Unleashing Prosperity Through Deregulation of the Medicare Program (Executive Order 14192)- Request for Information
Submitted via text boxes at: https://www.cms.gov/medicare-regulatory-relief-rfi

Topic 1: Streamline Regulatory Requirements
1A. Are there existing regulatory requirements (including those issued through regulations but also rules, memoranda, administrative orders, guidance documents, or policy statements), that could be waived, modified, or streamlined to reduce administrative burdens without compromising patient safety or the integrity of the Medicare program?

The Diabetes Self-Management Training (DSMT) benefit in Medicare is currently over-regulated. Unlikely many counseling benefit in Medicare, DSMT was created directly in regulation rather than through the National Coverage Determination Process, so there is no formal way to petition for it to be updated. CMS has made small changes over the years, but the overall structure and regulation of the benefit has remain untouched for a quarter of the century. It was created in a time when medical records were kept on paper, referrals and prescriptions were printed or faxed rather than uploaded to a portal, and team-based care across departments and sites was far from a given. In the modern healthcare era, however, many of these regulations now stand in the way of patients accessing the care they need.

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.

CMS should 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 in 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.

References:

[1] American Diabetes Association. Standards of Medical Care in Diabetes–2017. Diabetes Care 2017; 40 (Suppl.1): S3

[2] Duncan I, Birkmeyer C, Coughlin S, Li QE, Sherr D, Boren S. Assessing the value of diabetes education. *Diabetes Educ*. 2009;35(5):752-760

[3] Strawbridge LM, Lloyd JT, Meadow A, et al. Use of Medicare's diabetes self-management training benefit. Health Education Behavior 2015; 42: 530-8.

1B. Which specific Medicare administrative processes or quality and data reporting requirements create the most significant burdens for providers?

CMS should remove or update the Defunct CMS Quality Standards for Diabetes Self-Management Training Program Accreditation. Below, we provide two mutually exclusive options for doing this. 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.

Topic 2: Opportunities to Reduce Burden of Reporting and Documentation
2A. What changes can be made to simplify Medicare reporting and documentation requirements without affecting program integrity?

CMS should streamline referral orders for the Diabetes Self-Management Training benefit
The recommendations listed below are additive and not alternatives to one another. We would suggest implementing all three.

Recommendation 1: Remove the 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,[1] 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.

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).

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

2B. Are there opportunities to reduce the frequency or complexity of reporting for Medicare providers?

ADCES would like to align itself with comments submitted by the Diabetes Advocacy Alliance (DAA) on the Medicare Diabetes Prevention Program. The MDPP is an evidence-based behavior change prevention program that can support Medicare beneficiaries in making changes to their daily eating and levels of physical activity, with a goal of achieving quantified weight loss targets. Research shows that even modest weight loss of 3-5 percent can prevent the development of type 2 diabetes or substantially slow down the progression of prediabetes to diabetes.[1] This benefit can also save money: for example, the MDPP Pilot saved $2,650 in Medicare expenditures over 15 months for each senior who completed the program.[2]

Diabetes prevention and care should be core elements of this administration's efforts to combat chronic disease and are more critical than ever before, as approximately 136 million American adults [3] are now living with either prediabetes (97.6 million) or diabetes (38.4 million), and diabetes-related costs are currently $413 billion per year.[4]

We appreciate CMS Deputy Administrator Abe Sutton noting the potential for the MDPP to achieve positive results in the administration's newly revamped strategy [5] for the Centers for Medicare and Medicaid Innovation (CMMI). However, enrollment for the MDPP stood at just 9,015 Medicare beneficiaries [6] at the end of March 2024, which is striking considering more than half a million have participated in the CDC's National Diabetes Prevention Program (National DPP).[7] There are several reasons for this discrepancy of program uptake:

Far fewer suppliers. There are more than 1,500 CDC-recognized organizations [8] offering the CDC's National DPP compared with just 414 MDPP suppliers,[9] as of April 2024, for the MDPP.

