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VIA ELECTRONIC SUBMISSION: preventionx@hhs.gov

December 19, 2019

The Honorable Alex M. Azar, II
Secretary
U.S. Department of Health & Human Services
Office of the Chief Technology Officer
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

RE: Prevention X RFI Comment

Dear Secretary Azar:

The American Association of Diabetes Educators (AADE) appreciates the opportunity to offer comments in response to the U.S. Department of Health and Human Services (HHS) Request for Information (RFI) on effective prevention strategies to address chronic diseases, including prediabetes and type 2 diabetes. 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 close to 14,000 professional members 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.

Since 2012, AADE has worked alongside the Centers for Disease Control and Prevention (CDC) to scale and sustain the National Diabetes Prevention Program (DPP). AADE has trained more than 1400 lifestyle coaches, provided advanced training to help lifestyle coaches enhance their skills, and activated over 70 National Diabetes Prevention Program sites across 24 states. As an organization, we have provided technical assistance, technology, and trainings to departments of public health, health systems and hospital associations, pharmacies and federally-qualified health centers, and diabetes self-management education and support (DSMES) programs.[1],[2],[3] Over eight years, and through two CDC cooperative agreements, AADE has helped thousands of people with prediabetes access CDC-recognized programs.

Given AADE's organizational focus on diabetes prevention, as well as the fact that our members work closely with people with prediabetes and type 2 diabetes to develop self-management strategies to prevent the progression of the disease and to reduce complications, we are uniquely positioned to offer comments on the Prevention X RFI.

[1] https://www.diabeteseducator.org/education/live-courses/building-your-diabetes-prevention-program
[2] https://www.diabeteseducator.org/prevention/data-analysis-of-participants-system
[3] https://www.diabeteseducator.org/prevention/lifestyle-coach-training

AADE values the focus that HHS has placed on scaling and deploying effective prevention strategies that reflect today's social and economic environment and has detailed our perspective on current barriers and opportunities to support prevention health in our comments below.

Barriers and Opportunities for Effective Preventative Health

1. *In your estimation, what have been the most significant barriers to more effective prevention and delayed progression of chronic health conditions in the US?*

AADE shares HHS' viewpoint that there is a general misalignment of incentives in the health system that account for some of the current gaps between the science of prevention and its implementation. As HHS looks towards innovation to address these gaps, AADE also urges HHS to consider necessary changes to the current system to allow for the potential of existing prevention programs to be fully realized. AADE 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). [4] 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.[5] This is especially important given that approximately 23.1 million adults ages 65 and older have prediabetes.[6] AADE believes that HHS can 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 preventative services. Below, AADE has identified barriers to care under specific federal programs and has proposed solutions to reduce some of these barriers.

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

AADE 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. 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 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

[4] 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).
[5] https://www.cdc.gov/media/releases/2017/p0718-diabetes-report.html
[6] https://www.cdc.gov/diabetes/pdfs/data/statistics/national-diabetes-statistics-report.pdf

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.

- **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.[7] As CMS looks at virtual programs, AADE 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:** AADE requests that CMS align with the DPRP on weight loss thresholds**.**

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[8]. 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 CMS provide beneficiaries 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 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, 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 deliver services to beneficiaries.

Provide targeted solutions for special populations

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

AADE 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,[9] AADE requests that CMS allow for targeted solutions, including, but not limited to, payment adjustments for special populations.

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

DSMT provides significant benefits for people with diabetes, including lower hemoglobin A1C, weight loss, improved quality of life, healthy coping skills and reduced healthcare costs.[10],[11] This helps to slow the progression of the disease and protects against diabetes-related complications. Despite the undisputed benefits of DSMT for people with diabetes, estimates suggest that only 5 percent of Medicare beneficiaries with newly diagnosed diabetes utilize DSMT services.[12],[13],[14] AADE, the Diabetes Advocacy Alliance, 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:

- 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. AADE encourages HHS to revisit this issue and consider implementing the necessary programmatic changes to improve access to this important benefit.

> *4. Despite extensive evidence suggesting the health benefits of diet and behavior change in preventing chronic health conditions such as obesity and type 2 diabetes, many populations continue to see steady increases in the prevalence of these conditions. Why are more Americans not adopting diet and behavioral changes?*

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

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

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

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

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

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

Bringing Innovation to the DSMT Benefit

The previous example illustrates the need 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 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.[15] 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.[16] AADE believes there is an opportunity to bring innovation to the DSMT benefit to increase beneficiary access and utilization of this benefit. The Prevention X initiative could provide a platform to explore innovative, community-based DSMT models.

Screening and Awareness of Current Programs

An additional barrier to people participating in the National DPP or utilizing their DSMES/DSMT benefits can also be attributed to lack of awareness regarding the existence and/or benefits of such programs. Healthcare providers, including primary care providers, and those at risk for type 2 diabetes may not be familiar with programs like the National DPP, which impacts enrollment and participation in such programs.

AADE, and our coalition partners in the Diabetes Advocacy Alliance, 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.[17] AADE 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 which continues to pose a significant barrier to advancing prevention strategies.

Social Determinants of Health

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 diet and behavioral changes. Individuals may face challenges with food access and/or food insecurity, transportation, housing, educations, etc. which can influence and impact adoption of certain health behaviors. 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,

[15] https://www.ncqa.org/hedis/measures/comprehensive-diabetes-care/
[16] https://www.cdc.gov/diabetes/dsmes-toolkit/background/benefits.html
[17] https://www.uspreventiveservicestaskforce.org/Page/Document/UpdateSummaryFinal/screening-for-abnormal-blood-glucose-and-type-2-diabetes

and the Appalachian Diabetes Control and Translation.[18] 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 in diabetes care. Addressing SDOH and health disparities is not disease specific. AADE encourages HHS to explore initiatives that reduce health disparities as a means of supporting all Americans that may be at risk for chronic diseases.

