



American Association of Clinical Endocrinologists

245 Riverside Avenue • Suite 200 • Jacksonville, FL 32202 • Ph: (904) 353-7878 • Fax: (904) 353-8185 • www.aace.com

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The Honorable Orrin Hatch
Chairman
U.S. Senate Finance Committee
Washington, D.C. 20510

The Honorable Ron Wyden
Ranking Member
U.S. Senate Finance Committee
Washington, D.C. 20510

The Honorable Johnny Isakson
Co-Chair
Chronic Care Working Group
Washington, D.C. 20510

The Honorable Mark Warner
Co-Chair
Chronic Care Working Group
Washington, D.C. 20510

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

We write on behalf of the American Association of Clinical Endocrinologists (AAACE) to commend you for establishing a Chronic Care Working Group to focus on providing cost-effective care to Medicare patients with multiple chronic diseases. The success of your work is critically important to maintaining a viable and sustainable Medicare program and keeping the promise of health care our country has made to older Americans.

AAACE represents more than 7,000 endocrinologists in the United States and abroad. AAACE is the largest association of clinical endocrinologists in the world. A majority of AAACE members are certified in endocrinology, diabetes and metabolism and concentrate on the treatment of patients with endocrine and metabolic disorders including diabetes, thyroid disorders, osteoporosis, growth hormone deficiency, cholesterol disorders, hypertension and obesity.

The impact of chronic disease on the Medicare population and on the health care system is well-stated in your letter of May 22nd soliciting comments on chronic care reform efforts. Some general concepts such as increased patient education for better self-management and tools to effect stronger compliance with medication adherence can be universally applied to improve the management of chronic diseases. However, most chronic diseases have a distinct pathophysiology and require a unique approach to their prevention and treatment, as is the case with diabetes. The human and economic costs of diabetes are so compelling that we respectfully submit that diabetes warrants specific action in any legislation that is put forth for consideration by the Chronic Care Working Group.

An estimated 11.2 million Americans over age 65 (nearly 26 percent) have been diagnosed with diabetes. A recent study published by the American Diabetes Association (ADA) estimated the annual per person healthcare costs of individuals age 65 and above with diabetes were \$11,825 in 2012, with much of this cost paid by the Medicare program. The annual cost of diabetes to the healthcare system is now \$322 billion. A third of the Medicare budget, 1 in 3 Medicare dollars, is spent on controlling the high blood glucose levels that characterize diabetes or the cardiac, nerve, kidney and newly recognized cancer-related complications of the disease. Sadly, diabetes is the number one cause of blindness, kidney failure and amputation in this country and is a leading promoter of strokes, heart attacks and heart failure. So, rather than being a single disease, diabetes is actually a multitude of expensive and debilitating diseases and co-morbidities.

The Centers for Disease Control and Prevention (CDC) estimate that half of all Americans age 65 or older have pre-diabetes and are at risk for developing type 2 diabetes. The incidence rate of diabetes for individuals in this age category is high, with an estimated 30 percent transitioning to diabetes within four years. Unless this trend is reversed, diabetes could be the constellation of diseases that bankrupts the Medicare program.

We believe the escalation of the diabetes epidemic demonstrates a broken healthcare system that is failing patients. Despite some remarkable research breakthroughs that have led to advances in the diagnosis, prevention and treatment of diabetes, these benefits are not resulting in reduced prevalence rates or improved patient outcomes.

The federal government spends billions of dollars on diabetes activities each year across 35 federal agencies, including current appropriations in excess of \$1 billion for research at the National Institute for Diabetes and Digestive and Kidney Diseases (NIDDK). We commend Congress for continuing the financial commitment to support diabetes research but we believe this investment is not being effectively leveraged to reduce the burden of the disease. The development of new treatments and innovations in patient care are not being effectively translated to the clinical setting because of bureaucratic inefficiencies, ineffective delivery systems and modes of care that have not kept pace.