Regulations that exclude qualified providers. MDPP regulations do not allow organizations that provide only fully virtual, evidence-based diabetes prevention programs to participate in the MDPP. CMS's most recent updates to the MDPP rules allowed in-person suppliers to add distance-learning virtual programs, and this may have slightly increased the availability of MDPP. However,

CDC fully recognized suppliers that are only virtual are not allowed to register as Medicare suppliers, at all. This limitation suppresses supply of MDPP. Fully virtual providers could drastically increase access to the MDPP services, especially in rural and other communities that presently lack suppliers of MDPP in-person services.

Regulations that dissuade some CDC-recognized providers from applying to be MDPP providers. There are many organizations that could apply to be program providers of the MDPP, but don't do so, because the MDPP is different from and harder to implement than the CDC's National DPP. This lack of alignment means MDPP providers are subject to many different rules and regulations, often requiring differing internal accounting and reporting systems. Other challenges include:

1. The MDPP is not aligned with the National DPP on risk-reduction metrics. To reduce burden on both suppliers and beneficiaries, the MDPP should align with National DPP metrics, which include not only weight-reduction measures, but also include measuring participant's physical activity minutes and hemoglobin A1C reduction.

2. Current CMS regulations require nonprofit and charitable organizations to provide the Social Security numbers of all members of their Boards of Directors, which stops many such groups from applying to be Medicare providers.

3. Travel to and from in-person facilities is difficult for many older adults, yet MDPP regulations prohibit participant make-up sessions delivered by virtual means, which would ease provider and participant burden, and as mentioned above, preclude MDPP by fully virtual means.

4. Because MDPP is limited to in-building programs for the most part, participants currently cannot report their weight to their program coaches via digital apps or scales, although these are allowed in CDC fully recognized programs, and thus are supportive of advances in digital health innovation.

Regulations out of sync with other types of behavior change programs covered by Medicare. Currently, MDPP has a once-in-a-lifetime limit for Medicare beneficiaries. We urge CMS to remove the once per lifetime cap on MDPP benefits, which does not exist in the CDC's National DPP and unnecessarily restricts participation in and effectiveness of the MDPP. CMS should allow repeat participation in the MDPP, just as it is allowed for intensive behavioral therapy for obesity and smoking cessation programs, because it is recognized that multiple attempts are often required for lasting behavioral changes. Not all Medicare beneficiaries that begin an MDPP program can complete the number of sessions necessary to achieve behavior change that is required to reduce their risk of developing type 2 diabetes, for reasons that might include changes in health status, or other major life events or caregiving responsibilities. Additionally, beneficiaries may spend several decades on Medicare, especially if they enter the program well before 65 (e.g., via a permanent disability), and the strategies they learned at a younger age may no longer align with their life circumstances in later years.

References

[1] https://www.nejm.org/doi/full/10.1056/NEJMoa012512

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

[3] https://www.cdc.gov/diabetes/php/data-research/index.html.

[4] https://diabetesjournals.org/care/article/47/1/26/153797/Economic-Costs-of-Diabetesin-the-U-S-in-2022

[5] https://www.cms.gov/newsroom/blog/making-america-healthy-again-innovationhealthier-lives

[6] https://www.rti.org/impact/evaluation-medicare-diabetes-prevention-program

[7] https://www.cdc.gov/diabetes-prevention/index.html

[8] https://www.cdc.gov/diabetes-prevention/index.html

[9] https://www.rti.org/impact/evaluation-medicare-diabetes-prevention-program

Topic 3: Identification of Duplicative Requirements

3C. How can Medicare better align its requirements with best practices and industry standards without imposing additional regulatory requirements, particularly in areas such as telemedicine, transparency, digital health, and integrated care systems?

ADCES would like to align itself with comments submitted by the Diabetes Technology Access Coalition regarding rescinding the National Coverage Determination (NCD) 40.2 – Home Blood Glucose Monitors. Currently, NCD 40.2 restricts coverage of home blood glucose monitoring, including via CGMs, to individuals with diabetes. Rescinding this NCD would improve access to continuous glucose monitors (CGMs) for individuals *without* diabetes who experience hypoglycemia, which is consistent with the latest clinical evidence and standards of care.

