

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

September 12, 2025

The Honorable Mehmet Oz
Administrator
Centers for Medicare & Medicaid Services (CMS)
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

RE: Calendar Year 2026 Medicare Physician Fee Schedule Proposed Rule (CMS-1832-P)

Dear Administrator Oz:

The Association of Diabetes Care & Education Specialists (ADCES) appreciates the opportunity to comment in response to the *Medicare and Medicaid Programs; CY 2026 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; and Medicare Prescription Drug Inflation Rebate Program Proposed Rule (CMS–1832–P)* as published in the *Federal Register* on July 16, 2025 (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 11,000 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.

I. Payment for Medicare Telehealth Services Under Section 1834(m) Group Behavioral Counseling for Obesity

In Section II.D. 1.c.2. CMS is proposing to add G0473 (Face-to-face behavioral counseling for obesity, group (2-10), 30 minutes) to the telehealth services list for CY26. ADCES supports this addition as we agree with CMS that the service is appropriate for provision via telehealth. We would also note that comparable services such as G0447 (Face-to-face behavioral counseling for obesity, individual, 30 minutes), 97804 (Medical Nutrition Therapy, group, 30 minutes) and G0109 (Diabetes Outpatient Self-Management Training, group, 30 minutes) have all long been on the telehealth services list.

Please see our comments below in response to the Prevention and Management of Chronic Disease Request for Information for additional opportunities for CMS to improve access to IBT for obesity (G0473 and G0447).

II. <u>Valuation of Specific Codes</u> Valuation of Specific Codes for CY 2026 Remote Monitoring

In Section II.E. 4. (30), CMS is proposing to maintain the valuation of 99091, which is the remote patient monitoring code used for, among other things, monthly review of insulin infusion pump data. **ADCES supports the maintenance of this code's valuation** as a means to continue to encourage providers to prescribe and monitor the use of pumps for people with diabetes, a class of devices of which access is already highly limited in Medicare.

III. <u>Policies to Improve Care for Chronic Illness and Behavioral Health Needs</u> Prevention and Management of Chronic Disease—Request for Information (RFI)

In Section II.I. 2., CMS makes requests for information on the prevention and management of chronic disease within Medicare. Below we offer feedback on this RFI on ways to reduce the burden of diabetes, obesity, prediabetes, and other cardiometabolic conditions through existing Medicare benefits. Specifically, our comments address the Diabetes Self-Management Training benefit, Intensive Behavioral Therapy for Obesity benefit, Medical Nutrition Therapy benefit, and Medicare Diabetes Prevention Program. We also respond to CMS's queries on motivational interviewing.

i. Prevention and Management of Chronic Disease: Improvements to the Diabetes Self-Management Training Benefit

Diabetes Self-Management Training (DSMT) is an evidence-based service that teaches people with diabetes how to reduce their risk of diabetes-related complications and improve their quality of life through self-management. DSMT has been shown to help people with diabetes achieve lower hemoglobin A1C, weight loss, improved quality of life, healthy coping skills, and reduced healthcare costs. ¹ In a study including 250,000 Medicare beneficiaries, beneficiaries who completed DSMT demonstrated an average cost savings of \$135 per month. ²

Despite all these benefits, only 5 percent of Medicare beneficiaries who have been newly diagnosed with diabetes use DSMT services within the first year.³ Reasons for this low utilization are myriad but we would like to focus your attention on ways that CMS's administration of the Medicare DSMT benefit creates unnecessary barriers that restrict access to care and how CMS's DSMT accreditation program restricts the number of programs available through complicated and burdensome compliance requirements.

In the attached technical appendix, we discuss five areas of modifications to the DSMT regulations that would improve access to this low-cost, effective service to help beneficiaries manage their diabetes to reduce complications and slow disease progression. The key issues we recommend CMS address include:

- 1. Streamlining referral orders to reduce paperwork burden and remove barriers to referring for the DSMT service,
- 2. Increasing flexibilities for group vs individual care determinations to allow for a more patient-centered approach to care rather than a one-size-fits-all approach,
- 3. Increasing the availability and flexibility of hours to allow providers to deliver care when people with diabetes need it throughout their lifetime, not on a pre-determined schedule that overlooks the progressive nature of diabetes and frontloads hours into the first year,
- 4. Simplifying aspects of the regulations governing program accreditation to make it easier for new programs to open and existing programs to continue and expand operations,
- 5. Allowing DSMT and medical nutrition therapy (MNT) to be delivered on the same day, and
- Allowing DSMT suppliers who meet statutory accreditation standards found in 42 USC 1395x, but who offer their DSMT programs virtually or through asynchronous video, to offer DSMT to Medicare beneficiaries.

