September 13, 2021

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-1751-P
P.O. Box 8016,
Baltimore, MD 21244-8016

Re: File Code CMS–1751–P. Medicare Program; CY 2022 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Provider Enrollment Regulation Updates; Provider and Supplier Prepayment and Post-Payment Medical Review Requirements.

Dear Administrator Brooks-LaSure:

On behalf of the 27 member organizations of the Diabetes Advocacy Alliance (DAA), we are pleased to submit comments to the Centers for Medicare and Medicaid Services (CMS) regarding the CY 2022 Medicare Payment Policies under the Medicare Physician Fee Schedule (PFS) proposed rule (file code CMS-1751-P). We will focus our comments on the sections of the proposed rule concerning the Medicare Diabetes Prevention Program (MDPP) expanded model (section III.L.) and payment for Medical Nutrition Therapy and related services (sections II.K. and III. I.). We appreciate that CMS/CMMI is willing to consider, develop, and implement modifications to the MDPP expanded model to improve its chances for success. We have also commented on payment for Medical Nutrition Therapy and related services (sections II.K. and III. I.)

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 also potentially 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 combatting 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.

Proposed Changes to Medicare Diabetes Prevention Program Expanded Model (Section III.K.)

The DAA fully supports the following changes to the MDPP expanded model in the proposed rule and agrees that these changes would remove some of the barriers to potential MDPP suppliers and thus over time, make the program available to more Medicare beneficiaries. The proposed rule acknowledges the need for these changes, noting that with only 3,600 beneficiaries having participated to date, MDPP participation is extraordinarily low when compared with a potential MDPP-eligible Medicare beneficiary base of 14.6 million (86 Fed. Reg. 39304), and the estimate in CDC's National Diabetes Statistics Report 2020 that about 1 out of 2 (47%) individuals has prediabetes in the 65 and older demographic.

1. Removal of the second year of the MDPP set of services on a prospective basis. The DAA fully supports the proposed change to eliminate Year 2 of MDPP and agrees that such removal "would make MDPP attractive to more MDPP eligible organizations and beneficiaries" (86 Fed. Reg. 39301) and that "the requirement to offer a second year of the MDPP set of services has also caused confusion among MDPP suppliers because it is inconsistent with the CDC National DPP requirements and curriculum" (86 Fed. Reg. 39302). Indeed, even if CMS finalizes its proposal to eliminate the 2nd year, this only resolves one of many inconsistencies between the MDPP expanded model and the CDC's National DPP. This lack of consistency is a major flaw that needs to be urgently addressed if the expanded model is to be a success. It creates in effect two programs that suppliers must administer, and thus, is a barrier to potential MDPP suppliers enrolling and offering the program to seniors.

2. Increasing payments in year one of the program. The DAA fully supports the proposed change "to redistribute a portion of the ongoing maintenance sessions phase performance payments to certain core and core maintenance session performance payments to address stakeholder concerns that the current MDPP payment structure does not cover reasonable costs of MDPP suppliers to deliver the MDPP set of services" (86 Fed. Reg. 39307). DAA member organizations that are MDPP suppliers and have participated in the expanded model since its inception have repeatedly noted the problem of underpayment of reasonable costs incurred in various forms of communication with CMMI/CMS staff. Additionally, the DAA notes that CMMI/CMS needs to further increase payment for attendance and align the average total reimbursement with the original pilot.

3. Elimination of a supplier enrollment application fee. The DAA fully supports the proposed change to eliminate the Medicare enrollment application fee ($599) for potential MDPP suppliers. The DAA agrees that this requirement "places a unique burden on MDPP suppliers" (86 Fed. Reg. 39310). The proposed rule points out that "approximately 39 percent of these entities are non-traditional suppliers that serve their local communities to increase diversity, equity, and inclusion of their services, including but not limited to YMCAs, county health departments, community health centers, and non-profit organizations that focus on health education that otherwise would neither enroll nor be able to enroll as a Medicare supplier" and that "they frequently furnish non-health care services to the community" (86 Fed. Reg. 39310). This proposal will improve the MDPP program's ability to reach diverse and underserved communities.

