

VIA ELECTRONIC SUBMISSION: <http://www.regulations.gov>

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:

The Association of Diabetes Care & Education Specialists (ADCES) appreciates the opportunity to comment in response to the *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* proposed rule (CMS-1784-P) as published in the *Federal Register* on August 7, 2022 (the “proposed rule”).

ADCES is an interdisciplinary professional membership organization dedicated to improving prediabetes, diabetes, and cardiometabolic care through innovative education, management, and support. With more than 12,000 professional members including nurses, dietitians, pharmacists, and others, ADCES has a vast and diverse network of practitioners working to optimize care and reduce complications. ADCES supports an integrated care model that lowers the cost of care, improves experiences, and helps its members lead so better outcomes follow.

ADCES applauds the numerous steps taken in this rule to improve access to and streamline the provision of diabetes self-management training (DSMT), medical nutrition therapy (MNT), and the Medicare Diabetes Prevention Program. As detailed in our proposed rule comments below, ADCES remains committed to working with CMS to ensure that all Medicare beneficiaries with diabetes, prediabetes, obesity, and other cardiometabolic conditions have access to high-quality, equitable care.

Below are comments from ADCES on the following sections of the proposed rule:

- **Section II.D** Payment for Medicare Telehealth Services Under Section 1834(m) of the Act
- **Section II.I** Supervision of Outpatient Therapy Services, KX Modifier Thresholds, Diabetes Self-Management Training (DSMT) Services by Registered Dietitians and Nutrition Professionals, and DSMT Telehealth Services
- **Section III.I** Medicare Diabetes Prevention Program (MDPP)
- **Section III.L.** Expand Diabetes Screening and Diabetes Definitions

We also offer comments related to issues not addressed in the rule for future consideration to improve the diabetes self-management training, medical nutrition therapy, and intensive behavioral therapy for obesity benefits.

Section II.D. Payment for Medicare Telehealth Services under Section 1834(m)

4. Payment for Outpatient Therapy Services, DSMT, MNT when furnished by staff to beneficiaries in their homes via telehealth

ADCES supports the proposal to extend telehealth coverage through 2024 when HOPD institutional staff provide DSMT or MNT to beneficiaries in their homes and thanks CMS for recognizing this critical access issue. In CMS's recounting of the ending of HWW, it states, "In developing post-PHE guidance, CMS initially took the position that institutions billing for services furnished remotely by their employed practitioners (where the practitioners do not bill for their own services), would end with the PHE for COVID-19 along with the HWW waivers." However, neither DSMT nor MNT are services "where the practitioners do not bill for their own services" as both require Medicare-enrolled billing providers and/or rendering providers to be documented on the claim and are routinely billed for by the practitioner in a variety of out-patient settings. Therefore, we believe that DSMT and MNT should be able to be delivered via telehealth from the HOPD setting and billed for under the MPFS without limitations as is the case when delivered via telehealth from other settings.

In the proposed rule, CMS states, "We are seeking comment on current practice for these services [DSMT and MNT] when billed, including how and to what degree they continue to be provided remotely to beneficiaries in their homes." Though we were not able to obtain exact metrics during the window of the comment period, as a CMS-approved national accreditation organization for DSMT, ADCES has routine contact with a high volume of accredited programs. Our communications with HOPD-based programs leads us to conclude that a substantial number are still providing telehealth DSMT from the HOPD setting to patients receiving care from their homes.

In the proposed rule, CMS asks "whether these services may fall within the scope of Medicare telehealth at section 1834(m) of the Act." ADCES agrees that DSMT and MNT when provided via telehealth from the HOPD setting should be regulated under 1834(m) as there is no difference between telehealth DSMT or MNT delivered from the HOPD setting and telehealth DSMT or MNT delivered from the clinic setting. Both the patient and provider benefit from the quality standards and other programmatic regulations that DSMT programs must comply with and are the same in all care settings. Therefore, we believe the regulations governing billing for these services when delivered via telehealth should be unified under 1834(m).

