



*Better health through
laboratory medicine.*

June 17, 2014

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Director, Clinical Laboratory Evaluation Program
Wadsworth Center, NY State Department of Health
Empire State Plaza, P.O. Box 509
Albany, New York 12201-0509

Dear Ms. Shulman,

On January 13, 2014, the New York State (NYS) Department of Health issued a directive to Laboratory Directors regarding the off-label use of Glucose Meters in professional settings. Although we share the Department's desire to ensure that point-of-care (POC) blood glucose devices are used safely and appropriately, we are concerned that the NYS program acted prematurely in issuing this document and that this policy may impede the delivery of quality patient care. AACCC therefore urges the Department to rescind this document.

The main purpose for issuing this directive appears to be the Food and Drug Administration's January 7, 2014 draft guidance on the use of "Blood Glucose Monitoring Test Systems for Prescription Point of Care Use." The comment period for this document just ended. The FDA has received extensive comments on the draft that it must now review. Based on expert input, agencies frequently make substantive changes to draft guidance. AACCC is concerned that NYS has made policy decisions, and is enforcing them, based on a draft FDA document that is likely to change.

The Department also references the Centers for Medicare and Medicaid Services (CMS) CLIA standards as a rationale for this policy notice. Once more, we think the agency has prematurely taken action on this issue. CMS is currently developing separate guidance that will further define the complex issues and requirements surrounding the use of POCT blood glucose meters in off-label situations. We recommend NYS state wait and consider CMS's review of this issue before making and implementing policy changes will significantly impact hospitals within their state and possibly nationwide.

AACCC recognizes that there are many complicated and difficult decisions that must be made, such as who can perform the tests, the settings in which these test can performed, and what types of studies are required. We believe these are important issues that must be discussed and dealt with collaboratively within the health care community. The good news is that this dialogue has started and is moving forward. AACCC urges NYS to rescind or temporarily suspend its policy directive until the ongoing federal efforts are completed and these issues are resolved collaboratively by the oversight bodies and interested stakeholders.


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By way of background, AACC is the principal association of professional laboratorians-- including MDs, PhDs and medical technologists. AACC's members develop and use chemical concepts, procedures, techniques and instrumentation in health-related investigations and practice in hospitals, independent laboratories and the diagnostics industry worldwide. The AACC provides international leadership in advancing the practice and profession of clinical laboratory science and medicine and its applications to health care. If you have any questions, please call me at (336) 716-2639, or Vince Stine, PhD, Director, Government Affairs, at (202) 835-8721.

Sincerely,

Steven H. Wong 

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President, AACC