PART 410 - Improving Payment Accuracy for Diabetes Self-Management Training (DSMT)

A number of issues have prevented utilization of the DSMT benefit. NCOA has noteworthy expertise on chronic care issues and works in close collaboration with hundreds of community-based organizations that provide services to millions of older Americans on a daily basis. NCOA’s Center for Healthy Aging supports the expansion and sustainability of evidence-based chronic care, health promotion and disease prevention programs in the community and online. We provide technical assistance, information, and resources to help organizations build capacity for implementing these programs. We also generate and disseminate new knowledge about best practices to improve outcomes. Our extensive work in this area and close collaboration with various experts, including leaders of community-based organizations that offer DSMT, has led to our comments below.

Accreditation Process
First, the accreditation process is difficult and expensive. It takes an average of 3-6 months for an organization to become certified. This becomes additionally trying given that each community based organization (CBO) has to undergo the accreditation process, even when using the same program as other CBOs. The current process is a significant barrier to organizations that have potential to offer DSMT and limits access to the program. We encourage CMS to shorten the accreditation process for organizations using an already approved program, as an alternative to the current process. The expected result of simplifying the process and maintaining a list of approved programs is that more organizations would apply for accreditation, and the program would be more widely accessible.

Credentials of Individuals Furnishing DSMT Services
We applaud the fact that CMS has acknowledged that confusion regarding the credentials of the individual furnishing DSMT services has created a significant barrier to organizations obtaining reimbursement for DSMT services. The CMS regulations for DSMT require that an organization first obtain accreditation from a CMS-approved national accreditation organization (NAO). The national accreditation standards allow for an accredited DSME program to provide services by a registered nurse, registered pharmacist, or registered dietitian. When an organization completes the accreditation process, using a registered nurse or registered pharmacist, some of the Medicare Administrative Contractors (MACs) choose to refuse payment for the services – even though the organization meets the accreditation requirements set forth by the NAO and have current accreditation for the entity. The decision of the MAC to deny coverage of DSMT services, provided by an entity with current accreditation by a NAO, further restricts access to essential DSMT services at critical consumer access points. Beneficiaries often seek diabetes education from nursing and pharmacy access points in community settings. Therefore, clinical areas that have registered pharmacists and registered nurses are excellent areas to deliver critical DSMT services to beneficiaries. Registered nurses and registered pharmacists are uniquely qualified to deliver this service, in community settings, as noted in the current NAO accreditation standards. Therefore, we recommend that the CMS establish a policy that supports an entity that meets the NAO accreditation standards to obtain reimbursement under the entity, when the service is provided by a registered nurse or registered pharmacist.
Additionally, CMS should seriously consider establishing a policy that if a digital version of DSMT is approved by a NAO, CMS should cover that program as if it were provided in person. There is evidence that digital DSMT programs are also effective.\(^1\) We would welcome the opportunity to discuss this further.

**Self-Referral**

Access to DSMT might also increase if CMS allows self-referral. There is a lot of confusion about diabetes education and whether or not the patient has received formal education through an accredited or recognized DSMT program. Treating providers simply are not aware that DSMT is available for their patients. If self-referral is not an option, NCOA suggests at a minimum that CMS expand the list of providers who can refer Medicare beneficiaries for DSMT. Currently, only the “treating provider managing the patient’s diabetes” can refer a patient for DSMT. NCOA recommends expanding to allow specialists that are treating a beneficiary’s comorbidity or complications (e.g., arthritis, gangrene, vision loss) as well as physicians and other qualified health professionals (i.e., registered nurses, registered dietitians, medical social workers) treating the patient in the hospital, emergency room, physician’s office, clinic, home setting, or other health setting. CMS should also consider requiring a referral to DSMT for patients with diabetes who are readmitted to the hospital with complications of diabetes and those who are frequently in emergency rooms.

