September 11, 2023

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-1784-P
P.O. Box 8016,
Baltimore, MD 21244-8016

Dear Administrator Brooks-LaSure:

On behalf of the undersigned member organizations of the Diabetes Advocacy Alliance (DAA), we are pleased to submit comments to the Centers for Medicare & Medicaid Services (CMS) regarding CMS-1784 P, RIN 0938-AV07, Medicare and Medicaid Programs; CY 2024 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Advantage; Medicare and Medicaid Provider and Supplier Enrollment Policies; and Basic Health Program.

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 the many meetings and discussions that we have had with members of your staff over the past few years. Earlier this year, we met with Dr. LaShawn McIver, who at the time was the Director of the Office of Minority Health (OMH), and key members of her staff, who

are developing a Diabetes Strategy for CMS. We would like to especially thank Dr. Bill Mayer, who has conducted two meetings with DAA member representatives. Dr. Mayer has shared information with us and been open to listening to our concerns, both in group settings, and one-to-one with a few DAA member organizations.

In our collective review of the CY 2024 Medicare Physician Fee Schedule (PFS), we are pleased to see some proposed changes that address some concerns we have expressed to you over the years, and we highlight these items in our comments, below. We also offer several additional recommendations that could help to build on these proposals to further expand access to and affordability of Diabetes and prediabetes prevention and treatment in the U.S. so we can once and for all defeat this deadly, yet treatable disease.

I. Expand Diabetes Screening and Modify Diabetes Definition (Section III.L.)

DAA Supports These Proposals in the PFS:

- **Finalize proposals to cover the Hemoglobin A1c (HbA1c) test for diabetes screening purposes and expand frequency limitations for diabetes screening to twice within a rolling 12-month period.**

Members of the DAA fully support CMS' proposal to "add the HbA1c test to the types of diabetes screening tests covered under § 410.18(c), in consultation with recommendations by appropriate organizations." (p. 785) We greatly appreciate that you have heard our arguments over several years, and those of other organizations, that CMS should follow the USPSTF's recommendation for diabetes screening, which includes the use of the HbA1c test, because it has "certain unique advantages and disadvantages compared to the FPG and GTT tests that should be considered by the practitioner and patient when choosing a diabetes screening test." (p. 789) Importantly, this proposal also aligns with standards of care to reimburse HbA1c for the purposes of diagnosis. Allowing use of the HbA1c test to identify beneficiaries for referral to diabetes prevention programs reduces a barrier to physicians identifying patients with prediabetes and referring them to evidence-based treatment including the MDPP, because patients would not be required to fast or adjust behavior to be screened.

We similarly appreciate and support the CMS proposal to "simplify frequency limitations for diabetes screening by aligning to the statutory limitation of not more than twice within the 12-month period following the date of the most recent screening test of that individual." (pgs. 785-86) This change will allow physician-led care teams to screen as clinically appropriate for individual beneficiaries based on their unique needs, thereby improving patient outcomes. DAA members urge CMS to **expand on these proposals by waiving cost sharing for the beneficiary patient deductible for HbA1c tests to encourage their uptake and matching commercial coverage of the HbA1c test for screening and diagnosis.**

Again, we greatly appreciate the afore-mentioned changes to Medicare Diabetes screening coverage policies, which if finalized, will yield historic, positive changes in Medicare beneficiaries' ability to access diabetes and prediabetes screening. **But the fact that beneficiaries have a deductible cost for HbA1c tests remains a major barrier.** This deductible disproportionately affects low income and other vulnerable beneficiaries and can cause them to refuse a test that could lead to a diagnosis of prediabetes and referral to MDPP programs or get them started on treatment for previously undiagnosed diabetes. Screening for diabetes and prediabetes is a USPSTF Grade B benefit, which means that when screening for diabetes is covered, it must be covered without patient responsibility. Medicare therefore should also not require patient cost sharing for this critical screening test.

