

Congress of the United States
Washington, DC 20515

August 27, 2018

The Honorable Alex Azar
Secretary, Department of Health and Human Services
200 Independence Ave, SW
Washington, DC 20201

Dear Secretary Azar,

We are writing as members of the Congressional Diabetes Caucus to express further concern over recent findings that many of the blood glucose testing systems furnished to Medicare beneficiaries fail accuracy standards, but also to express concern over the lack of response to this issue from the Centers for Medicare and Medicaid Services (CMS).

On December 6, 2017, the co-chairs of the Congressional Diabetes Caucus wrote to then Acting Secretary of HHS Eric Hargan to highlight a recent study examining the accuracy of commonly used personal-use blood glucose testing systems. We also wrote to point out that according to data from your Office of the Inspector General, more than 61 percent of test strips furnished to Medicare beneficiaries during the period of October through December 2016 would have failed the study's accuracy standards. In our letter, we asked that Acting Secretary Hargan apprise the Caucus on what steps, if any, the CMS and Food and Drug Administration (FDA) are taking to ensure seniors with diabetes receive products that work as intended, and urged him to take action to implement and enforce product performance standards for diabetes testing supplies.

Acting Secretary Hargan responded to us via a letter on January 24, 2018. The letter went into detail on steps the FDA is taking or plans to take to better ensure product accuracy and reliability. With respect to CMS, however, Acting Secretary Hargan indicated that the agency is monitoring health outcomes data for beneficiaries receiving replacement strips, and that "to date [CMS] has not detected any negative trends."

We find it disconcerting that the agency tasked with ensuring that the nation's elderly and disabled have access to quality healthcare items be satisfied with the furnishing of blood glucose test systems that clearly fail accuracy standards. Seniors shouldn't have to worry about the efficacy of their glucose testing equipment. Moreover, the agency should be concerned that it is wasting taxpayer resources on deficient product.

We urge you to reconsider these problems, and take immediate steps to ensure that CMS puts into place adequate safeguards to protect the lives and safety of Medicare beneficiaries' with diabetes and the public resources entrusted to their stewardship. These safeguards should include product performance standards designed to ensure that Medicare beneficiaries have access to accurate and reliable blood glucose testing systems.

Sincerely,



Tom Reed
Member of Congress
Co-Chair of the Diabetes Caucus



Diana DeGette
Member of Congress
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Vice-Chair of the Diabetes Caucus



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