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

December 14, 2015

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

Dear Chairman Hatch and Ranking Member Wyden:

On behalf of the American Association of Clinical Endocrinologists (AACE), I write to express our concerns for the safety of our patients who obtain diabetes testing supplies through the Medicare National Mail Order Program that is part of the Competitive Bidding Program for Durable Medical Equipment, Prosthetics, Orthotics and Supplies (CBP).

AACE represents more than 7,000 endocrinologists in the United States and abroad. AACE is the largest association of clinical endocrinologists in the world. A majority of AACE 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.

There is mounting evidence that the safeguards to ensure patient access to a wide range of suppliers and diabetes testing supplies that Congress put in place when establishing the Medicare Competitive Bidding Program for DMEPOS have proven to be ineffective with patients still at risk of adverse medical events.

AACE and the American College of Endocrinology (ACE) convened a consensus conference in September 2014, to evaluate the clinical science, utility, and access to blood and continuous glucose monitoring. Representatives from leading professional societies, government agencies, industry groups, public advocacy organizations, large employers, and healthcare payers met to consider the current state of knowledge regarding glucose monitoring and its implementation in clinical practice. One of the major conclusions of the conference addressed patient safety and the diabetes testing supplies obtained through the CBP National Mail Program was the following:

“A proliferation of unbranded and often inaccurate glucose monitoring (GM) systems has occurred in the market place, driven by mail-order diabetes suppliers under the Center for Medicare and Medicaid Services (CMS)-mandated competitive bidding process. Patients typically gain no real savings benefits from unbranded meter use, and safety risks imposed by GM inaccuracies are reported and well known. Switching from branded to unbranded meters and glucose strips is frequently initiated by intermediary profit-driven durable medical equipment (DME) suppliers. Such behavior should be prohibited by regulators and should not be tolerated by prescribers. The U.S. Food and Drug Administration (FDA) needs to enforce existing regulations, during both the approval and the post-marketing surveillance processes. It appears that some manufacturers obtain FDA approval for prototype strips and then later modify their production practices, which no longer meet the initially approved quality. The inability of the FDA to remove these previously approved but now inaccurate strips from the market is a flaw in the regulatory system.” (Endocrine Practice Vol 21 No. 5 May 2015)

More recently in June 2015, Puckrein et al. (“CMS Competitive Bidding Program Disrupted Access to Diabetes Supplies with Resultant Increased Mortality,” American Diabetes Association 75th Scientific Sessions, 5–7 June 2015, Boston, MA) reported that Medicare beneficiary access to diabetes-testing supplies was disrupted in the nine test markets during Round 1 of the Competitive Bidding Program implementation in 2011. This disruption was linked to reductions in use of testing supplies, increases in mortality, a doubling of inpatient admissions, and higher associated Medicare costs.

Just last month (November, 2015), the National Minority Quality Forum issued a report titled "Centers for Medicare & Medicaid Services Competitive Bidding Program: Assessment of Impact on Beneficiary Acquisition of Diabetes Testing Supplies/And DMEPOS Associated Health Outcomes" where the report documented the disruption in physician-prescribed patient care plans for testing blood glucose increased with the implementation of Round 2 of the Competitive Bidding Program in 2013. This analysis revealed that in a subset of beneficiaries the disruption to the care plan for blood glucose testing lead to increased mortalities and more than twice as many inpatient hospital admissions. Overall Medicare costs doubled for beneficiaries in the study group.

As implemented, Medicare has used the Competitive Bidding Program to significantly reduce the cost of diabetes testing supplies by restricting access to improved technology devices and limiting choice for patients and healthcare professionals based primarily on cost. The result has been an increase in patient adverse events, including higher mortality rates and hospitalizations, which ironically have led to overall higher Medicare costs.

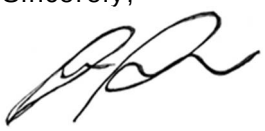
AACE urges Congress to take the following steps in light of these findings and in the interest of patient safety:

1) Authorize CMS to delay re-compete of Round 2 with respect to the National Mail Order Program for diabetes testing supplies until the program is reviewed and it can demonstrate that the CBP for diabetes testing supplies does not jeopardize patient safety and harm patients.

2) Pass the National Diabetes Clinical Care Commission Act (S. 586) that, among other things, would convene the Food and Drug Administration (FDA) the Centers for Medicaid and Medicare Services (CMS) and other federal agencies, with providers and patients to ensure a consistent and effective approach to policies in areas where there is overlapping jurisdiction. At the 2014 Glucose Monitoring Consensus Conference 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 through the National Mail Order Program.

We hope you will seriously consider these recommendations. AACE stands ready to work with you to ensure patients have access to the safe and effective diabetes testing supplies they require.

Sincerely,



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December 14, 2015

The Honorable Fred Upton
Chairman
House Energy & Commerce Committee
Washington, D.C. 20515

The Honorable Frank Pallone
Ranking Member
House Energy & Commerce Committee
Washington, D.C. 20515

Dear Chairman Upton and Ranking Member Pallone:

On behalf of the American Association of Clinical Endocrinologists (AACE), I write to express our concerns for the safety of our patients who obtain diabetes testing supplies through the Medicare National Mail Order Program that is part of the Competitive Bidding Program for Durable Medical Equipment, Prosthetics, Orthotics and Supplies (CBP).

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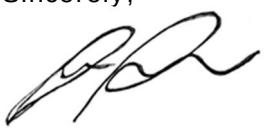

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December 14, 2015

The Honorable Kevin Brady
Chairman
House Ways & Means Committee
Washington, D.C. 20515

The Honorable Sander Levin
Ranking Member
House Ways & Means Committee
Washington, D.C. 20515

Dear Chairman Brady and Ranking Member Levin:

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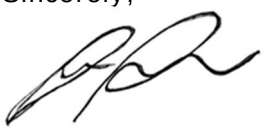

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