**Co-insurance and Deductible Requirement**

NCOA strongly encourages CMS to designate DSMT as an “additional preventive service.” Just as CMS noted with proposed coverage for diabetes prevention, DSMT is also “consistent with the types of additional preventive services that are appropriate for Medicare beneficiaries.” Medicare has the authority to waive certain requirements and we believe that DSMT would also meet the requirements of the Act because DSMT is specifically designed to prevent diabetes complications and advancement of the disease. In contrast, CMS waives the deductible and co-insurance for medical nutrition therapy (MNT), which is generally a complementary service to DSMT. This change would eliminate the coinsurance and the requirement to meet the deductible, and thus beneficiaries would not have to face out of pocket costs for DSMT. A 2015 study at Harvard found that coverage and costs of DSMT services indeed prevent access to care.\(^2\)

Waiving the out of pocket costs for this benefit will encourage beneficiaries to utilize the benefit at a greater rate without adding to their financial burden.

**DSMT and Medical Nutrition Therapy (MNT) Restriction**

CMS should also reconsider the current limitation on billing for MNT and DSMT on the same day. Consumers with a diagnosis of diabetes are eligible for both DSMT and MNT on the same day. While DSMT covers a range of topics related to managing this chronic condition, MNT focuses entirely on nutrition. Most clinical recommendations suggest that consumers benefit from both services. As a result, many programs provide a combined DSMT and MNT course. Unfortunately, the current Medicare regulations prohibit the delivery of DSMT and MNT on the same day to the

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same consumer. However, it is encouraged that a provider delivers a combined DSMT and MNT education program. As a result, the provider has an unnecessary burden of interrupting the education process and forcing the consumer to return on another day to obtain MNT and a separate day from DSMT. This presents an undue hardship for our most vulnerable population, including low-income consumers and persons in rural areas. We suggest that CMS consider eliminating the current prohibition of providing DSMT and MNT on the same day to the same beneficiary.

**Lifetime Benefit**

The DSMT benefit is currently a one-time benefit of ten hours. Diabetes is a progressive disease that is marked by continual changes in recommended disease treatment regimens, increasing disease complication risk, and continual comorbidity risk. A one-time, ten (10) hour, education session does not provide the beneficiary with the necessary education supports as they try to manage their disease over multiple years. In addition, adult learning requires reinforcement and continual refresher training. A beneficiary that has developed disease complications and medication changes would benefit from participating in a full DSMT service, in subsequent years after completing the initial ten (10) hour training. Unfortunately, if a beneficiary participated in a one-time DSMT program, they are not eligible to receive the full benefit of DSMT education for the life of the disease. The limitation of providing expanded refresher training is contrary to established adult learning concepts and reduces the potential preventive health benefits of DSMT on the lifelong need for self-management skills needed to effectively manage a chronic, progressive disease. We recommend that CMS consider expanding the refresher training benefit to all beneficiaries so that they can receive additional refresher training in subsequent years without limitation.

**Rate of Reimbursement**

The current rate of reimbursement for DSMT does not compensate for the level of resources that are required to fully implement the program. As a result, the financial investment required to fully provide DSMT services exceeds the total amount of reimbursement. Therefore, the low compensation serves as a tremendous barrier to scaling the program. A higher level of reimbursement for DSMT would provide the financial resources required to make the program sustainable and allow for expansion to the target population.

The provision of DSMT services requires significant resource allocation before and after the service delivery – an uncompensated requirement to provide the service. Before the initial DSMT service can be delivered, the clinician must first obtain the clinical history of the beneficiary, review the clinical history with the referring provider, and then coordination with the consumer for an initial consultation. The clinical review includes a review to determine if the consumer meets the clinical eligibility criteria and a review to determine if the consumer would be a good candidate for individual and group DSMT services. This initial work is generally performed outside of the individual face-to-face encounter and is therefore work performed that is not factored into the reimbursement formula.

