Association of
Diabetes Care & Education
Specialists

125 South Wacker Drive, Suite 600, Chicago, Ilinois 60606 800.338.3633 DiabetesEducator.org

VIA ELECTRONIC SUBMISSION: http://www.regulations.gov

February 3, 2020

Dear Members of the National Clinical Care Commission:

The Association of Diabetes Care & Education Specialists (ADCES), formerly known as the American Association of Diabetes Educators (AADE), appreciates the opportunity to offer comments in response to the National Clinical Care Commission's (the Commission) request for public comments regarding the context, policies, effectiveness, promising practices, and limitations and gaps related to the prevention and treatment of diabetes and its complications.

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 network of practitioners working to optimize care and reduce complications. ADCES offers an integrated care model that lowers the cost of care, improves experiences and helps its members lead so better outcomes follow. ADCES' responses to the Commission's questions are provided below.

1. Context: What social, economic and/or environmental factors have the greatest impact on health care in general- and also on prevention (type 2) and/or management of diabetes (both type 1 and type 2)? What can be done by the federal government to address those social/economic/environmental factors?

Social Determinants of Health

As discussed by the Commission at the November 2019 in-person meeting, social determinants of health (SDOH) are important to the overall health of populations and play a key role in why more Americans may not adopt and sustain diet and behavioral changes that prevent, delay, or promote successful self-management of chronic diseases. Federal agencies, like the CDC and CMS, have taken steps to address SDOH and their impact on chronic diseases, like diabetes. The CDC has a number of initiatives focused on addressing health disparities in at-risk or vulnerable populations, including the National DPP, the Native Diabetes Wellness Program, and the Appalachian Diabetes Control and Translation.[1] CMS' Office of Minority Health established the Health Equity Collaborative to convene key stakeholder groups in the diabetes community to better address and screen for SDOH and develop strategies to address disparities

[1] https://www.cdc.gov/diabetes/disparities.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fdiabetes%2Fprograms%2Fvulnerable.html

in diabetes care. SDOH and health disparities are not specific to one disease or one federal agency. ADCES encourages the Commission to consider interagency communication and coordination to reduce health disparities as a means of supporting all Americans who may be at risk for chronic diseases, especially as different agencies seek to address the SDOH.

Food insecurity is one specific area that directly affects diabetes self-management, and according to recent studies may also increase a person's risk of developing type 2 diabetes.[2] ADCES believes there is an opportunity for entrepreneurs and/or the creation of public-private partnerships to develop innovative models to address food insecurity. Programs like Farming for Life, developed by the Sansum Diabetes Research Institute (SDRI), are examining the concept of "food as medicine" in the context of type 2 diabetes and food insecurity. In the Farming for Life program, physicians prescribe produce grown at local farms to people with diabetes once per week for 10 weeks.[3] These types of programs directly assist individuals by increasing access to fresh produce in a manner that is accessible and affordable. The program engages local farms and healthcare providers to bridge the gap between the clinical and community settings. Entrepreneurs and/or public-private partnerships could build upon such models, even going as far as working with healthcare providers, local farms, and food banks to develop medically tailored meals and meal kits. The federal government should continue to support innovative, community-based solutions to issues such as food insecurity.

Screening and Awareness of Current Programs

Screening and program awareness are critical factors in preventing or delaying the onset of type 2 diabetes and/or supporting individuals with diabetes in the management of the disease. Healthcare providers, including primary care providers, and those at risk for type 2 diabetes may not be familiar with programs like the National Diabetes Prevention Program (DPP), which impacts enrollment and participation in such programs. ADCES, and our coalition partners in the Diabetes Advocacy Alliance (DAA), suggest that one way to increase healthcare provider understanding of prediabetes and diabetes risk factors includes simplifying and promoting existing guidelines, like the U.S. Preventive Services Task Force (USPSTF) guideline for Abnormal Blood Glucose and Type 2 Diabetes Mellitus: Screening released on October 26, 2015.[4] ADCES believes that this guideline helps to better define who might be at risk for type 2 diabetes and provides a basis for improving screening, diagnosis, and referrals; however, additional clarity is needed, specifically around whether clinicians should screen based on the full set of risk factors in the guideline and coverage considerations surrounding copays. A clear requirement that health plans must cover these intensive behavioral counseling programs, including diabetes prevention programs, would help advance payment for prevention programs- something that continues to pose a significant barrier to advancing prevention strategies

Coverage Limitations

ADCES believes there is a general misalignment of incentives in the health system that account for some of the current gaps in diabetes prevention and management. In this context, one of the economic

[2] https://www.ajmc.com/newsroom/understanding-the-connection-between-food-insecurity-and-type-2-diabetes
[3] https://www.sansum.org/farming-for-life/
[4] https://www.uspreventiveservicestaskforce.org/Page/Document/UpdateSummaryFinal/screening-for-abnormal-blood-glucose-and-type-2-diabetes

factors that has the greatest impact on health care in general is coverage and payment for diabetes related services, devices, and medications.

