THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

JAN 2 4 2018

The Honorable Tom Reed
U.S. House of Representatives
Washington, DC 20515

Dear Representative Reed:

Thank you for your letter, cosigned by Representative Diana DeGette, regarding Medicare coverage and payment for home blood glucose monitors covered under the Medicare Part B benefit for durable medical equipment. The Department of Health and Human Services shares your commitment to the health and well-being of all Medicare beneficiaries, as well as all patients using home blood glucose monitors.

To legally market a blood glucose test system in the United States, manufacturers must submit data to the Food and Drug Administration (FDA) that is sufficient to support 510(k) clearance for that device. The submitted data must include data which demonstrates the substantial equivalence of the device to a legally marketed predicate device, in particular with respect to its accuracy and reliability when used by patients at home. Studies based on testing protocols such as those designed by the Diabetes Technology Society (DTS) as part of its new surveillance program can reasonably be expected to provide the necessary type of data.[1] If a 510(k) submission contained data similar to the failing meter data in the DTS study, that product would not be likely to receive FDA clearance due to poor accuracy as compared to predicate devices (i.e., it would be deemed "Not Substantially Equivalent").

In general, the accuracy and reliability of blood glucose meter technology has improved over the past decade. However, FDA has received postmarket signals indicating that some cleared blood glucose meter systems were less accurate when assessed in the field than the data in their premarket submission would predict. FDA is working toward addressing any issues that may adversely affect the accuracy of tests in the field.

One potential source of inaccuracy FDA has identified relates to inadequate quality systems. If a manufacturer does not a have a robust quality system, it may manufacture and distribute blood glucose test strips that do not work as well as the ones used in its premarket studies. For example, if overly permissive criteria are used to evaluate whether a "lot" of test strips meets its performance specifications, then large lots of test strips may not work as expected. These criteria are not typically evaluated by FDA in 510(k) submissions.

These concerns prompted FDA to reach out to the stakeholder community—including patients, health care providers, and industry—to discuss the problem and some potential solutions. FDA

[1] See the website for the Blood Glucose Monitoring System Surveillance Program, available at: https://www.diabetestechnology.org/surveillance.shtml.

expressed support for DTS's effort to create a surveillance program and participated in developing its robust and unbiased testing protocols for this effort. FDA has also performed 101 foreign and domestic inspections in the past 5 years (resulting in 19 Warning Letters) across multiple glucose meter manufacturers with a specific focus on identifying and correcting violations related to manufacturing quality.

In addition, FDA published a final guidance document, "Self-Monitoring Blood Glucose Test Systems for Over-the-Counter Use,"[2] on October 11, 2016, which requests that manufacturers describe the test strip manufacturing testing protocols and acceptance criteria in their premarket blood glucose meter submission so that FDA may review these prior to marketing. This guidance will help clarify quality expectations and increase awareness of this critical issue among foreign and domestic manufacturers.

FDA is already using the results of the DTS study to focus its investigation strategy and to prioritize enforcement resources for companies who manufacture home-use blood glucose test systems. Through these efforts, FDA can more quickly identify firms who may be distributing blood glucose tests strips that do not work as they should. This will improve the on-market reliability of these devices and help patients have assurance that the glucose testing devices they rely on are accurate and safe.

In addition, the Centers for Medicare & Medicaid Services (CMS) has been closely monitoring health outcomes data for beneficiaries receiving replacement test strips under the National Mail-Order Program's Medicare competitive bidding program, and to date has not detected any negative trends. CMS will continue to monitor this data closely.

We appreciate your interest in these important issues as we work towards our mutual goal of strengthening the Medicare program for all beneficiaries. If you have additional questions, please do not hesitate to contact Acting Assistant Secretary for Legislation, Barbara Pisaro Clark, at (202) 690-7627. The same letter has been sent to Representative DeGette.

Sincerely,

Eric Hargan

Eric D. Hargan

[2] Available at https://www.fda.gov/downloads/ucm380327.pdf