March 1, 2019

The Honorable Lamar Alexander
United States Senate
Washington, DC 20510

The Honorable Patty Murray
United States Senate
Washington, DC 20510

Dear Chairman Alexander and Ranking Member Murray:

The Diabetes Advocacy Alliance (DAA) appreciates the opportunity to provide comments to the Senate Committee on Health, Education, Labor, and Pensions on how the 116th Congress can address America's rising health care costs. We would also encourage the Committee to make these recommendations to the Administration and state governments. The DAA is a coalition of 24 diverse member organizations, representing patient, professional and trade associations, other non-profit organizations, and corporations, all united in the desire to change the way diabetes is viewed and treated in America. Since 2010, the DAA has worked to increase awareness of, and action on, the diabetes epidemic among legislators and policymakers. The organizations that comprise the DAA share a common goal of elevating diabetes on the national agenda so we may ultimately defeat diabetes.

As you may know, over 30 million Americans have diabetes and an additional 84 million adults are at risk of developing the disease. In addition, the annual cost of diagnosed diabetes has skyrocketed to $327 billion and will continue to rise unless something is done. Annual spending on this public health emergency has increased 26 percent over a five-year period. Health care spending for Americans with diabetes are 2.3 times greater than those without diabetes. Finally, one out of every seven healthcare dollars is spent treating diabetes and its complications and Medicare spends one out of every three dollars on people with diabetes. Both the human and economic toll of this disease is devastating.

Prioritize Diabetes Prevention

Prevention of type 2 diabetes is a priority for the DAA and it must be a priority for the Senate HELP Committee, Administration, and other health care stakeholders in the U.S. if we are to address rising health care costs and spending and work to improve the health of millions of Americans. Scientific research has demonstrated conclusively that type 2 diabetes can be prevented or delayed in adults with prediabetes through both community-based and online settings. The Centers for Disease Control and Prevention's (CDC) National Diabetes Prevention Program (National DPP) is a public-private partnership that seeks to reduce the growing problem of prediabetes and type 2 diabetes in the United States. The National DPP is an

evidence-based lifestyle intervention that helps combat the diabetes epidemic. The program evolved from a successful National Institutes of Health (NIH) clinical trial that found individuals with prediabetes – those at the highest risk for the disease – can reduce their risk for type 2 diabetes by 58 percent with lifestyle intervention and modest weight loss of 5-7 percent. Seniors were even more successful, decreasing their risk by 71 percent. Further research translating the clinical trial from a one-on-one intervention with a clinician to a community, group-based setting showed the results could be replicated for an average cost of $425-$600 per participant. Approximately 1,700 organizations nationwide 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 in-person diabetes prevention programs beginning April 1, 2018.

Given the growth of the National DPP and the need for CDC support to implement Medicare coverage of in-person diabetes prevention programs, robust funding for CDC, and dedicated funding for the CDC Division of Diabetes Translation (DDT), are more important than ever. Approximately 15-30 percent of people with prediabetes will develop type 2 diabetes within 5 years without intervention. Additional funding for National DPP is needed to expand the program to meet the needs of the 84 million Americans with prediabetes and to help change the trajectory of the disease.

The DAA provides the following recommendations to the Senate HELP Committee on ways to improve the MDPP benefit.

Overarching Theme -- Align MDPP services with evidence base & CDC National DPP

During the MDPP rulemaking process, the DAA urged CMS to align with the Centers for Disease Control and Prevention's (CDC) Diabetes Prevention Recognition Program (DPRP) guidelines to maintain close alignment with the evidence-based DPRP so MDPP suppliers are not hampered by conforming to two different and complex standards. We appreciate that CMS has aligned closely with the CDC National Diabetes Prevention Program (National DPP) standards but encourage CMS to further align with the evidence base where misalignment currently exists. We call out several examples below including the once-per-lifetime limit and coverage of virtual DPPs as areas of inconsistency and misalignment between the DPRP and MDPP.