National Diabetes Prevention Program

ADCES is a strong supporter of the National DPP and has a close partnership with CDC to ensure people with prediabetes access these important services. Lifestyle coaches are the workforce for the National DPP, and their ability to support participants, provide guidance, and help groups work together effectively are essential for a successful lifestyle change program. Lifestyle Coaches may or may not be "qualified health professionals", but all are trained to deliver the National DPP curriculum. It is critical to have a diverse, expansive workforce to reach the 84.1 million adults with prediabetes in this country. Unfortunately, not all commercial payers, health entities, and payment systems are structured to support billing and reimbursement from individuals who are not considered qualified health professionals, especially those working in faith-based or community-based settings. This systematic and structural issue directly effects the sustainability and success of the National DPP. Effective prevention strategies do not always fit into the box of traditional healthcare provided in a clinical setting. Individuals must be able to receive services within the community and outside of a clinical setting, and have those services covered by governmental and commercial payers. Similarly, providers must be able to provide such services in alternative settings and receive payment for those services.

Additionally, given the scope and impact of diabetes, many private payers still do not cover the National DPP. ADCES asserts that this program should be covered, free of charge for the beneficiary, much like the services covered under the essential health benefits. This program should also be offered as part of a basic benefits package offered by employers.

New Diabetes Technologies

New diabetes technologies are entering the market, though coverage and payment guidelines have not evolved at the same pace. This has resulted in overly complicated, or even a lack of, access for people with diabetes, clinicians, and suppliers. Such coverage challenges can be readily seen when looking at coverage for continuous glucose monitoring (CGM) systems. CGMs have transformed how people with diabetes manage their blood glucose, and can help to lower their A1C, reduce hypoglycemia, and increase time in range for people with type 1 diabetes and type 2 diabetes who use insulin. Medicare and Medicaid policies continue to limit coverage for these devices.[5]

ADCES advocates for the removal of the Medicare coverage restriction that limits access to therapeutic 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 beneficiaries. 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 for prescribers and the claims for the additional test-strips are often denied.

[5] https://diatribe.org/medicaid-cgm

In addition to removing Medicare coverage restrictions that limit access to CGM systems, ADCES also encourages the Commission to explore how state Medicaid plans can improve coverage for these devices. Despite widespread coverage in both the public and private sectors, there are still approximately 15 state Medicaid plans that do not cover CGM, and other states with considerable restrictions, i.e. CGM is covered for children only.[6] This represents another significant barrier to ensuring that diabetes-related devices and technologies are widely accessed and utilized.

Medicaid

As mentioned above, Medicaid coverage policies vary greatly in coverage for devices. They also differ in terms of coverage for the National DPP and diabetes self-management services. This creates disparities among states. To the extent possible, ADCES urges the federal government to consider some type of uniform national diabetes coverage policy or some type of coverage guidance to describe baseline or minimum coverage for state Medicaid programs.

2. Policies: What policies should the federal government implement to improve diabetes prevention and/or management? What is the evidence to support those?

ADCES appreciates the Commission's interest in implementing federal policies to improve diabetes prevention and/or management. We believe an effective starting place for this effort would be to consider necessary changes to the current system to allow existing programs to fully reach their potential. ADCES strongly supports existing programs like the National DPP, the Medicare Diabetes Prevention Program (MDPP), and coverage for diabetes self-management and support (DSMES), also referred to as diabetes self-management training (DSMT) by the Centers for Medicare & Medicaid Services (CMS). [7] These programs, especially the National DPP and Medicare DPP, represent existing innovations in preventing or delaying the onset of type 2 diabetes and serve as important interventions in reducing the risk for the estimated 84.1 million adults with prediabetes in the U.S.[8] This is especially important given that approximately 23.1 million adults ages 65 and older have prediabetes.[9] ADCES believes that recommendations made by the Commission will play a critical role in addressing some of the existing barriers to allow these programs to reach their maximum potential and increase the number of individuals that utilize these important diabetes prevention and management services.