DAA Supports This Proposal in the PFS:

- **Finalize proposals to streamline the definition of diabetes by removing codified clinical test requirements, which are currently required for diabetes screening, Medical Nutrition Therapy (MNT), and Diabetes Self-Management Training (DSMT) services.**

DAA members agree with and support the proposed revised definition of diabetes for purposes of diabetes screening, and the proposal to remove codified clinical test requirements from the definition of diabetes and prediabetes for MNT and DSMT services.

DAA members appreciate that CMS recognizes that it is unnecessary to codify clinically specific test criteria into the regulatory definition of diabetes, which "reduces flexibility for the agency and health care system to adapt to evolving clinical standards without potentially producing programmatic benefit." CMS proposes to shorten the definition of diabetes for screening purposes to describe diabetes simply as diabetes mellitus, a condition of abnormal glucose metabolism, thereby eliminating the distinction between screening for prediabetes and diabetes. This new definition will help improve the referral process, reduce returned referrals and claims that were denied, and therefore improve patient access to diabetes care services. This new definition will also preemptively solve any future problems if the diagnostic criteria were to change and create misalignment between the benefits' regulations and standard of care.

II. Diabetes Self-Management Training (DSMT) and Medical Nutrition Therapy (MNT) Services

<u>Billing Clarification When Acting on Behalf of a DSMT Entity</u>

DAA Supports This Proposal in the PFS:

- **Finalize language that clarifies billing when Registered Dietitian Nutritionists (RDNs) act on behalf of a DSMT entity.**

DAA members appreciate that CMS has heard the concerns expressed by the Association of Diabetes Care & Education Specialists (ADCES) and the American Diabetes Association (ADA), which have noted that "§ 410.72(d) has caused confusion" about whether RDNs can bill for DSMT services provided by other providers. CMS's proposed language would distinguish between when RDNs are providing/billing for Medical Nutrition Therapy (MNT) and when they are acting on behalf of an accredited DSMT entity and billing for the services of the program provided by multiple professionals.

We thank CMS for proposing a regulatory change that provides an addition to § 410.72 Registered dietitians' and nutrition professionals' services, stating: "(d) Professional services. *Except for DSMT services furnished as, or on behalf of, an accredited DSMT entity,* registered dietitians and nutrition professionals can be paid for their professional MNT services only when the services have been directly performed by them." This helpful technical correction will provide clarity when RDNs bill for DSMT to ensure they are abiding by regulatory guidelines.

<u>Payment for Medicare Telehealth Services</u> (Section II.D)

DAA Supports These Proposals in the PFS and Urges CMS to Finalize Them:

- **Extend telehealth flexibilities, including permanently allowing one-hour trainings required for insulin-dependent beneficiaries to be provided via telehealth, permanently allowing distant site DSMT practitioners to report DSMT services that are furnished via telehealth (including when performed by others within the DSMT entity), and allow institutional providers to continue to bill for DSMT and MNT services when furnished remotely through the end of CY 2024.**
- **Regulate DSMT and MNT delivered via telehealth from an HOPD setting under 1834(m), which section II.I.4 of this rule is amending, with respect to DSMT to clarify telehealth billing.**
- **When finalizing these policies, DAA recommends including some language modifications to account for programs billing under facility NPIs and pharmacy-based programs.**

We support the alignment of regulations for providing/billing for telehealth DSMT with DSMT delivered in person. However, we have concerns with the exact language proposed for 410.78(b)(2)(x). We are concerned that tying this change solely to "any distance site practitioner" will mean that DSMT billed under the hospital/clinic NPI rather than a professional's NPI will still be subject to the original set of telehealth rules that only allow telehealth services to be provided/billed for by a subset of the provider types who deliver DSMT. This will become particularly crucial if CMS moves forward with regulating DSMT and MNT delivered in the HOPD setting under 1834(m). We are also concerned that the proposed language will not apply to pharmacy-based programs that submit claims as suppliers and will preclude pharmacy-based accredited DSMT programs from delivering DSMT via telehealth in the future.

Members of the DAA support the CMS proposal to extend telehealth coverage through 2024 when hospital out-patient department (HOPD) institutional staff provide DSMT or MNT to beneficiaries in their homes. In response to the question as to whether these services may fall within the scope of Medicare telehealth at section 1834(m) of the Act, DAA members agree.