Secondly, the national accreditation standards require that the beneficiary be directed to appropriate diabetes support services outside of the DSMT sessions. By definition, the provision of services to support consumers in obtaining additional education and resources -- outside of the
DSMT course -- is another uncompensated resource allocation. The total reimbursement is a primary deterrent to the expansion of DSMT services.

**Number of Covered Hours**
The current DSMT benefit covers ten hours, which is insufficient. The limitation on the number of hours is a major barrier to access. NCOA encourages CMS to expand the number of covered hours. Various experts agree that additional sessions are required to provide beneficiaries with the skills necessary for lifelong self-management of their diabetes. The additional hours can save on costs for other more expensive health care services that result from poor self-management practices. For example, the Stanford program provides for fifteen covered hours.

Each consumer that completes the DSMT program, must also have a face-to-face individual post-intervention evaluation and follow-up plan. The completion of the post-intervention individualized follow-up plan is a national accreditation requirement. Once the follow-up plan is completed the DSMT program is required to consult with the referring provider to review the follow-up plan. The DSMT benefit only provides reimbursement for one (1) hour of individual services. The one hour of individual services is often completed during the initial assessment and the development of the individualized education plan – prior to the initial DSMT services begin. Therefore, the mandatory post intervention individualized follow-up planning and referring provider consultation must be provided without reimbursement.

**Telehealth Geographic Restriction**
The provision of DSMT via telehealth is an established accepted practice and is essential to meeting the needs of hard-to-reach populations. Unfortunately, DSMT telehealth services fall under the telehealth geographic restriction and therefore cannot be delivered in community settings. The telehealth geographic restriction has particularly detrimental effects on rural and low-income populations in urban areas. The current geographic restriction requires that DSMT only be provided to consumers in designated rural clinical settings only. As a result, vulnerable rural populations in community settings that would otherwise meet the geographic requirement for telehealth, are restricted from receiving DSMT delivered via telehealth processes, unless they transfer from a participating community location to a rural clinic location. In addition, high-risk low-income minority populations have similar difficulty in obtaining DSMT in clinical settings, even in urban areas. As a result, many populations are further restricted from receiving DSMT due to the detrimental impact of the telehealth geographic restriction for DSMT and MNT. We recommend that CMS consider eliminating the geographic restriction for providing DSMT and MNT in order to expand the opportunity for the target population to benefit from the receipt of DSMT and MNT services.

**Supervision Requirements**
Finally, NCOA suggests that CMS permit DSMT to be furnished under general, as opposed to direct, supervision. This would overcome another access barrier and increase the availability of these services. Currently, CMS requires providers of the DSMT benefit to receive direct supervision from a Medicare certified practitioner. In our view, the certified practitioner need not be required to be present in the room when the services is furnished in order to achieve fidelity. Current training standards are sufficient to ensure that direct supervision should not be required. General supervision would improve access and potentially reduce costs. CMS has made a similar
proposal in the current rule for Chronic Care Management (CCM) and Transitional Care Management (TCM) to permit greater flexibility in providing the benefit.

PARTS 410 AND 424 - Medicare Diabetes Prevention Program
In March 2016, NCOA was thrilled with the announcement that Medicare would release rules to expand and cover the diabetes prevention programs for Medicare beneficiaries with prediabetes. The announcement was based on a successful demonstration project the YMCA of the USA completed through the Centers for Medicare and Medicaid Innovation (CMMI) that found participation in the YMCA’s Diabetes Prevention Program saved $2,650 over 15 months.3 NCOA is a long-time supporter of the National Diabetes Prevention Program (National DPP) at the Centers for Disease Control and Prevention (CDC) which was the basis of the demonstration project and we strongly support Medicare’s expansion of the National DPP. In particular, NCOA applauds CMS for its proposal to expand the DPP both as an in-person service and as an online service.

As noted in our comments regarding the DSMT benefit, NCOA has noteworthy expertise on MDPP issues and works in close collaboration with hundreds of community-based organizations that provide services to millions of older Americans on a daily basis.

