

Congress of the United States
Washington, DC 20515

December 6, 2017

The Honorable Eric D. Hargan
Acting Secretary, Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Acting Secretary Hargan:

As co-chairs of the Congressional Diabetes Caucus, we write to express concern about the accuracy of blood glucose testing systems furnished to Medicare beneficiaries. Critical daily treatment decisions are based on readings from blood glucose monitors and test strips. We therefore ask that you apprise the Caucus on what steps, if any, the Centers for Medicare and Medicaid Services (CMS) and Food and Drug Administration (FDA) are taking to ensure seniors with diabetes receive products that work as intended.

We were alarmed by a recent study of commonly used personal-use blood glucose testing systems that found that only six of 18 systems tested met the study's accuracy standard.¹ According to data from the Office of the Inspector General, more than 61 percent of test strips furnished to Medicare beneficiaries during the period October through December 2016 would have failed the study's accuracy standards.² In other words, more than half of the strips sold to Medicare beneficiaries and paid for by the Medicare program during that period did not meet standards to produce accurate blood glucose readings. These findings suggest an absence of meaningful product performance standards with respect to diabetes testing products and supplies sold under the Medicare Competitive Bidding National Mail Order program.

Given the importance of blood glucose measurement to manage diabetes, we are concerned about the study implications on patient health and safety. Some stakeholders have even suggested that CMS suspend the National Mail Order Program in light of these and other potential problems that are limiting seniors' access to quality products. We therefore urge you to take action to implement and enforce product performance standards for diabetes testing supplies. Seniors should be able to rely on the accuracy of the blood glucose testing systems obtained from Medicare. Taxpayer dollars also should not be spent on products that are inaccurate, unsafe, of dubious quality or that are mislabeled or misbranded.

We ask that you respond to this letter no later than January 29, 2018. Please reach out to Logan Hoover (logan.hoover@mail.house.gov) with Congressman Reed and Polly Webster (polly.webster@mail.house.gov) with Congresswoman DeGette with any questions. We look forward to hearing from you.

Sincerely,



TOM REED
Member of Congress



DIANA DEGETTE
Member of Congress

¹ Blood Glucose Monitor Surveillance Program, <https://www.diabetestechology.org/surveillance.shtml>; Klonoff, D., *et.al.*

² HHS OIG Data Brief, June 2017, OEI-04-16-00473.