

June 17, 2016

Thomas Hamilton
Director, Survey and Certification Group
Centers for Medicare and Medicaid Services
7500 Security Blvd.
Mailstop: C2-21-16
Baltimore, Maryland 21244-1850

Subj: Memorandum (S&C 16-18-CLIA)

Dear Mr. Hamilton,

On April 1, 2016, the Centers for Medicare and Medicaid Services (CMS) issued Memorandum S&C: 16-18-CLIA that makes a number of policy changes to the Clinical Laboratory Improvement Amendments (CLIA), including allowing primary source verification (PSV) as evidence of laboratory compliance with the CLIA personnel qualifications and bachelor's and associate's degrees in nursing as meeting the testing personnel requirements for high and moderate complexity testing, respectively. The American Association for Clinical Chemistry (AACC) has a number of comments and questions about these actions.

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 laboratory science to advance healthcare collaboration, knowledge, expertise, and innovation.

AACC supports CMS' decision to permit clinical laboratories to use Primary Source Verification (PSV) "as evidence of compliance with the personnel qualifications" mandated by CLIA. This change gives laboratories another means for "verifying and documenting the qualifications of its laboratory personnel." AACC suggests, however, that the agency also permit organizations that provide professional certification to fill the role of PSV, provided they have verified the information sought by CMS.

In the memorandum, CMS also states that "a bachelor's degree in nursing meets the requirement of having earned a bachelor's degree in biological science for high complexity testing personnel" and then follows with a statement that "an associate's degree in nursing meets the requirement of having earned an associate's degree in a biological science for moderate complexity testing personnel." CMS' decision to grant nurses equivalency is a significant change to the CLIA personnel requirements that should have gone through the normal rulemaking process rather than being issued as an agency directive.

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AACC is concerned that CMS made this decision without first getting input from consumers and the healthcare community. We are concerned that this unilateral decision by the agency, if it stands, sets a dangerous precedent for altering personnel requirements without public consultation. AACC recommends that in the near term CMS suspend its decision permitting nurses to perform moderate and high complexity testing. The agency should then publish a proposed rule, review any public comments, and then decide whether to proceed with this policy change.

AACC agrees that nurses are invaluable members of the healthcare team. However, their education and training necessarily covers a breadth of medical disciplines and therefore does not delve into the depths of scientific concepts underlying clinical laboratory testing. CMS' decision to accept nursing degrees as equivalent to the currently accepted degrees would exempt nurses from having to complete valuable clinical laboratory training prior to performing patient testing. AACC respectfully requests that CMS, regardless of how it proceeds, explain the rationale and objectives behind its decision to accept nursing degrees as equivalent to degrees in biological sciences.

AACC looks forward to working with CMS as it continually works to improve the CLIA standards. If you have any questions, please email Vince Stine, PhD, AACC Director of Government Affairs, at vtstine@aacc.org.

Sincerely,

A handwritten signature in cursive script that reads "Patricia M. Jones".

Patricia M. Jones, PhD, DABCC, FACB
President, AACC