September 9, 2024

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services,
Department of Health and Human Services
Attention: CMS-1807-P
P.O. Box 8016,
Baltimore, MD 21244-8016

RE: CMS-1807-P

Dear Administrator Brooks-LaSure:

The undersigned member organizations of the Diabetes Advocacy Alliance (DAA) are pleased to submit comments to the Centers for Medicare & Medicaid Services (CMS) regarding proposed rule: **Medicare and Medicaid Programs; CY 2025 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Prescription Drug Inflation Rebate Program; and Medicare Overpayments**.

The DAA is diverse in scope, with our members representing patient, professional and trade associations, other non-profit organizations, and corporations, all united to change the way diabetes is viewed and treated in America. Since 2010, the DAA has worked with legislators and policymakers to increase awareness of, and action on, the diabetes epidemic.

DAA members share a common goal of elevating diabetes on the national agenda so we may ultimately defeat this treatable, but deadly chronic disease. We are committed to advancing person-centered policies, practical models, and legislation that can improve the health and well-being of people with diabetes and prediabetes. An essential component to our goal is combating health disparities and addressing social determinants of health. Our advocacy to policymakers highlights key strategies to prevent, detect and manage diabetes and care for those affected by it. Our educational outreach also illustrates the health equity implications of existing or new policies, regulations, and legislation, and provides alternatives to address the drivers of these inequities.

DAA members have greatly appreciated discussions and meetings that we have had with Center for Medicare and Medicaid Innovation (CMMI) staff members over the decade since the CMMI pilot launched, especially most recently with David Dietz, Colleen Barbero, and Tina Cooley. They have been open to receiving comments from DAA members about improvements to the Medicare

Diabetes Prevention Program (MDPP) aimed at expanding the program's reach to more Medicare beneficiaries and improving its overall effectiveness at preventing diabetes. To this end, more recently they have shared their plans to increase the number of MDPP suppliers and better address health inequities, including efforts to reach Medicare beneficiaries in rural areas who could benefit from the MDPP. DAA members agree these are important goals and reiterate our openness to collaborating with CMMI staff in efforts to recruit and maintain MDPP suppliers and better address health inequities.

In our collective review of the CY 2025 Medicare Physician Fee Schedule (PFS), we are pleased to see some proposed changes that address DAA priorities, highlighted below. We also offer several additional recommendations that could help build on several proposals to further advance CMS's core goals of expanding access to and affordability of diabetes prevention and treatment in the United States, so that we can once and for all defeat this deadly, yet treatable disease.

Medicare Diabetes Prevention Program (MDPP)

DAA member organizations support the changes proposed by CMS to further conform and align MDPP Standards with the CDC's 2024 Diabetes Prevention Recognition Program (DPRP) Standards. Such alignment will ease some administrative hurdles for supplier organizations that currently provide both National DPP and MDPP services. Alignment with DPRP standards will make it easier to recruit suppliers to the MDPP that are already National DPP suppliers and/or lapsed MDPP suppliers that may find the lack of CDC-CMS alignment burdensome.

We applaud CMS for proposing to use the same definitions for delivery modalities 1-3 as the CDC's DPRP (i.e., in-person, distance learning, and in person with a distance learning component). We believe these types of definitional symmetries will help to promote consistency between both programs and reduce burden among suppliers. In this same vein of promoting consistent standards between both programs, we reiterate our previous recommendation for CMS to include DPRP modalities 4 and 5 (online/fully virtual and combination with an online component) in the MDPP.

