

September 10, 2018

Seema Verma
Administrator
Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-1693-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, Maryland 21244-1850

SUBMITTED ELECTRONICALLY VIA <http://www.regulations.gov>

Re: Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Competitive Bidding Program (CBP) and Fee Schedule Amounts, and Technical Amendments to Correct Existing Regulations Related to the CBP for Certain DMEPOS

On behalf of the Endocrine Society (Society), representing more than 18,000 physicians and scientists in the field of endocrinology, we appreciate the opportunity to provide comments on the proposed rule revising the Competitive Bidding Program (CBP) for the calendar year 2019. Founded in 1916, the Society represents physicians and scientists engaged in the treatment and research of endocrine disorders. The Society looks forward to working closely with the Centers for Medicare and Medicaid Services (CMS) as it moves forward in updating the CBP and would like to offer the following comments on areas of interest to our members.

While we appreciate that the CBP was created as a mechanism to reduce costs to the Medicare program and its beneficiaries, the Society is concerned that its implementation has disrupted access to the supplies needed to manage diabetes. We believe this 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," 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.

Since the expansion of the CBP, the number of mail-order distributors was reduced from 891 to 21 and reimbursement for a vial of 50 test strips was reduced from \$14 to \$10.41.² By comparison, in 2011, a bottle of test strips received a reimbursement of \$34.³ As a result, many distributors can no longer afford to provide beneficiaries with high-quality test strips and are forced to either carry lower cost (and

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 *ibid*

³ *ibid*



lower quality supplies), assume the difference in cost and payment for the strips, or close their doors. This has led to an abundance of inaccurate, low-cost blood glucose monitoring systems 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 study⁴ 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.

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.

It is critical that CMS reevaluate the effectiveness of this program and provide the necessary oversight to ensure that people with diabetes have easy access to safe and accurate devices, including the patient's preferred brand. 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.

Because of continued payment reductions for supplies, the resulting dwindling number of suppliers, and the influx of the lower quality supplies, the program has not only reduced a patient's ability to access the supplies needed to manage their diabetes but it has also contributed to an increase in mortality, inpatient admissions, and high inpatient costs.⁵ We urge CMS 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 the FY 2018 and FY 2019 budget deal, Congress included language from the *Protecting Access to Diabetes Supplies Act* to include the 50 percent and anti-switching rules in the CBP. The 50 percent rule will require distributors to make available at least 50 percent of all types of diabetes technology supplies that were on the market before the implementation of the CBP. Under this rule, suppliers will be required to:

- attest to an ability to obtain an inventory of test strips consistent with the inventory mix in the supplier's bid;
- participate in a surveillance program to ensure compliance with the 50 percent rule; and

⁴ Diabetes Technology Society. Blood Glucose Monitoring System Surveillance Program. June 2017.

⁵ "Impact of CMS Competitive Bidding Program on Medicare Beneficiary Safety and Access to Diabetes Testing Supplies: A Retrospective, Longitudinal Analysis,"



- provide the beneficiary without influencing or incentivizing them to switch to another brand.

The new law will also require CMS to use multiple data sources that measure utilization of diabetes supplies outside of the program to ensure compliance with the 50 percent rule. CMS must also establish a surveillance program and terminate any supplier who fails to comply with the rule.

Thank you for your consideration,

A handwritten signature in black ink that reads "Susan Mandel".

Susan Mandel, MD
President
Endocrine Society