MDPP Designation as “Additional Preventive Services”
NCOA is pleased CMS is proposing to designate MDPP services as “additional preventive services” available under Medicare Part B. In the proposed rule, CMS explains it can use CMMI’s waiver authority to designate MDPP as an “additional preventive service.” However, CMS does not specifically indicate in the proposed rule that it will also waive the cost-sharing requirement. By designating MDPP as an additional preventive service, we interpret the proposed rule to mean that eligible participants will not be responsible for any cost-sharing for participation. We urge CMS to clarify that by defining this benefit as an additional preventive service they intend for beneficiaries to participate in the MDPP with no cost-sharing. Ensuring this intervention is accessible to Medicare beneficiaries at risk of developing type 2 diabetes must be a top priority and providing coverage with no cost-sharing will enhance program and participant success.

NCOA would like to address CMS’ underlying position in this section of the proposed rule which states: “MDPP services do not meet the requirement in section 1861(ddd)(1)(B) of the Act that they have received a recommendation with a grade of A or B by the USPSTF.” NCOA would like to clarify that the U.S. Preventive Services Task Force (USPSTF) has provided multiple final guidelines which recommend the DPP with a grade of B.4 The USPSTF recommendations are based on the National DPP and Diabetes Prevention Program clinical trial evidence. Private health plans, including Anthem Blue Cross of California, are correctly interpreting the USPSTF guideline and providing coverage of National DPP to enrollees with no cost-sharing beginning as soon as July 2016. NCOA urges CMS to clarify that intensive weight

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management interventions (such as the DPP) have received a B grade from USPSTF so as not to confuse health plans, health care professionals or patients.  

**MDPP Benefit Description**

NCOA supports the concept that MDPP providers must offer a 12-month program and use a curriculum that has been approved by the CDC through its Diabetes Prevention Recognition Program (DPRP). NCOA believes that the wording in the proposed rule – which calls for suppliers “using the CDC-approved DPP curriculum” – could imply that all MDPP suppliers must use the CDC PreventT2 curriculum, which could stifle innovation of curricula that achieve results similar to or better than that of the current CDC curriculum. NCOA urges CMS to clarify in the final rule that MDPP suppliers must use a CDC approved curriculum which, as stated in the DPRP standards, can include a curriculum developed by a supplier that has been submitted, reviewed, and approved by CDC.

In the MDPP guidance, CMS proposes that MDPP be a one-time benefit for Medicare beneficiaries at risk for type 2 diabetes. NCOA encourages CMS to include in future rulemaking an exemption for participants who experience a major life event that impacts his/her ability to attend MDPP sessions. Examples of major life events may include: newly developed health condition by participant or a loved one; change in job status; or death of a loved one.

Finally, in describing the curriculum requirements, the proposed rule suggests that “each MDPP session be at least an hour in duration.” We urge CMS to revise this language in future rulemaking to require that sessions be ‘approximately’ one hour in duration. Session duration is not part of the DPRP standards and a rigid requirement on session duration does not take into account factors that may influence session length such as member participation.

**Enrollment of New MDPP Suppliers**

NCOA supports CMS’ proposal that any organization recognized by the CDC, with either preliminary or full recognition, is eligible to apply for enrollment in Medicare beginning on or after January 1, 2017. The CDC DPRP standards set forth requirements for organizations seeking pending or full recognition to deliver National DPP. The standards state that an organization will receive pending recognition from CDC if it agrees to the curriculum, duration and intensity requirements established under DPRP. Under the DPRP, organizations have 6 months to begin delivering National DPP classes and collecting data from the time they receive pending status. NCOA notes that CMS uses the word “preliminary” in the proposed rule to define a category of MDPP suppliers. CMS should clarify in future rulemaking the definition of preliminary compared to the CDC’s definition of “pending” and whether CMS is requiring organizations have 6 months or one year of data submissions prior to attaining preliminary status and recognition. In a webinar on August 9th, CMS suggested that organizations would need to offer DPP services for at least a year before qualifying for full recognition as a MDPP supplier. NCOA supports this requirement.