Current literature, which includes both randomized control trials (RCTs) and real-world evidence (RWE), demonstrates that CGMs are a highly safe and effective tool for all individuals with diabetes, whether they use insulin or not. [1]. Further, evidence strongly supports CGM use among individuals without diabetes but experience hypoglycemia, such as individuals who have had bariatric surgery. These individuals can experience severe reoccurring hypoglycemic events, which can be life threatening, and are relatively common following bariatric surgery, even in the absence of diabetes. [2]. There is significant clinical evidence that demonstrates that CGM use post-bariatric surgery significantly reduces the occurrence of hypoglycemic events and recognizing this,

the American Diabetes Association (ADA) recommends the use of CGMs by post-bariatric surgery patients to monitor for hypoglycemia, alongside other international organizations, such as the Society for Endocrinology in the United Kingdom and the European Society of Endocrinology. [3].

In place of a rescinded NCD 40.2, the Durable Medical Equipment Medicare Administrative Contractors (DME MACs) should update their CGM Local Coverage Determinations (LCDs) to incorporate coverage criteria that expands coverage to populations where the clinical evidence supports CGM use, which they are currently forbidden from doing by NCD 40.2.

Relatedly, Medicare beneficiaries continue to face unnecessary barriers to accessing insulin pumps as the current insulin pump NCD is based on clinical evidence that is more than 20 years out of date, is not consistent with commercial insurance coverage criteria, and is misaligned with coverage for CGMs, which is especially worrying given the increased use of AID systems and their inclusions in relevant standards of care. [4]. Recognizing the harms of this severely outdated coverage criteria, a group of clinicians supported by DTAC submitted an insulin pump NCD reconsideration request more than three years ago in February 2022. To this day, CMS has not acted on the request. In the intervening three years, developments have emerged that further supports the reconsideration request, as a RCT demonstrated that the use of an AID system was associated with improved clinical benchmarks compared to only using a CGM among adults with insulin-treated type 2 diabetes, [5], and the Food and Drug Administration (FDA) approved AID systems for the type 2 diabetes population. [6]. These developments further underscore the importance of updating the NCD for insulin pumps so it is aligned with the coverage criteria for CGMs. We thus urge the agency to act on this request by promptly issuing a proposed NCD for insulin pumps that considers the latest body of literature and standards of care.

References:

[1] See, e.g., Ronnie Aronson, et. al., *IMpact of flash glucose Monitoring in pEople with type 2 Diabetes Inadequately controlled with non-insulin Antihyperglycaemic ThErapy (IMMEDIATE): A randomized controlled trial*, 25 Diabetes, Obesity, and Metabolism 1024 (2023), https://dom-pubs.pericles-prod.literatumonline.com/doi/10.1111/dom.14949; David A. Price, et. al., *Episodic Real-Time CGM Use in Adults with Type 2 Diabetes: Results of a Pilot Randomized Controlled Trial*, 12 Diabetes Therapy 2089 (2021), https://pmc.ncbi.nlm.nih.gov/articles/PMC8177263/; Thomas Martens, et. al., *Effect of Continuous Glucose Monitoring on Glycemic Control in Patients with Type 2 Diabetes Treated With Basal Insulin: A Randomized Clinical Trial*, 325 Journal of the American Medical Association 2262 (2021), https://jamanetwork.com/journals/jama/fullarticle/2780593.

[2] Allison B. Goldfine and Mary Elizabeth Patti, *How Common is Hypoglycemia After Gastric Bypass?*, 24 Obesity 1210 (2016), https://onlinelibrary.wiley.com/doi/10.1002/oby.21520; Hilla Knobler, et. al., *Symptomatic and Asymptomatic Hypoglycemia following Three Different Bariatric Procedures Is a Frequent and Severe Complication*, 68 Diabetes Supplement 1 (2019), https://diabetesjournals.org/diabetes/article/68/Supplement_1/2109-P/60081/; Sarah Malik, et. al., *Recognition and management of hyperinsulinemic hypoglycemia after bariatric surgery*, 10 Obesity Research & Clinical Practice 1 (2016), https://www.sciencedirect.com/science/article/abs/pii/S1871403X15001064?via%3Dihub; Anand

Athavale and Venu Madhav Ganipisetti, *Postbariatric Surgery Hypoglycemia*, StatPearls/Nat'l Library of Med. (Aug. 2023), https://www.ncbi.nlm.nih.gov/books/NBK592417/

[3] American Diabetes Association Professional Practice Committee, *Obesity and Weight Management for the Prevention and Treatment of Type 2 Diabetes: Standards of Care in Diabetes–2025*, 48 Diabetes Care S167 (2025), https://diabetesjournals.org/care/article/48/Supplement_1/S167/157555/); J. Hazlehurst, et. al., *Society for Endocrinology Guidelines for the Diagnosis and Management of Post-Bariatric Hypoglycaemia*, 13 Endocrine Connections (Apr. 2024), https://ec.bioscientifica.com/view/journals/ec/13/5/EC-23-0285.xml.