We also support the proposed elimination of the requirement for in-person injection training. However, we have concerns with the exact language proposed for 410.78(e)(3). Specifically, we are concerned that "distance site practitioner" language may not apply to programs billing under a facility NPI rather than a personal provider NPI or to pharmacy based DSMT programs, and we encourage CMS to account for this in its final policy.

DAA Recommendation:

- **Adopt alternate language for the new sections labeled 410.78(b)(2)(x) and § 410.78(e)(3).**

We encourage CMS to consider alternate language for the new section: 410.78(b)(2)(x) whereby any distant site practitioner ***or approved entity*** who can ***bill for*** diabetes self-management training services may do so on behalf of others who personally furnish the services as part of the DSMT entity.

We also encourage CMS to consider alternate language for the new section: 410.141(e)(3) such that the distant site practitioner ***or approved entity*** who ***furnishes*** the DSMT services may bill and receive payment when a professional furnishes injection training for an insulin-dependent patient using interactive telecommunications technology when such training is included as part of the DSMT plan of care referenced at § 410.141(b)(2).

DAA Recommendation:

- **Finalize additional changes to further strengthen and expand access to DSMT and MNT services by allowing them to be delivered on the same day.**

The preclusion of payment for DSMT and MNT when delivered on the same day stems from the MNT benefit's law. Despite CMS' own 2002 memo[1] explicitly finding no need to have a waiting period between DSMT and MNT, CMS determined at the time that the legislative language required some form of waiting period and picked the shortest period possible (one day). The result is that beneficiaries referred to both DSMT and MNT need to schedule their visits on separate days even if a single clinic or provider can provide them with both services. This waiting period is explicitly not evidence-based per CMS's own findings and therefore, we **would encourage CMS to consider that implementing a zero-day waiting period, thus allowing DSMT and MNT to be delivered on the same day, would meet the definition of a "time period determined by the Secretary" from the law,** as nothing in the law requires the time period be a non-zero number of days, and align with subsequent guidance from the agency.

DAA Recommendation:

- **Eliminate patient cost-sharing for DSMT services.**

Cost-sharing for DSMT presents an additional barrier for lower-income beneficiaries to receive this highly underutilized service. Having to pay for 100 percent of the service until the deductible is met and then 20 percent between meeting the deductible and reaching the out-of-pocket maximum represents a significant barrier to self-management of one of the most expensive medical conditions and creates inequitable access to care for lower-income beneficiaries. The DAA encourages CMS to explore all options available under its existing authorities to waive the cost sharing for DSMT, whether program-wide or as part of testing models related to diabetes.

DAA Recommendation:

- **Simplify billing for MNT and DSMT from the HOPD setting.**

Uptake of MNT by people with diabetes is very low. The CY 2022 Medicare Physician Fee Schedule (pps. 39259 through 39261) reported that between 2018-2020, participation of MNT utilization among Medicare beneficiaries was less than two percent. While the benefit has undergone policy changes aimed at increasing beneficiary utilization of MNT, barriers still exist. Billing for MNT when it is delivered from a hospital outpatient department is complex, providers and billers need to navigate a complicated path of cross-referencing numerous documents to understand Medicare policies, requirements, and guidelines. The myriad practical questions faced when trying to set up care delivery and billing systems and the challenges in trying to find answers to those questions came to the forefront at the onset of the COVID-19 Public Health Emergency (PHE) when the need for telehealth flexibilities became apparent. While instructing a hospital to bill for Part B MNT services the same as in-person services will help streamline billing between virtual and in-person services, unfortunately, facilities often do not know how to bill for it as an in-person service. Accordingly, we recommend CMS leverage this opportunity to

[1] Evidence for Coverage of MNT for Beneficiaries Who Have Received DSMT During the Same Time Periodhttps://www.cms.gov/medicare-coverage-database/view/ncacal-decision-memo.aspx?proposed=N&NCAId=53&fromdb=true#:~:text=Pursuant%20to%20the%20exception%20at%2042%20CFR%20410.32,orders%20additional%20hours%20during%20that%20episode%20of%20care.

work collaboratively with stakeholders to further streamline billing requirements for both in-person and virtual MNT and DSMT services when provided from a HOPD setting.

