American Association of Diabetes Educators
200 West Madison Street, Suite 800, Chicago, Illinois 60606 800.338.3633 Fax 312.424.2427
www.diabeteseducator.org

VIA ELECTRONIC SUBMISSION: OHQ@hhs.gov

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Dear Members of the National Clinical Care Commission:

As the National Clinical Care Commission (the Commission) enters its second year of activity, the American Association of Diabetes Educators (AADE) offers our continued support of the Commission's efforts to evaluate federal programs related to complex metabolic or autoimmune diseases, like diabetes. We look forward to watching the progress of the Commission in the next year and stand ready to assist and support the Commission as it collects data and develops final policy recommendations.

AADE is an interdisciplinary association of healthcare professionals dedicated to integrated clinical care and self-management as key components in the care of people with diabetes and related chronic conditions. AADE represents nearly 14,000 diabetes care and education specialists including nurses, nurse practitioners, PAs, dietitians, pharmacists, exercise specialists, and others. AADE has a vast network of clinicians working with people who have, are affected by, or are at risk for diabetes. Our members have regular interactions with the programs offered by many of the federal agencies that serve on the Commission. As such, we wish to offer our perspective on the current state of some of the existing federal programs.

AADE has identified barriers to care under specific federal programs and has proposed solutions to reduce some of these barriers. Many of the barriers presented in this letter relate to how the diabetes prevention and self-management benefits are structured under the Medicare program. AADE recognizes that CMS faces statutory and systematic constraints and appreciates ongoing efforts to streamline policies and improve access to services. Despite these efforts, people with diabetes and clinicians face challenges in navigating a complex and often inefficient Medicare system, which greatly affects how care is delivered for many within the diabetes community. We recognize that that the Commission's scope of review across federal programs is broad; however, given the impact of current Medicare policies, AADE believes that this is an area where the recommendations made by the Commission could result in substantial, meaningful policy changes. The Commission could make a significant impact on care delivery, access, and innovation by reviewing how diabetes care is provided under the Medicare program and making the necessary policy recommendations to improve these care delivery models.

**Addressing Barriers to Diabetes Self-Management Training (DSMT) Under Medicare**

AADE seeks to address the barriers that prevent Medicare beneficiaries from utilizing the Medicare Diabetes Self-Management Training (DSMT) benefit. Despite the undisputed benefits of DSMT for people with diabetes – lower hemoglobin A1C, weight loss, improved quality of life, healthy coping skills

and reduced healthcare costs – only an estimated 5 percent of Medicare beneficiaries with newly diagnosed diabetes use DSMT services.[1],[2],[3] AADE, the Diabetes Advocacy Alliance (DAA) and other stakeholders within the diabetes community are asking both Congress and CMS to address the barriers to DSMT by making the following changes to the current Medicare benefit for DSMT:

- Allow the initial 10 hours of DSMT to remain available until fully used;
- Cover an additional 6 hours of DSMT services during the first year and in subsequent years, if medically necessary;
- Permit DSMT and Medical Nutrition Therapy (MNT) services to be covered when provided on the same day;
- Exclude DSMT services from Part B cost-sharing and deductible requirements;
- Permit physicians and qualified nonphysician practitioners working in coordination with a treating physician or qualified nonphysician to refer for DSMT services;
- Revise the Medicare Benefit Policy Manual to ensure that hospital outpatient departments can provide DSMT services in community-based locations; and
- Establish a 2-year demonstration program for the coverage of virtual DSMT under the Medicare program.

AADE and our coalition partners have been pursuing federal legislation, the Expanding Access to DSMT Act, to remove some of these barriers, and have also approached CMS to address areas of concern that might fall under the purview of the HHS Secretary.

**Streamlining Requirements for Accredited DSMT Programs**

In order to provide DSMT services to Medicare beneficiaries, entities must be accredited by a CMS-approved national accreting organization (AO). AADE is one of currently only two CMS-approved AOs for entities that provide outpatient DSMT to Medicare beneficiaries. The AADE Diabetes Education Accreditation Program (DEAP) assists entities with both achieving and maintaining their DSMT accreditation. AADE routinely hears from accredited programs, programs seeking accreditation, and individual providers about the complexity of the accreditation requirements. Accredited programs follow rigorous documentation, compliance, and reporting requirements to meet CMS accreditation standards. Programs report challenges with meeting such rigorous requirements. This requires considerable staff resources, which is difficult to sustain given low reimbursement for DSMT. Additionally, Medicare Administrative Contractors (MACs) appear to interpret the criteria and requirements differently, leading to claim denials. AADE recommends easing documentation requirements, improving consistency across MACs, and reducing administrative burden. AADE would be happy to provide the Commission with more information regarding this issue.