Changes to MDPP Expanded Model That Are Still Needed to Supply MDPP for Beneficiaries Everywhere, and to Improve Equity

The DAA posits that, while the three proposed changes to the MDPP expanded model detailed in the CY 2022 proposed rule are helpful, these changes are insufficient to significantly modify the trajectory of undersupply, and thus under-utilization of these services. The proposed rule acknowledges that "Currently, more than 1,000 organizations nationally are eligible to become MDPP suppliers based on their preliminary or full CDC DPRP status. However, only 27 percent of eligible organizations are participating in MDPP" (86 Fed. Reg. 39304). The DAA believes this low participation level is because any CDC-recognized supplier of diabetes prevention programs that wishes to be an MDPP supplier must maintain two separate programs: one that meets CDC Full Recognition requirements, and another that meets MDPP requirements. Many more MDPP suppliers are needed to improve the chances of success for the MDPP expanded model and to reach more Medicare beneficiaries who are eligible for the program but are not currently being served. **Solution: Bring the MDPP expanded model into full alignment with the CDC's National DPP.**

<u>MDPP Expanded Model Must Come into Full Alignment with the CDC's National DPP</u>

The lack of full alignment between the National DPP and the MDPP causes suppliers that wish to participate in both programs to have to offer, in effect, two different programs. For example, a supplier must establish two distinct work flows for enrollment, program delivery data collection, employee/coach tracking, and monitoring of enrollee outcomes, including two different analysis systems for what should be the same program. This doubles the burden and cost of delivery of diabetes prevention programs for organizations that, as CMS has noted, have a larger mission of serving many needs of their communities. The result: Suppliers that deliver National DPP programs to the under-65 age group must think twice, and are disincentivized, from rolling out the MDPP to Medicare beneficiaries aged 65 and older.

The quantity of MDPP suppliers will continue to be grossly inadequate to the need until CMS and CDC, agencies after all within the same Executive Agency, have the same supplier qualifications from a clinical quality perspective, the same operational and reporting requirements, and the same supplier payment structures. To summarize what must change, the DAA has prepared and attached a separate document that is a comprehensive table that lists all differences between National DPP and the MDPP expanded model. We provide narrative detail with the following points.

- <u>Make MDPP expanded model screening criteria consistent with National DPP criteria for individuals to be eligible to participate.</u> The National DPP has flexible criteria for suppliers to use to identify individuals at risk for type 2 diabetes that are consistent with clinical guidelines for the diagnosis of prediabetes that are co-authored, with the CDC, by the American Diabetes Association and are consistent with the USPSTF guideline for screening for diabetes and prediabetes. In contrast, the MDPP criteria for the fasting blood glucose (FPG) test range are narrower than the range in the National DPP criteria.
    - <u>*National DPP*</u>: To qualify, participants can be screened for prediabetes via the A1c test (5.7 – 6.4%) or FPG in the range of 100 – 125 mg/dl or the oral glucose tolerance test (OGTT) in the range of 140 – 199 mg/dl; OR a positive screening on the Prediabetes Risk Test, self-administered online or via a paper-and-pencil test.

- *MDPP expanded model*: Beneficiaries can be screened via FPG in the range of 110-125 mg/dl or OGTT in the range of 140-199 mg/dl or the A1c test (5.7 – 6.4%); however, the DAA notes that CMS does not cover the cost of the A1c test for screening and diagnosis.