We appreciate the steps CMS has already taken in recent years to improve the DSMT benefit and the opportunity to provide our thoughts to further improve the benefit through this RFI.

Below are the technical details on how CMS could modify DSMT regulations to improve access to care and reduce paperwork burdens on providers. The first four sections are ordered based on the section of the code that they discuss and the fifth would be addressed exclusively subregulatorily. In sections where multiple "recommendations" are presented, these are additive and presented in the order of the code they impact and not the order of importance. However, within sections where we present "options" for how to solve the problem at hand, those options are mutually exclusive and presented in order of our preference from most comprehensive to most narrow. The majority of the proposed regulatory changes would also require conforming changes to the Medicare Benefit Policy Manual.⁴

1. Streamline Referral Orders

The recommendations listed below are additive and not alternatives to one another. We would suggest implementing all three.

Recommendation 1: Remove requirement that referring providers certify the number of sessions, frequency, and areas of need.

Rationale: DSMT programs that have achieved accreditation with a CMS-certified accrediting organization (ADA or ADCES) are required to perform an initial assessment in which they identify the beneficiary's areas of need to achieve the goals of their care plan through personalized training and education, meaning the requirement that the referring provider also do this is redundant. Physicians and other referring providers do not have the time to assess all the myriad barriers that every patient has to self-management. Primary care professionals referring to DSMT programs should identify a need for DSMT,⁵ offer a referral, complete a referral order, and share the diabetes care plan with the DSMT team. Currently, DSMT programs are doing their comprehensive assessment, identifying different or additional areas of need, then sending a note back to the referring provider for them to rewrite the referral order, often delaying necessary care by weeks or

months, which is costly, inefficient, puts paperwork above patients, and reduces access to care. Correspondingly, the referral order should not require a list of topics or session frequency because 1) those are driven by the needs of the patient which the DSMT program will assess, and 2) the referring provider has little to no way of knowing what frequency of sessions is available to the beneficiary at any given DSMT program or how many hours are available for beneficiaries who have received and utilized a DSMT referral in the past.

Suggested Modification: Delete 42 CFR §410.141(b)(2)(i)

Recommendation 2: Remove the requirement that referring providers certify their role in the patient's care and that their care plan is necessary.

Rationale: Inherent to a physician or qualified nonphysician practitioner referring a patient to DSMT is an attestation that they are part of the care team that is managing the patient's diabetes and that the training requested is necessary for diabetes management. To require an additional statement to these facts is redundant with their signing of the referral order for the service. Additionally, if providers were referring to DSMT without being part of the care team or without it being necessary, that would be counter to the current statute and regulations surrounding fraud in the Medicare program, which CMS does not need to redefine for the purpose of the DSMT benefit (and which it does not routinely define for other benefits). Because this requirement is non-standard and redundant with the signing of the referral order, it is understandably missed by referring providers, which has been noted on CMS audits. This can require programs to send a note back to the referring provider to update documentation, which, as described above, delays care and adds no value, therefore reducing efficiency.

Suggested Modification: Delete 42 CFR §410.141(b)(2)(ii).

Recommendation 3: Remove the requirement that changes to the plan of care be signed by the treating provider.

Rationale: Again, this requirement simply does not align with the way that care is provided, and it is not clear how this was ever intended to be operationalized. Per recommendation 1 above, programs are already having to go back to the referring provider for new referral orders if they assess the patient to have additional needs beyond those that the provider identified on the initial referral. Once that has been done (or if referral orders are streamlined to allow programs to identify needs), it is not clear what a "change to the plan of care" would mean as it relates to a DSMT program. If it refers to DSMT programs implementing slight modifications to what topics are discussed with the patient due to a newly identified area of need, this is unreasonable and infeasible for programs to achieve due to the paperwork burden is presents. Or, if it refers to programs implementing medication dose changes, insulin titration, diabetes device initiation and training, and ongoing support resource coordination, this should not be part of the DSMT regulation as this is an interprofessional team and the scope of practice is regulated through discipline, state and organization-specific protocols and policies.