We know that Type 2 diabetes and the costly complications of the disease are largely preventable. Just think of the potential to “cure” the millions of Americans with pre-diabetes by preventing the onset of the disease with appropriate early interventions and the delivery of effective, high quality care reflecting current standards of diabetes care.

As the Chronic Care Working Group undertakes this important work, AACE strongly urges you to incorporate the National Diabetes Clinical Care Commission Act (S. 586) into your legislative efforts. This legislation establishes a commission of clinical care experts from the private sector, patient advocates and federal government representatives to address gaps in diabetes care as seen by the physicians who deliver the care and the patients who receive it. The Commission will provide an impetus for change by re-evaluating federal diabetes activities, eliminating duplicative and inconsistent policies, identifying new approaches to quality improvement and making recommendations to Congress and the Secretary of Health and Human Services.

Providing a mechanism for the federal government to receive clinical expertise and practical experience to help inform the development, coordination and implementation of federal diabetes activities and policies will greatly enhance the success of these efforts and will ensure patients receive the care they need.

A National Diabetes Clinical Care Commission could foster improved diabetes care for beneficiaries by facilitating expedited regulatory reforms with respect to the coverage and delivery of care. For example, the diabetes screening recommendations issued in 2008 by the United States Preventive Health Services Task Force (USPSTF) were inconsistent with NIDDK-sponsored research on diabetes screening and standards of care used in the private sector. At the end of last year (2014), USPSTF issued proposed modified recommendations much more consistent with AACE and ADA screening guidelines and private insurance coverage policies.

A National Diabetes Clinical Care Commission would bring together to the same table the Food and Drug Administration (FDA) the Centers for Medicaid and Medicare Services (CMS) and other federal agencies to ensure a consistent and effective approach to policies in areas

where there is overlapping jurisdiction. At the 2014 Glucose Monitoring Consensus Conference convened by AACE and the American College of Endocrinology we discovered that there is little communication between FDA and CMS with respect to the quality and safety of blood glucose monitoring systems sold under the Medicare Competitive Bidding Program (CBP). Under the current CBP, some diabetes testing supplies that have received FDA warning letters with respect to safety and accuracy continue to be marketed and distributed to beneficiaries.

The issue of FDA-approved continuous glucose monitors (CGMs) is another example of the deficiencies in the current regulatory structure and how poor coordination and implementation of policies lead to a breakdown in the delivery of high quality care. Currently, patients using a CGM through private plans who turn 65 are suddenly denied coverage for their CGM under Medicare, even if it has been part of a successful care plan.

Looking ahead to transformative and expensive technologies like the bionic pancreas on the medical event horizon, we must encourage government agencies to interact effectively with stakeholders to facilitate appropriate technology deployment to the patients who will benefit most from tight and near automatic blood glucose control.

At a hearing earlier this spring before the Senate Health, Education Labor and Pensions Committee (HELP), former FDA Commissioner Margaret Hamburg suggested that the National Institutes of Health (NIH) and FDA should work more closely with CMS when it comes to biomedical product development and use. Dr. Hamburg noted that each of the different components of the process operate in silos when they are really interdependent. She went on to state, "We really need to take an ecosystem approach." Including S. 586 in the efforts of the Chronic Care Working Group would build that ecosystem for the benefit of people with pre-diabetes, diabetes, and all the chronic care diseases and conditions caused by diabetes.

For these reasons, AACE believes the objectives of S. 586 and your efforts to improve care for Medicare beneficiaries with chronic conditions are in strong alignment. We hope you will recognize the Commission bill as a valuable component of any legislative package you develop to address this critical issue. S. 586, and the identical companion bill H.R. 1192, is supported by the organizations representing the diabetes community.

Congratulations on the launch of the initiative and for highlighting this very important issue. AACE strongly supports your efforts and we stand ready to work with you.

Sincerely,



George Grunberger, MD, FACP, FACE
President



Howard M. Lando, MD, FACP, FACE
Chair, Legislative Committee