6. What are the key barriers to commercialization of effective prevention products, services, and other strategies with clear public health benefit?

One of the most significant barriers impacting commercialization of effective prevention products, services, and strategies can be linked to the lack of coverage and payment for prevention-related initiatives. This occurs both with commercial and governmental payers. As mentioned above, there are challenges surrounding Medicare coverage and payment for the MDPP and DSMT benefits. We see similar challenges and inconsistencies with state Medicaid plans and commercial payers. This presents challenges for those individuals seeking care and for those delivering care. Below are examples that highlight the key barriers to commercialization.

National Diabetes Prevention Program

AADE is a strong supporter of the National DPP and, as mentioned, 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; however, 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 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. In order to support Buckets 2 and 3, 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.

Coverage for New Diabetes Technologies

In addition to coverage challenges related to diabetes services, new diabetes technologies are entering the market; however, 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 Medicaid 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.[19] Most commercial payers cover these devices, and recently, Medicare also began to cover CGM under Part B. Despite widespread coverage in both the public and private sectors, state Medicaid plans have

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

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

been slow to keep up with these changes. 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.[20] AADE recognizes that each state is different and faces its own challenges in making changes to state Medicaid plans. This represents another significant barrier to ensuring that diabetes-related devices and technologies are widely accessed and utilized.

Prevention X Theory of Change

1. *What are some of the most effective, but not well-publicized prevention strategies (e.g. those found in CDC's 6|18 and HI-5 programs) within Buckets 2 and 3 (or anywhere on the continuum between them)? What has been their key to success? Specifically, we are also interested in interventions that have proven effective on a smaller (e.g., health system or community) scale and are candidates for further testing or expansion.*

Promoting and Supporting the National DPP

As discussed throughout this letter, CDC's National DPP is an effective prevention initiative that was created to address the growing burden of prediabetes and type 2 diabetes in the U.S. The National DPP is public-private partnership that provides a framework in which to offer evidence-based, cost-effective interventions that help prevent or delay type 2 diabetes. The goal of the National DPP is to create opportunities for people with prediabetes to participate in high-quality, lower cost lifestyle change programs to reduce their risk of type 2 diabetes and improve their overall health.[21] Approximately 1,700 organizations across the U.S. now offer CDC-recognized diabetes prevention lifestyle change programs, both in-person and virtually, to individuals at risk for type 2 diabetes. In addition, Medicare began covering CDC-recognized diabetes prevention programs on April 1, 2018.

The National DPP is another example of an existing prevention strategy that can be further elevated, supported, promoted, and highlighted to increase participation and improve health outcomes. The National DPP drives our nation's diabetes prevention activities, and more efforts must be undertaken to educate health care providers and people at risk for type 2 diabetes about the program. To fully support the National DPP, we must collectively strive for increased referrals from healthcare providers and increased enrollment from those with prediabetes. As discussed, AADE also supports improved screening efforts for prediabetes and connecting individuals to prevention programs as a follow-up to those screenings.

Creating a Pathway for Virtual DSMT

In addition to supporting the National DPP, AADE suggests that HHS explore virtual diabetes self-management (DSMT) programs for people with diagnosed diabetes. In-person DSMT programs provide significant benefits to Medicare beneficiaries, but may be inadequate or inaccessible for certain Medicare beneficiaries for a variety of reasons beyond their zip code. Expanding Medicare coverage to include virtual DSMT programs have the potential to improve and expand access to and uptake of the DSMT benefit. HHS and CMS could conduct a demonstration to test virtual diabetes self-management training (DSMT) programs in Medicare available to all beneficiaries with diabetes, not just those living in specific areas of the country

[20] https://diatribe.org/medicaid-cgm
[21] https://www.cdc.gov/diabetes/prevention/what-is-dpp.htm

2. *How can entrepreneurs and/or technology help drive the development and scaling of prevention strategies that address common chronic conditions?*

Addressing Food Insecurity

As discussed, SDOH can directly impact the overall health and well-being of individuals in this country. SDOH also affect the ability of individuals to prevent or manage chronic diseases like diabetes. 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.[22] AADE 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.[23] These types of programs directly assist individuals with accessing 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 model, even going as far as working with healthcare providers, local farms, and food banks to develop medically tailored meals and meal kits.

Scalable Digital Health Solutions

Many look to technology for innovation in the health and prevention space, but not all individuals have access to or feel comfortable using technology. Companies like Rewire Health have created hybrid models that leverage digital technology with a physical and interactive front-end user experience.[24] This allows health education programs to be customized to address health literacy and cultural relevance, while also supporting data collection efforts and reducing cost barriers. There is an opportunity to build upon this model, especially for diabetes prevention and self-management programs.

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AADE appreciates the opportunity to offer comments in response to the Prevention X RFI. We are happy to provide the Secretary of HHS with any supplemental information on any of the topics addressed in this letter. 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,

Charles Macfarlane, FACHE, CAE, Chief Executive Officer

[22] https://www.ajmc.com/newsroom/understanding-the-connection-between-food-insecurity-and-type-2-diabetes
[23] https://www.sansum.org/farming-for-life/
[24] http://www.rewirehealth.com/