In addition, the DAA encourages CMS to align the weight loss thresholds in MDPP with the DPRP as well as those cited in the original Diabetes Prevention Program study. Further, the two programs have inconsistent blood-based screening requirements with a higher value of fasting plasma glucose (FPG) needed in MDPP. We encourage CMS to further align with the CDC DPRP standards in these areas. The two different values serve as a barrier to clinical practices adhering to evidence-based screening guidelines.

Modify reimbursement to cover reasonable costs

The DAA is concerned that current MDPP reimbursement levels do not cover MDPP supplier reasonable costs. We encourage CMS to modify MDPP reimbursement to ensure payments for

core and maintenance sessions are structured and resourced in a way that supports the patient and enables them to get the services they need. We urge CMS to consider payment levels that adequately cover the cost of providing core and maintenance session services, respectively. In addition, we ask CMS to ensure that MDPP suppliers receive MDPP payments in a timely manner. Small community-based organizations do not have the capital on hand to wait months to receive payments. DAA is concerned about the impact payment delays could have on the ability of some MDPP suppliers to remain part of the program if long waits exist.

The DAA also urges CMS to consider the *distribution* (as opposed to the amount) of payments over the course of the program. For example, most supplier costs (e.g., administrative costs, staffing, beneficiary engagement, recruitment, etc.) are incurred up front or in the initial weeks of the program. This requires MDPP suppliers to amass enough capital to pay for this largely on their own until they receive the first outcomes-based payments. Addressing these capital-related concerns will allow for a greater variety and number of MDPP suppliers (i.e., more community-based suppliers) to offer DPP to Medicare beneficiaries. We recognize and appreciate that CMS has already taken some steps to address this but we urge CMS to increase and rebalance reimbursement in the first year in future rule-making.

Provide targeted solutions for special populations

The DAA is concerned the existing MDPP benefit does not allow for targeted solutions for special populations including but not limited to dual eligibles. The current payment structure does not consider socioeconomic status. As noted in MDPP rule-making, 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,[1] we strongly urge CMS to allow for targeted solutions, including but not limited to payment adjustments, for special populations.

Additionally, evidence shows that patients who achieve weight loss of just 2% to 5% reap health benefits including improved glucose, systolic blood pressure, and triglycerides.[2] DAA is pleased that the CDC has previously acknowledged the impact of socioeconomic status on achieving National DPP goals but specific solutions must be identified for special populations across MDPP and National DPP.

First, we urge immediate, targeted relief from the requirement that each beneficiary achieve 5% weight loss for ongoing maintenance sessions to be covered by Medicare. This relief should apply to all dually eligible beneficiaries enrolled in MDPP and to all Medicare beneficiaries receiving MDPP services in low-income or underserved areas.

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

[2] Wing RR, Lang W, Wadden TA, et al. Benefits of modest weight loss in improving cardiovascular risk factors in overweight and obese individuals with type 2 diabetes. Diabetes Care 2011; 34: 1481-1486.

Additionally, insofar as transportation availability and costs can deter MDPP attendance, CMS should provide supplemental payments to suppliers in underserved areas for mitigating transportation for participating beneficiaries. Medicaid diabetes prevention program demonstrations have identified transportation as an acute barrier and we encourage CMS to address it in the MDPP.

Finally, we urge CMS to continue to align with CDC and the DPRP and to encourage and/or incentivize suppliers, through fully transparent policy, to deliver MDPP in low-income areas.