Suggested Modification: Delete 42 CFR §410.141(b)(2)(iii).

2. Increase Beneficiary Access to Individual Care

The options listed below are mutually exclusive. We recommend Option 1 as the most comprehensive and preferred solution and present Options 2, 3, 4, and 5 as progressively narrower, less productive alternatives.

Background: CMS in its regulations for the DSMT benefit currently sets a default that 9 of the 10 initial hours of DSMT will be delivered in a group care setting. Access to individual for the full 10 hours can only be obtained via certification of the referring provider that the beneficiary has one of a narrow list of exceptional circumstances that regulatory text implies is non-exhaustive, but CMS has declined for two decades to issue sub-regulatory guidance elaborating on whether certain common circumstances would or would not be considered exceptions to the group care default.

Option 1: Remove the default requirement that 9 of the 10 initial hours be in the group setting.

Rationale: Presuming that DSMT is delivered in a group setting for 90% of the hours with such a strict limit on the number of individual hours and restricting their use to only an initial assessment does not provide programs the flexibility they need to meet beneficiaries' immediate needs. While some beneficiaries may be well-suited to the current benefit design, recent CMS benefit utilization data suggests most are not. The current plan design leaves no room for programs to provide personalized or hybrid care that utilizes a mix of individual and group training, for example for beneficiaries who need extra one-on-one training on a certain topic. While the payment rate to a program for a beneficiary receiving individual care is higher than if that beneficiary were to receive group training, we do not see additional risk that there will be any undue financial influence that will lead programs to over-utilize individual care because programs do not have sufficient staff to convert all beneficiaries to individual care and it is a more efficient use of limited staffing resources for programs to conduct group classes and receive the lower group rate reimbursement multiplied by a higher number of beneficiaries.

Of note, we believe this is the only option for modifying the current individual vs group regulations that would create the possibility of a hybrid care model. The other options below simply increase access to beneficiaries receiving 100% individual care but, with the way the regulation is written, MACs may deny group claims for beneficiaries with individual care indicated on their referral order, precluding hybrid care. Hybrid care is likely to be the most cost-effective for the Medicare program, beneficiaries, and programs given that beneficiaries will receive the services they need, in the way they need them, at the time when they are most able to achieve positive outcomes.

Suggested Multi-Part Modification: 1) Amend 42 CFR §410.141(c)(1)(i)(D) to read, "Is furnished on an individual basis or in a group setting consisting of 2 to 20 individuals who need not all be Medicare beneficiaries", 2) delete 42 CFR §410.141(c)(1)(i)(F), and 3) Delete 42 CFR §410.141(c)(1)(ii).

Option 2: If CMS decides to keep the default that 9 of 10 hours are in the group setting, give programs the authority to determine whether a beneficiary needs individual training.

Rationale: As discussed above as part of streamlining referral orders, the referring provider may not have enough time during their visit with every beneficiary to ascertain whether the beneficiary would be a good candidate for group classes or if they need individual training, but they are the only individual currently allowed to make that determination. We recommend, in cases where the referring provider does not specify whether a beneficiary needs individual training, that this determination be built into the initial assessment in which DSMT programs evaluate areas of need. This aligns with the regulation of the Medical Nutrition Therapy (MNT) benefit which does not limit the registered dietitians' ability to allocate hours of the benefit across codes 97803 (individual follow-up MNT) vs 97804 (group MNT) to best meet the beneficiaries' needs.

Suggested Modification: Amend 42 CFR §410.141(c)(1)(ii)(B) to read "The beneficiary's physician (or qualified nonphysician practitioner) **or approved entity** documents..."

Option 3: If CMS decides to keep the group vs. individual hours determined exclusively by the referring provider, remove the non-exhaustive list of reasons for individual training.