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The proposed rules require suppliers to be screened according to the high categorical risk category defined in 424.518(c). The rationale given is that the MDPP suppliers have some similarities to home health agencies and should therefore need enrollment as a high-risk supplier type. We disagree with the analysis that MDPP suppliers are comparable to home health agencies. A MDPP supplier has to first obtain partial / full recognition by the CDC – prior to being able to register as a MDPP supplier. The requirement to meet the full-recognition criteria, set-forth by the CDC, establishes a level of program integrity and academic rigor that is substantially higher than what is required for home health agencies.

The requirement of obtaining CDC-recognition is more closely aligned with the current process of requiring providers of diabetes self-management therapy (DSMT) to first obtain accreditation by one of the National Accrediting Organizations (NAO). Under the current DSMT provider process, the provider must first obtain accreditation by a National Accreditation Organization, prior to obtaining approval to deliver the services to Medicare Part B beneficiaries. DSMT providers must submit proof of accreditation in order to be recognized to provide DSMT services to Medicare beneficiaries. Currently, DSMT providers register under the low categorical risk category. Support for the inclusion of DSMT providers, under the low categorical risk category, is the requirement of obtaining and maintaining accreditation by a National Accrediting Organization. MDPP providers are held to an equally high standard of securing and maintaining CDC recognition to provide the services, and are most closely aligned with the low categorical risk category as DSMT providers. The additional requirement of maintaining CDC recognition provides a significant level of academic rigor and program integrity requirements that far exceed what is required of home health agencies. Therefore, the organizational provider type should be subject to the low categorical risk category, similar to nationally accredited DSMT providers.

Finally, the DPRP standards are updated every three years by CDC and are slated to be updated next in 2018. The DAA urges CMS to address how Medicare standards will be updated in the future and consider how to align these updates with the DPRP update.

**Requirements for MDPP Coaches**

The proposed rule requires coaches who “deliver MDPP services to obtain a National Provider Identifier (NPI) to help ensure the coaches meet CMS program integrity standards.” NCOA encourages CMS to consider the differences between in person and online coaching. In online programs, the website program provides most of the course – coaching from an actual person is supplemental. Thus, CMS should work with its partners at the CDC to develop the best approach to enrolling online MDPP coaches.

**MDPP Eligible Beneficiaries**

In the proposed rule, CMS sets forth the following criteria for MDPP eligible beneficiaries: (1) are enrolled in Medicare Part B; (2) have as of the date of attendance at the first Core Session a body mass index (BMI) of at least 25 if not self-identified as Asian and a BMI of at least 23 if self-identified as Asian. These BMI thresholds are inconsistent with the thresholds set in the CDC’s DPRP. The CDC requirements state that “all of a program’s participants must be 18 years of age or older and have a BMI of greater than or equal to 24 (greater than or equal to 22 if
NCOA urges CMS to align the MDPP eligibility standards, specifically as they relate to BMI, with the CDC program standards.

NCOA is pleased that the eligibility criteria CMS is proposing allow for screening and diagnosis of prediabetes using the following tests: hemoglobin A1c, fasting plasma glucose, or oral glucose tolerance. It’s important that health care professionals and beneficiaries have a range of blood glucose test options to screen for prediabetes and determine eligibility. However, CMS should adjust the eligibility criteria based on fasting plasma glucose. CMS indicates participants would need a fasting plasma glucose of 110-125; clinically, anyone with a fasting plasma glucose of 100-125 is considered pre-diabetic. By not allowing beneficiaries in the range of 100-109 to participate, CMS would block access to two thirds of beneficiaries who are pre diabetic, and thus would benefit immensely from this program. Therefore, we encourage CMS to align the eligibility criteria using fasting plasma glucose with clinically recognized standards for pre-diabetes.

