January 26, 2016

VIA ELECTRONIC SUBMISSION TO: chronic_care@finance.senate.gov

The Honorable Orrin Hatch
Chairman
Committee on Finance
United States Senate

The Honorable Ron Wyden
Ranking Member
Committee on Finance
United States Senate

The Honorable Johnny Isakson
Senator
Committee on Finance
United States Senate

The Honorable Mark Warner
Senator
Committee on Finance
United States Senate

Dear Chairman Hatch, Ranking Member Wyden, Senator Isakson, and Senator Warner:

The Diabetes Advocacy Alliance™ (DAA) is pleased to submit comments in response to the Bipartisan Chronic Care Working Group Policy Options Document released in late-December 2015. The DAA represents a diverse group of patient advocacy organizations, professional societies, trade associations and corporations that share a common goal to improve diabetes prevention, detection and care; and to ultimately defeat diabetes. Consistent with that mission, we applaud the Working Group for its efforts to improve outcomes for Medicare patients with chronic conditions like diabetes. The DAA was excited to see that the Working Group is considering several policies of great importance to the diabetes community.

In our previous comments to the Working Group, we detailed the human and economic toll of diabetes, calling your attention to the fact that nearly 30 million Americans have diabetes and another 86 million are at risk of developing the disease.[1] Among the Medicare-age population, there are over 11 million adults with diabetes and another 26 million with prediabetes.[1] In fact, a startling 77 percent of adults age 65+ are living with either diabetes or prediabetes.[1] Diabetes is among the top drivers of health care costs in Medicare.[2] Already, 1 in 3 Medicare dollars is spent on people with diabetes.[3] The average annual excess expenditure of an adult age 65+ attributable to diabetes is over $11,800, and much of this cost is borne by Medicare.[4] The total annual cost of diabetes among adults age 65+ is projected to reach $168 billion in 2025, an increase of nearly 60 percent from 2010.[5]

Diabetes continues to be a growing public health and economic problem, particularly in the Medicare population, and warrants significant attention. On behalf of the undersigned members of the DAA, we respectfully submit our feedback related to the following policy under consideration by the Working Group:

Policy Feedback: Expanding access to prediabetes education

As stated in the Policy Options Document, the Working Group *"is considering recommending that Medicare Part B provide payment for evidence-based lifestyle interventions that help people with prediabetes reduce their risk of developing diabetes."* The DAA is very pleased to see this policy under consideration. In our comments submitted to the Working Group in June 2015, the DAA shared the importance of preventing or delaying type 2 diabetes among people in Medicare to avoid and/or mitigate the human and economic toll of diabetes. Specifically, the DAA recommended the Working Group support Medicare coverage for the National Diabetes Prevention Program (National DPP), which is an evidence-based lifestyle intervention, for Medicare beneficiaries with prediabetes. The DAA has been a strong proponent of the National DPP at the Centers for Disease Control and Prevention (CDC) since its inception in 2010. In addition, the DAA strongly supports the bipartisan

Medicare Diabetes Prevention Act (H.R. 2102/S. 1131) which, in line with the Working Group's proposal, provides Medicare coverage for the National DPP for individuals with prediabetes. A recent study by Avalere Health shows that this policy could reduce federal spending by $1.3 billion over 10 years.[6] This amount reflects a combination of an estimated $7.7 billion in new spending on the diabetes prevention program offset by an estimated $9.1 billion in savings. Savings from preventing diabetes would likely continue to increase beyond 10 years, suggesting even greater impact on longer-term federal spending.[6] Additionally, according to a December 2015 letter, sent by Senators Grassley and Franken and colleagues from the House of Representatives, to Health and Human Services Secretary Sylvia Burwell, a Center for Medicare and Medicaid Innovation (CMMI) award to Y-USA that provides coverage for the National DPP to Medicare beneficiaries is showing promising early results and its actuarial analysis is being fast-tracked as a result. **This CMMI demonstration is consistent with the Working Group's recommendation that Medicare Part B provide payment for evidence-based lifestyle interventions, like the National DPP, that help people with prediabetes reduce their risk of developing diabetes.**

