March 27, 2024

U.S. Department of Health and Human Services
Centers for Medicare & Medicaid Services
Attention: Gift Tee, Director, Division of Practitioner Services

Dear Mr. Tee,

The Association of Diabetes Care & Education Specialists (ADCES) and the American Diabetes Association (ADA) appreciate the opportunity to provide input to the Centers for Medicare and Medicaid Services on changes needed in the CY 2025 Medicare Physician Fee Schedule to ensure there are not major disruptions to the provision of diabetes self-management training (DSMT) and Medical Nutrition Therapy (MNT) via telehealth from the HOPD setting in 2025 and beyond.

ADCES is an interdisciplinary professional membership organization dedicated to improving prediabetes, diabetes, and cardiometabolic care through innovative education, management, and support. With more than 12,000 professional members including nurses, dietitians, pharmacists, and others, ADCES has a vast and diverse network of practitioners working to optimize care and reduce complications.

ADA is a nationwide, nonprofit, voluntary health organization founded in 1940 and made up of persons with diabetes, healthcare professionals who treat persons with diabetes, research scientists, and other concerned individuals. The ADA's mission is to prevent and cure diabetes and to improve the lives of all people affected by diabetes. The ADA, the largest non-governmental organization that deals with the treatment and impact of diabetes, represents the 133 million individuals living with diabetes and prediabetes. The ADA also reviews and authors the most authoritative and widely followed clinical practice recommendations, guidelines, and standards for the treatment of diabetes[1] and publishes the most influential professional journals concerning diabetes research and treatment.[2]

Background on Billing for Telehealth DSMT and MNT from the HOPD Setting

Since the outset of the COVID-19 Public Health Emergency, regulations regarding the delivery of DSMT and MNT via telehealth from various settings have evolved significantly. As of May 2023, CMS was prepared to end all telehealth DSMT and MNT from the HOPD setting alongside the end of the

[1] American Diabetes Association: Standards of Medical Care in Diabetes 2024, Diabetes Care 47: Supp. 1 (January 2024). Available at: https://diabetesjournals.org/care/issue/47/Supplement_1. Accessed March 25, 2024.
[2] The Association publishes five professional journals with widespread circulation: (1) Diabetes (original scientific research about diabetes); (2) Diabetes Care (original human studies about diabetes treatment); (3) Clinical Diabetes (information about state-of-the-art care for people with diabetes); (4) BMJ Open Diabetes Research & Care (clinical research articles regarding type 1 and type 2 diabetes and associated complications); and (5) Diabetes Spectrum (review and original articles on clinical diabetes management).

PHE and the Hospitals Without Walls (HWW) program. Hours after the PHE ended, CMS issued new guidance extending telehealth DSMT and MNT from the HOPD setting through December 31, 2023. Then in the CY24 MPFS, CMS proposed to further extend access through December 31, 2024, which was finalized with the rule in November 2023.

We believe these swings in policy were due, in part, to CMS's miscategorization of DSMT and MNT as "outpatient therapy services" and not a stand-alone services delivered and billed for independently under the Medicare Physician Fee Schedule. In the July 2020 Interim Final Rule (IFC) (CMS-5531-IFC), CMS erroneously grouped DSMT and MNT under therapy services. Doing so led to further error with CMS stating that the Medicare laws do not have a benefit category that "would allow registered dietitians [sic] the ability to directly bill Medicare for their services."[3] Outpatient therapy services are a distinct benefit category under Medicare Part B. Prior to the PHE, outpatient therapy services were not on the list of Medicare approved telehealth services such that physical therapists, occupational therapists, and speech language pathologists were not recognized as distant site providers for telehealth services. While CMS loosely addressed this issue in the CY21 Fee Schedule,[4] we believe that initially placing DSMT and MNT with outpatient therapy services[5] during the public health emergency further contributed to confusion as to whether these services were paid under the Medicare Physician Fee Schedule or the Outpatient Payment Prospective System. To date, the Hospitals and Critical Access Hospitals Frequently Asked Questions (dated June 26, 2023)[6] still lists MNT (CPT Codes 97802, 87903, 97804) and DSMT (G0108 and G0109) as examples of hospital outpatient therapy services.

