the Proposed Rule and the precedent it sets. The once-per-lifetime limit will punitively deny some beneficiaries the benefits of a program that reduces Medicare expenditures while also improving health outcomes and quality of life for those at risk for diabetes. Research demonstrates that weight loss is extremely difficult and complex and some beneficiaries may need multiple attempts to be successful.[4] The Medicare program publicly acknowledges the science showing the need for repeated use of healthy lifestyle counseling for weight management in its current coverage policy for obesity counseling. Under the Medicare obesity counseling benefit, doctors are allowed to reassess a beneficiary for additional obesity preventive benefits after a six month period if they failed to achieve the original weight loss goal (6.6 lbs).[5] Smoking cessation is another example of a difficult and dramatic lifestyle change that can require multiple attempts.[6] In this area too, Medicare coverage policy is aligned with the literature on tobacco cessation and Medicare covers smoking cessation services two times per year for beneficiaries.[7] The majority of private payers who cover and reimburse diabetes prevention programs consider the intervention an annual benefit and the DPP model test allowed participants to reenroll after the yearlong program if they were still eligible.

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[4] Wing RR and Phelan S. Long-term weight loss maintenance. American Journal of Clinical Nutrition 2005; 82: 2225-2255.

[5] Centers for Medicare & Medicaid Services. National coverage determination (NCD) for intensive behavioral therapy for obesity, November 2011. Available online: https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=353&ncdver=1&CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=All&KeyWord=obesity&KeyWordLookUp=Title&KeyWordSearchType=And&bc=gAAAABAAAAAA

[6] Jones J. *Smoking habits stable; most would like to quit*. Gallup News Services, 2006. http://www.gallup.com/poll/23791/smoking-habits-stable-most-would-like-quit.aspx (accessed 21 Aug 2013).

[7] Centers for Medicare & Medicaid Services. National coverage determination (NCD) for smoking and tobacco-use cessation counseling, March 2005. Available online: https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=308&ncdver=1&DocID=210.4&ncd_id=210.4&ncd_version=1&basket=ncd%25253A210%25252E4%25253A1%25253ASmoking+and+Tobacco%25252DUse+Cessation+Counseling&bc=gAAAAAgAAAAAAA%3D%3D&

The DAA strongly urges CMS to rescind the once-per-lifetime limit and similar to Medicare coverage of obesity counseling and tobacco cessation, provide beneficiaries additional opportunities to participate in and benefit from MDPP. This will also better align Medicare coverage with the commercial market. In the previous section, the DAA proposed CMS amend the structure of the benefit from a three year program, to a two year program which aligns with the translational research that tested DPP in small groups. In concert with this recommendation, we urge CMS to allow beneficiaries who did not successfully complete the two year program to reenroll in the MDPP following a six month waiting period as long as they meet eligibility criteria. Instituting a 6 month waiting period between attempts would align this benefit with the Medicare obesity counseling benefit and address concerns that suppliers might abuse the system by automatically reenrolling participants.

At minimum, the DAA encourages CMS to include in future rulemaking an exception for participants who experience a major life event that may impact his or her ability to attend MDPP sessions. We recognize and appreciate that CMS has already taken steps to address some concerns with the allowance for four make up sessions, but we believe there may be circumstances that prevent or derail participation for longer than those four sessions. Examples of major life events may include (but are not limited to): newly-developed health condition (not diabetes-related) by the participant; newly-developed health condition of a loved one; surgery or injury of participant or a loved one; and death of a loved one. We urge CMS to consider how such an event could impact participation in the core sessions independently from the maintenance sessions and create a viable exception process.

We understand and sympathize with the balance CMS is trying to strike: dis-incenting a revolving door approach or "gaming" while simultaneously ensuring Medicare beneficiaries have access to this important preventive service *and* that MDPP suppliers supply cost-effective MDPP services. Yet if CMS leaves the once-per-lifetime rule in place, more guidance is needed to ensure that MDPP suppliers have accurate Part B information before enrolling a beneficiary, especially given the time lag on confirmed Part B enrollment. Until a real-time notification system is established for MDPP suppliers to check beneficiary eligibility for MDPP, when a beneficiary (wittingly or unwittingly) applies to receive the benefit but is later determined to be ineligible based on the once-per-lifetime limit, CMS should supply guidance or payment to MDPP suppliers that would address the costs of services already provided before the MDPP supplier was notified that the beneficiary was determined to be ineligible.