Rationale: The current, non-exhaustive list of reasons why a referring provider can certify a beneficiary for individual training has created much confusion. Because the list says, "such as," it ultimately leaves interpretation of what is an acceptable reason up to the MACs. This leaves programs guessing as to whether care for a beneficiary who was referred to them with a non-listed reason for needing individual care will be compensated. CMS has declined requests from ADCES and ADA to issue an exhaustive list of acceptable reasons as guidance for programs/MACs and has refused to confirm, in writing, whether a number of potential diagnoses (like learning disabilities or social anxiety) would be deemed acceptable "special needs" under this section of the regulation. When this occurs, programs can be left 1) providing inappropriate and less effective group care that is in conflict with the National Standards for DSMES approved by CMS, 2) providing individual care that will ultimately be rejected for payment by their MAC, or 3) turning away referred beneficiaries because they believe that the referral will result in a denied claim/uncompensated care.

Suggested Modification: Amend 42 CFR §410.141(c)(1)(ii)(B) to read, "...beneficiary's medical record that the beneficiary **should receive individual training**" and strike the rest of the sentence.

Option 4: If CMS decides to keep the group vs. individual hours determined by the referring provider *and* to maintain a "such as" list of exceptions, add patient preference as a reason for individual hours.

Rationale: As noted above, the current list poses serious problems for programs and referring providers. Adding patient preference as a valid reason to allow individual care will provide an alternative for managing/referring providers who have identified with the beneficiary that individual care would be better for them and then gives programs greater certainty that their claims will be paid. It also creates access to care for patients who refuse to attend group care for a variety of

reasons, many of whom currently decline to return to DSMT after their initial assessment due to the group requirement.

Suggested Modification: Amend 42 CFR §410.141(c)(1)(ii)(B) to read, "...in a group training session, or that the beneficiary expressed a preference for individual care."

Option 5: If CMS does not want to amend this part of the regulation, we recommend CMS issue guidance to expand upon the "such as" clause of the regulation.

Rationale: As noted above, the non-exhaustive list in the regulation combined with a lack of guidance to clarify the regulation has created great uncertainty for programs.

Suggested Modification: No changes to regulation. We recommend that CMS work with ADCES and ADA to issue guidance with an *exhaustive* list of acceptable "special needs" and commit to *promptly* responding to requests from ADCES and ADA to certify whether additional "special needs" identified in the future are acceptable and then updating the guidance accordingly.

3. Increase the Availability and Flexibility of Hours in the Benefit

The recommendations listed below are additive and not alternatives to one another. We would suggest implementing them both.

Recommendation 1: Eliminate the 12-month clock on Initial Hours

Rationale: There is no evidence supporting that the initial hours of DSMT should be used in a 12-month period. While CMS' original intent might 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. CMS should instead eliminate the 12-month clock and allow the 10 initial hours to remain available until used.

Suggested Modification: Delete 42 CFR §410.141(c)(1)(i)(B)

Recommendation 2: Allow for an additional 10 hours of training upon a change in the condition, diagnosis, or treatment regimen.

Rationale: Diabetes is a progressive disease. One would expect the therapies—and therefore self-management strategies—needed to manage the disease to change over time. The 4 critical times to provide DSMT recommended by 7 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.⁶ The current benefit design of 10 initial hours and only 2 hours in subsequent years creates what essentially amounts to a once-in-a-lifetime benefit that only provides access to truly 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 2 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 or has not yet successfully mastered self-management behaviors despite prior training and therefore needs access to a meaningful number of additional hours, which we recommend not have an expiration timeframe. This is the language used in the MNT national coverage determination⁷ and regulation⁸ to reflect the progressive nature of diabetes and kidney disease and 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.

Suggested Modification: Add a new sub-section:

410.141(c)(3) **Additional Hours**. After receiving the initial training described in paragraph (c)(1) of this section, Medicare covers additional hours of training that meets the following conditions:

- (i) Following an evaluation of the beneficiary's need for additional training due to a change of diagnosis, medical condition, or treatment regimen related to the patient's diabetes or due to incomplete mastery of self-management behaviors, the physician (or qualified nonphysician practitioner) treating the beneficiary orders additional hours of training.
- (ii) Consists of no more than 10 hours individual or group training.
- (iii) Group training consists of 2 to 20 individuals who need not all be Medicare beneficiaries.
- (iv) Is furnished in increments of no less than one-half hour.