- Regarding use of the FPG test, the CDC uses the American Diabetes Association's (ADA) screening criteria, while CMS uses World Health Organization (WHO) screening criteria to identify prediabetes. Physicians in the US generally use ADA criteria for defining prediabetes, consistent with USPSTF guidelines. They also now are more likely to use an A1c test to screen for prediabetes and diabetes, given the lack of a need to fast prior to the test. Thus, CMS, and the MDPP, are out of step with US practices in terms of screening for prediabetes and diabetes, which can cause problems for Medicare beneficiaries and for suppliers, who need to administer and track two different sets of screening criteria. **Solution: The DAA urges CMS to align the MDPP expanded model with the National DPP in terms of screening criteria with the use of a standard FPG range (100-125 mg/dl) and recommends strongly that CMS cover the use of A1c test results to establish a diagnosis of prediabetes**.

- Add CDC-recognized fully virtual, distance learning, and hybrid providers of National DPP programs to the list of suppliers eligible for participation in the MDPP expanded model.
  - *National DPP*: The CDC permits suppliers to offer their programs via 4 modalities: in-person program instruction, fully virtual instruction, instruction via distance learning programs, or some hybrid combination of these modalities, so long as fully recognized diabetes prevention programs meet CDC's standards for patient engagement, quality, accessibility, and clinical outcomes.
  - *MDPP Expanded Model*: Suppliers have only one option: fully in-person instruction.

- The DAA acknowledges that CMS has made allowances during the ongoing COVID-19 public health emergency (PHE) for MDPP suppliers to use online and distance learning modalities, but only in cases where participants began their instruction via the in-person modality. Also, CMS has not made these exceptions permanent despite the uptick this fall in COVID-19 infections due to the Delta variant. Nor has CMS allowed fully virtual suppliers to offer their services during the PHE or on any other basis. If the MDPP program permitted all CDC fully recognized diabetes prevention program suppliers to serve the Medicare Population (subject to the existing Supplier rules), the supply, and thus the scope of the MDPP program, would be exponentially increased while giving beneficiaries the same choices of delivery modality enjoyed by other consumers. Furthermore, by expanding the model to other modalities, Medicare can reach beneficiaries in rural areas and can ensure MDPP is available to beneficiaries who have mobility, transportation, caregiving, and other issues that preclude them from being able to attend in-person instruction.

- The DAA would like to see regulatory changes to address this concern but realizes that a statutory solution may be required. To achieve this goal, the DAA is supporting the PREVENT DIABETES Act (House; Senate), which would require that any CDC fully-recognized diabetes prevention program suppliers be included in the MDPP Expanded Model conducted by CMMI under section 1115A of the Social Security Act (42 U.S.C. 1315a). Congressional sponsors have re-introduced this bill in the House (April 22, 2021) and Senate (June 22, 2021). However, we believe CMS possesses the requisite authority to make this change on its own and have found no provisions of 42 USC 1115 that limit CMS authority on this issue. **Solution: The DAA strongly urges CMS to align Medicare DPP with the National DPP and to allow organizations that are CDC Diabetes Prevention Recognition Program (DPRP) fully recognized, to apply to be MDPP suppliers and offer their programs to Medicare beneficiaries, especially since all CDC fully**

recognized diabetes prevention programs supply a service which has strong evidence from peer-reviewed studies and clinical trials that show efficacy and effectiveness in real-world settings.

- Make the MDPP expanded model more flexible to serve the needs of beneficiaries who experience health inequities. The National DPP offers its suppliers more flexibility to reach populations of people with prediabetes who experience health inequities due to social determinants of health.
    - *National DPP*: Allows flexibility for targeted solutions for special populations negatively affected by SDOH and makes allowances for flexibility in achieving the 5% weight loss target (e.g., establishing a 4% vs. 5% weight loss target after 12 months or 0.2% reduction in A1c as measures of program success; if the 4% weight loss target is used, 150 minutes of physical activity per week is required).
    - *MDPP expanded model*: Does not offer flexibility, such as for risk-adjusted payments to serve patient populations that may face transportation and other barriers to attendance and/or for whom the evidence has shown may be less likely to achieve the 5% weight loss threshold.

