

May 24, 2016

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

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

Dear Chairman Hatch and Ranking Member Wyden,

The Endocrine Society is the world's largest professional organization of endocrinologists, representing the interests of over 18,500 physicians and scientists engaged in the treatment and research of endocrine disorders, including diabetes and obesity. The Society is concerned about unintended consequences stemming from the Centers for Medicare and Medicaid Services Competitive Bidding Program (CBP) for patients with diabetes. We are concerned because patients have experienced access problems for their diabetes testing and device supplies through the CBP. We urge Congress to review the program to ensure that beneficiaries are able to effectively and safely manage their diabetes.

As members of the committee are aware, diabetes is a growing epidemic that affects more than 29 million¹ Americans and puts an additional 86 million at risk in the United States. In 2012, it was estimated that the total cost of diabetes exceeded \$322 billion, a 41 percent increase from 2007 primarily caused by the increased prevalence of diabetes in the U.S. population.^{2,3} By 2025, these costs are expected to reach \$514 billion—a figure comparable to the entire Medicare budget today.⁴ Diabetes contributes to the development of a number of complications, including cardiovascular disease, kidney failure, high blood pressure and cholesterol, retinopathy, and neuropathy. These conditions further complicate an individual's ability to manage their disease effectively and further contribute to the economic toll of diabetes in America. As the prevalence of diabetes in America continues to increase, it is critical that patients are able to effectively manage their disease to avoid unnecessary complications and hospitalizations.

¹ National Diabetes Statistics Report, 2014. The Centers for Disease Control and Prevention.

<http://www.cdc.gov/diabetes/pubs/statsreport14/national-diabetes-report-web.pdf>

² Dall T, Yang W, Halder P, et al. The economic burden of elevated blood glucose levels in 2012: diagnosed and undiagnosed diabetes, gestational diabetes, and prediabetes. *Diabetes Care*. 2014; 37:3172-3179.

³ American Diabetes Association. Economic costs of diabetes in the U.S. in 2012. *Diabetes Care*. 2013; 6:1033-1046.

⁴ Institute for Alternative Futures. Diabetes 2025: United States Overall Briefing Paper. www.altfutures.com/diabetes2025. Published 2011.



While the CBP was intended to reduce costs incurred by both the Medicare program and its beneficiaries, its implementation has disrupted access to the supplies needed to manage diabetes and has led to a greater number of high-cost, adverse events like hospitalizations and complications. A recent article, “Impact of CMS Competitive Bidding Program on Medicare Beneficiary Safety and Access to Diabetes Testing Supplies: A Retrospective, Longitudinal Analysis,” which was published in *Diabetes Care*⁵, found that the CBP disrupted the acquisition of diabetes testing supplies and that this contributed to an increase in mortality, inpatient admissions, and higher inpatient costs.

The CBP has also led to an abundance of inaccurate, low-cost blood glucose monitoring systems coming onto the market that pose a safety risk for people managing their disease. During the first round of the CBP in 2011, beneficiary access to diabetes testing supplies was disrupted in nine test markets; this disruption led to the reduction in use of testing supplies, increased mortality, a doubling of inpatient admissions, and higher costs to the Medicare program.⁶ The second round of the CBP in 2013 led to further disruption in blood glucose testing as prescribed by physicians; this exacerbated these adverse events and doubled Medicare costs for beneficiaries.⁷ We wanted to make you aware of this problem and encourage you to work with the Food and Drug Administration to enforce existing standards for blood glucose monitoring systems.

In addition to the problems Medicare beneficiaries with diabetes face under the CBP related to testing supplies, the program has also restricted access to supplies for diabetes devices like insulin pumps. The American Association of Diabetes Educators found that a large number of CBP bidders for insulin pumps and supplies in the Round 1 Recompete, which included a new category for External Infusion Pumps and Supplies, failed to actually provide these products entirely or furnished no more than one brand of the product. In order to bid in this program, a supplier must bid on all 14 HCPCS codes in the category. However, in practice this is not what has been taking place and supplies for patients have been disrupted as a result.

Because pump supplies are not interchangeable, it is alarming that some suppliers who participate in the CBP are only offering one brand. This means that a patient would have to change devices entirely in order to receive coverage under the Medicare program. The

⁵ Puckrein et al. Impact of CMS Competitive Bidding Program on Medicare Beneficiary Safety and Access to Diabetes Testing Supplies: A Retrospective, Longitudinal Analysis. *Diabetes Care* 39 (5). May 2016

⁶ Puckrein GA et al. Abstract 139-LB: CMS Competitive Bidding Program Disrupted Access to Diabetes Supplies with Resultant Increased Mortality. Presented at: American Diabetes Association (ADA) 75th Scientific Sessions; June 5-9, 2015; Boston

⁷ Ibid.



Society strongly believes that physicians should have the ability to provide patient-centered care by prescribing those diabetes devices (and their correlating supplies) rather than being limited to those provided by a CBP-participating supplier.

To remedy this problem, CMS should enforce the existing requirement that contract suppliers furnish all HCPCS codes within the product category. In addition, because some HCPCS codes included in the new category “External Infusion Pumps and Supplies” are not relevant to diabetes, CMS should refine this category to be more disease-specific. This would help ensure that future bidders are able and willing to carry the full range of products for insulin pumps and that treatment is not disrupted. To resolve these issues, we hope Congress will work with CMS to refine the DME category for diabetes supplies.

Thank you in advance for your attention to these important issues related to diabetes testing supplies and devices. We believe it is imperative that Congress works with CMS to ensure that the CBP does not disrupt access and contribute to adverse events for people with diabetes. Should you have any questions or would like additional information, please contact Meredith Dyer, Associate Director, Health Policy at mdyer@endocrine.org.

Thank you,

Henry Kronenberg, MD
President, Endocrine Society

cc:

Sean Cavanaugh, Deputy Administrator and Director of the Center for Medicare, Centers for Medicare & Medicaid Services

Janet Woodcock, M.D., Director, Center for Drug Evaluation and Research, U.S. Food and Drug Administration