



ASSOCIATION FOR MOLECULAR PATHOLOGY
Education. Innovation & Improved Patient Care. Advocacy.
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March 12, 2018

Seema Verma, MPH, Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1678-FC Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Request for Information: Revisions to Personnel Regulations, Proficiency Testing Referral, Histocompatibility Regulations and Fee Regulations under the Clinical Laboratory Improvement Amendments of 1988 (CLIA); CMS-3326-NC

Dear Administrator Verma:

On behalf of the Association for Molecular Pathology (AMP) I would like to thank you for the opportunity to provide comments on this request for information (RFI). AMP is an international medical and professional association representing approximately 2,300 physicians, doctoral scientists, and medical technologists who develop, perform or are involved with laboratory testing based on knowledge derived from molecular biology, genetics, and genomics. Membership includes professionals from the government, academic medicine, clinical testing laboratories, and the in vitro diagnostics industry.

We commend CMS on their efforts to update CLIA to better reflect current knowledge, changes in the academic context, and advancements in laboratory testing. AMP has been engaged in efforts to modernize CLIA regulations and ensure that the system of oversight continues to work to enhance standards and transparency while preserving innovation, minimizing cost and regulatory burden, and protecting the practice of medicine. We welcome the steps CMS is taking to gather more information on how they can improve current regulations to align with today's testing landscape.

Part A: Personnel Requirements

General Comments

In regards to the request for input on personnel requirements, AMP believes requirements to fill a specific position should emphasize an individual's experience and relevant coursework, rather than a specific type of degree earned. AMP believes that the best indicator of a candidate's qualifications is the amount of relevant training and experience they can bring to the position, which does not always directly correlate with the type, level, or title of degree achieved. Additionally, a greater focus on experience and relevant coursework has the potential to increase the number of qualified applicants to address shortages in the laboratory technician workforce. AMP requests that CMS establish thresholds for professional experience and relevant coursework, while allowing the laboratory director to make the final decision as to whether or not a candidate is qualified for the position. At this time, AMP does not have recommendations on what those thresholds should be.

Personnel Competencies

AMP believes that CLIA should harmonize the regulations, to have consistent, streamlined qualifications for personnel that are allowed to perform competency assessments. At this time, AMP does not have a preference

if that results in allowing general supervisors with associate degrees to also perform competency assessment on moderate complexity testing personnel or reversing their ability to perform the assessment for high complexity testing.

Part B: Proficiency Testing Referral

Discretion for Category 1 Proficiency Testing Referral

In some cases, more than one CLIA-certified clinical laboratory is involved in a patient's testing, and therefore, AMP believes that CMS should apply discretion in these situations. For example, more than one laboratory may perform immunohistochemistry for ER/PR and then send to another laboratory to perform the interpretation. Such a scenario can represent a technical / professional split between two unrelated entities, or represent two labs, with separate CLIA certifications, within the same health system. AMP believes that a laboratory should be required to report to CLIA if another, separate CLIA facility is involved in testing, both as a part of the clinical testing procedure and the proficiency testing process. Additionally, AMP feels that the process by which patient samples are normally processed by a laboratory in a clinical situation would be important to consider in such instances. Proficiency testing should help a reviewer to evaluate how well a laboratory likely performs while processing clinical samples and caring for patients rather than simply conveying information about how well a laboratory performs during proficiency testing. Thus, AMP is in favor of a proficiency testing paradigm that more accurately reflects clinical testing processes and allows for flexibility. AMP supports a system that works to identify patterns of wrongdoing, such as a "three strikes and you're out" approach, to help identify and reprimand laboratories that intentionally, egregiously violate proficiency testing referral rules.

Part C: Histocompatibility

Crossmatching

AMP is supportive of updating regulations to allow virtual crossmatching to replace physical crossmatching as a pre-requisite for organ transplantation. Virtual crossmatching is a widely accepted practice, with many laboratories already using the technology. This is a rapidly evolving field and AMP believes that it is important for patient care that there is a flexible regulatory paradigm that allows for innovation.

Part D: Fees

General Comments

As stated in AMP's [CLIA Modernization Proposal](#), we support volume-based methodology for collecting CLIA fees from laboratories. We believe that CMS should be able to collect an annual fee that is commensurate with the number of tests a laboratory offers, and that this fee be limited to cost recovery. Fees for public health laboratories that are outside the standard fees for accreditation inspections should be waived. Additionally, we feel that the annual fees should be required to be reviewed by CMS with the assistance of an advisory board on a regular basis to account for fluctuations in laboratory test volumes.

Thank you again for considering AMP's comments. We look forward to continued discussions on these topics and hope to serve as a resource on how changes would impact the field of molecular pathology. If you have any questions or if AMP can be of further assistance, please contact Tara Burke at TBurke@amp.org.

Sincerely,

Kojo S.J. Elenitoba-Johnson, MD
President, Association for Molecular Pathology