DAA Recommendation:

- **Eliminate the 12-month clock on initial hours of DSMT.**

While we appreciate that CMS's original intent may have been to encourage beneficiaries to receive a higher volume of training upfront to kick-start self-management, the result instead has been that most beneficiaries are losing access to a portion of those 10 initial hours after not utilizing them all during the initial 12-month period. Additionally, there is no clinical evidence supporting that the initial hours of DSMT should necessarily be used within a 12-month period. Accordingly, CMS should eliminate the 12-month clock and allow the 10 initial hours to remain available until used. Achieving this would only require CMS to delete 42 CFR §410.141(c)(1)(i)(B).

DAA Recommends:

- **Allowing for an additional 10 hours of DSMT upon a change in the condition, diagnosis, or treatment regimen.**

Diabetes is a progressive disease, and the therapies, including self-management strategies, need to be equipped to manage the disease changes over time. The four critical times to provide DSMT recommended by seven of the nation's leading diabetes care organizations are: 1) at diagnosis, 2) annually and/or when not meeting treatment targets, 3) when complicating factors develop, and 4) when transitions in life and care occur.[2] The current benefit design of 10 initial hours and only two hours in subsequent years creates what borders on a once-in-a-lifetime benefit that only provides access to *intensive* education on self-management strategies at one point in time. We fear that the current benefit design is encouraging referring providers to see the service this way as well, which may contribute to low utilization of the two follow-up hours currently available. Instead, the benefit should be flexible enough to allow referring providers to certify that a beneficiary has had a change in medical condition, diagnosis, or treatment regimen and therefore needs access to a new allocation of 10 hours, which also we recommend not have an expiration timeframe. This would align with the MNT national coverage determination and regulation which reflects the progressive nature of diabetes and kidney disease and the need for modified dietary strategies over time. The MNT benefit has not seen levels of utilization in subsequent years that would cause concern for overutilization or fraud, which we believe would be reflected in DSMT if a similar change were made.

III. Medicare Diabetes Prevention Program (MDPP) (Section III.I)

DAA Supports These Proposals and Urges CMS to Finalize Them:

- **Extension of the MDPP model through 2027 and clarifying that MDPP suppliers have the option to continue delivering their programs through distance learning/synchronous telehealth sessions.**

[2] Powers MA, Bardsley JK, Cypress M, et al. Diabetes Self-management Education and Support in Adults with Type 2 Diabetes: A Consensus Report of the American Diabetes Association, the Association of Diabetes Care & Education Specialists, the Academy of Nutrition and Dietetics, the American Academy of Family Physicians, the American Academy of PAs, the American Association of Nurse Practitioners, and the American Pharmacists Association. *The Diabetes Educator*. 2020;46(4):350-369.

- **Strengthening the payment structure by moving to a hybrid structure that pays for attendance on a fee for service basis, including allowing payment for up to 22 sessions during the 12-month core services period.**
- **Conforming to CDC Recognition Levels by finalizing the proposal to amend § 424.205(a) and (c) to remove "MDPP interim preliminary recognition" and replace it with "CDC preliminary recognition.**

DAA members strongly support the proposals in Section III.I. that call for extending the MDPP model through 2027, which will provide stability to the program. Stability is important as CMS and suppliers seek to grow beneficiary participation. We also support the proposal to clarify that MDPP suppliers have the option to continue delivering their programs through distance learning/synchronous telehealth sessions. We believe these important flexibilities will allow the MDPP to continue to grow and offer beneficiaries increased flexibility when it comes to how they would like to optimally receive services, which also has important equity implications in terms of reaching potentially underserved communities or individuals who face challenges making in-person appointments, including those lacking access to transportation, those with mobility issues, and individuals that struggle to take extended leave from work. In addition, we urge CMS to consider removing the requirement to maintain in-person recognition to allow distance learning-only suppliers to align with CDC's Diabetes Prevention Recognition Program (DPRP) standards, which we address in further detail in our recommendations, below.