- In fact, there are disincentives for serving special populations, including Medicare-Medicaid dually eligible individuals among others, inherent in the current reimbursement approach. These disincentives directly contribute to growing health disparities, especially among low-income participants in the MDPP. The DAA views this issue as vital to improving health equity. Addressing this inequity requires creative solutions. MDPP payments could be risk-adjusted, for example, to help suppliers cover the cost of providing the program to patient populations that may face transportation and other barriers to attendance and/or who the evidence has shown may be less likely to achieve the 5% weight loss threshold. Or CMS could adopt the 2021 CDC Standard which is a lower percentage of weight loss in combination with a certain amount of daily exercise.

- MDPP's lack of flexibility in this regard contributes to increased health inequities and lack of opportunities for Medicare beneficiaries to participate and benefit from the program. **Solution: The DAA strongly urges CMS to align with the National DPP and permit program suppliers to be flexible and make allowances for targeted solutions for special populations.**

- Designate MDPP suppliers as low risk categorical suppliers. CMS classifies all Medicare DPP suppliers as high risk, which is problematic for the types of nontraditional suppliers (e.g., local community-based organizations and charities, churches, etc.) that CMS acknowledges in the proposed rule that it would like to attract to the program (see page 571). High risk designation causes many of these organizations to decide not to apply due to new, burdensome, unnecessary requirements such as requirements for volunteer leaders' social security numbers. Also, to another point, the MDPP coach roster information requirements for the MDPP are more extensive than those required by the National DPP and represent information that is being collected both via the NPI application process as well as through bureaucratic coach roster requirements. **Solution: The DAA strongly urges CMS to designate MDPP suppliers as low risk categorical suppliers, like its designation for diabetes self-management training (DSMT) suppliers. The DAA also notes streamlining information collection so that it is only collected once would be helpful to nontraditional suppliers**.

Eliminate the Once-per-Lifetime Limit for MDPP Participation

The DAA notes that CMS is restricting the MDPP to a once-per-lifetime limit benefit. This limitation punitively denies 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. **The DAA strongly urges CMS to align the MDPP benefit with existing benefits for obesity and smoking cessation counseling, which acknowledge the need for repeated use of counseling for weight loss/weight management and smoking cessation, respectively.**

Increase Promotion of the MDPP Expanded Model to All Audiences

The proposed changes to the MDPP expanded model in the CY 2022 Medicare PFS are helpful to suppliers, but, as noted in detail above, more changes are needed to increase the model's chances of success. As CMS stated, "If we do not take action, we will not be able to scale MDPP as intended." (86 Fed. Reg. 39542). One area, however, that has not been addressed is awareness of the MDPP expanded model, especially among Medicare beneficiaries. While it will be important for CMS to communicate information clearly and effectively about any changes to the MDPP to potential suppliers to increase ***supply*** of the program, it will be equally important to promote the program to insurers, employers, and directly to Medicare beneficiaries, to increase ***demand*** for the program. **Solution: The DAA urges CMS to develop and implement actions to promote the MDPP expanded model to ensure that the program has the best chances for success**.

Payment for Medical Nutrition Therapy Services and Related Services (Section II.K.) and Medical Nutrition Therapy (Section III.I.)

Overall, the DAA commends CMS for proposing actions aimed to increase utilization of a vastly under-utilized Medicare benefit clearly proven to reduce chronic disease risk, delay disease progression, enhance the efficacy of medical/surgical treatment, reduce medication use, and improve patient outcomes including quality of life.[1] MNT provided by the RDN is a widely recognized component of medical guidelines for the prevention and treatment of heart disease, diabetes, renal disease, obesity, cancers, and many other chronic diseases and conditions as well as in the reduction of risk factors for these conditions. The DAA supports all the proposed changes related to the Part B MNT benefit for the reasons noted by the agency but notes CMS has not gone far enough in taking action to meet this goal. To that end, the DAA recommends:

1. **Update the definition of diabetes in § 410.130 Definitions to include HbA1c ≥ 6.5% as recommended in national standards of medical care for diabetes**. As is the case with classification and diagnostic guidelines for kidney disease, the definition of diabetes for the purposes of the MNT benefit has not been updated since the original NCD. HbA1c testing has been accepted among the clinical community as a diagnostic test for abnormal glycemic status for at least 10 years. Both the United States Preventive Services Task Force[2] and the American

[1] Grade 1 data. Academy Evidence Analysis Library, http://andevidencelibrary.com/mnt. [Grade Definitions: Strength of the Evidence for a Conclusion/Recommendation Grade I, "Good evidence is defined as: "The evidence consists of results from studies of strong design for answering the questions addressed. The results are both clinically important and consistent with minor exceptions at most. The results are free of serious doubts about generalizability, bias, and flaws in research design. Studies with negative results have sufficiently large sample sizes to have adequate statistical power."

[2] Abnormal Blood Glucose and Type 2 Diabetes Mellitus: Screening. U.S Preventive Services Task Force. October 26, 2015. https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/screening-for-abnormal-blood-glucose-and-type-2-diabetes. Accessed August 17, 2021.

Diabetes Association Standards of Care[3] recommend use of any of three testing methods to screen for abnormal blood glucose: fasting plasma glucose, HbA1c, and two-hour plasma glucose.

2. **Further expand the definition of renal disease in § 410.130 Definitions to include G Stage 1 Kidney Damage with normal kidney function (GFR 90 ml/min/1.73m^2 or higher) and G Stage 2 Mild CKD (GFR 60-89 ml/min/1.73m^2) to include the full breadth of non-dialysis dependent chronic kidney disease.**[4] Section 1861(s)(2)(V)(ii) of the Social Security Act allows for MNT for a "beneficiary with … renal disease who…is not receiving maintenance dialysis." Medicare expenditures increase dramatically from stages 1-2 to stages 4-5.[5] Covering MNT for these earlier stages of CKD is a low-cost intervention proven to slow or prevent CKD progression.[6] [7] Also, some G Stage 5 patients with a GFR below 15 ml/min/1.73m^2 may not yet be on dialysis and so not receiving nutrition services under the ESRD benefit. Such patients would benefit from MNT services under the Part B benefit. Of note, the ICD-10 code file associated with the MNT NCD (180.1) and issued by CMS to the Medicare Administrative Contractors for claims processing purposes includes the ICD-10 codes for all stages of CKD.[8] To address potential concerns about risk of fraudulent billing, the DAA suggests CMS create a modifier code to be appended to claims for Part B MNT services to indicate when a Medicare beneficiary with Stage 5 CKD is not receiving dialysis.
3. As CMS moves all regulatory provisions for MNT, DSMT, and registered dietitians as Medicare providers under one area of regulations, we recommend CMS also **provide additional clarity in Medicare Claims Processing and Benefit Policy Manuals on coverage and billing procedures for these services under the Physician Fee Schedule in all associated settings, including hospital clinics (billing on CMS 1500, billing on UB04), Federally Qualified Health Centers, Rural Health Clinics, and Critical Access Hospitals.** Currently providers and billers need to navigate a complex 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 PHE and the telehealth flexibilities. While MNT and Diabetes Self-Management Training (DSMT) services have always been on the list of Medicare approved telehealth services, instructing a hospital to bill for Part B MNT services the same as in-person services became problematic as facilities did not know how to bill for it as an in-person service. To that end, DAA members welcome opportunities to collaborate with CMS on developing and reviewing resources that will support providers.

The Diabetes/Obesity Connection

The issue of obesity, and how it connects with prediabetes and diabetes, is related to the changes the DAA believes are urgent to make to the MDPP expanded model to ensure its success. Since most adults

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[3] Classification and Diagnosis of Diabetes: *Standards of Medical Care in Diabetes—2021*. American Diabetes Association. Diabetes Care Jan 2021, 44 (Supplement 1) S15-S33; **DOI:** 10.2337/dc21-S002.