Entities Eligible to Deliver Program

In regard to the Working Group's request for feedback on whether to allow a diabetes prevention program to be delivered by entities that are currently not providers under the Medicare statute, the **DAA strongly urges the Working Group to allow such entities to deliver the National DPP.** The DAA strongly urges the Working Group to establish Medicare coverage for diabetes prevention for entities recognized by the CDC as qualified to deliver the National DPP. Currently, the CDC evaluates and then recognizes applicants that demonstrate clinical results, data reporting capability, and program delivery capability. Many of the current evidence-based National DPP providers are non-Medicare providers, including community-based organizations like the Y-USA and certified diabetes educators (CDEs). In addition, the Medicare Diabetes Prevention Act includes the following definition for "diabetes prevention program provider" which is inclusive of community-based organizations, CDEs, departments of health and federally qualified health centers:

> *"a diabetes prevention program provider may be, as determined appropriate by the Secretary, a supplier (as defined in subsection (d)), a provider of services (as defined in subsection (u)), a health insurance or services company, a community-based organization, or any other appropriate entity."*

The American Association of Diabetes Educators (AADE), Omada Health and the Y-USA are the largest providers of National DPP and provide several different options to participate including in person and virtual to meet the needs of participants; both in person and virtual have been shown to have similar weight loss outcomes.[7] The Y-USA, a non-profit community-based organization, has provided the National DPP in person to nearly 40,000 individuals in 43 states; Omada Health has served a similar number of individuals through their virtual program. Y-USA program participants have achieved an average weight loss of 5.4 percent at the end of the year-long intervention which is within the 5-7 percent weight loss recommendation developed as a result of the original National Institutes of Health (NIH) clinical trial which was reported in the *New England Journal of Medicine* in 2002[8] and upon which the National DPP is based. The AADE, through a cooperative agreement with the CDC since 2012, has established the National Diabetes Prevention Program, an accredited diabetes self-management training (DSMT) program in 16 states. AADE's program has proven to be widely successful and similarly cost-effective as other National DPP delivery settings.

While Y-USA and AADE are focused on delivering the National DPP in-person throughout the country, Omada Health and Weight Watchers International, Inc. offer virtual delivery or virtual plus in-person delivery and meet the curriculum and criteria required by the CDC. The Y-USA, CDEs, Omada Health, Weight Watchers and many other CDC-recognized National DPP providers are already delivering this valuable program to individuals with prediabetes throughout the country and meeting targets for

weight loss set by the CDC. In virtual programs like Omada Health's diabetes prevention program, participants are paired with a personal health coach and online peer group in their community for daily feedback and support.

The DAA strongly urges the Working Group to allow entities that are not currently providers under the Medicare statute, such as CDEs, the Y-USA, Omada Health and Weight Watchers, to deliver the National DPP to Medicare beneficiaries under Medicare Part B.

Program Requirements

The Working Group is also considering what requirements entities delivering evidence-based lifestyle interventions like the National DPP should be required to meet in order to be recognized as a provider. The CDC's National DPP has a set of standards in place that entities are required to meet in order to deliver the program and be recognized as an eligible provider of the National DPP. Prevention program providers are trained in delivering an intervention that is faithful to the one used in the original clinical trial, and the CDC encourages program providers to submit aggregate patient outcomes data before program recognition is officially granted. Recognized National DPPs either follow the curriculum that was tested in the translational clinical trial or conduct a clinical trial to demonstrate that the alternative program curriculum leads to clinically significant outcomes.

The **DAA encourages the Working Group to require entities to meet the standards set out by the CDC for the National DPP**. It should be noted, that in the Medicare Diabetes Prevention Act, the Secretary of Health and Human Services is required to establish criteria for a diabetes prevention program in accordance with the standards under the CDC's National DPP.