DAA members strongly support CMS's proposals to move from a performance-based attendance and outcomes (weight loss of 5 and 9 percent) payment structure to a hybrid structure that pays for attendance on a fee-for-service basis. We strongly support allowing payment for up to 22 sessions during the 12-month core services period. Finalizing these proposals should increase payments for MDPP suppliers, many of whom have been operating MDPP programs at a loss. Finalizing these proposals also helps reduce health inequities by reducing disincentives in the current outcomes-based reimbursement approach. Many MDPP suppliers serve populations that may be less likely to achieve the 5 percent weight loss threshold, and therefore, have operated at a financial loss.

DAA members have long made the case to CMS/CMMI to fully align the MDPP with CDC's National Diabetes Prevention Program (National DPP), to reduce or eliminate differences in program eligibility, delivery modalities, and program duration. Accordingly, we strongly support the proposed change to replace the current MDPP "interim preliminary recognition" with "CDC preliminary recognition," and encourage the agency to consider additional ways to continue streamlining requirements between the two similar programs, including in how suppliers are defined, as outlined below. Alignment of the two programs would give suppliers of the National DPP that wish to provide the MDPP incentives to do so. Alignment would reduce barriers to entry into the MDPP, increasing MDPP suppliers and increasing access to and utilization of the MDPP benefit by Medicare beneficiaries.

DAA Recommends These Changes to MDPP to Improve Program Viability:

- **Removing the once-in-a-lifetime benefit cap to allow repeat participation in the MDPP.**
- **Classifying MDPP suppliers as medium fraud risk to ease supplier registration requirements.**
- **Removing the requirement to maintain in-person recognition to allow distance learning-only suppliers to align with CDC's DPRP standards.**
- **Making the MDPP a permanent Medicare covered benefit.**
- **Allowing CDC-defined online providers of DPRP-recognized programs to apply to become suppliers in the MDPP.**

CMS should allow repeat participation in the MDPP, just as it is allowed for intensive behavioral therapy for weight loss and smoking cessation programs, because it is recognized that multiple attempts are often required for intensive behavior changes. Not all Medicare beneficiaries that begin an MDPP program can complete the number of sessions necessary to achieve behavior change necessary to reduce their risk of developing type 2 diabetes, for reasons that might include changes in health status, or other major life event or caregiving responsibilities. Accordingly, DAA members strongly encourage CMS/CMMI to eliminate the once-in-a-lifetime benefit restriction for the MDPP.

DAA members reiterate our strong calls for CMS to classify MDPP suppliers as medium fraud risks. For many current suppliers in the MDPP system, and candidates interested in applying, the CMS requirements regarding submission of social security numbers and other personally identifiable information by volunteer board members of community-based nonprofit organizations, such as the YMCA of the USA, a DAA member, remains one of the single greatest barriers to supplier participation in the MDPP. CMS acknowledges that the MDPP benefit is underutilized yet has not addressed the concerns expressed by potential MDPP suppliers that are non-clinical, community-based nonprofit organizations which are stymied by this unnecessarily burdensome requirement. We again urge CMS to address this issue. Further, on p. 53504 of the CY 2024 Notice of Proposed Rulemaking (NPRM), CMS cites its 2017 NPRM and asserts, without evidence, that there is an even higher risk for fraud from all-virtual DPPs than from in-person programs. We urge CMS to work with MDPP suppliers and companies who supply CDC-recognized diabetes prevention programs in the adult, non-Medicare population, and with the payers that cover these programs, to understand if there is in fact evidence of higher rates of fraud, as is required by the Evidence-Based Policymaking Act (or OPEN Government Data Act, Pub.L. 115–435).

