June 22, 2015

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 your request for ideas on ways to improve outcomes for Medicare patients with chronic conditions. 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 Committee for its ongoing efforts to address this pressing issue in the Medicare program, and urge that recommendations include policy options to address diabetes.

Diabetes continues to be a growing public health and economic problem, particularly in the Medicare population, and warrants significant attention. The Committee's effort presents a clear opportunity to leverage evidence about programs and resources that can prevent and better manage diabetes, and how investments in these efforts can benefit both beneficiaries and the Medicare program overall.

Diabetes is a chronic disease that exacts a significant human and economic toll in the US. More than 29 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] Nearly one-third of those with prediabetes are likely to progress to diabetes within 4 years.[2]

Diabetes is among the top drivers of health care costs in Medicare.[3] Already, 1 in 3 Medicare dollars is spent on people with diabetes.[4] 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.[5] 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.[6]

Moreover, diabetes is a gateway disease that affects many parts of the body and is associated with serious complications, such as heart disease and stroke, blindness, kidney failure, and lower-limb amputation.[1] Efforts to effectively prevent and manage diabetes can have positive outcomes for a host of other chronic diseases and conditions that affect people in Medicare. **Thus, we believe that preventing, identifying and treating diabetes is essential to preventing the onset of other, costly medical conditions.** Accordingly, we are hopeful that the chronic care working group will acknowledge the necessity for a comprehensive approach to diabetes and include

bipartisan policy solutions in their recommendations to the Chairman and Ranking Member.

Policy Ideas and Recommendations

On behalf of the undersigned members of the Diabetes Advocacy Alliance™ (DAA), we respectfully submit our ideas and comments as to what needs to be done to help improve outcomes for Medicare patients with diabetes, about 40 percent of whom face three or more chronic conditions.[7] Our ideas and comments are bucketed into three areas: 1)Identifying people with diabetes and prediabetes; 2)Preventing diabetes; and 3)Better managing diabetes.

1)Identify people with undiagnosed diabetes and prediabetes in Medicare so they can receive the intervention and care they need

Since 2005, Medicare has had a Diabetes Screening Benefit, which covers screening for diabetes and prediabetes with no co-pay up to two times a year for individuals with one or more risk factors for the disease. However, uptake of this benefit has historically been low, hovering at less than 12 percent.[8] A comprehensive and ongoing educational and awareness campaign targeted to seniors in Medicare with risk factors for type 2 diabetes has the potential to increase utilization of the Medicare Screening benefit and thereby increase identification of individuals with prediabetes and undiagnosed diabetes. **The undersigned members of the DAA believe that it is critical for CMS to initiate efforts to increase awareness and educate health care professionals and Medicare enrollees about the Medicare Diabetes Screening benefit and the risk factors that signify the need for screening to ultimately increase uptake of this important Medicare benefit.**

The introductory Welcome to Medicare physical and subsequent annual Wellness visits offer other opportunities for Medicare enrollees with risk factors for diabetes to be screened and detected. **The undersigned members of the DAA believe that CMS should take the necessary steps to increase screening for type 2 diabetes among individuals with risk factors for the disease as part of the Welcome to Medicare physical and annual Wellness visits.**

2)Prevent or delay diabetes among people in Medicare to avoid and/or mitigate the human and economic toll of diabetes

Although Medicare has a diabetes screening benefit, Medicare covers little else in the way of diabetes prevention, with coverage kicking in for services only after an individual is already diagnosed with type 2 diabetes. This is the case despite the strong, longstanding evidence base that exists in the Diabetes Prevention Program (DPP) for delaying or preventing type 2 diabetes. The DPP, a randomized clinical trial funded by the National Institutes of Health and reported in the *New England Journal of Medicine* in 2002, showed that adults with prediabetes could reduce their risk for developing type 2 diabetes by up to 58 percent through moderate weight loss and regular physical activity. Older adults, those age 60 and over, who made these same lifestyle changes reduced their risk of developing type 2 diabetes by 71 percent.[9] Follow-up research confirmed that these positive outcomes persisted for at least a decade after participating in the lifestyle intervention and that the program can be offered effectively *and* cost-effectively within group settings at YMCAs and other community-based locations.[10]

More recent research examined the 10-year effectiveness of the DPP among participants who were *adherent* to the lifestyle intervention—those who lost at least 5 percent of their body weight—and **showed that the lifestyle intervention "represents a good value for money—and it improved the quality of life for participants.**[11]

In 2010, under the Affordable Care Act, the National Diabetes Prevention Program (National DPP) was established to scale up the DPP intervention nationally to help

prevent or delay type diabetes among the tens of millions of Americans with risk factors for the disease. The CDC administers the National DPP and ensures that prevention program providers are trained and delivering an intervention that is faithful to the one used in the original DPP clinical trial.