We would note that the creation of this new category of "additional" hours would require some change in coding/billing to create a way to distinguish "follow-up" from "additional" hours on the claim so that MACs could distinguish whether 2 hours or 10 were available to the beneficiary that year. One option would be to retain the G0108 and G0109 billing codes for individual and group education, respectively, but create unique modifiers for initial, follow-up, and additional hours. Modifiers would also be helpful for research purposes to better understand beneficiary use patterns.

4. Remove or Update the Defunct CMS Quality Standards

The options listed below are mutually exclusive. We recommend Option 1 as the most comprehensive and preferred solution and present Option 2 as a less comprehensive alternative.

Option 1: Delete the original, now-defunct CMS quality standards from regulation.

Rationale: The CMS quality standards outlined in \$410.144(a) were written in 2000 and have yet to be updated. No programs currently use these standards and instead are accredited under one of the other two alternatives specified in \$410.144(b) or \$410.144(c). The National Standards for Diabetes Self-Management Education Programs (\$410.144(b)) are CMS's de facto quality standards and they are updated on a regular basis, making \$410.144(a) no longer necessary. Additionally, any alternative standards created by one of the national accrediting organizations (\$410.144(c)) are required to be certified by CMS as meeting or exceeding the standards in (\$410.144(a)), which creates problems as accrediting organizations (AO) have to go to great lengths to create standards

that both reflect the latest evidence base as is required of them in the AO regulations, and comport with the provisions in \$410.144(a). Despite the regulation being clear that programs only need to meet ONE of the standards listed in \$410.144(a-c), MACs and other payers that rely on CMS standards have routinely misinterpreted the requirement that all programs must uniquely certify that they align with \$410.144(a) in addition to complying with \$410.144(b) or \$410.144(c) and have denied all claims from programs who only submit evidence of compliance with (b) or (c) and not also (a). This results in delayed entry into or temporary removal from the CMS DSMT benefit program (or analogous private coverage) for entire programs, which is a serious access issue, especially for smaller programs that may struggle with the large paperwork burden already present in the DSMT benefit. All of this would be solved by deleting \$410.144(a) and all references to it and keeping \$410.144(b) and \$410.144(c) as the options for quality standards.

Suggested Modification: Delete 42 CFR §410.144(a) and create conformatory edits throughout the regulation that refer to 42 CFR §410.144.

Option 2: Update the CMS quality standards.

Rationale: As discussed above, the current CMS quality standards outlined in §410.144(a) are outdated, and references to them in other sections of the regulation (particularly §410.144(c)) continue to cause problems not just for accrediting organizations but for programs who have claims denied in bulk due to persistent misinterpretation of the regulations by MACs and other payers that mistakenly believe that programs must comply with both §410.144(c) and §410.144(a). Updating the quality standards at §410.144(a) would not reduce the confusion as to which standards programs much follow but would at least ensure the three different sets of standards are aligned.

Suggested Modification Process: While we strongly recommend CMS delete the original, outdated standards from regulation entirely, if CMS decides it must keep its own standards written into regulation, we recommend CMS undertake a process to update the language of \$410.144(a) to reflect the 2022 National Standards of Diabetes Self-Management Education Programs (those created pursuant to \$410.144(b)) and commit to updating \$410.144(a) in the immediate next physician fee schedule rule whenever the National Standards are updated in the future. We also request CMS immediately issue written guidance for the MACs once the update to \$410.144(a) has occurred. ADCES commits to helping CMS disseminate these changes to accredited programs and payers.

5. Allow DSMT and MNT to be delivered on the same day

The preclusion that DSMT and MNT cannot be delivered and billed for on the same calendar day stems from the MNT benefit's law that instructed the Secretary to determine the appropriate waiting period between the preexisting DSMT benefit and the newly created MNT benefit. 9 When CMS's Coverage Analysis Group undertook the determination process to develop the MNT benefit in 2002, 10 they explicitly stated they found no need to have a waiting period between DSMT and MNT. However, CMS determined at the time that a legislative instruction to determine the waiting period nevertheless required them to implement a waiting period, so they picked the shortest period possible (1 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 is providing both services.