CMS should remove the requirement to maintain in-person recognition for distance learning-only MDPP suppliers. As noted above, the DAA strongly supports continuing the current flexibility that MDPP suppliers have the option to continue delivering their programs through distance learning/synchronous telehealth sessions. We urge CMS to further expand on this proposal by removing the requirement to maintain in-person recognition for distance learning-only MDPP suppliers and allowing CDC-defined online providers of DPRP-recognized programs to apply to become suppliers in the MDPP. The CDC's NDRP standards already recognize four standard modes of delivering the service, including distance learning, online, and combination in addition to in-person, and recognizes program delivery organizations that deliver via all these modalities, including virtual-only providers. We encourage CMS to consider adopting these same definitions to its own MDPP, which would create further alignment between the two programs and reduce barriers to entry into the MDPP, increasing the number of MDPP suppliers and advancing CMS' goal of increasing access to and utilization of the MDPP benefit by Medicare beneficiaries.

CMS should make the MDPP a permanent Medicare covered benefit. Doing so could entice more potential suppliers to create their own diabetes prevention programs, seek CDC DPRP recognition, and apply to be MDPP suppliers, because such suppliers would know 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.

CMS should allow CDC-defined online providers of DPRP-recognized programs to apply to become suppliers in the MDPP. DAA members have greatly appreciated the many opportunities CMS has provided for us over the past few years to engage and interact with CMS staff. DAA members have repeatedly presented data and other information to support our request that CMS allow participation in

the MDPP by what DAA members – and importantly, the CDC – consider viable suppliers of diabetes prevention services, including fully online programs.

Contrary to CMS' assertion in the rule that only the in-person programs were evaluated by the actuary, there is evidence that the report did in fact evaluate multiple modalities of care, including online (virtual), because in addition to evaluating results from the first two years of the Y-USA DPP, CMS "supplemented" its 2016 report with DPP clinical trials conducted by the CDC, which we know featured modalities of care including distance learning, online, and combination in addition to in-person, and recognized organizations that deliver via all these modalities, including virtual-only providers.[3]

If CMS wants to increase supply of this health-enhancing program, expanding the model to all CDC recognized modalities is key. in the proposed rule's preamble, CMS cites the total MDPP enrollment nationally as of the end of 2021 at 4,848 individuals. CDC data show that by allowing all modalities of DPRP suppliers, more than 600,000 adults since 2012 have gone through a fully recognized DPRP. Moreover, the same MDPP evaluation report found that the CDC DPP trial program "significantly reduced the incidence rates of diabetes for pre-diabetes in the short term… [and] seemed to have a long-term effect on diabetes incidence as well."

In addition to drastically expanding the pool of potential new suppliers, aligning the definition of suppliers across the two programs would also mitigate burden on those suppliers that do currently participate in both programs and must meet two entirely different sets of eligibility and participation requirements.

We understand that CMS believes it lacks the legal authority to expand the CMMI Model Test to any supplier that is fully recognized by CDC's Diabetes Prevention Recognition Program (DPRP), and as we have stated in previous letters, we disagree. (Please see DAA letters to CMS available on the DAA's website: DAA CY 2023 Medicare Physician Fee Schedule Comments (September 2022); DAA Letter to Chiquita Brooks LaSure CMS Administrator Regarding CY 2022 Medicare PFS (September 2021); DAA Comments to CMS about FY 21 Medicare Physician Fee Schedule Proposed Rule (October 2020); DAA Letter to CMMI about MDPP Fixes Needed (May 2020).)

That being said, DAA member organizations are simultaneously working with members of Congress to reintroduce the **PREVENT DIABETES in Medicare Act**. (In the 117th Congress, bill numbers were H.R. 2807; S. 3246.) House and Senate leaders on this bill include Rep. Diana DeGette (D-CO-01), Co-Chair of the Congressional Diabetes Caucus, and Sens. Tim Scott (R-SC) and Mark Warner (D-VA). We were pleased last spring to see that President Biden's budget made a request consistent with this act.

