

June 22, 2015

The Honorable Johnny Isakson  
United States Senate  
131 Russell Senate Office Building  
Washington, DC 20510

The Honorable Mark Warner  
United States Senate  
475 Russell Senate Office Building  
Washington, DC 20510

Dear Senator Isakson and Senator Warner:

The American Diabetes Association (Association) appreciates the opportunity to provide recommendations to you, the co-chairs of the Senate Finance Committee's Chronic Care Working Group, on health care policy options that will improve care for Medicare patients with chronic conditions. The formation of the working group and the Committee's focus on the impact of chronic disease on the Medicare program could not come at a more crucial time.

Nationwide, nearly 30 million Americans have diabetes and an additional 86 million have prediabetes. When you take a close look at the Medicare program, the picture is even more startling. Currently, half of all Americans age 65 or older have prediabetes<sup>1</sup> and are at risk for developing type 2 diabetes. An estimated 11.2 million (nearly 30 percent) Americans over age 65 have been diagnosed with diabetes,<sup>2</sup> a figure that will continue to increase if we do not act to prevent diabetes in this population. The annual cost of diagnosed and undiagnosed diabetes and its devastating complications, gestational diabetes, and prediabetes skyrocketed to \$322 billion in 2012, a 48 percent increase in just five years. Medicare itself spends one out of three dollars on people with diabetes.<sup>3</sup>

### **Prevention**

To improve care for Medicare patients with chronic conditions, the Committee and Working Group must start by preventing chronic conditions, including a focus on the diabetes epidemic. Your May 22<sup>nd</sup> letter to stakeholders outlined the huge toll chronic conditions have on the Medicare program both in terms of sheer numbers and the financial toll. Diabetes is a huge cost driver in the Medicare program. But there is good news: we know of proven interventions to prevent and/or delay the onset of type 2 diabetes in many cases. The task then, is to make these interventions available to our seniors.

The National Diabetes Prevention Program (National DPP) at the Centers for Disease Control and Prevention (CDC) is a public-private partnership consisting of government agencies, private insurers, and community organizations designed to provide evidence-based community

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<sup>1</sup> Centers for Disease Control and Prevention. National diabetes fact sheet: national estimates and general information on diabetes and prediabetes in the United States, 2011. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, 2011.

<sup>2</sup> Centers for Disease Control and Prevention. National diabetes statistics report, 2014. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, 2014.

<sup>3</sup> Centers for Medicare and Medicaid Services. Medicare Health Support Overview. Baltimore (MD): CMS. Available from: [http://www.cms.gov/ccip/downloads/overview\\_ketchum\\_71006.pdf](http://www.cms.gov/ccip/downloads/overview_ketchum_71006.pdf)

programs to prevent type 2 diabetes in individuals at highest risk – specifically, individuals with prediabetes.

The National DPP originated from the successful Diabetes Prevention Program clinical trial carried out by the National Institute of Diabetes and Digestive and Kidney Diseases at the National Institutes of Health (NIH). The clinical trial found individuals with prediabetes can reduce their risk for type 2 diabetes by 58 percent with lifestyle changes including improved nutrition, increased physical activity and weight loss of 5-7 percent. The results were even stronger for seniors. Participants over the age of 60 reduced their risk for type 2 diabetes by 71 percent. Further research at the Division of Diabetes Translation at the Centers for Disease Control (CDC) translating the clinical trial to a community setting showed these results can be replicated in a group for a cost of less than \$450 per participant for the yearlong intervention. The National DPP is based on this effective low-cost community model.

Currently, the Medicare program will pay to screen a beneficiary for diabetes and Medicare will pay for drugs and services if that individual is determined to have diabetes. However, if it is determined the individual has prediabetes, the patient's doctor is unable to prescribe or refer the individual to the National DPP because it is not a covered benefit under the Medicare program. The dramatic success achieved by seniors in the original clinical trial and the overall success of the intervention in the community-based setting warrants coverage of this program for our nation's Medicare population.

As you stated in your letter, the private sector has extensive experience in targeting and engaging patients who have chronic conditions. The Association agrees and would like to point out that nearly thirty private insurers, hundreds of employers and numerous Medicare Advantage plans, including Humana, provide coverage for the National DPP to enrollees at high risk for type 2 diabetes. The private sector recognizes the huge strain diabetes has on their plans but also the huge benefit the National DPP can provide their enrollees and on their bottom line. UnitedHealth Group has said the program saves three dollars for every dollar invested in it and that expanding access to the National DPP will help people lead healthier lives in addition to decreasing what we spend on treating diabetes.

Legislation has been introduced in the Senate, the Medicare Diabetes Prevention Act (S. 1131), to provide Medicare coverage for the National DPP to individuals with prediabetes. **The Association urges you to include the Medicare Diabetes Prevention Act in the legislative solutions you present to Chairman Hatch and Ranking Member Wyden.** In requesting feedback from stakeholders, you mentioned "options for empowering Medicare patients to play a greater role in managing their health and meaningfully engaging with their health care providers." (#7) Medicare coverage for the National DPP will empower and provide Medicare beneficiaries with the necessary tools to manage their health and reduce their risk of developing type 2 diabetes and its horrific and costly complications including blindness, amputation, kidney failure, heart disease, and stroke.