We would like to raise the case of the state of Michigan as an example of where serious access problems have been on the verge of occurring due to the misalignment between telehealth rules for DSMT from the HOPD and clinic setting and the fact that CMS nearly ended telehealth DSMT/MNT from the HOPD setting and then only extended them through 2023 initially. Under the Michigan Medicaid program, DSMT can only be delivered from the HOPD setting or from a health department, and clinic-based programs are ineligible to participate in the Medicaid program. If changes are not made to allow

telehealth DSMT from the HOPD setting beyond 2024 (e.g., by regulating it under 1834(m)), DSMT programs in Michigan will be forced to decide between serving Medicaid beneficiaries (which requires staying in the HOPD setting) or offering telehealth services to Medicare beneficiaries (which would require they be moved to a clinic setting).

Section II.I. I. Supervision of Outpatient Therapy Services, KX Modifier Thresholds, Diabetes Self-Management Training (DSMT) Services by Registered Dietitians and Nutrition Professionals, and DSMT Telehealth Services

3. DSMT by RDNs

We thank CMS for issuing this correction that ADCES raised alongside the American Diabetes Association (ADA). The wording of § 410.72, as originally written, led some compliance officers to believe that RDNs could not bill on behalf of DSMT programs when services were rendered by others on the team, which we understand was not CMS's intent. We thank CMS for clarifying that the limitations on RDNs only billing for services directly performed by them does not apply to billing on behalf of DSMT programs.

4. DSMT Telehealth Issues

(a) Distance Site Practitioners

We thank CMS for their intent to simplify rules around billing for telehealth DSMT and to better align them with rules around billing for in-person DSMT. The confusion in 2020 of how DSMT programs could bill for telehealth when provided by the full set of practitioners who provide the service when delivered in-person demonstrated that the existing regulations governing telehealth by distance site practitioners were ill-suited to apply to a service that is designed to be delivered by a multi-disciplinary team.

To affect this change, CMS proposes to add a new section *§ 410.78 (b)(2)(x) Any distant site practitioner who can appropriately report diabetes self-management training services may do so on behalf of others who personally furnish the services as part of the DSMT entity.* However, we have concerns that this new section of the code, as written, would only apply to a minority of DSMT programs. When enrolling as Medicare DSMT programs, pharmacies with accredited DSMT programs enroll as suppliers and do not bill under the NPI of a specific practitioner, so we therefore believe that they would not be able to provide and bill for DSMT via telehealth due to not billing under a "distance site practitioner." Estimates from ADCES and ADA accreditation data indicate that over 200—or approximately 11% of all accredited DSMT programs—are housed within pharmacies. Many pharmacy programs have been initiated to address underserved communities in healthcare deserts, therefore, though their volume of patients may be low, they are often meeting a critically unmet need. In addition, due to how they bill as suppliers rather than providers, pharmacies face additional barriers to reimbursement from MACS who frequently misunderstand DSMT billing rules from the pharmacy setting, so care needs to be taken to minimize barriers for programs in this setting.

We have similar concerns with whether the language would apply to DSMT programs located in the HOPD setting if CMS were to, as it contemplates in an earlier section of the rule, be regulated under 1834(m). DSMT programs billing from the HOPD setting often bill under the hospital NPI rather than a provider NPI, which we worry could impact interpretation of *§ 410.78 (b)(2)(x)*. While the change in how

DSMT HOPD programs are regulated does not appear that it will change by 2024, we nonetheless encourage CMS to adopt language at § 410.78 (b)(2)(x) that would accommodate HOPD-based programs if that change were to be made in the future. Estimates from ADCES and ADA accreditation data indicate that over 1,200—or approximately 56%—of all accredited DSMT programs—operate out of the HOPD setting. Programs in these settings also often see larger numbers of patients, making their share of total beneficiaries served an even larger majority than their program share would indicate.

To accommodate both pharmacy-based programs and HOPD-based programs that together make up two-thirds of all DSMT programs, we recommend CMS instead adopt the following language at § 410.78 (b)(2)(x): *Any distant site practitioner **or approved entity that 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 proposed adding “or approved entity,” which is the language CMS uses in § 410.140 – 410.146 to describe DSMT programs that have been accredited as meeting CMS quality standards, to ensure that all program types are encompassed in this section of the code. We also propose replacing “who can appropriately report” DSMT with “that can bill for” DSMT. The phrase “appropriately report” is not used elsewhere in DSMT regulations and we are uncertain of its meaning here. Without CMS explicitly defining this phrase, we are concerned that MACs or health system compliance teams could misinterpret it and inappropriately deny claims for the service or prevent DSMT programs from providing services via telehealth in fear of denied claims. We instead suggest CMS use more common language such as “bill for.”