Impact

While we are grateful for the continued expanded access to telehealth DSMT from the HOPD setting, the last-minute swings between a future with full access and one with zero access in this setting have caused much turmoil within the DSMT community, with anecdotal reports that some programs at least temporarily stopped scheduling patients for care via telehealth in fall of 2023 due to the uncertainty as to whether it would be billable come January 2024, or made extreme plans to relocate the staff of their DSMT program out of the HOPD setting to ensure continued access to telehealth.

Much of the confusion for programs (and the billing departments submitting claims on their behalf) stems from the fact that DSMT is an identical service regardless of whether it is delivered from an HOPD, a clinic, or other out-patient setting. Programs are subject to identical quality standards set by CMS and its recognized accrediting organizations (currently ADCES and ADA), and therefore have the reasonable expectation that billing for their services will be consistently regulated across the arbitrary boundaries of different out-patient settings, which may not even be physical

[3] CMS-5531-IFC
[4] CMS-1734-F
[5] Example of Hospital Outpatient Therapy, Counseling and Education Services that May be furnished to a Beneficiary in the Hospital by Remote Hospital Clinical Staff Using Telecommunication Technology During the COVID-19 Public Health Emergency. https://www.cms.gov/about-cms/emergency-preparedness-response-operations/current-emergencies/coronavirus-waivers. Accessed March 21, 2024.
[6] https://www.cms.gov/files/document/hospitals-and-cahs-ascs-and-cmhcs-cms-flexibilities-fight-covid-19.pdf. Accessed March 21, 2024.

boundaries but rather conceptual ones in the case of departments being reclassified between clinic based and an HOPD.

While we are not able to determine the exact percent of care that is being delivered from the HOPD setting via telehealth, estimates from ADCES and ADA accreditation data indicate that over 1,200—or approximately 56%—of all accredited DSMT programs operate out of the HOPD setting. Programs in these settings also often employ more staff and provide a higher volume of services than programs in other settings, making their share of total beneficiaries served likely an even larger majority than their program share would indicate.

Additionally, our collective communications with HOPD-based programs in our capacities as national accreditation organizations for DSMT (ADCES and ADA) and as the provider association for diabetes care and education specialists (ADCES), lead us to conclude that a substantial number are still providing telehealth DSMT from the HOPD setting to patients receiving care from their homes and that abruptly ending access to telehealth DSMT from the HOPD setting while telehealth DSMT from other out-patient settings continues (assuming action from Congress on post-2024 telehealth), would create severe access issues in the short term for certain and likely also in the long term. In nearly all cases, the DSMT programs and MNT providers have no say in what setting their department is located within the health system for billing purposes, so it is incumbent upon CMS to ensure beneficiary access is not impeded by arbitrary rules created by CMS and imposed upon programs and providers by their health systems.

We are also receiving anecdotal but substantial reports that the lack of clarity as to how to bill for DSMT in the HOPD setting—whether for telehealth or in-person DSMT—has led hospitals to restrict the staff they have available to offer DSMT, even when demand outstrips supply. Ultimately, difficulty with billing from the HODP setting has left many departments with limited options to support necessary providers, thus impeding beneficiaries' access to a service that CMS itself has deemed a priority for increasing utilization.

Lastly, we would like to raise the case of the state of Michigan as one example of where serious access problems within Medicaid will occur if regulation of telehealth DSMT across settings is not standardized. Under the Michigan Medicaid program, DSMT can only be reimbursed if delivered from the HOPD setting or from a health department, and clinic based DSMT programs are ineligible to participate in the Medicaid program. If changes are not made to streamline regulations for telehealth DSMT across settings, DSMT programs in Michigan will be unable to serve both Medicaid and Medicare beneficiaries through both in-person and telehealth modalities.