ADCES 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 our comments relate to how the diabetes prevention and self-management benefits are structured under the Medicare program. ADCES recognizes that CMS faces statutory and systematic constraints and appreciates ongoing efforts to streamline policies and improve access to services. People with diabetes and clinicians face challenges in navigating a complex 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, ADCES believes that this is an area where the recommendations made by the Commission could result in substantial, meaningful policy

[6] https://diatribe.org/medicaid-cgm
[7] Note: The Centers for Medicare & Medicaid Services (CMS) use the term "training" (DSMT) to define their reimbursable benefit, but other entities use "education and support" (DSMES).
[8] https://www.cdc.gov/media/releases/2017/p0718-diabetes-report.html
[9] https://www.cdc.gov/diabetes/pdfs/data/statistics/national-diabetes-statistics-report.pdf

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

ADCES 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.[10],[11],[12] ADCES, the 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.

ADCES and our coalition partners have been pursuing federal legislation, the Expanding Access to DSMT Act (H.R. 1840/S. 814), 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. This legislation presents solutions to some of the challenges that beneficiaries face in utilizing the DSMT benefit.

Streamlining Requirements for Accredited DSMT Programs

In order to provide DSMT services to Medicare beneficiaries, entities must be accredited by a CMS-approved national accrediting organization (AO). AADE (ADCES) is one of currently only two CMS-approved AOs for entities that provide outpatient DSMT to Medicare beneficiaries. The AADE (ADCES) Diabetes Education Accreditation Program (DEAP) assists entities in both achieving and maintaining their DSMT accreditation. ADCES routinely hears from accredited programs, programs seeking accreditation, and individual providers about the complexity of the accreditation requirements, specifically, a

---

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

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

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

disconnect from the burden such requirements impose on clinical care in a reimbursement model that is out of alignment with the clinical and financial realities they are facing in 2020. DSMES providers follow rigorous documentation, compliance, and reporting requirements to meet the National Standards for DSMES, with additional requirements to meet CMS accreditation standards. 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. ADCES recommends easing documentation requirements, improving consistency across MACs, and reducing administrative burden. ADCES would be happy to provide the Commission with more information regarding this issue.

ADCES also urges CMS to standardize or set data standards for electronic medical records for DSMES/DSMT to ensure uniformity in data collection. Currently, data standards for electronic medical records vary greatly further adding to provider burden. Creating uniform data collection standards would help to streamline the referral process and ensure consistency across accredited and recognized DSMES programs.

Bringing Innovation to the DSMT Benefit

The previous two examples illustrate the need to address the current barriers that people with diabetes and clinicians face under the existing Medicare benefit for DSMT. Ultimately, ADCES asserts that it is time for HHS and CMS to rethink the benefit in its entirety to better align with contemporary models of care. 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.[13] 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.[14] ADCES believes there is an opportunity to bring innovation to the DSMT benefit to increase beneficiary access and utilization of this benefit. Redefining the benefit and considering recommendations like simplifying the referral requirements has the potential to improve care delivery for Medicare beneficiaries with diabetes.

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

ADCES supports the progress that the 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. ADCES recommends the prioritization of the following modifications to support the ongoing success and national expansion of the MDPP.

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

Allowing virtual programs to participate in MDPP

ADCES 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. ADCES 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

ADCES 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. ADCES has identified specific examples of where CMS may pursue better alignment with the DPRP and the evidence base.

- **Allow Programs to be Delivered in Multiple Delivery Modes:** As mentioned above, ADCES strongly advocates for the inclusion of virtual programs in the MDPP. This aligns with the CDC's DPRP guidelines. ADCES 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.[15] As CMS looks at virtual programs, ADCES urges HHS 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:** ADCES requests that CMS align with the DPRP on weight loss thresholds**.**

Remove the Once-Per-Lifetime Limit

ADCES 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[16]. 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. ADCES requests that CMS provide beneficiaries with additional opportunities to participate in the MDPP, much like Medicare coverage for obesity counseling and tobacco cessation.

---

[15] https://www.cdc.gov/diabetes/prevention/pdf/dprp-standards.pdf

[16] Wing RR and Phelan S. Long-term weight loss maintenance. American Journal of Clinical Nutrition 2005; 82: 2225-2255.

Adjust reimbursement to cover reasonable costs

Adequate and appropriate reimbursement continues to be a problem for MDPP suppliers. ADCES 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. ADCES urges HHS and CMS to consider a less burdensome and 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, ADCES 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 deliver services to beneficiaries.