(b) Telehealth Injection Training for Insulin-Dependent Beneficiaries

ADCES supports the proposal to eliminate the requirement that injection training be delivered in-person. As CMS notes, injection training has been occurring via telehealth under waivers for more than three years without issue, demonstrating that this should be allowed on a permanent basis. Similar to the issues raised above, we have concerns with the exact language proposed for 410.78(e)(3). As outlined above, we are concerned that “distance site practitioner” language may not apply to programs billing under a facility NPI rather than a personal provider NPI such as pharmacy-based programs and HOPD-based programs. We also again request that non-standard language of “reports the DSMT services” be changed to something with more plain language.

To accommodate both pharmacy-based programs and HOPD-based programs and use plain language, we recommend CMS instead adopt the following language: *410.141(e)(3) The distant site practitioner **or approved entity that 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).*

Section III.I. MDPP

ADCES supports the proposals to extend the MDPP model through 2027, which will provide stability to the program. 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.

We also support the proposal to move from a performance-based attendance and outcomes payment structure to a hybrid structure that pays for attendance on a fee-for-service basis and separately pays for outcomes (weight loss) on a performance basis. Finalizing these proposals will provide smoother, more stable payments to MDPP suppliers by spreading out smaller payments at more frequent intervals rather than larger payments at longer intervals. With equal the incentive for programs to maintain participant enrollment at every point throughout the year, we believe this could increase participation, especially in later months, and therefore increase payments for MDPP suppliers, many of whom have been operating their 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 providing greater payment for continuing to serve communities who face higher barriers and therefore need more access to care will improve health equity within the program.

We also support the proposed change to replace the current MDPP “interim preliminary recognition” with “CDC preliminary recognition,” as this better aligns the MDPP with CDC’s National Diabetes Prevention Program. Improved alignment of MDPP with National DPP standards would reduce barriers to entry into the MDPP, increasing MDPP suppliers and increasing access to and utilization of the MDPP benefit by Medicare beneficiaries.

While we thank CMS for the significant improvements made to the MDPP in the 2024 proposed rule, we would like to suggest additional steps that CMS could take next year to further improve access to the program.

- 1. Allow repeat participation in the MDPP,** just as it is allowed for intensive behavioral therapy for obesity and smoking cessation programs. Multiple attempts are often required for behavioral changes. Not all Medicare beneficiaries that begin an MDPP complete the number of sessions necessary to achieve sufficient behavior change 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. Accordingly, we strongly encourage CMS/CMMI to eliminate the once-in-a-lifetime benefit restriction for the MDPP.
- 2. 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 remains one of the single greatest barriers to supplier participation in the MDPP. Classifying MDPP suppliers as high fraud risk is not based on any evidence of fraud within MDPP and only serves to keep the supply of MDPP enrolled suppliers very low.

- 3. Remove the requirement to maintain in-person recognition for distance learning-only MDPP suppliers and allow CDC-defined online providers to enroll as MDPP suppliers.** We urge CMS to further expand on its support for distance learning for MDPP 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. The CDC's DPRP 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.
- 4. Make the MDPP a permanent Medicare covered benefit.** Doing so would 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.

Section III.L. Expand Diabetes Screening and Diabetes Definitions

ADCES greatly supports the creation of coverage of HbA1c as a screening test for diabetes. This change follows 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." This proposal also aligns with ADA standards of care to reimburse HbA1c for the purposes of diagnosis.

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." This change will allow providers to screen based on beneficiaries' unique needs, thereby improving patient outcomes. In addition, we would encourage CMS to expand on these proposals by waiving cost sharing for HbA1c tests to encourage their uptake and matching commercial coverage of the HbA1c test for screening and diagnosis.

We also support de-codifying the clinical criteria for diabetes diagnosis for the purposes of the DSMT and MNT benefits. This will simplify the referral process, improve uptake, reduce denied claims, and therefore improve access. It will also prevent beneficiaries with long-diagnosed diabetes from having to undergo unnecessary diagnostic tests if their original lab results are not accessible to the provider

currently managing their diabetes. We also support this change because it prevents future misalignment between the benefit's codified clinical criteria and standard of care (which happened recently with the MNT benefit for CKD).