Today, under the National DPP, diabetes prevention programs recognized by the CDC are available in all 50 states and the District of Columbia. Not inconsequentially, the potential exists for thousands of jobs to be created for health care coaches in community-based organizations and online providers of mobile health.

The Center for Medicare & Medicaid Innovation (CMMI) awarded a $12 million Health Care Innovation Award to Y-USA, recognizing the YMCA'S Diabetes Prevention Program's success and cost-effectiveness. In 2014, the Community Preventive Services Task Force recommended lifestyle interventions modeled on the DPP as effective and cost effective.[12]

The undersigned members of the DAA strongly believe that CMS should provide Medicare coverage for the National DPP for Medicare beneficiaries with prediabetes. In fact, there is currently legislation before Congress that would make the National DPP a Medicare-covered benefit to help seniors prevent or delay type 2 diabetes: Medicare Diabetes Prevention Act of 2015 (H.R. 2102/S. 1131).

A recent study by the consulting firm Avalere shows that this policy could reduce federal spending by $1.3 billion over 10 years. 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.[13]

Medical Nutrition therapy offers another potential avenue for reducing the risk of progression to type 2 diabetes among individuals with risk factors for the disease. Medical Nutrition Therapy (MNT) is a nutritional diagnostic, therapy and counseling service for disease management. When provided by a Registered Dietitian Nutritionist (RDN), MNT includes: 1) lifestyle, knowledge and skills assessment, 2) negotiation of individualized nutrition goals, 3) nutrition intervention, and 4) evaluation of clinical and behavioral outcomes. To ensure an individualized therapeutic plan, MNT is conducted through one-on-one sessions between an RDN and an individual. MNT provided by an RDN is similar to the one-on-one counseling provided during the DPP that was found to prevent or delay diabetes. MNT provided by registered dietitians or other qualified nutrition professionals could also help Medicare beneficiaries diagnosed with prediabetes delay or prevent their progression to type 2 diabetes. MNT provided by a Registered Dietitian Nutritionist (RDN) is an effective evidence-based practice that can result in weight loss and improved blood glucose levels.[14] Under current law, Medicare pays for MNT provided by a registered dietitian for beneficiaries with diabetes and renal diseases. However, Medicare does not cover MNT for beneficiaries diagnosed with prediabetes. There is currently legislation before Congress that would extend Medicare coverage for MNT services to people with prediabetes and risk factors for developing type 2 diabetes: Preventing Diabetes in Medicare Act of 2015 (H.R. 1686). **The undersigned members of the DAA believe that CMS should provide Medicare Coverage for MNT for people at risk for type 2 diabetes to help delay or prevent progression to type 2 diabetes.**

3)Improve treatment and care among people in Medicare with diabetes

For patients with diabetes, Diabetes Self Management Training (DSMT) provided by specially credentialed diabetes educators is a crucial component of an overall diabetes

treatment plan. 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.[15]

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. However, 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[16]—and yet only 64 percent of people with diabetes and 35 percent of family members have ever participated in a diabetes education program.[17] Moreover, 60% of health care professionals reported that they believe there is a need for major improvement in the availability of DSMT.[18] 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.

However, under the DSMT benefit, 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. **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.**

For adults who have managed their diabetes for many years and those who are newly diagnosed in the decade preceding Medicare enrolment (ages 55-64), aging into Medicare with diabetes currently poses significant access issues. More than 25% of people age 65+ have diabetes.[1] For older adults with diabetes, access to resources like DSMT and Continuous Glucous Monitoring (CGM) can be critical to continuing to manage their diabetes well and avoid diabetes-related complications.