Remove the once-per-lifetime limit

The DAA is seriously concerned about the once-per-lifetime limit for MDPP. The once-per-lifetime limit punitively denies some beneficiaries the benefits of a program that reduces Medicare expenditures while also improving health outcomes and quality of life for those at risk for diabetes. Research demonstrates that weight loss is extremely difficult and complex and some beneficiaries may need multiple attempts to be successful.[3] The Medicare program publicly acknowledges the science showing the need for repeated use of healthy lifestyle counseling for weight management in its current coverage policy for obesity counseling. Under the Medicare obesity counseling benefit, doctors are allowed to reassess a beneficiary for additional obesity preventive benefits after a six month period if they failed to achieve the original weight loss goal (6.6 lbs).[4] Smoking cessation is another example of a difficult and dramatic lifestyle change that can require multiple attempts.[5] In this area too, Medicare coverage policy is aligned with the literature on tobacco cessation and Medicare covers smoking cessation services two times per year for beneficiaries.[6] The majority of private payers who cover and reimburse diabetes prevention programs consider the intervention an annual benefit and the DPP model test allowed participants to reenroll after the year-long program if they were still eligible.

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

[4] Centers for Medicare & Medicaid Services. National coverage determination (NCD) for intensive behavioral therapy for obesity, November 2011. Available online: https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=353&ncdver=1&CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=All&KeyWord=obesity&KeyWordLookUp=Title&KeyWordSearchType=And&bc=gAAAABAAAAAA

[5] Jones J. *Smoking habits stable; most would like to quit*. Gallup News Services, 2006. http://www.gallup.com/poll/23791/smoking-habits-stable-most-would-like-quit.aspx (accessed 21 Aug 2013).

[6] Centers for Medicare & Medicaid Services. National coverage determination (NCD) for smoking and tobacco-use cessation counseling, March 2005. Available online: https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=308&ncdver=1&DocID=210.4&ncd_id=210.4&ncd_version=1&basket=ncd%25253A210%25252E4%25253A1%25253ASmoking+and+Tobacco%25252DUse+Cessation+Counseling&bc=gAAAAAgAAAAAAA%3D%3D&

The DAA strongly urges CMS to rescind the once-per-lifetime limit and like Medicare coverage of obesity counseling and tobacco cessation, provide beneficiaries additional opportunities to participate in and benefit from MDPP. This will also better align Medicare coverage with the commercial market. The DAA urges CMS to allow beneficiaries who did not successfully complete the MDPP to reenroll following a six-month waiting period if they meet eligibility criteria. Instituting a 6-month waiting period between attempts would align this benefit with the Medicare obesity counseling benefit and address concerns that suppliers might abuse the system by automatically reenrolling participants.

At minimum, the DAA encourages CMS to include in future rulemaking an exception for participants who experience a major life event that may impact his or her ability to attend MDPP sessions. We recognize and appreciate that CMS has already taken steps to address some concerns with the allowance for four make up sessions, but we believe there may be circumstances that prevent or derail participation for longer than those four sessions. Examples of major life events may include (but are not limited to): newly-developed health condition (not diabetes-related) by the participant; newly-developed health condition of a loved one; surgery or injury of participant or a loved one; and death of a loved one. We urge CMS to consider how such an event could impact participation in the core sessions independently from the maintenance sessions and create a viable exception process.

We understand and sympathize with the balance CMS is trying to strike: dis-incentivizing a revolving door approach or "gaming" while simultaneously ensuring Medicare beneficiaries have access to this important preventive service *and* that MDPP suppliers supply cost-effective MDPP services. Yet if CMS leaves the once-per-lifetime rule in place, more guidance is needed to ensure that MDPP suppliers have accurate Part B information before enrolling a beneficiary, especially given the time lag on confirmed Part B enrollment. Until a real-time notification system is established for MDPP suppliers to check beneficiary eligibility for MDPP, when a beneficiary (wittingly or unwittingly) applies to receive the benefit but is later determined to be ineligible based on the once-per-lifetime limit, CMS should supply guidance or payment to MDPP suppliers that would address the costs of services already provided before the MDPP supplier was notified that the beneficiary was determined to be ineligible.

Allow virtual programs to participate in MDPP

In addition, while Medicare began covering in-person diabetes prevention programs last year, the number of organizations enrolling as Medicare diabetes prevention program (MDPP) suppliers has been low and thus so has uptake of the new benefit. As of January 31, 2019, only ~100 suppliers have enrolled in MDPP. CMS launched a MDPP finder tool/website[7] recently, and for example, a search for MDPP within 250 miles of Nashville yielded sites only in Chattanooga (140 miles away) and Huntington (114 miles away).