[4] National Kidney Foundation. Estimated Glomerular Filtration Rate (eGFR). https://www.kidney.org/atoz/content/gfr. Accessed August 17, 2021.

[5] United States Renal Data System. Chapter 6: Healthcare Expenditures for Persons with CKD. https://adr.usrds.org/2020/chronic-kidney-disease/6-healthcare-expenditures-for-persons-with-ckd. Accessed August 17, 2021.

[6] de Waal D, Heaslip E, Callas P. Medical Nutrition Therapy for Chronic Kidney Disease Improves Biomarkers and Slows Time to Dialysis. J Ren Nutr. 2016; 26(1): 1-9.

[7] Kramer H, Yakes Jimenez E, Brommage D, et al. Medical Nutrition Therapy for Patients with Non-Dialysis-Dependent Chronic Kidney Disease: Barriers and Solutions. J Acad Nutr Diet. 2018; 118(10): 1958-1965.

[8] https://www.cms.gov/Medicare/Coverage/DeterminationProcess/downloads/CR12027.zip Accessed August 17, 2021.

with prediabetes and type 2 diabetes are people with overweight or obesity, access to the full continuum of care to treat obesity is another important tool to reduce new cases of type 2 diabetes and to help adults sustain weight loss in the longer term. The COVID-19 pandemic has clearly shown and reinforced the urgent need to address diabetes and obesity, as these two conditions have been shown to be major risk factors for hospitalizations and death from COVID-19. It has also demonstrated that different modalities can be effective in delivering therapy and treating medical conditions. The DAA would like to see coverage of the full continuum of care to treat obesity and is available to provide you with more information on this issue.

Revise the Timeframe for Consideration of Services Added to the Telehealth List on a Temporary Basis

The DAA supports the CMS proposal to retain many services added to the Medicare telehealth services list on a Category 3 basis until the end of CY 2023. The DAA disagrees that Medicare coverage for the telehealth services listed in Table 11 should end when the COVID-19 Public Health Emergency (PHE) ends, however. A number of these services provide important clinical benefits to beneficiaries, for example, by allowing beneficiaries who cannot access audio-visual telecommunications to have audio-only visits with their physician and allowing beneficiaries to be admitted to the hospital via telehealth instead of patient care being delayed until the physician can get to the hospital. Adding the services in Table 11 to Category 3 will allow stakeholders a reasonable amount of time to collect more information regarding utilization to support these services being added to the telehealth services list on a permanent basis after the conclusion of the PHE. We remain concerned, however, that statutory site-of-service restrictions will prevent Medicare beneficiaries from meaningfully accessing these needed telehealth services. We will continue to urge Congress to remove all telehealth originating site and geographic restrictions, and we urge CMS to interpret statutory language in a manner that provides Medicare beneficiaries with the broadest possible access to telehealth services.

Conclusion

The DAA greatly appreciates this opportunity to provide comments to sections of the CY 2022 Medicare PFS that are concerned with changes to the MDPP expanded model and to Medical Nutrition Therapy services and related services. We share a goal with CMS: innovative programs for Medicare beneficiaries that prevent diabetes and 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 Hannah Martin, DAA co-chair (hmartin@eatright.org) or Kate Thomas, DAA co-chair (kthomas@adces.org).

Sincerely,

The undersigned members of the Diabetes Advocacy Alliance

Academy of Nutrition and Dietetics
American Medical Association
American Optometric Association
American Podiatric Medical Association
Association of Diabetes Care & Education Specialists
Diabetes Leadership Council
Diabetes Patient Advocacy Coalition
Endocrine Society
Healthcare Leadership Council
Novo Nordisk Inc.
Omada Health, Inc.
WW International, Inc. (formerly Weight Watchers)
YMCA of the USA