CGM uses physician-prescribed, FDA-approved devices that detect and display glucose levels continuously, and reveal trends in glucose levels that often go unnoticed by using finger-stick measurements alone. Currently, over 95 percent of all private health plans cover CGMs for people with type 1 diabetes, but Medicare does not. In the ADA Guidelines, the evidence for the effectiveness of CGM is rated "A level" – the highest. Similarly, the American Association of Clinical Endocrinologists (AACE) and the Endocrine society also both deem CGM an important tool in the treatment of diabetes. And a comparative effectiveness review by AHRQ found CGM use to be superior beyond blood glucose meters alone.[19]

The undersigned members of the DAA believe that access to CGM is critical for seniors with diabetes who use CGM to effectively manage their diabetes and that Medicare should provide coverage for CGM furnished to CGM-qualified

individuals. There is currently legislation before Congress—Medicare CGM Access Act of 2015 (H.R. 1427/S. 804)—that would make CGM a Medicare-covered benefit.

Coordination of federal resources and aligning incentives to assure quality care are also important to assure that individuals with chronic diseases like diabetes achieve optimal outcomes

Currently, innovations from the federal research investment in diabetes and other chronic disease are not being effectively translated to the clinical setting. The federal government needs to better leverage its investment and try new approaches to diabetes to reverse the burden of this disease.

The undersigned members of the DAA believe that the creation of a National Diabetes Clinical Care Commission provides a mechanism to streamline federal investments in the disease to improve coordination and clinical care outcomes for people with diabetes and prediabetes. The National Diabetes Clinical Care Commission Act (H.R. 1192/S. 586), legislation currently before Congress, creates a commission comprised of diabetes experts, including endocrinologists and other specialists that treat the complications of diabetes, primary care physicians, patient advocates and representatives from the federal agencies most involved in diabetes care. The commission would make recommendations to Congress and the Secretary of HHS on improving diabetes care delivery and patient outcomes. The commission's purview would include:

- Making recommendations regarding clinically-based activities supported by federal resources to maximize their effectiveness in improving the quality of care provided to patients with diabetes and its complications.
- Assisting in the development, coordination and evaluation of clinical resources and tools produced by federal agencies and in disseminating this information to health care professionals and patients in their communities.
- Evaluating innovative care models and outcomes-based registry data for providing optimal cost-effective care.
- Evaluating the HHS diabetes screening program, annual wellness visit and other prevention activities that may reduce diabetes and its complications
- Identify problems related to the utilization of programs and data collection.
- Forward recommendations to Congress and the Secretary of HHS within three years and then sunsetting, all while operating with existing funds at no additional cost to the government.

Increasingly, in our health care system, there is a focus on delivering value-based care—and aligning incentives and measures to achieve this. As we move from fee-for-service reimbursement to alternative payment models, diabetes is an excellent example of a disease where we can measure improvement and outcomes. For patients with diabetes, value-based care will ultimately translate into receiving appropriate and effective care with optimal outcomes, including:

- Delayed mortality
- Reduced co-morbidities (amputations, AML)
- Reduced complications (depression, CKD, blindness)
- Prolonged high quality of life
- Reduced diabetes incidence
- Improved physical/emotional/psychological well-being of patients
- Decreased unplanned diabetes hospitalizations
- Increased knowledge/skills to self-manage

Unfortunately, the current state of quality measures for diabetes care is unsatisfactory, with nearly 100 different unique quality measures, 21 of which are included in CMS

programs. With a lack of alignment among programs driving quality, physicians, and most important, patients are unable to successfully meet their optimal outcomes. **The undersigned members of the DAA believe that CMS should work toward developing a core set of quality measures for diabetes that would encourage the delivery of value-based care by health care professionals, help people with diabetes achieve optimal outcomes, and be a good fit for new payment and delivery programs for the Medicare population.**

Diabetes is a serious and multi-faceted disease, and it is important for providers to be assessed holistically on multiple components of disease management. The lack of coordination and consensus among quality measures is a significant challenge for physicians who face different guidelines depending on a patient's source of coverage and health plan issuer.

In closing, we thank you for providing us with the opportunity to present the perspectives of the diabetes community and provide policy recommendations 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 recommendations in more detail.

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Sincerely,

Academy of Nutrition and Dietetics

American Association of Clinical Endocrinologists

American Association of Diabetes Educators

Diabetes Hands Foundation

Endocrine Society

Healthcare Leadership Council

Novo Nordisk Inc.