The persistence of this waiting period for over two decades is purely conformatory and explicitly not evidence-based per CMS's own findings. We would encourage CMS to consider that implementing a 0-day waiting period 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. Implementation of this change would require an update to the MNT NCD, 11 RD regulation, 12 and the MLN fact sheet for DSMT. 13

6. Allow accredited/recognized asynchronous DSMT programs to enroll as suppliers

Similar to how CMS had chosen in the CY26 MPFS proposed rule to allow "online" or asynchronous

Diabetes Prevention Programs that maintain recognition as National DPP's into Medicare as MDPP suppliers, ADCES request that CMS also consider making the same allowance for asynchronous

DSMT programs that are accredited/recognized through CMS-approved accrediting organizations (currently ADCES and ADA). A number of these programs have already achieved accreditation/recognition and operate in the private insurance and employer market. This change would also bring this modality option to Medicare beneficiaries.

ii. Prevention and Management of Chronic Disease: Improvements to Intensive Behavioral Therapy for Obesity Benefit

Access to the full continuum of care to treat obesity is critical for addressing obesity as a chronic disease and for diabetes prevention and management for Medicare beneficiaries. The goal of the Medicare Intensive Behavioral Therapy (IBT) benefit is to reduce rates of obesity and its comorbidities. However, CMS data show that, under the current benefit design, IBT for obesity is not being utilized to its full potential, thus falling short of the goal. Utilization has been increasing since the inception of the benefit, but, <u>as of 2022</u>, only 1% of the more than 13.8 million Medicare FFS beneficiaries with obesity received IBT for obesity.

ADCES urges CMS to exercise its existing authority to reconsider the National Coverage Determination for the Intensive Behavioral Therapy for Obesity Benefit (NCD 210.12). Specifically, CMS should expand the range of providers and settings beyond the current limitation of primary care providers working in a primary care setting. The benefit should be brought into alignment with standards of care by allowing additional qualified providers (specialty physicians, nurse practitioners, clinical nurse specialists, and physician assistant (PAs), clinical psychologists, registered dietitians or nutrition professional, and Medicare Diabetes Prevention Programs (MDPPs)) to independently provide and bill for this service upon referral from their primary care provider without limitation to the primary care setting. In April of this year, the Obesity Care Advocacy Network (OCAN) submitted a formal reconsideration petition for this National Coverage Determination. ADCES encourages CMS to act on the OCAN petition and open such a reconsideration with the goal of expanding access to this benefit.

iii. Prevention and Management of Chronic Disease: Improvements to Medical Nutrition Therapy Benefit

Nutrition plays a foundational role in prevention and treatment including in the care of people with diabetes, prediabetes, cardiovascular disease, hypertension, kidney disease, obesity and more. Currently, Medicare Part B only covers Medical Nutrition Therapy (MNT) with a registered dietitian

for beneficiaries with diabetes or certain stages of kidney disease. MNT is a high-value service that directly supports CMS's goals of preventing disease progression, lowering downstream costs and advancing whole-person care. Yet, it remains underutilized due to restrictive eligibility criteria, referral requirements and limitations on the number of hours covered. These barriers leave significant clinical and economic value on the table.

1. Use Existing Waiver and Demonstration Authorities to Test Expanded Access to MNT

ADCES urges CMS to use its existing waiver and demonstration authorities to test expanded access to MNT. While we recognize that statutory limits constrain permanent nationwide coverage expansions, CMS has authority under Section 1115A of the Affordable Care Act to waive certain requirements within the Medicare program when testing innovative models of care. Incorporating MNT in current and future demonstrations would allow CMS to evaluate the clinical and cost-saving potential of expanding MNT beyond diabetes and chronic kidney disease, as well as the integration of MNT for beneficiaries with chronic conditions such as prediabetes, obesity, and cardiovascular disease. By leveraging this authority, CMS can take an important step toward modernizing Medicare benefits, improving patient outcomes, and reducing downstream costs.