Additional Recommendations from ADCES

Diabetes Self-Management Training

While we thank CMS for the multiple improvements made to the DSMT benefit—particularly as it relates to telehealth—in the 2024 proposed rule, there are many additional aspects of the program that CMS could improve to bolster utilization. As part of an ongoing effort by CMS's Office of Minority Health (OMH) to develop a diabetes strategy for Medicare, ADCES compiled and transmitted to OMH representatives a detailed list of technical recommendations for improvements to the DSMT benefit. The key issues we recommend CMS address include streamlining referral orders, increasing flexibilities for group vs individual care determinations, increasing the availability and flexibility of hours, and simplifying aspects of the regulations governing program accreditation. A copy of our previously submitted list of recommendations has been attached to our comment submission to the 2024 fee schedule proposed rule in the Federal Register with the file name "DSMT Recommendations for CMS_230731."

Intensive Behavioral Therapy (IBT) for Obesity

ADCES reiterates its request that CMS review the IBT for obesity benefit and allow RDNs to serve as direct providers for the IBT for obesity benefit with the ability to see beneficiaries outside of the primary care setting upon referral from a primary care provider, but without direct oversight from one. We believe this would greatly improve beneficiary access to this high value, evidence-based service and address some of the health inequities that exist due to the current benefit design.

In fall 2022, the White House issued its National Strategy on Hunger, Nutrition, and Health,¹ which called for the expansion of Medicare beneficiaries' access to nutrition and obesity counseling and stated explicit support for "efforts to... allow appropriate providers to offer obesity screening and behavioral counseling". It is our understanding that the Academy of Nutrition and Dietetics has submitted a proposal and documentation to CMS in support of revisions to the IBT for obesity National Coverage Determination to add coverage for RDNs providing the service. ADCES encourages CMS to act on this request and issue a new NCD that improves access to qualified providers in a variety of settings.

Medical Nutrition Therapy

ADCES encourages CMS to apply its own rationale for decodifying the diagnostic criteria for diabetes to also decodify the diagnostic criteria for kidney disease for the purposes of the MNT benefit. CMS currently restricts coverage of MNT for CKD to glomerular filtration rates (GFRs) that correspond to states 3 and 4, leaving beneficiaries with states 1, 2, and 5 without access to care from a registered dietitian even though the law that created the benefit instructed CMS to cover MNT for beneficiaries with "a renal disease" and did not specify a subset of CKD stages.² Medicare expenditures increase

¹ <https://www.whitehouse.gov/wp-content/uploads/2022/09/White-House-National-Strategy-on-Hunger-Nutrition-and-Health-FINAL.pdf>

² Public Law No. 106-554, §105: Consolidated Appropriations Act, 2001. 114 Stat. 2763. December 21, 2000.

dramatically from stages 1-2 to stages 4-5.³ Covering MNT for these earlier stages of CKD is a low-cost intervention proven to slow or prevent CKD progression.^{4,5} Also, some stage 5 beneficiaries with a GFR below 15 ml/min/1.73m² may not yet be on dialysis and so not receiving nutrition services under the ESRD benefit. Such beneficiaries would benefit from MNT services under the Part B benefit.

Instead of restricting MNT for CKD to a codified range of GFRs, ADCES encourages CMS to instead replace the definition of “chronic renal insufficiency” in § 410.130 with “chronic kidney disease” defined in a way that does not limit the benefit to specific stages of the disease and allows providers to use their judgment as to which of their CKD patients would benefit from MNT from a registered dietitian.

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ADCES appreciates the opportunity to comment on this proposed rule. We hope to work with CMS to support the proposed policies contained within this rule as well as future policies to improve access to care for people with diabetes, prediabetes, obesity, and other cardiometabolic conditions. Please contact ADCES director of advocacy Hannah Martin at hmartin@adces.org should you have any questions regarding ADCES’ comments.

Sincerely,



Matthew Hornberger, MBA, Chief Executive Officer



Hannah Martin, MPH, RDN, Director of Advocacy

³ 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.

⁴ 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.

⁵ 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.