[7] Centers for Medicare and Medicaid Services. Accessed February 5, 2019. https://innovation.cms.gov/initiatives/medicare-diabetes-prevention-program/mdpp-map.html

MDPP has the potential to be transformative to the Medicare program but we knew from the beginning that it would take time to get it off the ground. However, Congress and the Administration can and should take steps now to improve accessibility and uptake of benefit which will help prevent diabetes and thus reduce spending on the disease. The DAA recommends that virtual programs be allowed to participate in MDPP. Virtual diabetes prevention programs have similar outcomes to in-person programs and are essential for beneficiary choice as well as access (particularly for vulnerable populations, individuals with transportation needs or those in rural areas with no access to an in-person program). Additionally, in urban areas providers face challenges in providing sufficient, culturally tailored programming for the large population. When looking at the Medicare population, mobility also becomes a significant issue and represents the most common disability among older Americans.[8] This makes getting to medical appointments or weekly in-person DPP sessions especially challenging. Lastly, many seniors consider themselves "snowbirds" and find themselves living in two different locations throughout the year and thus would be unable to complete a year-long in-person diabetes prevention course. A virtual MDPP option would enable them to participate regardless of their location.

Without the addition of virtual MDPP suppliers, large rural areas or underserved communities will not have reasonable access to MDPP suppliers. The fundamental value of community-based programs is delivery of needed services where consumers live and work, and the success of DPP programs relies heavily on lowering barriers to participant access. In the final Medicare Physician Fee Schedule (MPFS) rule, CMS estimated enrollment in MDPP for the initial year between 65,000 and 110,000 Medicare beneficiaries with demand leveling to 50,000 participants per year moving forward. The CMS Actuary calculated an estimated savings of $182 million based on these projections, with greater enrollment directly correlated with higher savings. Lack of widespread access for eligible beneficiaries will not only result in less access for beneficiaries, but decreased cost savings for the Medicare program. The continued exclusion of qualified virtual programs will be felt most by Medicare's most vulnerable populations.

In-person MDPP suppliers do not have the capacity to serve millions of seniors; allowing virtual providers to participate in MDPP will ensure Medicare beneficiaries have access to MDPP in the format of their choosing, regardless of where they live. Slowing the number of new cases of diabetes is vital to decreasing the human and economic burden of diabetes in America. While we have made great strides in promoting awareness, access and coverage for diabetes prevention programs, much more needs to be accomplished to slow the current diabetes trajectory both in terms of costs and number of lives impacted.

Improve Screening and Early Detection

As previously mentioned, over 30 million Americans have diabetes and unfortunately, 7.2 million of them – roughly 24 percent-- are undiagnosed. The statistics are even more alarming for individuals with prediabetes; of the 84 million American adults with prediabetes, 90 percent don't know they have it.

[8] https://www.census.gov/newsroom/press-releases/2014/cb14-218.html

Screening is the entry point for prevention and treatment, thus improving access and coverage for diabetes screening will help reduce the number of people with undiagnosed prediabetes, type 2 diabetes, and gestational diabetes which is paramount in our effort to change the trajectory of the diabetes epidemic and spending on this disease. Promoting a consistent interpretation of the U.S. Preventive Services Task Force (USPSTF) Screening for Abnormal Blood Glucose and Type 2 Diabetes Mellitus guideline and helping to implement and enforce this guideline must be a priority. The USPSTF diabetes screening guideline requires private health plans beginning in January 2017 to cover prediabetes/diabetes screening with no co-pay for individuals age 40 to 70 who are overweight or obese.

