May 4, 2015

Centers for Medicare and Medicaid Services
Center for Clinical Standards and Quality/
Survey & Certification Group

Re: Temporary Withdrawal-S&C: 15-11-CLIA and Reissuance as Draft,
With Draft Clarifications

Dear Sir/Madam:

The American Association for Clinical Chemistry (AACC) appreciates the opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) draft March 13, 2015 Survey and Certification Memorandum 15-11, which outlines the agency's regulatory requirements for blood glucose monitors (BGM) under the Clinical Laboratory Improvement Amendments of 1988 (CLIA'88). The agency is requesting information on how these devices are currently used in hospital settings and any problems identified with their use. In addition, CMS is seeking feedback on how to better educate clinical laboratories about the CLIA 'off-label' use requirements.

AACC is a global scientific and medical professional organization dedicated to clinical laboratory science and its application to healthcare. AACC brings together more than 50,000 clinical laboratory professionals, physicians, research scientists, and business leaders from around the world focused on clinical chemistry, molecular diagnostics, mass spectrometry, translational medicine, lab management, and other areas of progressing laboratory science such as BGM and point-of-care testing. Since 1948, AACC has worked to advance the common interests of the field, providing programs that advance scientific collaboration, knowledge, expertise, and innovation.

AACC supports CMS' intent to begin enforcing BGM regulations as specified in CLIA '88. However, we have some concerns about immediate and abrupt changes in the approach the agency has employed up until now. Our concerns, detailed below, primarily relate to the time it will take for hospitals to assess and, if necessary, adjust their practices to be in compliance with the new enforcement strategy and ensure uninterrupted patient care.

AACC recommends:

- CMS use its discretionary authority to 'educate' hospitals during a **transition period** that gives hospitals, manufacturers and the FDA time to address the issues inherent in implementing the CLIA provisions;

AACC recognizes:

- Hospitals and manufacturers will need time to adjust their practices to ensure compliance with newly enforced **regulatory requirements**;
- Hospitals will need to address any changes to their policies and procedures that would limit or otherwise affect **bedside testing** of glucose concentrations, which is an integral part of patient care; and
- Hospitals will have to assess and adjust their workforce as necessary to ensure they have enough **personnel** meeting the CLIA requirements to perform BGM testing.

Transition period
AACC recognizes that CMS must enforce the CLIA regulations. We support these efforts. However, much confusion has been generated recently within hospitals regarding when and where to use BGMs and who can perform this testing. AACC urges the agency to take a pragmatic, educational approach to this situation. We suggest CMS use its discretionary authority to give hospitals more time to review their policies and procedures to ensure they are in compliance with the regulations. This 'transition' period should be sufficient in length so that hospitals can develop and implement the necessary procedures and that manufacturers can seek and obtain needed FDA review for claims permitting the use of BGMs in critically ill populations. It is important to note, however, that this discretion should primarily extend to personnel requirements and other operational parameters; clinical laboratories should still be responsible for validating off-label testing protocols, as they would for any other laboratory-developed test. Although this transition period may not be a perfect answer, we believe this response would be best under the current difficult situation that has been triggered.

Regulatory Requirements
The CLIA'88 requirements specify that clinical laboratories must follow the manufacturer's instructions when performing a waived test. If a laboratory modifies the test or uses it 'off-label,' the test automatically becomes high complexity subject to more stringent personnel and quality control practices. AACC supports this requirement. We recognize that hospitals and other testing facilities that are using BGMs inconsistent with the product labeling will need to adjust their laboratory practices to comply with CLIA'88. AACC believes that all healthcare settings should address any limitations with the manufacturer's package insert as part of its policies, procedures and training materials.

Bedside Testing
Although we endorse the current CLIA requirements, we are concerned that immediate enforcement of the standards mentioned in Memorandum 15-11 regarding the use of waived BGMs in critically ill patients will unnecessarily disrupt and jeopardize patient care. Point-of-care blood glucose testing at the bedside has become standard of care for diabetes and insulin management protocols in many hospitals, including intensive care units, emergency rooms, operating rooms and other settings in which critically ill patients are managed. This testing is

conducted safely and effectively to measure and manage glucose levels in those patients. A sudden shift of all or most BGM testing from the bedside to the core laboratory for those patients most in need of this testing could significantly impact the ability of healthcare practitioners to diagnose and treat hyperglycemia and recognize hypoglycemia in a timely manner. The clinical protocols in place today require active and rapid monitoring of the patient and the interpretation of the glucose results in the context of clinical symptoms.

Personnel Shortage

Immediate and abrupt enforcement of the CLIA provisions regarding BGMs would create a shortage of available healthcare personnel to perform the testing if current practices place BGMs in the category of moderate or high complexity testing. In many hospitals, BGM testing is performed by nurses, patient care technicians, and medical assistants, many of whom would not meet the educational requirements for moderate or high complexity testing under state regulations. Given that a shortage of qualified medical laboratory technologists and clinical laboratory technicians already exists, it would be challenging, if not impossible, for healthcare facilities to find state-qualified staff to perform testing in the critical care units. The staffing shortages would limit patient access to blood glucose testing resulting in adverse patient outcomes. A 2010 report issued by the Bureau of Labor Statistics (BLS) indicates a worsening in the staffing gap. Hospitals will need time to develop and implement a plan for addressing this staffing to continue to provide BGM bedside testing.

I would like to reiterate AACC's support for a transition period that will allow hospitals and manufacturers to make the necessary changes to ensure compliance with the CLIA regulations. AACC looks forward to working with you on this most important issue. If you have any questions, please email me at ddkoch@emory.edu, or Vince Stine, PhD, AACC Director of Government Affairs, at vstine@aacc.org.

Sincerely,

David D. Koch, PhD, DABCC
President, AACC