2. Expand MNT Coverage to all Stages of Chronic Kidney Disease (CKD)

Coverage for MNT for chronic kidney disease is currently limited to individuals with a glomerular filtration rate (GFR) between 15-59 ml/min/1.73m.¹⁴ This excludes patients with CKD stages 1, 2 and 5, despite clinical evidence that early nutrition intervention can slow disease progression, improve cardiometabolic outcomes and reduce the long-term burden of kidney failure.^{15,16,17}

In the CY 2024 Medicare Physician Fee Schedule Rule, CMS removed the codification of clinical test criteria from the referral criteria for MNT and DSMT, instead relying on a general clinical definition for diabetes, allowing practitioners to apply up-to-date, evidence-based guidelines for the diagnosis of diabetes. Continuing to codify GFR ranges in regulation runs into the same challenges that codifying measures of abnormal blood glucose did: misalignment with evolving clinical guidelines for diagnosis and treatment of the disease. Therefore, CMS should apply the same rationale to MNT coverage of CKD, which would allow beneficiaries with any stage of CKD to be referred for MNT.

3. Support the Medical Nutrition Therapy Act in Congress

CMS should also work with Congress to address the perceived statutory limitations of MNT to beneficiaries with diabetes and kidney disease. The bipartisan Medical Nutrition Therapy Act (pending reintroduction in the 119th Congress) would explicitly grant CMS the authority to cover MNT for prediabetes, obesity, hypertension, cancer and other evidence-based conditions and would set out parameters for the Secretary to further expand this list based on emerging evidence in the future. This additional authority would align with the administration's focus on preventing and managing chronic disease and would open up more opportunities to intervene earlier in the trajectory of disease (e.g., at prediabetes or obesity instead of after a diagnosis of type 2 diabetes).

iv. Prevention and Management of Chronic Disease: Improvements to the Medicare Diabetes Prevention Program

As compared to rates of program recognition in the National DPP, supplier enrollment in the Medicare DPP lags significantly. This can be at least partially attributed to the inconsistencies between the NDPP and MDPP and other benefit design choices made by CMS. Below we propose several changes to improve benefit design and NDPP/MDPP alignment to improve access to the DPP for Medicare beneficiaries. ADCES is also cognizant that, with the addition of virtual suppliers to the program, that some amount of replacement will occur where participants that may have otherwise participated in an in-person or traditional telehealth MDPP will now choose an asynchronous program instead, which could leave the finite number of traditional-modality MDPPs in an even more precarious position with even less financial incentive to continue complying with the MDPP's more cumbersome participation criteria to remain as Medicare suppliers. This only underscores the need for CMS to make MDPP enrollment simpler for traditional suppliers.

Elimination of Once-in-a-Lifetime Participation Limits

A significant deviation of the MDPP from the NDPP is the limitation that beneficiaries may only participate (or begin to participate) in the program once in their lifetimes. This has continually been a problem, that was temporarily waived during the COVID-19 public health emergency, but it becomes even more salient with the addition of asynchronous DPPs to Medicare. The beneficiary experience of participating in a traditional in-person or synchronous telehealth MDPP is fundamentally different than participation in an asynchronous program. While this is both a reason for CMS to move forward with finalizing their proposal to allow asynchronous programs into MDPP and expand beneficiary choice, it also creates the potential for beneficiaries to enroll in one modality (synchronous vs asynchronous), determine that they do no enjoy that participation experience, drop out, and later realize they have now lost the ability to try a different modality program. There remain many reasons why a once-in-a-lifetime limit for MDPP has always been a shortcoming of the benefit, but the addition of asynchronous suppliers to the program underscores the need to make this change as soon as possible, in the CY27 MPFS proposed rule if not the CY26 final rule.

Make MDPP a Permanent Benefit

ADCES continues to support making the MDPP a permanent benefit in Medicare. While the additional 2-year extension of the MDPP model is helpful in providing a small level of certainty to existing suppliers, a rolling time horizon for the potential sunsetting of the test model does not provide the level of certainty that all DPPs need to undertake the effort and investment required to become a Medicare supplier.

