July 31, 2017

The Honorable Thomas Price, MD
Secretary, US Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Secretary Price,

We are writing on behalf of the American Association of Clinical Endocrinologists (AACE) to urge you to take immediate action to suspend the Medicare Competitive Bidding National Mail Order program for diabetes testing supplies. A recent study calling into question the accuracy of blood glucose testing systems furnished to Medicare beneficiaries through this program compels this aggressive step.

Self-monitoring of blood glucose (SMBG) levels is a fundamental component of diabetes self-management, especially in individuals with insulin-treated diabetes. Forcing patients to switch to a blood glucose system they are unfamiliar with or, worse, one that presents inaccurate test results, both jeopardizes patient safety and places additional financial burden on our healthcare system.

AACE and the American College of Endocrinology (ACE) convened a consensus conference in September 2014, to evaluate the 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 in clinical practice.

A major conclusion of the conference published in our signature journal, Endocrine Practice, was the following:

“A proliferation of unbranded and often inaccurate glucose monitoring (GM) systems has occurred in the marketplace, 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)

At the consensus conference, we also 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. Some diabetes testing supplies that received FDA warning letters with respect to safety and accuracy continued to be marketed and distributed to beneficiaries through the program. The National Clinical Care Commission Act (H.R. 309/S. 920), legislation that has passed the House of Representatives and now awaits Senate floor action, would convene FDA, CMS and other federal agencies, with healthcare professionals and patients to ensure a consistent and effective approach to policies in areas where there is overlapping jurisdiction.

As reported last year, the 2011 test rollout of the CMS Competitive Bidding Program (CBP) in nine markets was associated with significant disruption in access to blood glucose monitoring among insulin-treated Medicare beneficiaries. This disruption was associated with increased deaths, in-patient hospitalizations and related costs. Findings from a recent analysis of this same CMS data set confirms that the national program rollout in 2013 resulted in even greater disruption.
Because SMBG data are used in insulin dosing decision-making, obtaining accurate glucose data is critical. Inaccurate glucose information can lead to severe consequences, either by failing to detect hypoglycemia or by prompting patients to over-correct with insulin based on an erroneous hyperglycemia result.

Several studies have reported significant inaccuracy and lot-to-lot variability in up to 45% of the SMBG systems marketed at the time of those studies. However, we are most concerned by the recent findings from researchers at the Diabetes Technology Society (DTS), who assessed the accuracy of 18 blood glucose monitoring systems. Importantly, these 18 systems represented approximately 90% of the commercially available systems used from 2013 to 2015 by patients with diabetes in the US. It is also important to note that the protocols used for accuracy testing were developed in conjunction with the US Food and Drug Administration (FDA). As reported on the DTS website, only 6 of the 18 systems tested met the criteria for accuracy and safety.

It is critical to note that all of the glucose monitoring products used in the Medicare National Mail Order Competitive Bidding Program failed to meet the criteria for accuracy and safety. The Medicare mail order products tested represented 90% of Medicare mail order product volume as of Q4 2013 and 61% as of Q4 2016, based upon the respective OIG Medicare mail-order surveys. New products added by the current Medicare winners were not tested, as information about the availability of these brands was not known at the time the study was started. The products that passed the test and received the “Seal of Approval” were not available to Medicare beneficiaries through Medicare Mail order winning suppliers as of the Q4 2016 OIG survey.

The negative impact of CBP has persisted and worsened, further usurping the clinician-patient relationship and threatened public health safety. Given CMS’s failure to provide effective oversight and safeguard beneficiaries against harm, we urge you to take immediate steps to exclude diabetes testing supplies from the CBP until adequate safeguards are put into place to protect beneficiaries’ safety.

As the organization that represents clinical endocrinologists, safety of our patients is always a primary concern. We urge you to take action to suspend the Medicare NMO CBP program to protect our patients with diabetes on insulin from inaccurate testing that could result in significant harm to their health.

Sincerely,

Jonathan D. Leffert, MD, FACP, FACE, ECNU
President, AACE

George Grunberger, MD, FACE, FACE
Past President, AACE
President-Elect, ACE

*Joining Together to Make a Difference*