Recommendations

Instead of continuing to lump HOPD-based DSMT and MNT under “outpatient therapy services,” we believe that both these services should be consistently paid for under the Medicare Physician Fee Schedule and regulated under 1834(m) when delivered via telehealth from the HOPD setting. We believe the mechanism for achieving this lies in issuing sub-regulatory guidance to specify the components that must be submitted to the MAC on claim forms in an HOPD setting, to ensure the

requirements of 1834(m) are being met and therefore that these services can be subject to regulation under that section of the Social Security Act.

In the CY24 Fee Schedule, CMS added a new section *§ 410.78 (b)(2)(x)* allowing distance site practitioners within DSMT programs to bill on behalf of other providers furnishing DSMT services as part of the DSMT entity. In response to this proposal, we requested that CMS add "or approved entity" after "any distant site practitioner" to accommodate HOPD-based telehealth because services from that setting are billed under the hospital NPI, not a provider NPI. CMS rejected this suggestion stating, "For purposes of telehealth, though, the current statute is clear at section 1834(m)(4)(E) of the Act, that only physicians and nonphysician practitioners listed at section 1842(b)(18)(C) of the Act qualify as distant site practitioners, so that area of Medicare law that does not include hospitals or pharmacies."

However, 1834(m) states that care must be "*furnished by*" a physician or eligible practitioner, and it does not state that the care must be *billed under* the NPI of said eligible provider type. We believe this distinction in the language of the statute is where CMS's flexibility lies in regulating telehealth DSMT and MNT from the HOPD setting.

Currently, the way that claims are submitted from the HOPD setting obscures who services were furnished by, and we sympathize with CMS's interpretation that these services therefore cannot be regulated under 1834(m). However, we believe that CMS should be able to design and issue sub-regulatory guidance to endorse a standardized way for HOPDs to submit their claims for DSMT and MNT that capture the rendering provider's NPI, thus meeting the requirements of 1834(m) to substantiate that the service was "furnished by" an appropriate provider. This may mean modifying current billing forms like the UB-04 form to create an explicit location for this information, or it could mean designating existing boxes 76, 78, or 79 on the current UB-04 form as intended for this purpose when submitting a bill for telehealth DSMT or MNT. Either way, CMS will need to issue highly specific and clear guidance on this that can be easily operationalized by the thousands of HOPDs that will need to adopt this revised billing practice.

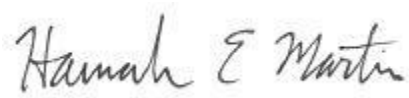
For the purposes of DSMT and retaining access to telehealth provided by all members of the DSMT entity, we believe CMS would then need to voluntarily interpret the term "bill for" in *§ 410.78 (b)(2)(x)* as having been satisfied when an appropriate distance site practitioner is listed as the rendering provider when a claim is submitted from the HOPD setting. Alternatively, CMS could add language to this section to clarify how this would apply to bills from the HOPD setting. E.g., "…who can appropriately bill for *or* ***who can appropriately be listed as the rendering provider in the HOPD setting for***…"

If CMS were to adopt our recommendations or identify another way to achieve maintained access to telehealth DSMT and MNT in the HOPD setting, ADCES and ADA would commit to providing extensive education to our accredited and recognized programs and members providing DSMT and MNT to facilitate a smooth transition and to minimize disruptions in access to care and payments for services rendered.

Conclusion

ADCES and ADA appreciate the opportunity to provide additional information about the importance of making changes in the CY25 Medicare Physician Fee Schedule to allow DSMT and MNT to continue to be delivered via telehealth from the Hospital Outpatient Department Setting. Please contact ADCES director of advocacy Hannah Martin at hmartin@adces.org and ADA vice president of regulatory affairs Laura Friedman at lfriedman@diabetes.org should you have any questions regarding these requested changes.

Sincerely,



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