Reevaluate the MDPP Supplier Risk Level

New MDPP suppliers are currently categorized as "high risk" suppliers, which is reserved for entities that have a high potential for fraud, waste, or abuse. With this classification comes onerous requirements including fingerprint-based criminal history check of board members of non-profit suppliers on top of the screening requirements for moderate and limited risk supplier categories.

Given the overall low reimbursement potential for MDPP services, the large percentage of the total payment that is tied to weight loss outcomes in the program, and the lack of evidence from CMS of meaningful levels of fraud within MDPP over the first 8 years of the model test, ADCES requests that CMS consider revising § 424.518 to move new MDPP suppliers from the "high risk" to "moderate risk" category where revalidating MDPP suppliers are classified.

v. Prevention and Management of Chronic Disease: Motivational Interviewing

In the RFI on prevention and management of chronic disease, CMS contemplates the future addition of separate coding and payment for motivational interviewing and asks a series of follow-up questions aimed at informing this addition. ADCES would request that CMS reconsider adding new codes for motivational interviewing.

Motivational Interviewing is best characterized as a technique or approach¹⁸ that can be employed as part of any counseling-based service¹⁹ rather than something that should be its own service or code set. In the realm of diabetes prevention and management, motivational interviewing is commonly used as part of medical nutrition therapy, diabetes self-management training, and diabetes prevention programs (all Part B covered services) as a tool to help people with or at risk of diabetes assess and pursue behavior change for self-management of their health. ADCES trains diabetes care and education specialists on this technique with the goal of better incorporating it into existing practices.^{20,21} Motivational Interviewing training is also offered to dietetics students²² and to dietitians working across practice settings and disease states to enhance their practice abilities²³ and is part of the Standards of Practice for dietitians.²⁴ The fields of medicine, psychology, and many others in physical, mental, and behavioral health care also use this technique as one of myriad behavior change strategies that can be deployed in behavior change counseling.

If motivational interviewing were to be given its own code set, we are concerned about the potential confusion that would be created with coding for existing services (DSMT, MNT, DPP, etc.) that already have aspects of Motivational Interviewing seamlessly incorporated into the service. It would be cumbersome and would provide no additional benefit to beneficiaries for providers to be asked to quantify the minutes spent employing Motivational Interviewing techniques vs other behavior change strategies during their counseling sessions for the purpose of billing these codes separately. We are also concerned about the overall complication of setting out parameters for who would be able to refer for, provide, oversee, and bill for Motivational Interviewing as a service and in combination with which other services given that it is a technique that can already theoretically be used by every billable provider type in Medicare for behavior change related to any disease state.

IV. <u>Medicare Diabetes Prevention Program</u>

In the Section III.E. of the rule, CMS proposes to test the inclusion of an asynchronous delivery modality including a new payment scheme for Online sessions. **ADCES supports CMS's decision to pilot the inclusion of asynchronous/online DPPs in Medicare**. As CMS notes, this change helps fulfill Medicare's 2018 goal of improving alignment of MDPP policies with CDC's Diabetes Prevention Recognition Program, with whose standards all MDPPs must comply.

Ideally this modality expansion will increase program participation among beneficiaries uninterested in traditional program modalities, but, as noted in our comments above in response to the Chronic Disease Prevention and Management RFI, there may be a substitution effect among participants that results in traditional modality MDPPs having fewer enrollees from Medicare or overall. CMS should use their own pilot data and data from the NDPP at CDC to closely monitor the additive vs substitution effects of including asynchronous/online DPPs in Medicare and should proactively explore ways to improve the ability for smaller programs offering traditional modalities to participate in MDPP so that we do not end up in a situation where large purveyors of asynchronous/online MDPP become the only available option due to supplier attrition.

V. MIPS Quality Measures Proposed for the CY 2026 Performance Period/CY 2028 MIPS Payment Year and Future Years

Screening for Abnormal Glucose Metabolism in Patients at Risk of Developing Diabetes ADCES supports the addition of the Screening for Abnormal Glucose Metabolism in Patients at Risk of Developing Diabetes measure to the MIPS program. Adding this measure to MIPS fills a gap in the program and aligns with the diabetes prevention efforts at the CDC and the stated goals of the administration to reduce the burden of chronic disease in the US.

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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 prevent and manage 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

Hamah & Martin

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