Omada Health

Pediatric Endocrine Society

YMCA of the USA

References

[1] Centers for Disease Control and Prevention. National Diabetes Statistics Report 2014. Available at http://www.cdc.gov/diabetes/pubs/statsreport14/national-diabetes-report-web.pdf. Accessed June 10, 2015.

[2] Diabetes Prevention Program Research Group. "Reduction in the Incidence of Type 2 Diabetes with Lifestyle Intervention or Metformin." *New England Journal of Medicine*. February 7, 2002.

[3]Thorpe K, Ogden L, Galactionova K. Chronic conditions account for rise in Medicare spending from 1986 to 2006. Health Affairs. Published online before print February 2010, doi: 10.1377/hlthaff.2009.0474.

[4] American Diabetes Association. Preventing diabetes in seniors. Available at http://www.diabetes.org/advocacy/advocacy-priorities/prevention/preventing-diabetes-in.html. Accessed June 15, 2015.
[5]American Diabetes Association. Economic cost of diabetes in the US in 2012. Published online before print March 6, 2013, doi: 10.2337/dc12-2625.
[6] Institute for Alternative Futures. Diabetes 2025. Available at http://www.altfutures.org/diabetes2025/. Accessed June 10, 2015.
[7] Wolff JL, Starfield B, Anderson G. Prevalence, expenditures, and complications of multiple chronic conditions in the elderly. Arch Intern Med. 2002; 162(20):2269-2276.
[8] http://www.cms.hhs.gov/PrevntionGenInfo/20_prevserv.asp
[9] Diabetes Prevention Program Research Group. Reduction in the Incidence of Type 2 Diabetes with Lifestyle Intervention or Metformin. New England Journal of Medicine. 346(6): 393-403, 2002.
[10] Diabetes Prevention Program Research Group. 10-Year Follow Up of Diabetes Incidence and Weight Loss in the DPPOS. Lancet. 2009;374(9702): 1677-1686 and Ackermann RT, Finch EA, Brizendine e, Zhou H, Marrero DG. Translating the DPP into the Community: The DEPLOY Pilot Study. American Journal of Preventive Medicine. 2008;35(4): 357-63.
[11] Herman WH et al. Effectiveness and Cost Effectiveness of Diabetes Prevention among Adherent Participants. American Journal fo Managed Care. 2013;19(3):194-202.
[12] Community Preventive Services Task Force. Combined diet and physical activity promotion programs to prevent type 2 diabetes among people at increased risk. Available at http://www.thecommunityguide.org/diabetes/index.html. Accessed June 18, 2105.
[13] Avalere. Estimated federal impact of H.R. 962/S. 452 The Medicare Diabetes Prevention Act. Available at http://www.diabetes.org/assets/pdfs/advocacy/estimated-federal-impact-of.pdf. Accessed June 15, 2015.
[14] Corpeleign E. et al. (2006). Improvements in glucose tolerance and insulin sensitivity after lifestyle intervention are related to changes in serum fatty acid profile and desaturase activites: the SLM study. *Diabetologia*. 49(10):2392-2401.
[15] Rubin RJ, Dietrich KA, Hawk AD. (1998).Clinical and economic impact of implementing a comprehensive diabetes management program in managed care. Journal of Clinical Endocrinology & Metabolism; and Duncan I, Birkmeyer C, Coughlin S, et al. (2009) Assessing the value of diabetes education. The Diabetes Educator;35(5):752-760; and Diabetes Self Management Education for Adults with Type 2 Diabetes Mellitus: A Systematic Review of the Effect on Glycemic Control: Lipman, et al; American Association of Diabetes Educators (2014)
[16] Nicolucci A, et al. Diabet Med 2013;30:767–77 and Kovacs Burns K, et al. Diabet Med 2013;30:778–88.
[17] Funnell M. Presented at AADE 2014 US DAWN2 study.
[18] Holt RIG, et al. Diabet Med 2013;30:789–98.
[19] AHRQ. Methods for insulin delivery and glucose monitoring: comparative effectiveness. Comparative effectiveness review #57. July 2012. Available at http://www.effectivehealthcare.ahrq.gov/ehc/products/242/749/CER57_Insulin-Delivery_FinalReport_20120703.pdf. Accessed June 18, 2015.