



March 4, 2013

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-3267-P
P.O. Box 8010
Baltimore, Maryland 21244-8010

Dear Sir/Madam:

The American Association for Clinical Chemistry (AACC) welcomes the opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) February 7, 2013 proposed rule to reduce unnecessary regulation within the Medicare program. As part of this initiative, CMS is proposing to modify the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) regulations to give the agency greater flexibility in determining the scope and severity of penalties for a clinical laboratory that sends proficiency testing (PT) samples to an outside laboratory for analysis.

In recent years, a number of clinical laboratories have inadvertently sent a PT specimen to another laboratory for testing. Frequently, this mistake is the result of laboratory personnel sending the specimen to an outside facility for reflex or confirmatory testing as specified in their standard operating procedures (SOPs). According to CMS, nearly one-third of the 41 cases of PT referral errors during 2007-2011 were the result of this type of mistake.

CMS has been diligently working to educate clinical laboratories about this problem. However, as is evident by the continued reports of PT referrals, not everyone has gotten the message. The agency is proposing to insert additional language within the CLIA regulations to further re-enforce and clarify that referring PT specimens to another laboratory, for any reason, is not permissible. AACC supports CMS's proposed change and its ongoing efforts to educate the laboratory community.

CMS is also proposing to impose lesser sanctions for first-time offenders that sent a PT sample to another facility in error as a result of "written, legally accurate and adequate" SOPs requiring reflex or confirmatory testing. AACC agrees with CMS's recommendation. We do suggest that CMS broaden the language so that it has greater discretionary authority in deciding when to apply the alternative sanctions. Inserting such language now would ensure that CMS didn't need to make future regulatory changes to address an unforeseen situation that may warrant lesser penalties.

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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 (410) 328-8672, or Vince Stine, PhD, Director, Government Affairs, at (202) 835-8721.

Sincerely,

A handwritten signature in black ink, appearing to read "Robert Christenson", enclosed in a thin black rectangular border.

Robert Christenson, PhD
President, AACC