Provide targeted solutions for special populations

ADCES encourages CMS to allow 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 underserved communities and the CDC has identified this as a priority area of DPP expansion,[17] ADCES requests that CMS allow for targeted solutions, including, but not limited to, payment adjustments for special populations.

3. Effectiveness: What specific recommendations do you have for federal agencies to be more effective and/or collaborate better to prevent and/or help manage diabetes? What is the basis for your recommendations?

Throughout this comment letter, ADCES has discussed examples of federal agencies taking action to improve diabetes prevention and management. We hope these are important steps towards improved coordination efforts and/or alignment of policies among agencies. For example, CMS' Medicare Diabetes Prevention Program requirements differ from the CDC's Diabetes Prevention Recognition Program (DPRP) guidelines. This has proven especially challenging for providers trying to provide these services and meet two different sets of requirements, which in turn affects access to and utilization of services. Additionally, it would be helpful to see federal agencies take a more streamlined or coordinated approach to data collection, requests for public comments, and implementation of programs addressing prevention and areas like the SDOH. It seems like many federal agencies are interested collecting data on similar topics and it would be helpful to the larger diabetes stakeholder community if there was alignment or communication regarding these efforts.

Further, ADCES believes it is critical that the federal government support policies that reduce silos in care delivery and engage all members of the care team, including diabetes care and education specialists. This includes making the necessary improvements to coverage and payment policies, reducing administrative barriers for providers, considering care models that extend beyond the traditional clinical setting, and addressing the current challenges with programs like the National DPP,

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

MDPP, and DSMES/DSMES. Diabetes care and ongoing self-management requires support beyond the traditional clinical setting and it is important to support providers like diabetes care and education specialists as key members of the interprofessional diabetes care team.

4. Promising Practices: What are the best and/or most promising practices to prevent diabetes and/or to improve diabetes outcomes? What is the evidence to support them?

The National DPP and DSMT are both evidence-based programs, as is the use of community health workers and care extenders for delivery of the National DPP. Unfortunately, as described in the previous sections of the letter, the system does not always support these evidence-based promising practices i.e. issues with coverage or recognition for these services. ADCES urges the Commission to address the barriers and systematic challenges that prevent these initiatives from reaching the larger population of individuals with diabetes and prediabetes.

In addition to current diabetes programs, ADCES believes the federal government may be able to utilize existing resources and channels to help connect people with prediabetes or diabetes with the information and care they need. For example, there may be opportunities to transition state-based tobacco quit lines to address chronic disease management more broadly. Quit lines could be transitioned to support efforts like falls prevention, diabetes prevention, DSMES, and others. The current quit lines provide an existing structure to provide outreach in multiple languages and in all states.

5. Limitations and gaps: What are the greatest limitations or gaps in federal programs to prevent diabetes and/or to improve diabetes outcomes? What could the federal government do to close the gaps? Are their specific research needs? Are their specific research needs or programs that would benefit for new or increased collaboration across federal agencies?

ADCES has outlined many of the limitations and gaps throughout our comment letter. Below we have identified additional actions the federal government could undertake to address limitations and gaps and improve diabetes outcomes.

- Remove existing restrictions around the release of de-identified data. The CDC is limited in the data that can be shared from the National DPP. Releasing a comprehensive data set has the potential to inform and improve delivery of the National DPP on both the national and local level.
- Prioritize coordination among federal agencies on diabetes policies, coverage, and programmatic changes.
- Remove the coverage barriers for the National DPP, MDPP, and DSMT/DSMES.
- Simplify referral requirements for DSMT to better align with commercial payers and improve access to this underutilized, yet critically important benefit.
- Fully address the programmatic and systematic barriers to DSMT, including reviewing the current Medicare regulations surrounding this benefit and Medicare Benefit Policy Manual in order to garner stakeholder feedback and make the necessary improvements to the programs.
- Standardize or set data standards for electronic medical records for DSMES/DSMT to ensure uniformity in data collection. Additionally, ADCES asks the federal government to

support smaller providers by expanding opportunities like the Medicare EHR Incentive Program and providing support for clinicians to further adopt and utilize electronic medical records.

* * * * *

ADCES appreciates the opportunity to offer public comments in response to the Commission's questions. 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@adces.org should you have any questions regarding ADCES' remarks.

Sincerely,

Charles Macfarlane, FACHE, CAE
Chief Executive Officer