More than fifty patient, consumer, health advocacy, public health, provider, and business groups support this bipartisan legislation because of its potential to reduce chronic disease in the Medicare population and save the program money. The Association, along with the American Medical Association and YMCA, commissioned Avalere Health to conduct a cost estimate of the Medicare Diabetes Prevention Act. Using conservative methodologies, Avalere found the legislation would save \$1.3 billion over 10 years. This policy will improve patient health outcomes, facilitate the delivery of high quality care to individuals at risk of developing diabetes, and reduce the growth in Medicare spending – all stated goals of the Working Group.

### **Care Coordination and Delivery Reform**

As previously mentioned, the diabetes epidemic cost the nation \$322 billion in 2012. Medical costs made up \$244 billion of which 43 percent can be attributed to hospital inpatient care alone. Our current delivery system is set-up to deal with acute health problems not the management of chronic disease which explains why so many health care dollars go towards hospital inpatient care. The severity of the diabetes epidemic is increasing as will spending on costly hospitalizations absent reform.

Because of the complex nature of diabetes, ongoing patient self-management education and support are critical to preventing acute complications and reducing the risk of long-term complications. New prevention initiatives in the Affordable Care Act (ACA) have steered us in the right direction. There are more than 8 million Americans with undiagnosed diabetes.<sup>4</sup> However, states that have expanded their Medicaid program have seen a 23 percent increase in the number of Medicaid enrollees with newly identified diabetes thus leading to the initiation of therapy for most, if not all. In comparison, states that did not expand Medicaid have only seen a 0.4 percent increase in the number of Medicaid enrollees with newly identified diabetes.<sup>5</sup> Early diagnosis and treatment lead to improved long-term health outcomes for people with diabetes. We've seen steady improvements in the proportion of people with diabetes achieving recommended goals for glycated hemoglobin, also referred to as A1C (a test reflecting a patient's average blood sugar level for the past three months), blood pressure, and cholesterol in the last 10 years. However, only 14.3 percent of adults with diabetes meet all of the recommended targets.<sup>6</sup> Variation in quality of diabetes care across providers and practice settings exists, especially for certain patient populations such as those with complex comorbidities, financial or other social hardships, and/or for patients with limited English proficiency, thus there remains significant potential to improve diabetes care through improved care coordination and disease management. **The Association urges the Working Group to expand and enhance care coordination and team-based care which aid in managing the complex care for a person with diabetes.**

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<sup>4</sup> Centers for Disease Control and Prevention. National diabetes statistics report, 2014. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, 2014.

<sup>5</sup> Kaufman HW, Chen Z, Fonseca VA, and McPhaul MJ. Surge in newly identified diabetes among Medicaid patients in 2014 within Medicaid expansion states under the affordable care act. *Diabetes Care* 2015; 10: 2337-2334.

<sup>6</sup> Ali MK, Bullard KM, Saaddine JB, Cowie CC, Imperatore G, and Gregg EW. Achievement of goals in the u.s. diabetes care, 1999-2010. *New England Journal of Medicine* 2013; 10: 1613-1624.

The Association's 2015 Standards of Medical Care support the Chronic Care Model (CCM) of delivering health care because its six core elements for the provision of optimal diabetes care have been shown to be an effective framework for improving the quality of diabetes care. The six elements include: (1) delivery system design (moving from a reactive to a proactive care delivery system where planned visits are coordinated through a team-based approach); (2) self-management support; (3) decision support (basing care on evidence-based, effective care guidelines); (4) clinical information systems (using registries that can provide patient-specific and population-based support to the care team); (5) community resources and policies (identifying or developing resources to support healthy lifestyles); and (6) health systems (to create a quality-oriented culture).

How and when care is delivered is critically important to people with diabetes. Preliminary data suggests that Patient Centered Medical Homes (PCMH) and Accountable Care Organizations (ACOs) can provide high-quality care for people with diabetes at decreased costs. Under a PCMH, a patient's care is coordinated through their primary care doctor in order to ensure they receive appropriate care when and where they need it and in a manner the patient can understand. An early PCMH demonstration project in North Carolina in the late-1990s involved more than 1,200 practices and 3,000 physicians. This Medicaid Managed Care initiative coordinated care for the sickest and most high-risk enrollees with diabetes and annual savings were estimated to be at least \$161 million through reductions in emergency room visits, pharmacy utilization, and both inpatient and outpatient care.<sup>7</sup> A similar PCMH initiative in Pennsylvania involving more than 56,000 patients with diabetes has seen achievement of diabetes self-management goals increase from 20 to 70 percent.<sup>8</sup> Consumers report greater satisfaction under team-based care models, such as the PCMH.<sup>9</sup>

ACOs, groups of doctors, hospitals, and other health care providers who voluntarily work together to provide coordinated high quality care to Medicare patients, also have potential to improve care delivery for people with diabetes. The Medicare ACO program was established to reduce health care costs by encouraging the formation of these networks to coordinate patient care and potentially receive bonus payments if care is delivered more efficiently. The early results of ACOs show improvements in people with diabetes reaching blood pressure and LDL-cholesterol targets and lower readmission rates.<sup>10</sup> While ACOs are still in the early stages and not all ACOs in the program are meeting the goals of improving outcomes and saving money, preliminary data suggests they can provide high quality care for people with diabetes at decreased cost.