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

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

[3] https://www.cdc.gov/diabetes/dsmes-toolkit/background/benefits.html

**Bringing Innovation to the DSMT Benefit**

The two previous examples seek to address the current barriers that people with diabetes and clinicians face under the existing Medicare benefit for DSMT. Ultimately, AADE asserts that it is time for Medicare to rethink the benefit in its entirety to better align with contemporary models of care, including value-based care models. The existing DSMT benefit was first established in 2000, and no longer reflects current quality standards, despite the revisions to the National Standards. Other payers are moving towards alternative care models for DSMT/DSMES services, as demonstrated by the HEDIS measures.[4] The evidence clearly demonstrates that DSMT assists people with diabetes to self-manage the disease, reduces A1C levels, and prevents complications, yet the outdated Medicare fee-for-service model for providing DSMT services hinders many eligible beneficiaries from accessing these important and life-changing services.[5]

**Medicare Diabetes Prevention Program (MDPP) Expanded Model- Recommended Program Modifications**

AADE supports the progress that CMS has made in the first year of the MDPP, while recognizing that additional actions must be taken to increase the number of organizations enrolling as MDPP suppliers, as well as the number of Medicare beneficiaries who utilize this benefit to prevent or delay type 2 diabetes. AADE recommends the prioritization of the following modifications to support the ongoing success and national expansion of the MDPP.

***Allowing virtual programs to participate in MDPP***

AADE strongly supports Medicare coverage of CDC-recognized lifestyle change programs and believes that the availability of virtual programs will increase access and utilization for those unable to participate in an in-person program for 12-24 months. This directly aligns with CMS' focus on addressing the social determinants of health, as the populations who could most benefit from virtual MDPP include Medicare beneficiaries living in rural areas, those who are unable to readily access transportation in urban areas to attend in-person sessions, and those that face other factors, such as poverty and mobility impairments that present barriers to accessing the new MDPP benefit.

In-person MDPP suppliers simply do not have the capacity to serve millions of Medicare beneficiaries. Allowing virtual providers to participate in MDPP will ensure that beneficiaries are able to access the MDPP in the format that best meets their needs. AADE strongly supports and is willing to assist CMS with the development of a model test of virtual MDPP services.

***Align MDPP services with the evidence base and CDC National DPP***

AADE believes it is critical for CMS to align with the CDC's Diabetes Prevention Recognition Program (DPRP) guidelines. This alignment ensures that MDPP suppliers are not faced with the challenge of having to comply with two distinct and complex standards. AADE has identified specific examples of where CMS may pursue better alignment with the DPRP and the evidence base.

[4] https://www.ncqa.org/hedis/measures/comprehensive-diabetes-care/
[5] https://www.cdc.gov/diabetes/dsmes-toolkit/background/benefits.html

- **Allow Programs to be Delivered in Multiple Delivery Modes:** As mentioned above, AADE strongly advocates for the inclusion of virtual programs in the MDPP. This aligns with the CDC's DPRP guidelines. AADE notes that the CDC allows for services to be provided through different delivery modes, such as in-person, online (virtual), distance learning (telehealth), and a combination of those delivery modes.[6] As CMS looks at virtual programs, AADE urges the agency to also consider the positive impact that offering programs via telehealth, distance learning, or a combination of online and in-person programs may have in improving beneficiary access and uptake of the MDPP.
- **Weight Loss Threshold (9 percent):** AADE requests that CMS align with the DPRP on weight loss thresholds**.** There is no evidence to support the 9 percent weight loss threshold included in the MDPP.

***Remove the Once-Per-Lifetime Limit***

AADE also recommends that CMS remove the once-per-lifetime limit for MDPP. Weight loss is a complex, challenging, and ongoing process, with individuals often needing multiple attempts to achieve their weight loss goals[7]. Medicare beneficiaries may experience life events, such as a change in health status for themselves or for a loved one, surgery, or even the death of a loved one that may impact their ability to attend MDPP sessions over 12-24 months. By retaining a once-per-lifetime limit, CMS is denying Medicare beneficiaries the benefits of this important program. AADE requests that beneficiaries are provided with additional opportunities to participate in the MDPP, much like Medicare coverage for obesity counseling and tobacco cessation.