Payment Structure and Bridge Payment

The DAA applauds CMS for moving toward performance-based payment. This structure, in accordance with how the MDPP model test was performed and the stated goals of CMS, promotes valuable, cost-saving interventions rather than a volume-based focus.

Although the DAA is not commenting on specific payment provisions, we want to ensure core and maintenance sessions and their payments are structured and resourced in a way that supports the patient and enables them to get the services they need. We urge CMS to consider

payment levels that adequately cover the cost of providing core and maintenance session services, respectively.

The DAA also urges CMS to consider the *distribution* (as opposed to the amount) of payments over the course of the program. For example, most supplier costs (e.g., administrative costs, staffing, beneficiary engagement, recruitment, etc.) are incurred up front or in the initial weeks of the program. This will require MDPP suppliers to amass enough capital to pay for this largely on their own until they receive the first outcomes-based payments. Addressing these capital-related concerns will allow for a greater variety and number of MDPP suppliers (i.e., more community-based suppliers) to offer DPP to Medicare beneficiaries. We recognize and appreciate that CMS has already taken some steps to address this. We urge CMS to keep this in mind as the Proposed Rule is finalized.

Another issue is how the payments are distributed when a beneficiary switches between suppliers. While we applaud CMS for anticipating this and proposing a bridge payment to make up for costs, this may not be enough depending on the timing of the switch. For example, if the beneficiary has already met most of their weight goals or entered the maintenance portion of the program, most of the payments will have already gone to Supplier A while Supplier B is then responsible for administering the entire maintenance session portion of the benefit without reaping any of the rewards of the performance-based payment. Even if the volume of such switching is low, capital will still be required to fill in the gap between the cost to administer the program and the amount of funds the supplier is eligible to receive at that point based on how far the beneficiary has gone through the program.

The DAA understands CMS' need to account for Medicare program costs but also believes that to promote widespread access to MDPP, we must ensure that providers are incentivized to invest in these critical programs.

Payment Considerations for Social Risk Factors

The DAA is concerned CMS is proposing a payment structure that does not consider socioeconomic status. As noted in the Proposed Rule, low-income participants lose, on average, one percentage point less weight than other participants**.** (Evidence shows that type 2 diabetes is most prevalent in underserved communities and the CDC has identified this as a priority area of DPP expansion.[8]) Additionally, evidence shows that patients who achieve weight loss of just 2% to 5% reap health benefits including improved glucose, systolic blood pressure, and triglycerides.[9] In the proposed DPRP standards, CDC implied, but did not directly explain or include any type of evaluation formula that it intends to adjust for socioeconomic status. DAA is pleased that CDC seems to have acknowledged the impact of socioeconomic status but CDC will need to transparently propose how it plans to use data to adjust for socioeconomic status including what the formula will be. We urge CMS to continue to align with CDC and the DPRP

[8] https://www.cdc.gov/diabetes/programs/national-dpp-foa/index.html

[9] Wing RR, Lang W, Wadden TA, et al. Benefits of modest weight loss in improving cardiovascular risk factors in overweight and obese individuals with type 2 diabetes. Diabetes Care 2011; 34: 1481-1486.

and to encourage and/or incentivize suppliers, through fully transparent policy, to deliver MDPP in low-income areas.

MDPP Supplier Enrollment and Preliminary Recognition
On these sections, the DAA would like to once again emphasize the need for timely guidance from CMS. To help ensure a successful implementation of MDPP, we suggest CMS create a timeline of when suppliers and other stakeholders can expect to receive guidance from CMS and what will be contained in each portion of the guidance. We also recommend CMS create a process through which MDPP suppliers can get questions answered outside of the regular rulemaking process as they begin the process of enrollment and claims submission. Such a process will be critical as the enrollment will be new both to MDPP suppliers and the Medicare program. CMS should consider making some answers public, or publishing a FAQ, if the topic is not proprietary for an individual MDPP supplier.

In addition, we urge CMS to provide guidance on how beneficiaries can continue to receive the MDPP benefit (with as smooth of a transition as possible) if a MDPP supplier loses its preliminary recognition status, fails to achieve full recognition status, goes out of business, or is otherwise unable to continue to deliver the benefit.

MDPP Supplier Standards
The DAA wishes to underscore that DPP suppliers already conform to high standards in the DPRP which mitigate fraud, waste and abuse.

