



American Association of Clinical Endocrinologists

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Dear Colleagues,

AAACE is issuing this safety alert to inform our members of the inaccuracy of many blood glucose monitoring systems currently available, and especially those supplied to Medicare beneficiaries.

At the AAACE/ACE Consensus Conference on Glucose Monitoring held in Washington, DC on September 28-29, 2014, investigators presented results of studies regarding the accuracy of several blood glucose monitoring systems currently available in the US. Investigators revealed that 17-60% of systems they tested failed to meet minimum accuracy requirements as defined by the International Organization for Standardization (ISO) DIN EN ISO 15197:2003 standard, which is used by the US Food and Drug Administration (FDA) when assessing 510(k) pre-market applications for these devices. Further, 33-86% of meters studied failed to meet the more current and stringent ISO 2013 standard.

However, some clinicians may not be aware of the performance differences between glucose monitors and the possible risk involved with those that don't meet accuracy standards. Proliferation of these inaccurate meters has been encouraged by the Medicare Competitive Bidding Program (CBP). The American Association of Diabetes Educators (AADE) surveyed the 23 CBP mail-order suppliers and found that none of the suppliers promote products reflecting greater than 50 percent of the at-large market, as intended by Congress, and that only three of the suppliers actually carried each brand of testing supplies that they reported to Medicare they were providing. As a result, Medicare beneficiaries are being induced to switch to inaccurate, non-branded meters predominantly promoted by mail-order suppliers even though the patients' copays are the same regardless of the blood glucose monitoring system purchased, and regardless of whether the meter is obtained at retail or by mail-order. There is no cost benefit to patients for using non-branded meters; costs are the same whether the transaction is retail or mail order.

An AAACE membership survey found that over 50% of respondents' patients have experienced adverse events related to CBP supplies, and 75% of respondents do not believe test supplies provided by CBP meet the care needs of their patients. Another AADE survey found that 27% of patients with type 1 diabetes had experienced health problems due to inaccurate readings.

Therefore, clinicians are urged to stipulate the specific brand/model of the blood glucose meters they prescribe and check with their local pharmacies to make sure that their prescriptions are filled as written. As a safeguard, clinicians should include "no substitutions" or "dispense as written" (DAW) in the prescription. All large retail companies are honoring branded prescriptions and not attempting to switch brands away from what you have deemed appropriate for your patients. Medicare covers all brands and has an open formulary for SMBG systems.

Further, because some manufacturers of glucose monitoring products provide little or no medical device reporting (MDR) of adverse events associated with the use of their systems (a violation of FDA regulations), clinicians are urged to remain vigilant regarding any problems or adverse events associated with the blood glucose meters their patients are using. If issues are identified, clinicians should report these problems to the Manufacturer and User Facility Device Experience (MAUDE) database at the following website:

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm>

Thank you for your attention to this important matter.

Sincerely,

R. Mack Harrell, MD, FACP, FACE, ECNU

President, American Association of Clinical Endocrinologists