***Adjust reimbursement to cover reasonable costs***

Adequate and appropriate reimbursement continues to be a problem for MDPP suppliers. AADE remains concerned that current MDPP reimbursement levels do not cover MDPP supplier costs, especially given the considerable cost burden associated with the tracking requirements set forth by the MDPP. The complexity of the current payment structure has created barriers to supplier participation. AADE urges the consideration of a more sustainable payment structure for MDPP suppliers to support them in their efforts to provide beneficiaries with the services they need to achieve better health outcomes. Additionally, AADE has requested that CMS ensure MDPP suppliers receive payment in a timely manner. This is especially important to support small, community-based programs that lack the capital to wait months to receive payments. Reimbursement challenges, delayed payments, and financial sustainability all play a significant role in the ability of MDPP suppliers to delivery services to beneficiaries.

***Provide targeted solutions for special populations***

AADE encourages CMS to allow for targeted solutions for special populations accessing the MDPP, such as dual eligible beneficiaries. Low-income participants lose, on average, one percentage point less weight than other participants**.** Given that evidence shows that type 2 diabetes is most prevalent in

[6] https://www.cdc.gov/diabetes/prevention/pdf/dprp-standards.pdf
[7] Wing RR and Phelan S. Long-term weight loss maintenance. American Journal of Clinical Nutrition 2005; 82: 2225-2255.

underserved communities and the CDC has identified this as a priority area of DPP expansion,[8] AADE continues to request that CMS allow for targeted solutions including, but not limited to, payment adjustments for special populations.

**Medicare Coverage of Innovative Diabetes Technologies and Services**

AADE joined the DAA in working with the broader diabetes community in 2017 and 2018 to successfully resolve a Medicare coverage issue related to beneficiary coverage of continuous glucose monitors (CGMs) used in conjunction with smart devices. This issue was ultimately resolved, yet it brought to light the fact that CMS lacks the flexibility to cover innovative technologies and services. Now more than ever, new diabetes technologies are entering the market for people with diabetes; however, Medicare coverage and reimbursement guidelines have not evolved at the same pace. This has resulted in overly complicated, or even a lack of, access for Medicare beneficiaries with diabetes, clinicians, and suppliers. The same is true for diabetes-related services related to prevention and self-management. As healthcare practice and delivery methods continues to evolve, AADE recommends that the Commission explore these areas related to Medicare coverage and reimbursement of innovative diabetes technologies and services.

There are other challenges in ensuring that Medicare beneficiaries have access to safe and effective devices and technologies to manage their diabetes. Below are additional areas that AADE recommends the Commission review:

- AADE advocates for the removal of the Medicare coverage restriction that limits access to therapeutic continuous glucose monitoring (CGM) systems to beneficiaries who have been performing frequent (four or more times a day) self-testing with a blood glucose monitor (BGM), though Medicare only covers three test strips per day for insulin-using patients. While additional test strips may be covered by Medicare with additional documentation, many suppliers will not provide additional test-strips because the additional documentation is overly burdensome and the claims for the additional test-strips are often denied.

- AADE has expressed serious concerns with the National Competitive Bidding Program (CBP) since its implementation in 2011. AADE urges the Commission to work with CMS to address the many flaws inherent to this program. The CBP, as currently designed and functioning, limits choice of testing systems for Medicare beneficiaries and reduces access to safe, effective, and high-quality products. This has resulted in an increase in diabetes-related complications, negative health outcomes, and healthcare costs. CMS must immediately address issues of access, quality, and safety for Medicare beneficiaries accessing diabetes testing supplies.

**National Diabetes Prevention Program**

AADE is a strong supporter of the National Diabetes Prevention Program (DPP) and has a close partnership with the Centers for Disease Control and Prevention (CDC) to ensure people with prediabetes access these important services. As discussed at the September Commission meeting, AADE

[8] https://www.cdc.gov/diabetes/programs/national-dpp-foa/index.html

supports the Commission in their examination of existing models utilized by commercial payers to determine coverage and payment for National DPP Lifestyle Coaches, specifically in ensuring appropriate reimbursement for coaches who many not fall under the category of "qualified healthcare professionals" yet play a critical role in administering the National DPP. AADE appreciates the Commission's attention to this issue, which is central to the sustainability and success of the National DPP.

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AADE appreciates the opportunity to share our perspective with the Commission. We are happy to provide the Commission with any supplemental information on any of the topics addressed in this letter, and once again offer our willingness to serve as a resource as the Commission navigates these critical issues. Please contact Kate Thomas, Director of Advocacy, by phone at 312-601-4821 or via email at kthomas@aadenet.org should you have any questions regarding AADE's remarks.

Sincerely,

Karen Kemmis, PT, DPT, RN, MS, GCS, CDE, FAADE
AADE President

Charles Macfarlane, FACHE, CAE
Chief Executive Officer