We also applaud the CMS proposal to adopt a previous DAA recommendation to permit beneficiaries to take a makeup session on the same day as a regularly scheduled session. Our experience supports your reasoning that "this new requirement would contribute minimal additional complexity to the payment structure while creating a flexibility that would have value for the program, particularly for beneficiaries in the core phase of MDPP who may not have transportation to 2 in-person sessions in one week or have the flexibility to make time on more than one day per week for a distance learning session." Medicare beneficiaries who participate in in-person MDPP programs will benefit from reduced travel to and from program sites for make up sessions and MDPP suppliers will benefit from such a change as well. We urge CMS to expand on this recommendation and more fully align the MDPP with the CDC's DPRP guidance that makeup sessions can be delivered via any modality. Like the proposed change to allow a makeup session on the same day as another MDPP session, we believe this will provide even greater flexibility and more consistency between the two programs, reduce burden among suppliers, and promote compliance among program participants, all with little downside.

We also appreciate and support that CMS is proposing to make administrative changes to help Medicare Administrative Contractors (MACs) process same day makeup sessions in MDPP.

The DAA strongly supports CMS exploring avenues to allow for more flexible standards for self-reporting weight, something for which the DAA has long advocated. We believe common sense strategies to report weight have the potential to reduce burden among program participants, thereby increasing compliance with and completion of the program, particularly among non-in person participants, which will be critical to the program's growth and expansion, particularly in rural areas. Regarding submitting two date-stamped photos to document weight for MDPP participants in distance learning programs, we were pleased to see CMS realize the difficulty of MDPP participants taking one picture of themselves that shows both their weight on a scale and their face. We believe the proposed two-photo option may continue to pose a challenge for some MDPP beneficiaries, especially those who may live alone, lack a phone with a camera, and/or lack someone who can photograph them. We note that when photos are taken by a mobile phone, they already have in their metadata both the date and time stamp as well as geolocation when taken. Accordingly, we recommend CMS allow such metadata to count toward the date-stamped requirement.

We note that CMS has proposed a new option to collect weights during live, synchronous video conferencing, wherein the MDPP Coach observes the beneficiary weighing themselves and the resulting weight record. While we appreciate this effort by CMS to offer additional options for reporting weight for participants who are remote, we worry this new option may be difficult to implement in practice, as supplier staff would need to be available for weight-check appointments, and such visits are unlikely to be billable. They would also have to schedule a time that works for both coach and participant, which could be challenging. To reduce burden on both the supplier and the beneficiary, the DAA recommends that MDPP participants be able to submit photo or video weight records without a synchronous component. Importantly, these changes could expand access to the MDPP for rural and underserved populations.

Overall, we are encouraged by these proposed additional flexibilities that can ensure accurate recordings, while helping to overcome barriers and close access gaps. We encourage CMS to continue exploring additional methods to report weights, such as using digital scales that report weights directly to the Coach or to a mobile phone application where that data can be forwarded.

To further reduce burden on both suppliers and beneficiaries, we propose that MDPP align with NDPP on the risk-reduction metrics which include not only weight-reduction measures, but also include measuring participant's physical activity minutes and A1C reduction:

1) weight loss in the range of 5-7% of baseline body weight;

2) a combination of a loss of 4% of baseline body weight and at least 8 sessions associated with an average of 150 minutes/week of physical activity;

3) a combination of a loss of 4% of baseline body weight and at least 17 sessions attended; or

4) a modest reduction in hemoglobin A1C (A1C) of 0.2%."[1]

Weight loss is not the only way to demonstrate risk reduction, and some populations may find it challenging to lose 5% of their weight. MDPP already allows for verified A1C as an eligibility criterion and according to the Medicare website, beneficiaries that qualify to get diabetes screenings, which

includes those eligible for the MDPP, can get up to 2 A1C checks each year (within 12 months of their most recent screening).[2]

DAA member organizations also support the CMS proposal to remove the MDPP bridge payment and align rule language with previous rulemaking. We agree that the bridge payment is no longer necessary.

We greatly appreciate that CMS has proposed several steps to more fully align the MDPP with the CDC's National DPP and its 2024 DPRP Standards. However, there are several important opportunities for further alignment that we believe CMMI should explore in earnest that would promote symmetry between the programs, reduce burden on MDPP suppliers, and support program growth to additional regions and beneficiaries.