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<sup>7</sup> Steiner BD, Denham AC, Ashkin E, Newton WP, Wroth T, Dobson LA Jr. Community care of North Carolina: improving care through community health networks. *Ann Fam Med* 2008; 6: 361-367.

<sup>8</sup> Gabbay RA, Siminerio L. Pennsylvania statewide implementation of the chronic care model and patient centered medical home impacts diabetes care (Abstract). *Diabetes* 2010; 59(Suppl.1):A345.

<sup>9</sup> Nielsen, M., Gibson, L., Buelt, L., Grundy, P., & Grumbach, K. (2015). The Patient-Centered Medical Home's Impact on Cost and Quality, *Review of Evidence*, 2013-2014.

<sup>10</sup> Centers for Medicare & Medicaid Services. Pioneer accountable care organizations succeed in improving care, lowering costs. July 2013. Available online: <http://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-Releases/2013-Press-Releases-Items/2013-07-16.html>

Racial and ethnic minorities are disproportionately affected by diabetes. Not only do certain populations have higher prevalence rates, but they are also more likely to have worse diabetes control and higher rates of complications.<sup>11</sup> Team-based care has the potential to reduce health disparities and improve diabetes management and care for specific racial, ethnic and socioeconomic populations who are below average in meeting these targets. The key principles of both the CCM and PCMH align well with recommended diabetes care as it relates to patient-centered care, self-management, patient empowerment, and team-based care.<sup>12</sup> **The Association urges the Working Group to adopt new and expand existing models of care delivery that prioritize quality, value and patient-centeredness.**

### **Access and Continuity of Care**

Seniors with diabetes also face serious obstacles in accessing the prescription drugs and durable medical equipment they need to manage their disease.

The Association is pleased the Affordable Care Act closes the Medicare Part D “donut hole.” However, it won’t be fully eliminated until 2020. In the meantime, individuals with diabetes continue to be impacted by the donut hole and contact the Association because they are unable to afford their drug costs. Improving access and affordability to prescription drugs for people with chronic conditions (#4) will remove a major barrier that currently affects a beneficiary’s ability to comply with necessary care and thus to avoid adverse outcomes and complications.

As people with diabetes age into Medicare they can lose access to the tools needed to successfully manage their diabetes. For example, Medicare only covers the use of an insulin pump for a narrowly defined group of individuals and does not provide coverage for continuous glucose monitors (CGMs) at all for people with diabetes. Despite the fact that a person may have been successfully managing diabetes for years through the use of an insulin pump, if he or she does not meet specific and what the Association and other scientific stakeholders assert are outdated diagnostic criteria, Medicare will not cover the insulin pump. This is true even in situations where the pump has allowed that person to have tighter control of blood glucose, reduce the risk for severe hypoglycemia and hyperglycemia, and reduce wide variations in blood glucose levels for many years prior to aging into the Medicare system. Such disruptions in care are unconscionable.

Similarly, CGMs are a useful tool to lower blood glucose levels in selected adults with diabetes, including individuals aging into the Medicare program who have been managing their diabetes with a CGM device for years. The Medicare CGM Access Act of 2015 (H.R. 1427/ S. 804) would provide Medicare coverage for CGMs and enable people with diabetes to improve their care and disease management.

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<sup>11</sup> Peek M.A, Cargill A, and Huang E.S. Diabetes health disparities: a systematic review of health care interventions. *Medical Care Research and Review* 2007; 64: 101S-156S.

<sup>12</sup> Bojdziewski T, Gabbay RA. Patient-centered medical home and diabetes. *Diabetes Care* 2011; 34: 1047-1053.

The private sector provides wide access to diabetes services and technologies including the insulin pump and CGMs because they recognize the value these technologies provide to people with diabetes in successfully managing their disease. **The Association urges the working group to improve access and continuity of care for people with chronic diseases like diabetes, including ensuring when individuals age into Medicare they are able to continue to access ongoing therapies, treatments, services and technologies that aid in the management of their disease.** Such a policy will empower Medicare beneficiaries with diabetes to better manage their health and engage with their providers about their disease management (#7).

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Diabetes is a serious epidemic that is affecting more and more seniors and costing the nation hundreds of billions of dollars each year. The Association greatly appreciates the opportunity to provide recommendations for the Working Group to consider as it seeks to improve care for individuals with chronic conditions like diabetes. We look forward to supporting the efforts of the Working Group and the Finance Committee on this important issue. Should you have any questions or need additional information, please do not hesitate to contact Amy Wotring, Associate Director, Federal Government Affairs, at [awotring@diabetes.org](mailto:awotring@diabetes.org) or 703-299-2087.

Sincerely,

A handwritten signature in cursive script, reading "Gina Gavlak".

Gina M. Gavlak, RN, BSN  
Chair, National Advocacy Committee