Since the USPSTF diabetes screening guideline was published in October 2015, there has been confusion among health insurers, employers, health care professionals and patient organizations about the full scope and coverage implications of the guideline which went into effect in January 2017. Health plans and other stakeholders in the diabetes community have raised two questions/concerns about the diabetes screening guideline. First, whether or not health plans are required to cover participation in an intensive behavioral counseling program with no co-pay for individuals with abnormal blood glucose. Second, whether clinicians should screen based on the full set of risk factors – boxed recommendation and those under "Clinical Considerations" – which would trigger no co-pay from patients who meet this full range of criteria.

The DAA is concerned that the payer community does not view USPSTF guidelines as mandates potentially due to lack of enforcement. Clarification of the USPSTF diabetes screening guideline, including publication of a FAQ by the Departments of Labor, Treasury and Health and Human Services, would provide valuable guidance to health plans and others and help identify more individuals with undiagnosed diabetes and prediabetes and get them into the care or prevention program they need thus reducing health care spending on this devastating disease. Congress may also consider what additional actions it may take to clarify with payers that USPSTF guidelines must be implemented as intended. When diabetes prevention programs are not fully deployed and accessible to the working population, the Medicare program and Medicare beneficiaries bear the burden of increased incidence of diabetes, increased costs, and more advanced disease state.

Improve Care

Many serious health complications of diabetes can largely be prevented with proper treatment and care. It is critical that people with diabetes have access to a team of health care professionals, medications, devices, and self-management education to help them manage their diabetes successfully. For the past seven years, the DAA has worked with the Department of Health and Human Services Office of Disease Prevention and Health Promotion (ODPHP) to promote Healthy People 2020 diabetes objectives. Through this work, we have convened work group meetings with federal health agencies and co-hosted numerous webinars related to

emerging technologies in diabetes care, improving access to diabetes care in rural areas, telehealth, and more.

Tools & Technologies

Diabetes is a complex disease that requires ongoing self-management by patients, including making numerous decisions throughout the day, as part of their management and treatment regimen. People with diabetes need access to a range of tools, technologies and services including new innovations that help them and their caregivers monitor and manage their disease. The DAA was pleased to work with Members of Congress and federal health agencies to successfully address Medicare coverage of continuous glucose monitors (CGMs) for people with diabetes in 2017. While gaining Medicare CGM coverage was significant and will have a meaningful impact on seniors with diabetes, more needs to be done to address Medicare coverage of innovative diabetes technologies and services. For example, Medicare's current benefit categories, provider definition and reimbursement mechanisms do not allow for coverage or payment of certain diabetes technologies, algorithms, or type 2 management programs[9,10] which are evidence-based and effective at helping people with diabetes manage their disease and reduce health spending.

The DAA is currently working with other diabetes stakeholders, including the JDRF, National Federation of the Blind, and diabetes device manufacturers, to develop solutions for improved Medicare coverage of innovative diabetes technologies and solutions. We look forward to working with Congress and the Administration in the coming months to move these solutions forward.

Diabetes Self-Management Training

Diabetes is a complex disease that requires ongoing self-management by patients, including making numerous decisions throughout the day, as part of their management and treatment regimen. Diabetes self-management training (DSMT) is an evidence-based service that teaches people with diabetes how to effectively self-manage their diabetes and cope with the disease. The service, covered by Medicare Part B and most private health insurance plans, includes teaching the person with diabetes how to self-manage healthy eating, physical activity, monitoring blood glucose levels and using the results for self-management decision making, adhering to medications, coping and problem solving with every day struggles to help reduce risks for diabetes complications. A patient-centered approach to care is vital for DSMT.

The benefits of DSMT are undisputed. Studies have found that DSMT is associated with improved diabetes knowledge and self-care behaviors, lower hemoglobin A1c, lower self-reported weight, improved quality of life, healthy coping and reduced health care costs.[11] The

[9] O'Neil PM, Miller-Kovach K, Tuerk PW, et al. Randomized controlled trial of a nationally available weight control program tailored for adults with type 2 diabetes. Obesity 24 (2016) 2269-2277.
[10] Holland-Carter L, Tuerk PW, Wadden TA, et al. Impact on psychosocial outcomes of a nationally available weight management program tailored for individuals with type 2 diabetes: results of a randomized controlled trial. Journal of Diabetes and its Complications 31 (2017) 891-897.
[11] American Diabetes Association. Standards of Medical Care in Diabetes – 2017. Diabetes Care 2017; 40 (Suppl.1): S34.

