Recommendations for Improving the Medicare Benefit for Outpatient Diabetes Self-Management Training

Association of Diabetes Care & Education Specialists

July 31, 2023

Below are four sections in which we discuss potential modifications to the Outpatient Diabetes Self-Management Training (DSMT) regulations that would improve utilization of the benefit directly or would promote program participation, which improves utilization through increased access. 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.

The four sections are ordered based on the section of the code that they discuss. 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. Most of the proposed regulatory changes would also require conforming changes to the Medicare Benefit Policy Manual,[1] which is currently many years outdated and is what programs and Medicare Administrative Contractors primarily rely on to understand the rules governing the benefit.

We also present a final section of additional thoughts on how to improve utilization of the DSMT benefit that are either related to long-term changes (like development of quality measures) or are our thoughts on potential reinterpretations of the underlying statute that could necessitate additional changes to the regulation or sub-regulatory guidance.

In addition to requesting the changes below, we would like to thank CMS for the recent proposal in the CY2024 Medicare Physician Fee Schedule proposed rule to remove the codified diagnosis criteria for diabetes for the purposes of the DSMT (and medical nutrition therapy (MNT)) benefits and create coverage for hemoglobin A1c as a screening test. We agree with CMS's assessment that this will empower health care professionals to apply clinically accurate and appropriate criteria in determining referral needs.

1. Streamline Referral Orders

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

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 approved entity (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

[1] Medicare Benefit Policy Manual. Chapter 15. https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/bp102c15.pdf

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,[2] 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 than 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

---

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

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 needs, 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. **<u>Group vs. Individual Care</u>**

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 alternatives.

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 more even 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. Often, programs trying to get up and running, especially programs that serve the most underserved communities and rural areas, have to turn patients away until they can achieve a high enough referral volume to support group classes, which delays care and harms the ability of these programs to build strong relationships and address the specific needs of their target population.
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 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 group vs. individual hours.

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 care. We recommend, instead, that this be built into the initial assessment in which DSMT programs evaluate areas of need. This aligns with the regulation of MNT which does not limit RDNs' ability to allocate hours of the benefit across codes 97803 (individual follow-up MNT) vs 97804 (group MNT).

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 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) identified by ADCES 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 unlimited 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.

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. **Increased Hours Availability and Flexibility**

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.[3] 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

[3] 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.

treatment regimen 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[4] and regulation[5] 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, 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.
(v) The physician (or qualified nonphysician practitioner) treating the beneficiary must document, in the referral for training and the beneficiary's medical record, the specific medical condition (described in paragraph (d) of this section) that the follow-up training must address.

4. Delete or Update the 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 CMS quality standards.

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

[4] 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&fromdb=true#:~:text=Pursuant%20to%20the%20exception%20at%2042%20CFR%20410.32,orders%20additional%20hours%20during%20that%20episode%20of%20care.
[5] 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

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 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).

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 2021 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. 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.

<u>Additional Thoughts on Improving Utilization of the DSMT Benefit</u>
In addition to the changes outlined above that correspond directly to changes in regulation, there are several more complex issues that impact utilization of DSMT that we would like to provide comment on. In some cases, these comments reflect our understanding of what CMS may already be considering. In other cases, they reflect our thoughts on policy changes that CMS may have previously deemed not possible under current statute.

- ADCES supports the development and implementation of quality measures that improve referrals to and utilization of the DSMT benefit.

- ADCES supports any efforts from CMS to promote the availability of the DSMT benefit and the efficacy of DSMT services to physicians and qualified nonphysician practitioners—particularly those working in primary care.

- **Cost-sharing for DSMT presents a barrier for lower-income beneficiarie**s. Having to pay for 100% of the service until the deductible is met and then 20% between meeting the deductible

and reaching the out-of-pocket maximum represents a significant barrier to self-management of one of the most expensive medical conditions and creates inequitable access to care for lower-income beneficiaries. ADCES recognizes that CMS likely does not have the authority to completely and permanently waive the DSMT cost-sharing requirements, but **CMS does have the authority to test the removal of cost-sharing under the CMS Innovation Center** as it has done in the Accountable Care Organization models, and we would support the inclusion of co-pay-free DSMT in applicable models from the Innovation Center.

- **Allowing DSMT and MNT to be delivered on the same day**. This preclusion stems from the MNT benefit's law.[6] Despite the 2002 MNT CAG memo[7] explicitly finding no need to have a waiting period between DSMT and MNT, CMS determined at the time that the legislative language required some form of waiting period and picked the shortest period possible (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 can provide them with 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,[8] RD regulation,[9] and the MLN fact sheet for DSMT.[10]

- **Allow all treating physicians and qualified nonphysician practitioners to refer**. When the DSMT benefit was created in law, Congress specified that referring providers be only those who are "managing the individual's diabetic condition," which has been interpreted to preclude many providers who are in a position to identify the need for DSMT—such as those managing downstream complications of diabetes or those in emergency or hospital settings—from referring beneficiaries to the service. Beneficiaries who may not have a primary care provider, endocrinologist, or other provider managing their condition or whose managing provider is unaware of DSMT or otherwise not providing a referral or whose managing provider they have not had an appointment within a long period of time are left unable to access DSMT, which further compounds their poor self-management. ADCES believes that a wider range of providers should be allowed to refer for the service similar to how the MNT benefit does not limit referral authority to the "managing" requirement. **We would encourage CMS to take a broader view of what it means to "manage the individual's diabetic condition"** to include management of down-stream complications (podiatry, cardiology, neurology, etc.), including acute episodes of

---

[6] 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."

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

[8] https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?ncdid=252

[9] https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-B/part-410/subpart-B/section-410.72

[10] https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/DSMT-Fact-Sheet-909381.pdf

care related to the patient's diabetes (emergency department and providers in hospital in-patient settings). This could be achieved through issuance of sub-regulatory guidance clarifying the interpretation.

Thank you for the opportunity to provide our thoughts on ways for CMS to improve the DSMT benefit to increase utilization and for the steps CMS has already taken in recent years to achieve this goal. We fully support CMS's goals and would welcome the opportunity to participate in the development of the new policies however we are able. If you have any questions about the information presented above, please contact ADCES director of advocacy Hannah Martin (hmartin@adces.org).

Sincerely,

Matthew Hornberger, MBA
Chief Executive Officer
ADCES

Hannah Martin, MPH, RDN
Director of Advocacy
ADCES

Sacha Uelmen, RDN, CDCES
Director of Diabetes Education & Prevention Programs
ADCES