Policy Feedback: Expanding access to diabetes education

The DAA seeks clarification about the Working Group's request for feedback on whether there is evidence to support coverage of services analogous to diabetes self-management training (DSMT) for beneficiaries who are at risk of complications from other chronic conditions. DSMT (or "diabetes education") consists of teaching individuals with diabetes how to control their diabetes and eliminate or mitigate the known devastating consequences of unchecked diabetes. It covers techniques for self-monitoring blood glucose levels, medication management and insulin injection administration, nutrition geared to diabetes control, appropriate exercise, and diabetes problem solving designed to eliminate or reduce diabetes complications. Patients who complete a DSMT program are better able to manage their disease and comply with their diabetes treatment regimen.[9]

However, as stated in the Working Group's document, DSMT may currently only be delivered by a limited set of providers. In our June 2015 comments to you, the DAA explained that in 1997, Congress authorized DSMT as a Medicare benefit, with the goal of providing a more comprehensive level of support to educate beneficiaries about diabetes and self-management techniques, reduce the known risks and complications of diabetes, and improve overall health outcomes. Unfortunately, as acknowledged by CMS, DSMT remains a woefully underutilized benefit despite its proven benefits in improving outcomes, reducing diabetes-related complications, improving care compliance and reducing health care costs. The recent DAWN2 study (Diabetes Attitudes, Wishes and Needs), surveyed a random sample of over 500 people with diabetes, more than 120 family members and 280 health care professionals in the US and found that 45 percent of people with diabetes and 40 percent of their family members report that managing diabetes is stressful[10,11]—and yet only 64 percent of people with diabetes and 35 percent of family members have ever participated in a diabetes education program.[10,11] Moreover, 60 percent of health care professionals reported that they believe there is a need for major improvement in the availability of DSMT.[12] An American Medical Association (AMA) physician working group and the National Committee for Quality

Assurance (NCQA) have issued recommendations to foster greater adoption of DSMT taught by diabetes educators.

Under the DSMT benefit adopted in 1997, Congress failed to include as providers certified diabetes educators – the main group of health care professionals who provide most of the essential training and education for this service. A bill currently before Congress—Access to Quality Diabetes Education Act (H.R. 1726/S.1345)—would, in fact, recognize state-licensed or –registered certified diabetes educators as Medicare providers. When previously scored, CBO estimated the legislation would have an unscorable, de minimis impact on the federal budget. **The undersigned members of the DAA believe that CMS should designate certified diabetes educators as Medicare providers of DSMT, thereby providing seniors in Medicare with greater access to DSMT.**

Additional clarifications

The DAA agrees with the Working Group that preventing progression of prediabetes to type 2 diabetes is better for individuals and the nation's health care spending. However, we'd like to clarify that the scientific and medical community does not recognize a state of "prediabetes" prior to the onset of type 1 diabetes, primarily because type 1 onset is relatively rapid in comparison to type 2 diabetes, and also because there are no known ways at this time to prevent the onset of type 1 diabetes. Thus we ask that you amend the language in the section entitled "Reason for Consideration" that mentions progression from prediabetes to type 1 diabetes.

Finally, we urge the Working Group to revisit the full comments submitted by the DAA in June 2015 (also attached). These comments include additional recommendations provided by the DAA that were not included in the policy options document and address policies that are crucial to improving health outcomes for people with diabetes.

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In closing, we thank you for acknowledging the importance of expanding access to prediabetes education, including coverage for diabetes prevention programs, and DSMT for people with diagnosed diabetes. We appreciate the opportunity to present the perspectives of the diabetes community and provide feedback related to the Working Group's policy options that could improve outcomes for Medicare patients with diabetes and other chronic conditions. We believe that addressing diabetes is critical to improving care and outcomes for these beneficiaries and for improving the fiscal health of the Medicare program. The DAA is committed to working with you on these important issues and we welcome the opportunity to discuss our feedback in more detail.
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Sincerely,

Academy of Nutrition and Dietetics
American Association of Diabetes Educators
American Clinical Laboratory Association
Diabetes Hands Foundation
Endocrine Society
Healthcare Leadership Council
National Kidney Foundation
Novo Nordisk, Inc.
Omada Health
Pediatric Endocrine Society
Weight Watchers International, Inc.
YMCA of the USA

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