Diabetes Self-Management Education and Support algorithm of care, recommended in a joint position statement of the American Diabetes Association, American Association of Diabetes Educators, and Academy of Nutrition and Dietetics, defines four critical points of time for Diabetes Self-Management Education and Support delivery: at diagnosis; annually for assessment of education, nutrition and emotional needs; when complicating factors arise that influence self-management; and when transition in care occur.[12] Unfortunately, despite its critical importance for people with diabetes and the fact that DSMT has been a covered benefit under Medicare for over 15 years, a recent study found only five percent of Medicare beneficiaries with newly diagnosed diabetes used DSMT services.[13] According to another source, among fee-for-service Medicare beneficiaries age 65 and older with diagnosed diabetes, only 1.7 percent had a Medicare claim for DSMT in 2012.[14]

CMS highlighted the "significant underutilization" of DSMT in the CY 2011 MPFS, in which the agency noted the effectiveness of DSMT services and the importance of facilitating access to DSMT. In July 2016, as part of the proposed CY 2017 MPFS rule, CMS once again highlighted the low utilization of DSMT and solicited public comment on barriers contributing to access and the under-utilization of the benefit. The DAA provided comments to the agency and commended CMS for recognizing the alarmingly low utilization of this critically important benefit.

Ensuring that Medicare beneficiaries with diabetes understand that DSMT is a covered benefit and utilize this benefit is a priority for the DAA and we look forward to exploring ways we can partner with CMS to advance this goal. From the DAA's perspective, to improve DSMT access and utilization rates, several critical barriers must be addressed. The DAA worked with Congressional leaders in the 115th Congress to introduce the "Expanding Access to DSMT Act" which addressed barriers to DSMT in Medicare. The DAA is working with the sponsors to get the legislation reintroduced in the 116th Congress and recently worked with IHS Markit on a budget analysis of the legislation which found it could save the Medicare program between $4.9 - $9.4 billion over 10 years if implemented. Consistent with the legislation, the DAA recommends Congress and the Administration take the following actions to remove barriers to DSMT in Medicare:

- Extend the initial 10 hours of DSMT covered by Medicare beyond the first year until fully utilized and cover additional hours based on individual need;
- Allow medical nutrition therapy (MNT) and DSMT to be provided on the same day;
- Remove patient cost-sharing;
- Broaden which providers can refer to DSMT beyond the provider managing the beneficiary's diabetes to include other providers caring for the patient; and

[12] Powers MA, Bardsley J, Cypress M, et al. Diabetes self-management education and support in type 2 diabetes; a joint position statement of the American Diabetes Association, American Association of Diabetes Educators, and the Academy of Nutrition and Dietetics. Diabetes Care 2015;38:1372-1382.
[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] Statistic from Health Indicators Warehouse. Available at: https://www.healthindicators.gov/Indicators/Diabetesmanagement-benefit-use-diabetic-older-adults-percent_1263/Profile/ClassicData

- Clarify agency policy that hospital outpatient department based DSMT programs can expand to community based locations, including alternate non-hospital locations.

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Again, thank you for the opportunity to provide comments on steps the 116th Congress should take to address America's rising health care costs as well as steps the Committee can recommend the Administration or state governments should take. The DAA looks forward to engaging with the Senate HELP Committee on this initiative moving forward. Should you have any questions, feel free to reach out to one of the DAA's Co-chairs: Meredith Dyer at mdyer@endocrine.org, Karin Gillespie at kgil@novonordisk.com, or Meghan Riley at mriley@diabetes.org.

Sincerely,

Academy of Nutrition and Dietetics
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Diabetes Patient Advocacy Coalition
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WW *(formally Weight Watchers International)*
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