

August 21, 2017

Secretary Tom Price
Department of Health and Human Services

Dear Secretary Price,

On behalf of the Endocrine Society, I am writing to express concern about the Centers for Medicaid and Medicare Services (CMS) Competitive Bidding Program (CBP) and its impact on patient access to diabetes devices and testing supplies.

The Endocrine Society is the oldest and largest global professional membership organization representing the field of endocrinology. We are dedicated to advancing hormone research and excellent care of patients with diabetes, obesity, osteoporosis, infertility, rare cancers, thyroid conditions and other endocrine disorders. Our more than 18,000 members include scientists, physicians, educators, nurses, and students, in 122 countries around the world. As diabetes experts, our members are concerned about the impact of the CBP on patient access to devices and supplies.

As you know, the CBP was created as a mechanism to reduce costs incurred by both the Medicare program and its beneficiaries. However, the implementation of this program 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*, 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.¹

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. Accurate blood glucose monitoring is a critical component in effectively managing diabetes, particularly for patients who use these devices to adjust their insulin doses. We are concerned that the CBP is forcing patients who receive these devices and supplies through the mail order program to use products that do not meet FDA's standards.

The Society recently participated in a study² conducted by the Diabetes Technology Society (DTS) which evaluated 18 blood glucose monitoring systems, representing 90% of those commercially available to patients with diabetes. The study utilized FDA protocols to test these devices and found that only 6 of the 18 met the criteria for accuracy and safety. Of the blood glucose monitors tested, each system offered through CBP's mail order program failed to meet these standards.

¹ 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

² Diabetes Technology Society. Blood Glucose Monitoring System Surveillance Program. June 2017.



It is critical that CMS reevaluate the effectiveness of this program and provide the necessary oversight to ensure that people with diabetes have access to safe and accurate devices. While we recognize the importance of lowering healthcare costs to the system and for patients enrolled in Medicare or Medicaid, it is necessary that this is done with proper oversight to ensure FDA's standards for quality and safety are met. We urge you to reevaluate the CBP and enforce existing standards set by the FDA to ensure the blood glucose monitors are accurate. We also ask that you review the DTS study findings to determine which supplies meet these standards in the mail order program.

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 was not what had been occurring.

We were pleased that CMS recognized the access problems resulting from this program by announcing a delay of the 2019 Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) CBP to review the program. We hope that CMS will ensure that people with diabetes have access to insulin pumps and supplies in reviewing the DMEPOS program.

For our patients' health and safety, we urge you to make changes within Medicare/Medicaid to ensure people with diabetes have access to safe and accurate blood glucose monitors and ensure access to insulin pumps and supplies. If we can be of assistance, please do not hesitate to contact Meredith Dyer, Director of Health Policy at mdyer@endocrine.org when our expertise may be of value.

Sincerely,

Barbara Byrd Keenan, FASAE, CAE
Chief Executive Officer