Regarding MDPP supplier enrollment forms, the DAA urges CMS to use sub-regulatory processes to provide MDPP suppliers with as much advance notice and guidance as possible to enable providers to be ready to begin accepting beneficiaries on April 1, 2018. To this end, we encourage CMS to (1) share as early as possible the forms MDPP suppliers will need to fill out to enroll as Medicare suppliers; (2) solicit input on the form from DAA and other key stakeholders; and (3) work with the Medicare Administrative Contractors (MACs) to ensure they are ready to work with MDPP suppliers as they become enrolled.

Engagement Incentives
The DAA is pleased to see that CMS is contemplating engagement incentives that support patients in their pursuit of the clinical goals of MDPP. Items or services that are not traditionally covered by Medicare such as gym memberships, fitness trackers, and digital scales may significantly improve beneficiary success in the MDPP benefit. That said the types of incentives CMS proposes in the rule are new to fee-for-service Medicare as far as we know and CMS has not provided any information on the evidence base, if any, for the proposed incentives. We note states' efforts to incentivize healthy behaviors in the Medicaid program have had limited impact and are difficult to administer.[10] We strongly urge CMS to collect data from MDPP

[10] Blumenthal KJ, Saulsgiver KA, Norton L, et al., Medicaid Incentive Programs to Encourage Healthy Behavior Show Mixed Results to Date and Should be Studied and Improved, 32 Health Affairs 3, March 2013. See also, Askelson

suppliers to study the effects of the various incentives furnished to MDPP beneficiaries, including whether beneficiaries receiving the incentives actually maintained participation. This will help inform effective incentive designs that could be offered to beneficiaries and inform best practices.

We urge CMS to clarify that MDPP suppliers are prohibited from requiring MDPP participants to shoulder any of the costs of such incentives, including incentive structures that financially penalize beneficiaries. We also urge CMS to solicit further input regarding the feasibility of MDPP suppliers bearing the costs of such incentives given that it may be difficult for suppliers to amass the resources needed to provide such incentives before claims payments are received without cost-shifting.

Virtual Medicare DPP

We are extremely disappointed that virtual delivery of MDPP is not included in the Proposed Rule. Virtual delivery of MDPP 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.) The data collected from the CDC's National DPP now includes information on thousands of participants who have received the DPP from qualified virtual providers. These include significant numbers within the Medicare population, and were not considered in the original actuarial assessment by CMS. CMS and the CMS Actuary have the discretion to consider data either submitted or referenced in the comments to this rulemaking to make a final determination of improved patient health outcomes and/or cost neutrality or cost savings. Therefore, DAA urges CMS and the CMS Actuary to consider data CDC has gathered from virtual DPP providers since the Physician Fee Schedule (PFS) for CY 2017 was released in July 2016. The DAA notes there are no statutory or regulatory prohibitions on CMS or the CMS Actuary to consider this available data. The data for virtual DPP demonstrates comparable efficacy to that of the in-person DPP providers in the CDC database and is the same data source CMS relied upon when making a determination that expansion of the in-person program is justified because of the improved patient health outcomes and overall efficacy. The DAA strongly supports inclusion of virtual DPP in the expanded model and if CMS is able to include data from virtual DPP in the recertification implementation of MDPP it should do so – as long as implementation of the MDPP benefit is not slowed beyond the April 1, 2018 start date in the Proposed Rule.

If CMS is still unwilling to include virtual DPP providers as eligible to furnish MDPP services as a fee-for-service supplier, we encourage CMS to provide confirmation and guidance that Medicare Advantage plans can contract with CDC recognized DPPs, including virtual DPP providers, to fulfill their obligations under the final rule, and can utilize these providers to meet network adequacy requirements.

NM, Wright B, Bentler S, et al., Iowa's Medicaid Expansion Promoted Healthy Behaviors But Was Challenging to Implement and Attracted Few Participants, 36 Health Affairs 5, May 2017.

If CMS does not adopt our recommendation to include virtual DPP providers as eligible MDPP suppliers in the Final Rule, we stand ready to work with you on a separate model test of virtual MDPP services conducted in parallel with the MDPP expanded model as is described in the Proposed Rule. Coverage of virtual 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 CMMI 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.

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 Meghan Riley at mriley@diabetes.org 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 Diabetes Association

American Podiatric Medical Association

Endocrine Society

Healthcare Leadership Council

National Council on Aging

Novo Nordisk, Inc.

Omada Health

Weight Watchers International

YMCA of the USA