[4] *Standards of Care in Diabetes – 2025*, 48 Diabetes Care S1 (2025), https://diabetesjournals.org/care/issue/48/Supplement_1; George Grunberger, et. al., *American Association of Clinical Endocrinology Clinical Practice Guideline: The Use of Advanced Technology in the Management of Persons With Diabetes Mellitus*, 27 Endocrine Practice 505 (2021), https://www.endocrinepractice.org/action/showPdf?pii=S1530-891X%2821%2900165-8; Lawrence Blonde, et. al., *American Association of Clinical Endocrinology Clinical Practice Guideline: Developing a Diabetes Mellitus Comprehensive Care Plan—2022 Update*, 28 Endocrine Practice P923 (2022), https://www.endocrinepractice.org/article/S1530-891X(22)00576-6/fulltext.

[5] Yogish Kudva, et. al., *A Randomized Trial of Automated Insulin Delivery in Type 2 Diabetes*, New England Journal of Medicine (Mar. 19, 2025), https://www.nejm.org/doi/full/10.1056/NEJMoa2415948.

[6] *FDA Clears First Device to Enable Automated Insulin Dosing for Individuals with Type 2 Diabetes*, Food and Drug Administration (Aug. 26, 2024), https://www.fda.gov/news-events/press-announcements/fda-clears-first-device-enable-automated-insulin-dosing-individuals-type-2-diabetes.

Topic 4: Additional Recommendations

4A. We welcome any other suggestions or recommendations for deregulating or reducing the administrative burden on healthcare providers and suppliers that participate in the Medicare program.

1. CMS should 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 1.1: 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 1.2: 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.[1] The current benefit design of 10 initial hours and only 2 hours in subsequent years creates what borders on a once-in-a-lifetime benefit that only provides access to intensive education on self-management strategies at one point in time. We fear that the current benefit design is encouraging referring providers to see the service this way as well, which may contribute to low utilization of the 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 determination[2] and regulation[3] 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.

2. CMS should 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.[4] When CMS's Coverage Analysis Group undertook the determination process to develop the MNT benefit in 2002,[5] 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,[6] RD regulation,[7] and the MLN fact sheet for DSMT.[8]

References:

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

[2] Medical Nutrition Therapy Benefit for Diabetes & ESRD. CAG-00097N. Available at: https://www.cms.gov/medicare-coverage-database/view/ncacal-decision-memo.aspx?proposed=N&NCAId=53

[3] 42 CFR §410.132(b)(5). Available at: https://www.ecfr.gov/on/2018-11-23/title-42/chapter-IV/subchapter-B/part-410/subpart-G/section-410.132

[4] Text from the SSA: [MNT is available to a beneficiary who] "has not received diabetes outpatient self-management training services within a time period determined by the Secretary."

[5] Medical Nutrition Therapy Benefit for Diabetes & ESRD. CAG-00097N. Evidence for Coverage of MNT for Beneficiaries Who Have Received DSMT During the Same Time Period. Available at: https://www.cms.gov/medicare-coverage-database/view/ncacal-decision-memo.aspx?proposed=N&NCAId=53#:~:text=Evidence%20for%20Coverage%20of%20MNT%20for

%20Beneficiaries%20Who%20Have%20Received%20DSMT%20During%20the%20Same%20Time%20Period

[6] Medical Nutrition Therapy. National Coverage Determination 180.1. Available at: https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?ncdid=252

[7] 42 CFR § 410.72. Available at: https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-B/part-410/subpart-B/section-410.72

[8] Centers for Medicare and Medicaid Services. MLN Fact Sheet. Provider Information on Medicare Diabetes Self-Management Training. Available at: https://www.cms.gov/files/document/mln909381-provider-information-medicare-diabetes-self-management-training.pdf