We encourage CMS to clarify in the final rule that Medicare will begin reimbursing for hemoglobin A1c as a screening test for prediabetes and diabetes. Currently, Medicare covers and reimburses fasting blood sugar tests to screen for diabetes. The hemoglobin A1c test is only covered and reimbursed under Medicare if a beneficiary has already been diagnosed with diabetes and it’s ordered by a doctor.

NCOA supports CMS’ proposal allowing for self-referral, community-referral, or health care practitioner referral to obtain MDPP services. We have heard from the field that the option for self-referral has been a major factor in the program’s success. In addition, NCOA is pleased CMS allows for a beneficiary with previous diagnosis of gestational diabetes (GDM) to be eligible for MDPP. We urge CMS to clarify that individuals with previous GDM will be able to self-report their history of GDM to become eligible for MDPP.

**Site of Service**

NCOA commends CMS for proposing to allow in-person and remote/virtual delivery of MDPP services. One reason the CDC’s National DPP has been so successful is because it does not adhere to a ‘one-size-fits-all’ approach to diabetes prevention. For individuals with prediabetes, there may be pros and cons for participating in either an in-person or virtual program and providing options to beneficiaries is important in helping patients enroll, participate, and succeed in meeting program goals. Virtual programs with human coaches offer comparable quality MDPP services compared to in-person services as is assessed in the recent evidence report of diabetes prevention programs conducted by the Institute for Clinical and Economic Review (ICER). The CDC has already established successful processes for enrolling and monitoring digital programs, which CMS can utilize in developing the benefit for digital programs.

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We understand and support CMS’s priority to protect program integrity. Key to that approach should be the requirement for MDPP providers to follow the policies and procedures set by the CDC. CMS and CDC should harmonize any different policies and procedures so MDPP providers can function efficiently without needing to meet different requirements from multiple agencies.

We support the requirement to crosswalk enrollees submitted to the CDC as part of the DPRP with those submitted to CMS for reimbursement. Consideration should be given to the differences in data obtained from those who access a digital intervention versus an in-person program. The typical digital DPP enrollee touches the website many times each week for a variety of reasons (e.g., take a lesson, enter weight, diet and physical activity, and communicate with their coach and their peers). This additional data can be used to not only better serve the enrollee, but also serve as a robust data analysis platform to guard against fraud and abuse. Any audits should take advantage of this robust data.

**Quality Monitoring and Reporting**

We encourage CMS to align quality monitoring and reporting standards for MDPP suppliers with that of the CDC National DPP. The CDC already has a process in place in which they collect data from each program yearly and audit the programs as needed. One useful quality measure could measure people who lower their risk of developing type 2 diabetes by lowering their A1C value. Although weight loss was the measurement of success in the DPP study and is a DPRP standard, there is also evidenced-based correlation between a drop in A1C and reduction in risk.

**Timing of MDPP Expansion**

NCOA urges CMS to expand MDPP nationally January 1, 2018. The CDC’s National DPP, which is the foundation of the MDPP, has been in place for nearly five years and has been immensely successful at building and developing program infrastructure, standards, and certification. Half of all Medicare beneficiaries have prediabetes and are at risk for type 2 diabetes. Implementing this benefit nationally in its first year will provide critically important access and coverage of the National DPP to thousands of our nation’s at-risk seniors, helping them prevent or delay the onset of this costly and debilitating disease and its complications. Further, a “phase-in” of DPP would be unlike other “phase-ins” undertaken by CMS, which have primarily focused on swapping one payment system in for another rather than the wholesale exclusion of a particular service for a specific group of patients.

Time and again, DPP has been proven to reduce beneficiaries’ risk of developing chronic disease – thus also reducing health care costs. DPP has been proven clinically and economically effective in the Medicare context, as well as in other health care populations. It has been proven effective by private researchers, as well as public researchers like the National Institutes of Health (NIH). It has been proven effective in a variety of care settings, including both in-person and virtual settings. There is absolutely no reason why the program should not be implemented nationwide.