As we understand it, last spring, Rep. DeGette requested technical assistance (TA) from CMS on further iterations of the PREVENT DIABETES Act, but no TA has yet been issued. If, as the President's budget indicates, the Administration, the DAA and Congressional members all believe that MDPP should be expanded to improve supply, we would hope that CMS would promptly and fulsomely respond to Congress' request for technical assistance. Our Hill champions believe, as we do, that permitting CDC fully recognized online and virtual providers of diabetes prevention programs to apply to be MDPP suppliers will open the door for participation in the MDPP for populations of Medicare beneficiaries that currently lack access to other types of program modalities. CMS recognized in the NPRM preamble (88

[3] https://www.cms.gov/Research-statistics-Data-and-Systems/Research/ActuarialStudies/Downloads/Diabetes-Prevention-Certification-2016-03-14.pdf

Federal Register, p.52505) that the virtual deliver modality "will make MDPP more accessible to beneficiaries who reside in rural communities and who may have transportation and other barriers to attending in-person classes." As Sen. Tim Scott (R-SC) said upon the introduction of the bill in the 117th Congress, "our bill supports programs that can delay or prevent the full onset of diabetes. By opening the door to virtual suppliers, we can ensure all patients have access to care regardless of zip code." The DAA will continue our efforts to pursue this meaningful legislation that would expand access to potentially lifesaving diabetes management services for Medicare beneficiaries, and we urge CMS to do everything within its own power to support these efforts, including but not limited to responding to the request for technical assistance. In addition, we urge the Agency to exhaust all possible regulatory avenues for expanding the pool of MDDP suppliers, such as by lowering the risk classification of MDDP suppliers from high to medium risk, as was mentioned previously.

IV. The Continuing Challenge of Obesity Care for Beneficiaries with Diabetes and Prediabetes

Since most adults with prediabetes or type 2 diabetes are people with overweight or obesity, access to the full continuum of care to treat obesity is critical for addressing diabetes prevention, treatment, and care in Medicare beneficiaries. The American Diabetes Association, in its *Standards of Care in Diabetes – 2023*, states:

- "There is strong and consistent evidence that obesity management can delay the progression from prediabetes to type 2 diabetes and is highly beneficial in treating type 2 diabetes. In people with type 2 diabetes and overweight or obesity, modest weight loss improves glycemia and reduces the need for glucose-lowering medications, and larger weight loss substantially reduces A1C and fasting glucose and has been shown to promote sustained diabetes remission through at least 2 years. Several modalities, including intensive behavioral counseling, obesity pharmacotherapy, and bariatric surgery, may aid in achieving and maintaining meaningful weight loss and reducing obesity-associated health risks."

Accordingly, DAA members urge CMS to exercise its existing authority and support ongoing Congressional efforts to expand access to the full continuum of care for obesity coverage for diabetes and prediabetes prevention and treatment. The Treat and Reduce Obesity Act (TROA) of 2023 (H.R. 4818; S. 2407) includes provisions that would address gaps in the CMS Part D policy and improve the current Medicare benefit for intensive behavioral therapy for obesity (IBTO). The TROA, for example, would amend Section 1860D–2(e)(2)(A) of the Social Security Act to permit anti-obesity medications to be covered by Medicare "if the drug is used for the treatment of obesity (as defined in section 1861(yy)(2)(C)) or for weight loss management for an individual who is overweight (as defined in section 1861(yy)(2)(F)(i)) and has one or more related comorbidities." The bill would also improve access for beneficiaries with prediabetes or diabetes to IBTO, by expanding the range of qualified health care providers able to deliver this service upon referral, which the DAA supports provided these providers have appropriate training and coordinate with the patient's primary care team.

Conclusion

The undersigned members of the DAA greatly appreciate this opportunity to provide comments to sections of the CY 2024 Medicare Physician Fee Schedule. 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 2024 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 members of the Diabetes Advocacy Alliance

Academy of Nutrition and Dietetics
American Diabetes Association
American Medical Association
Association of Diabetes Care & Education Specialists
Diabetes Leadership Council
Diabetes Patient Advocacy Coalition
Endocrine Society
National Kidney Foundation
Noom Inc.
Omada Health
Teladoc Health
Weight Watchers (WW)
YMCA of the USA