To start, the DPRP includes suppliers of asynchronous online content. The DAA continues to implore CMS to allow suppliers of asynchronous online NDPPs to become MDPP suppliers. Several DAA members are also pursuing legislation that would require CMS to open the MDPP to suppliers of asynchronous online MDPP programs (the PREVENT DIABETES Act [H.R. 7856).

As we have recommended in prior years' Medicare PFS comments, we also continue to request that CMS remove the once-in-a-lifetime limit for Medicare beneficiaries to participate in the MDPP. We believe that CMS should allow repeat participation in the MDPP, just as it is allowed for intensive behavioral therapy for obesity and smoking cessation programs, because it is recognized that multiple attempts are often required for lasting behavioral changes. Not all Medicare beneficiaries that begin an MDPP program can complete the number of sessions necessary to achieve behavior change that is required to reduce their risk of developing type 2 diabetes, for reasons that might include changes in health status, or other major life events or caregiving responsibilities. Additionally, beneficiaries may spend several decades on Medicare, especially if they enter the program well before 65 (e.g., via a permanent disability), and the strategies they learned at a younger age may no longer align with their life circumstances in later years. Accordingly, the undersigned DAA members strongly encourage CMS/CMMI to eliminate the once-in-a-lifetime benefit restriction for the MDPP.

Lastly, we continue to support making the MDPP a permanent benefit in Medicare. Doing so could entice more National DPP suppliers to apply to be MDPP suppliers and could entice potential suppliers to create new diabetes prevention programs, seek CDC DPRP recognition, and apply to be MDPP suppliers, because such suppliers would know that the tremendous efforts involved in establishing a program and becoming an MDPP supplier would be an investment in what could be a long-term MDPP product offering for their Medicare beneficiary constituents. We recognize that to justify expansion, CMS must demonstrate that the program benefits patient care and helps to control Medicare costs. We believe the recommendations offered above would promote the program's expansion and support this end goal. We also offer the joint support of our undersigned organizations as well as the whole of the DAA to promote the program, including any finalized changes, and to continue to attract new suppliers, boost physician referrals, and enroll additional beneficiaries in the program.

Conclusion

The undersigned members of the DAA greatly appreciate this opportunity to provide comments to the MDPP sections of the CY 2025 Medicare PFS. Over the years, we have appreciated the many opportunities that you and other CMS/CMMI staff have provided to us to express our concerns, and we are pleased to see some of these concerns addressed in the CY 2025 Medicare PFS. We want to continue our dialogue with you and work to address some outstanding concerns described in this letter.

We share a goal with CMS: innovative preventive services and programs for Medicare beneficiaries that address prevention of diabetes and improve treatment and care of diabetes to stabilize health in a cost-effective, health equitable manner. We stand ready to provide more information if requested and would be available for consultation as it relates to your questions or our comments. To contact the DAA, please connect with Katie Adamson, DAA Co-Chair, with the YMCA of the USA (katie.adamson@ymca.net).

Sincerely,

The Undersigned Member Organizations of the Diabetes Advocacy Alliance

Academy of Nutrition and Dietetics
American Diabetes Association
American Medical Association
American Podiatric Medical Association
Association of Diabetes Care & Education Specialists
Black Women's Health Imperative
Diabetes Leadership Council
Diabetes Patient Advocacy Coalition
Endocrine Society
National Association of Chronic Disease Directors
National Council on Aging
Noom, Inc.
Omada Health, Inc.
Teladoc Health
WeightWatchers
YMCA of the USA

[1]Centers for Disease Control and Prevention. Diabetes Prevention Recognition Program: Standards and Operating Procedures. p.10. June 1, 2024. https://www.cdc.gov/diabetes-prevention/media/pdfs/legacy/dprp-standards.pdf. Accessed August 28, 2024.

[2]Centers for Medicare and Medicaid Services. Diabetes screenings. https://www.medicare.gov/coverage/diabetes-screenings. Accessed September 3, 2024.